BMJ Open

A 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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-067161
Article Type:	Protocol
Date Submitted by the Author:	05-Aug-2022
Complete List of Authors:	Lowry, Sophie; Health Innovation Network Goff, Louise; Kings College Lonodn, Diabetes and Nutritional Sciences Irwin, Sally; Health Innovation Network Brady, Oliver; Health Innovation Network Curran, Natasha; Health Innovation Network Lelliott, Zoe; NIHR ARC South London, Sevdalis, Nick; King's College London, Walker, Andrew; Health Innovation Network
Keywords:	DIABETES & ENDOCRINOLOGY, EDUCATION & TRAINING (see Medical Education & Training), QUALITATIVE RESEARCH

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1 **A mixed methods implementation study of a**
2 **virtual culturally tailored diabetes self-**
3 **management programme for African and**
4 **Caribbean communities (HEAL-D) in south**
5 **London and its scaling up across NHS regions**
6 **in England: study protocol**

7

8 **Authors**

9 Sophie Lowry[1] (0000-0003-1707-9133), Louise Goff[2] (0000-0001-9633-8759), Sally Irwin[1]
10 (0000-0003-4125-2258), Oliver Brady[1] (0000-0002-9097-0486), Natasha Curran[1] (0000-
11 0003-0165-7314), Zoe Lelliott[1] (0000-0002-6596-3057T), Nick Sevdalis[3] (0000-0001-7560-
12 8924), Andrew Walker[1] (0000-0003-1128-8954)

13

14 Affiliations:

15 [1] Health Innovation Network, London, UK;

16 [2]Department of Nutritional Sciences, King's College London, Faculty of Life Sciences and

17 Medicine, London, UK

18 [3]Centre for Implementation Science, Institute of Psychiatry, Psychology and Neuroscience,

19 King's College London, London, UK;

20 **Corresponding author**

21 Full name: Sophie Lowry

22 Postal address: Health Innovation Network, Ground Floor, Minerva House, 5 Montague

23 Close, London SE1 9BB

24 Email: sophie.lowry2@nhs.net

25 Word count: 3148

1

KEY WORDS

1. Diabetes

2. Education

3. Self-management

4. Implementation

5. Implementation Science

6. HEAL-D

7. Virtual

8. Scale-up

ABSTRACT

Introduction

The NHS Insight Prioritisation Programme (NIPP) was established to accelerate the

implementation and evaluation of innovation that supports post-pandemic ways of working.

Supporting this, the Academic Health Science Network (AHSN) and NIHR Applied Research

Collaboration (ARC) 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 inequalities 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

co-developed. Initially a face-to-face programme, HEAL-D pivoted to virtual delivery in

response to the COVID-19 pandemic.

2

49 The purpose of this study is to explore (1) the feasibility and acceptability of a virtual model

50 of delivery for HEAL-D in south London and (2) the factors affecting its scale-up across other

51 areas in England.

Methods and analysis

53 The study will have two strands: (1) a mixed methods prospective evaluation of the virtual

54 delivery of HEAL-D in south London using routinely collected service-level data, service

55 delivery staff and service user interviews, and observations; (2) a prospective qualitative

56 study of the scale-up of this virtual delivery comprising of interviews and focus groups with

57 members of the public, and commissioners and providers of diabetes services across

58 England. Qualitative data will be analysed using thematic analysis. Quantitative analysis will

59 use descriptive statistics and reporting summary tables and figures. The study will be

60 grounded in well-established implementation frameworks and service user involvement.

Ethics and Dissemination

62 'Minimal Risk Registration' ethical clearance was granted by King's College London's

63 Research Ethics Office (ref: MRA-21/22-28498). Results will be published in a peer-reviewed

64 journal and summaries will be provided to the study funders and participants.

Registration details

66 N/A

STRENGTHS AND LIMITATIONS OF THIS STUDY

68 • The study design will enable the rapid gathering of insights and identification of

69 practical barriers and enablers to implementation, whilst delivering maximum benefit

70 to service users.

71 • A key strength is the co-design and delivery of the study, which brings together a

72 collaboration between the HIN and ARC South London, in partnership with people

73 from African and Caribbean communities with a lived experience of diabetes.

3

74 • A limitation of the approach is the absence of a control group and the use of routinely

75 collected data, which means the study is unable to determine true causation or

76 effectiveness.

INTRODUCTION

77

National Insights Prioritisation Programme

78

79 Approximately one year after the emergence of the COVID-19 pandemic in England, the

80 National Health Service (NHS) began considering what could be learned from the ongoing

81 COVID-19 pandemic response such that effective innovations that were necessitated by the

82 pandemic could be sustained within routine services (and, conversely, what innovations may

83 require removal because they were no longer fit for purpose or did not add value). To this

84 effect, in 2021 the NHS Insight Prioritisation Programme (NIPP) was established by the

85 Accelerated Access Collaborative (AAC) and the National Institute for Health and Care

86 Research (NIHR) to accelerate the implementation and evaluation of innovation that

87 supports post-pandemic ways of working, builds service resilience, and delivers benefits and

88 value to patients in England. The objectives for NIPP are to (1) facilitate NIHR Applied

89 Research Collaborations' (ARCs; which carry out applied health research to improve patient

90 care) and the Academic Health Science Networks' (AHSNs; which aim to support spread

91 and adoption of promising innovations) contribution to NHS Reset and Recovery plan by

92 producing insights rapidly for promising innovations, (2) identify innovations that will

93 contribute to Integrated Care Systems (ICSs) and regional needs, and (3) build local

94 capacity and expertise for evaluation and implementation.

Academic Health Science Networks and Applied Research Collaborations

95

96 AHSNs were established by NHS England to accelerate spread and adoption of innovation

97 in health and care. There are 15 AHSNs across England, each working locally, as well as

98 nationally, as intermediaries to bring together partners from across the health and care

4

99   system to 'transform lives through healthcare innovation' at pace and scale.[1] The NIHR

100   funds 15 ARCs to undertake applied health and care research based on local population

101   needs. Each ARC is a partnership between local universities, NHS organisations, local

102   authorities and AHSN (N.B. ARC and AHSN geographical boundaries are coterminous). In

103   south London (UK), the NIHR ARC South London and AHSN (called the Health Innovation

104   Network, or HIN) have a specific focus on implementation – the former leads on

105   implementation science projects, whilst the latter leads on practical implementation support

106   to evidenced innovations. Within the south London context, implementation science is

107   understood as "the scientific study of methods to promote the systematic uptake of research

108   findings and other evidence-based practices into routine practice", with the ultimate aim to

109   improve the quality and effectiveness of care.[2] The HIN specifically takes an

110   implementation science informed approach to supporting its work on spread and adoption of

111   innovation.[3,4]

112   As part of the NIPP, the HIN and the NIHR ARC south London are collaborating on the

113   implementation and evaluation of a culturally tailored self-management and education

114   intervention for UK African and Caribbean communities with type 2 diabetes (T2D), Healthy

115   Eating and Active Lifestyles for Diabetes (HEAL-D) – described in detail in the next section.

Diabetes and HEAL-D

117   It is estimated that T2D affects between 3.5 and 5% of the UK population,[5] however, the

118   prevalence in UK African and Caribbean communities is estimated to be up to three times

119   higher than that of white Europeans.[6] This increased prevalence, coupled with evidence of

120   ethnic disparities in outcomes,[7,8] results in these communities being disproportionately

121   affected by T2D.

122   To tackle ethnic inequalities in T2D healthcare access, an evidence-based, culturally tailored

123   T2D self-management and education programme for adults of African and Caribbean

124   heritage has been developed. Healthy Eating & Active Lifestyles for Diabetes (HEAL-D) was

5

125 co-developed between 2016 and 2018 in collaboration with people living with T2D and

126 community leaders from African and Caribbean community organisations.[9] The programme

127 encompasses culturally tailored, group-based, face-to-face education, behaviour change,

128 and participatory physical activity, delivered by trained dietitians and lay educators.[10]

129 A randomised controlled feasibility trial, conducted in 2018-19 and published in 2021,

130 demonstrated that the HEAL-D programme is highly acceptable for both participants and

131 healthcare providers.[11] Following its initial development as a face-to-face intervention,

132 HEAL-D pivoted to virtual delivery and is now delivered as a series of live sessions over

133 video call (hereafter, HEAL-D online) in response to the COVID-19 pandemic. HEAL-D

134 online has now been commissioned across south London, with referrals managed through a

135 centralised online booking hub, Diabetes Book & Learn, which is designed to improve

136 access to diabetes courses in south London. Individuals can be referred to Diabetes Book &

137 Learn via healthcare professionals or self-referral, and the service enables people to choose

138 a course to suit them, wherever they live or work, using online booking or a phone booking

139 line.

140 To date, studies have not explored the online version of HEAL-D. Therefore, to support

141 further commissioning of the service, it is necessary to understand if an online self-

142 management and education programme for T2D is acceptable and accessible to people

143 from African and Caribbean communities. Additionally, studies have not explored the

144 delivery of HEAL-D outside south London and if the service can be implemented at scale.

145 **Study aims**

146 Through the NIPP, the HIN and NIHR ARC South London will evaluate the local

147 implementation of HEAL-D online in south London and its scale-up across other regions in

148 England. The primary aims of this study are to evaluate the feasibility and acceptability of the

149 HEAL-D online service across south London and to assess scalability requirements beyond

150 south London. Specifically, the evaluation will explore (i) service user and service delivery

6

151   staff acceptability, (ii) outcomes delivered for service users and service, (iii) factors

152   influencing the implementation of HEAL-D online in south London, and (iv) the scaling of the

153   service from an operational delivery and commissioning perspective.

154   The study will have two strands (1) an evaluation of HEAL-D online in south London and (2)

155   a study of the scale-up of HEAL-D online beyond south London.

156   The two strands will address the following questions:

157   Evaluation of HEAL-D online in south London:

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

159   2. Is HEAL-D online acceptable and feasible for service delivery staff?

160   3. What benefits do service users gain from participating in HEAL-D online?

161   4. Does HEAL-D online improve service outcomes?

162   5. How does a digital model of delivery affect participation?

163   6. What factors affect the feasibility of implementation and delivery of HEAL-D online in

164   south London?

165   Scaling-up of HEAL-D online across England:

166   1. What factors affect the scale-up of HEAL-D online from an operational delivery and

167   commissioning perspective? Specifically linked to:

168   a. Feasibility to implement and deliver HEAL-D online at pilot sites

169   b. Understanding the potential impact of a digital model of participation

170   # METHODS AND ANALYSIS

171   **Study Design**

172   This is a mixed methods prospective evaluation of HEAL-D online in south London and a

173   prospective qualitative study on scaling the HEAL-D online service.

7

174   Tables 1 and 2 outline the evaluation framework and metrics. The evaluation framework is

175   based on the established implementation outcome framework proposed by Proctor et al.,[12]

176   in which patient-level outcomes are impacted by service-level outcomes, which in turn are

177   influenced by implementation outcomes (the latter defined as the observable effects of

178   deliberate and purposive actions to implement a new service, such as HEAL-D online).

8

179   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 wellbeing using Problem Areas In Diabetes (PAID-5) questionnaire.	Service provider
Service outcomes (e.g. 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.

9

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 (e.g. 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: HbA1c, blood pressure and cholesterol	Service provider

10

180

181 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, SOPs, 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

182

11

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.[10] 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. Firstly, we will apply an established model for multi-level outcome assessment for such evaluations.[12] The model includes patient-level, service-level, and implementation outcomes. Secondly, the 'Exploration-Preparation-Implementation-Sustainment' (EPIS) framework will inform the approach to analysis.[13] 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

Evaluation of HEAL-D online in south London

HEAL-D online service users: HEAL-D online has been commissioned for approximately 100 service users (i.e. 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 post-course questionnaire (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 [14]. 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 (e.g., dieticians, physiotherapists, lay educators, service managers) will be invited to participate in an interview.

Purposive sampling will be used for all qualitative data collection to ensure the evaluation considers a range of perspectives. Recruitment for interviews will continue until the target sample is achieved, which is estimated to allow saturation to be met.

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: Adult members of the public from African and Caribbean communities who have a lived experience of type 2 diabetes 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 (i) service-level data routinely collected by the service provider, (ii) data from service delivery staff interviews, (iii) data from service user interviews and questionnaires, (iv) observations of HEAL-D online, and (v) 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, dropout and did not attend (DNA) rates, completion rates, and the Problem Areas In Diabetes (PAID-5) questionnaire.[15] PAID-5 is a patient-reported outcome measure to explore disease status and wellbeing for people with diabetes. Demographic data will be used to understand potential health inequalities / 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 HbA1c, blood pressure and cholesterol. This is to help understand the factors affecting the routine collection of clinical outcome data (e.g. quality, completeness, burden) as part of on-going service improvement and the factors affecting the implementation and scale-up of the service.

A post-course telephone questionnaire is administered by the service provider as part of routine care (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 intended and is important in understanding the relationship between intervention, its implementation, and outcomes.[16] 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 (e.g. 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 (i.e., 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 (i.e., 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 (e.g. 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 (e.g. caring responsibilities, mobility issues).

Additionally, semi-structured 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 (i.e., 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. 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.[17] Interview recordings will be transcribed professionally, identified

information will be removed and transcripts will be coded in NVivo. 10% 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.[18]

Quantitative Data

Analysis will use descriptive statistics (mean, standard deviation, 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.[11]

DISCUSSION

This study will evaluate the implementation and scale-up of HEAL-D online, as part of the

NHS Insight Prioritisation Programme (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, whilst 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.

LIST OF ABBREVIATIONS

AHSN: Academic Health Science Network

ARC: Applied Research Collaboration

COVID-19: Coronavirus disease

EPIS: Exploration, Preparation, Implementation, Sustainment framework

GSTT: Guy's and St Thomas' NHS Foundation Trust

HEAL-D: Healthy Eating and Active Lifestyles for Diabetes

HIN: Health Innovation Network

NHS: National Health Service

NIHR: National Institute for Health and Care Research

NIPP: National Insights Prioritisation Programme

PAID-5: Problem Areas In Diabetes

PPI: Patient and public involvement

PROM: Patient-reported outcome measure

REFERENCES

1   Giles C, Day A. Is there a role for an embedded knowledge specialist in an organisation like an Academic Health Science Network? A retrospect of a one year pilot. *Business Information Review* 2021;**38**:138–43. doi:10.1177/02663821211032861

2   Eccles MP, Mittman BS. Welcome to Implementation Science. *Implementation Science* 2006;**1**:1. doi:10.1186/1748-5908-1-1

3   Sibley A, Ziemann A, Robens S, *et al.* Review of spread and adoption approaches across the AHSN Network. Wessex AHSN 2021. https://www.ahsnnetwork.com/app/uploads/2021/05/Spread-and-adoption-review-final.pdf?utm_source=AHSNs&utm_medium=toolkit&utm_campaign=Spread%20and%20adoption%20report

4   Walker A, Dale C, Curran N, *et al.* Leading the spread and adoption of innovation at scale: an Academic Health Science Network's perspective. *BMJ Leader* 2021;**5**:155. doi:10.1136/leader-2020-000252

5   Wilson C, Alam R, Latif S, *et al.* Patient access to healthcare services and optimisation of self-management for ethnic minority populations living with diabetes: a systematic review. *Health & Social Care in the Community* 2012;**20**:1–19. doi:10.1111/j.1365-2524.2011.01017.x

6   Becker E, Boreham R, Chaudhury M, *et al.* The health of minority ethnic groups. 2004.https://lemosandcrane.co.uk/resources/National%20Statistics%20-%20Health%20Survey%20for%20England%202004.pdf (accessed 21 Feb 2022).

7   James GD, Baker P, Badrick E, *et al.* Type 2 diabetes: a cohort study of treatment, ethnic and social group influences on glycated haemoglobin. *BMJ Open* 2012;**2**:e001477. doi:10.1136/bmjopen-2012-001477

8   Lanting LC, Joung IMA, Mackenbach JP, *et al.* Ethnic Differences in Mortality, End-Stage Complications, and Quality of Care Among Diabetic Patients: A review. *Diabetes Care* 2005;**28**:2280–8. doi:10.2337/diacare.28.9.2280

9   Goff LM, Moore AP, Harding S, *et al.* Development of Healthy Eating and Active Lifestyles for Diabetes, a culturally tailored diabetes self-management education and support programme for Black-British adults: A participatory research approach. *Diabetic Medicine* 2021;**38**:e14594. doi:10.1111/dme.14594

10 Goff LM, Moore AP, Rivas C, *et al.* Healthy Eating and Active Lifestyles for Diabetes (HEAL-D): study protocol for the design and feasibility trial, with process evaluation, of a culturally tailored diabetes self-management programme for African-Caribbean communities. *BMJ Open* 2019;**9**:e023733. doi:10.1136/bmjopen-2018-023733

11 Goff LM, Rivas C, Moore A, *et al.* Healthy Eating and Active Lifestyles for Diabetes (HEAL-D), a culturally tailored self-management education and support program for type 2 diabetes in black-British adults: a randomized controlled feasibility trial. *BMJ Open Diab Res Care* 2021;**9**:e002438. doi:10.1136/bmjdrc-2021-002438

12 Proctor E, Silmere H, Raghavan R, *et al.* Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;**38**:65–76. doi:10.1007/s10488-010-0319-7

13 Moullin JC, Dickson KS, Stadnick NA, *et al.* Systematic review of the Exploration, Preparation, Implementation, Sustainment (EPIS) framework. *Implementation Science* 2019;**14**:1. doi:10.1186/s13012-018-0842-6

14 Guest G, Bunce A, Johnson L. How Many Interviews Are Enough?: An Experiment with Data Saturation and Variability. *Field Methods* 2006;**18**:59–82. doi:10.1177/1525822X05279903

15 McGuire BE, Morrison TG, Hermanns N, *et al.* Short-form measures of diabetes-related emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. *Diabetologia* 2009;**53**:66. doi:10.1007/s00125-009-1559-5

16 Carroll C, Patterson M, Wood S, *et al.* A conceptual framework for implementation fidelity. *Implement Sci* 2007;**2**:40. doi:10.1186/1748-5908-2-40

17 Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006;**3**:77–101. doi:10.1191/1478088706qp063oa

18 Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Adm Policy Ment Health* 2011;**38**:4–23. doi:10.1007/s10488-010-0327-7

123456789...60 (column of line numbers down left margin)

STATEMENTS

Authors' contributions

LG, AW, ZL, NC and NS conceived of and proposed the study. 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.

Funding statement

The development of HEAL-D was supported by funding from National Institute for Health and Care Research (NIHR). The study is funded by NHS England (grant number N/A) with a peer review process by National Insights Prioritisation Programme (NIPP) commissioned by the NHS Accelerated Access Collaborative and NIHR.

This study/project is supported by the NIHR Applied Research Collaboration South London (NIHR ARC South London) at King's College Hospital NHS Foundation Trust. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

NS is a member of King's Improvement Science, which offers co-funding to the NIHR ARC South London and is funded by King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London and South London and Maudsley NHS Foundation Trust), and Guy's and St Thomas' Foundation.

Competing interests statement

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.

Acknowledgements

We are grateful to all those involved in the co-design of HEAL-D from Baitul Rahman Masjid

Mosque, Diabetes UK, Muslim Association of Nigeria, Peckham, St John's Church,

Peckham, The Latter Rain Outpouring Revival Church.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

APPENDICES

Appendix 1. Post HEAL-D online course questionnaire

No.	Question	Possible answers
1	How did you hear about HEAL-D?	GP Diabetic nurse Dietician Family / friend Other (please note)
2a	When you first heard about HEAL-D, what 3 main things did you expect to get out of the course?	
2b	To what extent were these expectations met? Were your expectations exceeded, met, partially met or not met?	Exceeded met partially met not met
3	For the following questions, on a scale of 1-5 where 1 is not a problem and 5 is a serious problem, please can you rate the following statements:	
3a	Feeling scared when you think about living with diabetes	1 Not a problem 2 Minor Problem 3 Moderate problem 4 Somewhat a serious problem 5 Serious problem
3b	Feeling depressed when you think about living with diabetes	
3c	Worrying about the future and the possibility of serious complications	
3d	Feeling that diabetes is taking up too much of your mental & physical energy every day	
3e	Coping with the complication of diabetes	
4	For the following questions, please rate the following statements about HEAL-D on a	

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

		scale of 1 – 5 where 1 is strongly agree and 5 is strongly disagree
4a	HEAL-D has helped me learn to manage my diabetes	1 Strongly agree 2 Agree 3 Neither agree nor disagree 4 Disagree 5 Strongly disagree
4b	I have learnt practical skills that I will apply to my daily life	
4c	I feel motivated to follow the HEAL-D advice	
4d	HEAL-D has helped me feel supported in living with diabetes	
4e	It has helped me to feel confident in managing my diabetes	
4f	It was helpful to meet other people with diabetes	
5	For the next questions, please rate the following aspects of HEAL-D on a scale of excellent, good, average or poor. And can you please let me know why you have given this rating?	
5a	Initial phone call with HEAL-D team	Excellent Good Average Poor
5b	HEAL-D starter pack	
5c	Exercise classes	
5d	Cooking session	
5e	Delivery by the facilitators	
5f	Interaction with the facilitators	
5g	Interaction with other people on your cohort	
6	Thinking about the video calling facilities,	
6a	How easy did you find it to use? On a scale of 1—5 where 1 is very easy and 5 is very difficult	1. Very Easy 2. Easy 3. Neither easy nor difficult 4. Difficult 5. Very difficult
6b	How did you find the instructions for using bluejeans? Excellent, good, average or poor?	Excellent Good

		Average
		Poor
7a	Have you lost any weight since you started the course?	
7b	Have you noticed a reduction in your waist measurements?	
8	If HEAL-D was available face-to-face or remote, which would you prefer?	Face to face Remote No preference
9	When would be your preferred timing for attending HEAL-D?	No preference Weekday daytime Weekday evening Saturday morning
10	Overall - Please tell us what went well	
11	Overall - Please tell us if there is anything that you believe would enhance the course	
12	Overall - Would you recommend HEAL-D to family/friends	Yes No
13	Do you have any other comments/feedback?	
14	We are currently completing an evaluation of the HEAL-D programme, and we are asking people to complete a telephone / video interview in order to find out their experiences. It will be similar to this questionnaire, and will take approx. 30 minutes. You will also be offered £15 for your time. If you would be interested in taking part, can you please confirm that you are happy for me to share	Yes No

	your details with the project team?	
15	HEAL-D is currently only delivered in South London, but we are looking to develop it further. Would you be interested in hearing about HEAL-D in the future?	Yes No

Appendix 2. Key lines of enquiry to inform the interview guide development for the evaluation of HEAL-D online in south London

Service users

- What is your experience of and perceptions about the acceptability of HEAL-D online?

- What implications does a digital model of delivery have on participation?

- What impacts (positive and negative) have you gained from participating in HEAL-D online?

- How could the model be improved?

Service delivery staff

- What is the feasibility and acceptability of HEAL-D online for African and Caribbean people with diabetes?

- What perceived impacts (positive and negative) does the model have for patients, the service and health system?

- What implications does a digital model of delivery have on participation?

- What factors affect the implementation and delivery of HEAL-D online in south London?

- How could the model be improved?

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Appendix 3. Key lines of enquiry to inform interview guide development for the scale up HEAL-D study

Public members topics guide

- What are your preferences around accessing a self-management course online versus face to face, and why?

- Describe the potential challenges of attending an online course?

- Describe the potential benefits of attending an online course?

Commissioners of diabetes services topic guide

- What evidence would be required for you to commission a HEAL-D online course?

- What are the barriers and facilitators to commissioning HEAL-D?

Service providers and professionals delivering diabetes topic guide

- What are the potential challenges you may face when implementing and delivering a virtual course?

- What benefits can you see to delivering a virtual course?

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

| The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. | The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations. |

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	1	1-2	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	2-3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	3	4-7	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale*	4	8, 12	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	5-6	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Please note: the STaRI checklist is most appropriate checklist, however as this is a protocol of an evaluation (guided by implementation science and theory) not all items are applicable. Where highlighted (by ''), information has been included in the protocol about the checklist item but it does not directly correlate with the StaRI description.*

1

Aims and objectives*	**5**	7	The aims of the study, differentiating between implementation objectives and any intervention objectives.			
Design	**6**	8	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons			
Context*	**7**	12-13	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).			
Targeted 'sites'	**8**	N/A	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	13-14	The population targeted by the intervention and any eligibility criteria.	
Description	**9**	N/A	A description of the implementation strategy	5-6	A description of the intervention	
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described			
Outcomes	**11**	9-11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	9-11	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets	
Process evaluation	**12**	9-11	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work			
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention	
Sample size	**14**	13-16	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)			
Analysis	**15**	17	Methods of analysis (with reasons for that choice)			
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks			

Please note: the STaRI checklist is most appropriate checklist, however as this is a protocol of an evaluation (guided by implementation science and theory) not all items are applicable. Where highlighted (by ''), information has been included in the protocol about the checklist item but it does not directly correlate with the STaRI description.*

2

Results *(all N/A as this is a protocol)*

Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		

Discussion

Structured discussion	**25**	3-4, 17-18	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	N/A	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	N/A	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)

General

Statements	**27**	22-23	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest

Please note: the STaRI checklist is most appropriate checklist, however as this is a protocol of an evaluation (guided by implementation science and theory) not all items are applicable. Where highlighted (by ''), information has been included in the protocol about the checklist item but it does not directly correlate with the STaRI description.

3

BMJ Open

A 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

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1 # A mixed methods implementation study of a

2 # virtual culturally tailored diabetes self-

3 # management programme for African and

4 # Caribbean communities (HEAL-D) in south

5 # London and its scaling up across NHS regions

6 # in England: study protocol

7

8 **Authors**

9 Sophie Lowry[1] (0000-0003-1707-9133), Louise Goff[2] (0000-0001-9633-8759), Sally Irwin[1]
10 (0000-0003-4125-2258), Oliver Brady[1] (0000-0002-9097-0486), Natasha Curran[1] (0000-
11 0003-0165-7314), Zoe Lelliott[1] (0000-0002-6596-3057T), Nick Sevdalis[3] (0000-0001-7560-
12 8924), Andrew Walker[1] (0000-0003-1128-8954)

13

14 Affiliations:

15 [1] Health Innovation Network, London, UK;

16 [2] Department of Nutritional Sciences, King's College London, Faculty of Life Sciences and

17 Medicine, London, UK

18 [3] Centre for Implementation Science, Institute of Psychiatry, Psychology and Neuroscience,

19 King's College London, London, UK;

20 **Corresponding author**

21 Full name: Sophie Lowry

22 Postal address: Health Innovation Network, Ground Floor, Minerva House, 5 Montague

23 Close, London SE1 9BB

24 Email: sophie.lowry2@nhs.net

25 Word count: 3283

1

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

26 # KEY WORDS

27 1. Diabetes

28 2. Education

29 3. Self-management

30 4. Implementation

31 5. Implementation Science

32 6. HEAL-D

33 7. Virtual

34 8. Scale-up

35

36 # ABSTRACT

37 **Introduction**

38 The NHS Insight Prioritisation Programme (NIPP) was established to accelerate the

39 implementation and evaluation of innovation that supports post-pandemic working.

40 Supporting this, the Academic Health Science Network (AHSN) and National Institute for

41 Health and Care Research (NIHR) Applied Research Collaboration (ARC) in South London

42 are testing and evaluating the implementation and scale-up of a Type 2 diabetes (T2D)

43 intervention.

44 T2D is estimated to be three times more prevalent in UK African and Caribbean communities

45 than in white Europeans. To tackle ethnic inequities in T2D healthcare access, an evidence-

46 based, culturally tailored self-management and education programme for African and

47 Caribbean adults (Healthy Eating & Active Lifestyles for Diabetes, HEAL-D) has been co-

48 developed with people with lived experience. Initially a face-to-face programme, HEAL-D

49 pivoted to virtual delivery in response to COVID-19.

2

50 The purpose of this study is to explore the (1) feasibility and acceptability of a virtual delivery

51 model for HEAL-D in south London and (2) factors affecting its scale-up across other areas

52 in England.

53 **Methods and analysis**

54 The study will have two strands: (1) mixed methods prospective evaluation of HEAL-D virtual

55 delivery in south London using routinely collected service-level data, service delivery staff

56 and service user interviews, and observations; (2) prospective qualitative study of the scale-

57 up of this virtual delivery comprising of interviews and focus groups with members of the

58 public, and diabetes services commissioners and providers across England. Qualitative data

59 will be analysed using thematic analysis. Quantitative analysis will use descriptive statistics

60 and reporting summary tables and figures. The study will be grounded in well-established

61 implementation frameworks and service user involvement.

62 **Ethics and Dissemination**

63 'Minimal Risk Registration' ethical clearance was granted by King's College London's

64 Research Ethics Office (ref: MRA-21/22-28498). Results will be published in a peer-reviewed

65 journal and summaries provided to the study funders and participants.

66 **Registration details**

67 N/A

68 # STRENGTHS AND LIMITATIONS OF THIS STUDY

69 • The study design will enable the rapid gathering of insights and identification of

70 practical barriers and enablers to implementation, whilst delivering maximum benefit

71 to service users.

72 • A key strength is the co-design and delivery of the study, which brings together a

73 collaboration between the HIN and ARC South London, in partnership with people

74 from African and Caribbean communities with a lived experience of diabetes.

3

75   • A limitation of the approach is the absence of a control group and the use of routinely

76   collected data, which means the study is unable to determine true causation or

77   effectiveness.

INTRODUCTION

78

National Insights Prioritisation Programme

79

80 Approximately one year after the emergence of the COVID-19 pandemic in England, the

81 National Health Service (NHS) began considering what could be learned from the ongoing

82 COVID-19 pandemic response such that effective innovations that were necessitated by the

83 pandemic could be sustained within routine services (and, conversely, what innovations may

84 require removal because they were no longer fit for purpose or did not add value). To this

85 effect, in 2021 the NHS Insight Prioritisation Programme (NIPP) was established by the

86 Accelerated Access Collaborative (AAC) and the National Institute for Health and Care

87 Research (NIHR) to accelerate the implementation and evaluation of innovation that

88 supports post-pandemic ways of working, builds service resilience, and delivers benefits and

89 value to patients in England. The objectives for NIPP are to (1) facilitate NIHR Applied

90 Research Collaborations' (ARCs; which carry out applied health research to improve patient

91 care) and the Academic Health Science Networks' (AHSNs; which aim to support spread

92 and adoption of promising innovations) contribution to the NHS Reset and Recovery plan by

93 producing insights rapidly for promising innovations, (2) identify innovations that will

94 contribute to Integrated Care Systems (ICSs) and regional needs, and (3) build local

95 capacity and expertise for evaluation and implementation.

Academic Health Science Networks and Applied Research Collaborations

96

97 AHSNs were established by NHS England to accelerate spread and adoption of innovation

98 in health and care. There are 15 AHSNs across England, each working locally, as well as

99 nationally, as intermediaries to bring together partners from across the health and care

4

100   system to 'transform lives through healthcare innovation' at pace and scale.[1] The NIHR

101   funds 15 ARCs to undertake applied health and care research based on local population

102   needs. Each ARC is a partnership between local universities, NHS organisations, local

103   authorities and AHSN (N.B. ARC and AHSN geographical boundaries are coterminous). In

104   south London (UK), the NIHR ARC South London and AHSN (called the Health Innovation

105   Network, or HIN) have a specific focus on implementation – the former leads on

106   implementation science projects, whilst the latter leads on practical implementation support

107   to evidenced innovations. Within the south London context, implementation science is

108   understood as "the scientific study of methods to promote the systematic uptake of research

109   findings and other evidence-based practices into routine practice", with the ultimate aim to

110   improve the quality and effectiveness of care.[2] The HIN specifically takes an

111   implementation science informed approach to supporting its work on spread and adoption of

112   innovation.[3,4]

113   As part of the NIPP, the HIN and the NIHR ARC south London are collaborating on the

114   implementation and evaluation of a culturally tailored self-management and education

115   intervention for UK African and Caribbean communities with type 2 diabetes (T2D), Healthy

116   Eating and Active Lifestyles for Diabetes (HEAL-D) – described in detail in the next section.

117   **Diabetes and HEAL-D**

118   It is estimated that T2D affects between 3.5 and 5% of the UK population,[5] however, the

119   prevalence in UK African and Caribbean communities is estimated to be up to three times

120   higher than that of white Europeans.[6] This increased prevalence, coupled with evidence of

121   ethnic disparities in outcomes,[7,8] results in these communities being disproportionately

122   affected by T2D.

123   To tackle ethnic inequities in T2D healthcare access, an evidence-based, culturally tailored

124   T2D self-management and education programme for adults of African and Caribbean

125   heritage has been developed. Healthy Eating & Active Lifestyles for Diabetes (HEAL-D) was

5

126   co-developed between 2016 and 2018 in collaboration with people living with T2D and

127   community leaders from African and Caribbean community organisations.[9] The programme

128   encompasses culturally tailored, group-based, face-to-face education, behaviour change,

129   and participatory physical activity, delivered by trained dietitians and lay educators.[10]

130   A randomised controlled feasibility trial, conducted in 2018-19 and published in 2021,

131   demonstrated that the HEAL-D programme is highly acceptable for both participants and

132   healthcare providers.[11] Following its initial development as a face-to-face intervention,

133   HEAL-D pivoted to virtual delivery and is now delivered as a series of live sessions over

134   video call (hereafter, HEAL-D online) in response to the COVID-19 pandemic. HEAL-D

135   online has now been commissioned across south London, with referrals managed through a

136   centralised online booking hub, Diabetes Book & Learn, which is designed to improve

137   access to diabetes courses in south London. Individuals can be referred to Diabetes Book &

138   Learn via healthcare professionals or self-referral, and the service enables people to choose

139   a course to suit them, wherever they live or work, using online booking or a phone booking

140   line.

141   To date, studies have not explored the online version of HEAL-D. Therefore, to support

142   further commissioning of the service, it is necessary to understand if an online self-

143   management and education programme for T2D is acceptable and accessible to people

144   from African and Caribbean communities. Additionally, studies have not explored the

145   delivery of HEAL-D outside south London and if the service can be implemented at scale.

146   **Study aims**

147   Through the NIPP, the HIN and NIHR ARC South London will evaluate the local

148   implementation of HEAL-D online in south London and its scale-up across other regions in

149   England. The primary aims of this study are to evaluate the feasibility and acceptability of the

150   HEAL-D online service across south London and to assess scalability requirements beyond

151   south London. Specifically, the evaluation will explore (i) service user and service delivery

6

152   staff acceptability, (ii) outcomes delivered for service users and service, (iii) factors

153   influencing the implementation of HEAL-D online in south London, and (iv) the scaling of the

154   service from an operational delivery and commissioning perspective.

155   The study will have two strands (1) an evaluation of HEAL-D online in south London and (2)

156   a study of the scale-up of HEAL-D online beyond south London.

157   The two strands will address the following questions:

158   Evaluation of HEAL-D online in south London:

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

160   2. Is HEAL-D online acceptable and feasible for service delivery staff?

161   3. What benefits do service users gain from participating in HEAL-D online?

162   4. Does HEAL-D online improve service outcomes?

163   5. How does a digital model of delivery affect participation?

164   6. What factors affect the feasibility of implementation and delivery of HEAL-D online in

165   south London?

166   Scaling-up of HEAL-D online across England:

167   1. What factors affect the scale-up of HEAL-D online from an operational delivery and

168   commissioning perspective? Specifically linked to:

169   a. Feasibility to implement and deliver HEAL-D online at pilot sites

170   b. Understanding the potential impact of a digital model of participation

METHODS AND ANALYSIS

Study Design

173   This is a mixed methods prospective evaluation of HEAL-D online in south London and a

174   prospective qualitative study on scaling the HEAL-D online service.

175   Tables 1 and 2 outline the evaluation framework and metrics. The evaluation framework is

176   based on the established implementation outcome framework proposed by Proctor et al.,[12]

177   in which patient-level outcomes are impacted by service-level outcomes, which in turn are

178   influenced by implementation outcomes (the latter defined as the observable effects of

179   deliberate and purposive actions to implement a new service, such as HEAL-D online).

8

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

180　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 wellbeing using Problem Areas In Diabetes (PAID-5) questionnaire.	Service provider
Service outcomes (e.g. 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.

9

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 (e.g. 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: HbA1c, blood pressure and cholesterol	Service provider

10

181   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, SOPs, 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

182

11

Patient and public involvement

184 Co-design has been integral to development of HEAL-D, and the original intervention was

185 designed in collaboration with members of African and Caribbean communities in south

186 London.[10] Patient and public involvement (PPI) will continue to be key throughout the

187 course of this project and a group of people with African and Caribbean heritage will be

188 recruited to support the study. These individuals will be service users who have completed

189 the HEAL-D online programme and lay partners who have offered to support future

190 development of the programme.

191 These individuals will form a reference group, and a series of workshops will be held with

192 them at key stages – including to inform the development of study materials and to inform

193 the analysis and reporting of the findings.

Theoretical frameworks

195 The evaluation is grounded on well-established implementation frameworks. Firstly, we will

196 apply an established model for multi-level outcome assessment for such evaluations.[12]

197 The model includes patient-level, service-level, and implementation outcomes. Secondly, the

198 'Exploration-Preparation-Implementation-Sustainment' (EPIS) framework will inform the

199 approach to analysis.[13] EPIS is an evidence-based framework providing a temporal lens to

200 explore the different stages of the implementation process, incorporating service and

201 system-level contextual factors that may impact on early phase preparatory work,

202 subsequent implementation and medium to longer-term sustainability.

Setting

204 Evaluation of HEAL-D online in south London

205 The evaluation will focus on the delivery of HEAL-D online in south London. HEAL-D online

206 has been commissioned for 12-months (starting in February 2022) as a pilot service and will

207 be hosted via Diabetes Book & Learn. The programme will be managed and delivered by

208 Guy's and St Thomas' NHS Foundation Trust (GSTT), London, UK.

209   Scaling-up of HEAL-D online

210   The scale-up study will explore how HEAL-D online could be scaled, implemented and

211   adopted in other regions in England.

212   **Participants and recruitment**

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

214   evaluations.

215   All sample sizes have been determined based on feasibility considering the total sample

216   available and the principle of saturation that we expect to observe in what participants will

217   report. For the latter, we have used established guidance that suggests that early themes

218   may appear in interview analysis of approximately 6 individuals, and stabilise within 12

219   interviews; taken together, our sampling framework establishes these recommended

220   numbers within a feasible timescale and resource available to carry out the evaluation [14].

221   Additionally, the sample size will be increased accordingly if, once the target sample is

222   achieved, saturation is not met.

223   Evaluation of HEAL-D online in south London

224   *HEAL-D online service users*: HEAL-D online has been commissioned for approximately 100

225   service users (i.e. approximately 10-15 courses) as part of routine care via Diabetes Book &

226   Learn. The programme will be delivered by GSTT as the service provider. The evaluation will

227   use data collected as part of routine care provided to HEAL-D online service users, which

228   includes a post-course questionnaire (Appendix 1). The questionnaire will be used to identify

229   participants who are willing to take part in interviews. The study will aim to invite 20

230   individuals to participate in an in-depth interview, but data collection will be guided by the

231   principle of saturation [14]. The questionnaire and interviews will assess individual

232   experiences of participating in the programme to understand the feasibility and acceptability

233   of HEAL-D online.

234   *Service delivery staff:* The evaluation will seek perspectives from staff involved in

235   implementing and delivering HEAL-D online in south London. A target of 10 staff (e.g.,

236   dieticians, physiotherapists, lay educators, service managers) will be invited to participate in

237   an interview. Some service delivery staff may have taken part in previous HEAL-D

238   evaluations [11].

239   Purposive sampling will be used for all qualitative data collection to ensure the evaluation

240   considers a range of perspectives. For service user interviews, this sampling will be guided

241   by considering age, gender and time since diagnosis, whereas for service delivery staff this

242   will consider different professional groups.

243   Scaling-up of HEAL-D online

244   *Commissioners and providers of diabetes services:* Approximately 15 key individuals from

245   commissioning and provider organisations from other regions in England will be invited to

246   take part in semi-structured interviews.

247   *Members of African and Caribbean communities:* Approximately 22 adult members of the

248   public from African and Caribbean communities who have a lived experience of type 2

249   diabetes will be invited to participate in focus groups and interviews. Community members

250   will be approached via community organisations with information about the study and an

251   invitation to participate.

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

253   collection.

254   **Data collection methods and sources**

255   Evaluation of HEAL-D online in south London

256   The study will use (i) service-level data routinely collected by the service provider, (ii) data

257   from service delivery staff interviews, (iii) data from service user interviews and

258   questionnaires, (iv) observations of HEAL-D online, and (v) project documentation. Table 1

259   outlines the data collection methods and data sources in more detail.

260 Data routinely collected by the service provider will be used to meet the study aims (Table

261 1). Approximately 100 service users will access the service during the study period. This will

262 include data on service user demographic characteristics (age range, gender, ethnicity and

263 comorbidities), attendance rates, dropout and did not attend (DNA) rates, completion rates,

264 and the Problem Areas In Diabetes (PAID-5) questionnaire.[15] PAID-5 is a patient-reported

265 outcome measure to explore disease status and wellbeing for people with diabetes.

266 Demographic data will be used to understand potential health inequities / access issues,

267 including digital exclusion. The study will not examine clinical outcome data to determine

268 effectiveness, as this falls outside the scope. However, it will explore the feasibility of

269 routinely collecting clinical outcome data for HbA1c, blood pressure and cholesterol. This is

270 to help understand the factors affecting the routine collection of clinical outcome data (e.g.

271 quality, completeness, burden) as part of on-going service improvement and the factors

272 affecting the implementation and scale-up of the service.

273 A post-course telephone questionnaire is administered by the service provider as part of

274 routine care (Appendix 1). The questionnaire collects post-course PAID-5 scores along with

275 service user experience, satisfaction, and perceived benefits of the programme.

276 One-to-one semi-structured interviews with HEAL-D online service users (n=20) will be used

277 to understand experience, satisfaction, acceptability, and perceived outcomes. Interview

278 participants will also be asked about the implications of a digital model for this type of

279 structured education for diabetes. One-to-one semi-structured interviews with service

280 delivery staff (n=10) will be used to explore acceptability, feasibility, issues of inclusion and

281 equity, potential improvements, and the factors affecting the implementation and scale-up of

282 the service.

283 Input unit costs and core elements of the service and pathway will be explored to understand

284 the factors that affect the implementation and scale-up of the service (from an operational

285 delivery and commissioning perspective), which will be collected via project documentation

286 and interviews.

287 Fidelity is the extent to which an intervention is delivered as intended and is important in

288 understanding the relationship between intervention, its implementation, and outcomes.[16]

289 The study will establish a checklist to assess fidelity to the core components and principles

290 underpinning HEAL-D online, which will include aspects of the structure and format, ethos,

291 quality of delivery (e.g. providers are trained to deliver HEAL-D), participant adherence, and

292 staff and participant perceptions on relevance and acceptability. The checklist will be piloted

293 and refined, as necessary. To manage the burden of data collection for the study team, staff

294 and patients, a range of pragmatic methods will be used to assess fidelity against the

295 checklist:

296 • Self-reporting by service users and service delivery staff via interviews - participants

297   will be asked to explore items in the fidelity checklist.

298 • Patient adherence numbers (i.e., the number of attendees per session per course) –

299   using routinely collected data from the training provider.

300 • Observation of HEAL-D online sessions – using the fidelity checklist, a senior staff

301   member in the service provider team will observe one session per HEAL-D online

302   course (i.e., over 10-15 courses), with the study team choosing the session at

303   random.

304 Scaling-up of HEAL-D online

305 Table 2 outlines the data collection methods and data sources in more detail for the scaling-

306 up of HEAL-D.

307 One-to-one semi-structured interviews (n=6) and focus groups (n=16, 2 focus groups of 8

308 people each) with members of the public from African and Caribbean communities with lived

309 experience of diabetes will be used to understand their perspective about the provision of

310 online learning (e.g. accessibility, acceptability, benefits, risks and limitations). These will be

311 used to understand perceptions of the potential acceptability and implications of a digital

312 model of participation in a structured education programme for diabetes. The combination of

313   interviews and focus groups is to ensure perspectives are obtained from people who may be

314   unable to attend a focus group due to personal circumstances (e.g. caring responsibilities,

315   mobility issues).

316   Additionally, semi-structured interviews (n=15) will be conducted with commissioners and

317   providers of diabetes services in other areas of England, which will be used to understand

318   the feasibility of a scaling up model from an operational delivery and commissioning

319   perspective.

320   For both aspects of the study (i.e., evaluation of HEAL-D online in south London and scaling

321   up of HEAL-D online), all interviews and focus groups will be conducted via video call,

322   telephone or in person (as appropriate with COVID-19 guidelines, and participant

323   preference). All topic guides will be piloted and refined where necessary. Appendices 2 and

324   3 outline the key lines of enquiry that will be used to inform the development of the topic

325   guides for the qualitative data collection (interviews and focus groups). These topic guides

326   will be finalised with input from key stakeholders, including public representatives, and will

327   be piloted as part of the development process.

328   **Data analysis and interpretation**

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

330   reference group.

331   Qualitative Data

332   Thematic analysis will be used to analyse qualitative data following the approach outlined by

333   Braun and Clarke.[17] Interview recordings will be transcribed professionally, identified

334   information will be removed and transcripts will be coded in NVivo. 10% of the interview data

335   will be double coded and consensus will be reached through a dialogue. Coded themes will

336   be reviewed using the Exploration-Preparation-Implementation-Sustainment (EPIS)

337   framework and discussed among the study team.[18]

338   Quantitative Data

339   Analysis will use descriptive statistics (mean, standard deviation, range, percentages) and

340   reporting summary tables and figures. Where relevant and feasible, data will be compared

341   between the face-to-face delivery of HEAL-D in the existing feasibility study of the

342   intervention.[11]

DISCUSSION

344   This study will evaluate the implementation and scale-up of HEAL-D online, as part of the

345   NHS Insight Prioritisation Programme (NIPP), which aims to gather rapid insights to support

346   the NHS' recovery to COVID-19. The study comprises 1) mixed methods evaluation to

347   understand the feasibility and acceptability of a virtually delivered, culturally tailored diabetes

348   self-management programme for African and Caribbean communities (HEAL-D online) in

349   south London and 2) a prospective qualitative study exploring the scaling up of HEAL-D

350   online.

351   The study design has been chosen to rapidly gather insights and to identify practical barriers

352   and enablers to implementation, whilst delivering maximum benefit to participants and

353   service users. A key strength of the approach is the co-design and delivery of the study,

354   which brings together a collaboration between the HIN (which directly supports scaled

355   implementation of evidenced interventions, such as HEAL-D) and ARC South London (which

356   studies implementation processes and outcomes), in partnership with people from African

357   and Caribbean communities with a lived experience of diabetes. The known limitation of the

358   approach is the absence of a control group and the use of routinely collected data, which

359   means the study is unable to determine true causation or effectiveness. However, it does

360   allow the assessment of the implementation and scale-up of HEAL-D online in a real world

361   setting to inform rapid service improvement and transformation to address an unmet need

362   for underserved communities.

363 **ETHICS AND DISSEMINATION PLAN**

364 Ethical clearance for this study was granted by King's College London's Research Ethics

365 Office under the 'Minimal Risk Registration' procedure (registration confirmation reference

366 number MRA-21/22-28498). All participants will provide written informed consent to

367 participate, including for their interviews to be recorded.

368 Results will be published in an international peer-reviewed journal and summaries will be

369 provided to the study funders as well as reference group members and study participants.

370

371

372

373

374

375

376

377

378

379

380

381

382

383

384

385 **LIST OF ABBREVIATIONS**

386 **AHSN:** Academic Health Science Network

387 **ARC:** Applied Research Collaboration

388 **COVID-19:** Coronavirus disease

389 **EPIS:** Exploration, Preparation, Implementation, Sustainment framework

390 **GSTT:** Guy's and St Thomas' NHS Foundation Trust

391 **HEAL-D:** Healthy Eating and Active Lifestyles for Diabetes

392 **HIN:** Health Innovation Network

393 **NHS:** National Health Service

394 **NIHR:** National Institute for Health and Care Research

395 **NIPP:** National Insights Prioritisation Programme

396 **PAID-5:** Problem Areas In Diabetes

397 **PPI:** Patient and public involvement

398 **PROM:** Patient-reported outcome measure

399

400

401

402

403

404

405

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

406 **STATEMENTS**

407 **Authors' contributions**

408 LG, AW, ZL, NC and NS conceived of and proposed the study, with SL, SI and OB

409 contributing to further study development. SL wrote the first draft of the manuscript. All

410 authors contributed edits to the manuscript. The corresponding author attests that all listed

411 authors meet authorship criteria and that no others meeting the criteria have been omitted.

412 The authors read and approved the final manuscript.

413 **Funding statement**

414 The development of HEAL-D was supported by funding from National Institute for Health and

415 Care Research (NIHR). The study is funded by NHS England (grant number N/A) with a

416 peer review process by National Insights Prioritisation Programme (NIPP) commissioned by

417 the NHS Accelerated Access Collaborative and NIHR.

418 This study/project is supported by the NIHR Applied Research Collaboration South London

419 (NIHR ARC South London) at King's College Hospital NHS Foundation Trust. The views

420 expressed are those of the author(s) and not necessarily those of the NIHR or the

421 Department of Health and Social Care.

422 NS is a member of King's Improvement Science, which offers co-funding to the NIHR ARC

423 South London and is funded by King's Health Partners (Guy's and St Thomas' NHS

424 Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London

425 and South London and Maudsley NHS Foundation Trust), and Guy's and St Thomas'

426 Foundation.

427 **Competing interests statement**

428 NS is the director of the London Safety and Training Solutions Ltd, which offers training in

429 patient safety, implementation solutions and human factors to healthcare organisations. LG

430   is involved in the delivery of the HEAL-D programme that is being evaluated in this research.

431   The other authors have no conflicts of interest to declare.

436

437

438

439

440

441

442

443

444

445

446

447

448

449

450

451

1
2
3   452 **REFERENCES**
4
5
6   453 1 Giles C, Day A. Is there a role for an embedded knowledge specialist in an organisation
7   454   like an Academic Health Science Network? A retrospect of a one year pilot. *Business*
8   455   *Information Review* 2021;**38**:138–43. doi:10.1177/02663821211032861
9
10   456 2 Eccles MP, Mittman BS. Welcome to Implementation Science. *Implementation Science*
11   457   2006;**1**:1. doi:10.1186/1748-5908-1-1
12
13   458 3 Sibley A, Ziemann A, Robens S, *et al.* Review of spread and adoption approaches
14   459   across the AHSN Network. Wessex AHSN 2021.
15   460   https://www.ahsnnetwork.com/app/uploads/2021/05/Spread-and-adoption-review-
16   461   final.pdf?utm_source=AHSNs&utm_medium=toolkit&utm_campaign=Spread%20and%2
17   462   0adoption%20report
18
19
20   463 4 Walker A, Dale C, Curran N, *et al.* Leading the spread and adoption of innovation at
21   464   scale: an Academic Health Science Network's perspective. *BMJ Leader* 2021;**5**:155.
22   465   doi:10.1136/leader-2020-000252
23
24   466 5 Wilson C, Alam R, Latif S, *et al.* Patient access to healthcare services and optimisation
25   467   of self-management for ethnic minority populations living with diabetes: a systematic
26   468   review. *Health & Social Care in the Community* 2012;**20**:1–19. doi:10.1111/j.1365-
27   469   2524.2011.01017.x
28
29   470 6 Becker E, Boreham R, Chaudhury M, *et al.* The health of minority ethnic groups.
30   471   2004.https://lemosandcrane.co.uk/resources/National%20Statistics%20-
31   472   %20Health%20Survey%20for%20England%202004.pdf (accessed 21 Feb 2022).
32
33   473 7 James GD, Baker P, Badrick E, *et al.* Type 2 diabetes: a cohort study of treatment,
34   474   ethnic and social group influences on glycated haemoglobin. *BMJ Open*
35   475   2012;**2**:e001477. doi:10.1136/bmjopen-2012-001477
36
37   476 8 Lanting LC, Joung IMA, Mackenbach JP, *et al.* Ethnic Differences in Mortality, End-
38   477   Stage Complications, and Quality of Care Among Diabetic Patients: A review. *Diabetes*
39   478   *Care* 2005;**28**:2280–8. doi:10.2337/diacare.28.9.2280
40
41   479 9 Goff LM, Moore AP, Harding S, *et al.* Development of Healthy Eating and Active
42   480   Lifestyles for Diabetes, a culturally tailored diabetes self-management education and
43   481   support programme for Black-British adults: A participatory research approach. *Diabetic*
44   482   *Medicine* 2021;**38**:e14594. doi:10.1111/dme.14594
45
46   483 10 Goff LM, Moore AP, Rivas C, *et al.* Healthy Eating and Active Lifestyles for Diabetes
47   484   (HEAL-D): study protocol for the design and feasibility trial, with process evaluation, of a
48   485   culturally tailored diabetes self-management programme for African-Caribbean
49   486   communities. *BMJ Open* 2019;**9**:e023733. doi:10.1136/bmjopen-2018-023733
50
51   487 11 Goff LM, Rivas C, Moore A, *et al.* Healthy Eating and Active Lifestyles for Diabetes
52   488   (HEAL-D), a culturally tailored self-management education and support program for type
53   489   2 diabetes in black-British adults: a randomized controlled feasibility trial. *BMJ Open*
54   490   *Diab Res Care* 2021;**9**:e002438. doi:10.1136/bmjdrc-2021-002438
55
56   491 12 Proctor E, Silmere H, Raghavan R, *et al.* Outcomes for implementation research:
57   492   conceptual distinctions, measurement challenges, and research agenda. *Adm Policy*
58   493   *Ment Health* 2011;**38**:65–76. doi:10.1007/s10488-010-0319-7
59
60

494 13 Moullin JC, Dickson KS, Stadnick NA, *et al.* Systematic review of the Exploration,
495   Preparation, Implementation, Sustainment (EPIS) framework. *Implementation Science*
496   2019;**14**:1. doi:10.1186/s13012-018-0842-6

497 14 Guest G, Bunce A, Johnson L. How Many Interviews Are Enough?: An Experiment with
498   Data Saturation and Variability. *Field Methods* 2006;**18**:59–82.
499   doi:10.1177/1525822X05279903

500 15 McGuire BE, Morrison TG, Hermanns N, *et al.* Short-form measures of diabetes-related
501   emotional distress: the Problem Areas in Diabetes Scale (PAID)-5 and PAID-1.
502   *Diabetologia* 2009;**53**:66. doi:10.1007/s00125-009-1559-5

503 16 Carroll C, Patterson M, Wood S, *et al.* A conceptual framework for implementation
504   fidelity. *Implement Sci* 2007;**2**:40. doi:10.1186/1748-5908-2-40

505 17 Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in*
506   *Psychology* 2006;**3**:77–101. doi:10.1191/1478088706qp063oa

507 18 Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based
508   practice implementation in public service sectors. *Adm Policy Ment Health* 2011;**38**:4–
509   23. doi:10.1007/s10488-010-0327-7

510

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

APPENDICES

Appendix 1. Post HEAL-D online course questionnaire

No.	Question	Possible answers
1	How did you hear about HEAL-D?	GP Diabetic nurse Dietician Family / friend Other (please note)
2a	When you first heard about HEAL-D, what 3 main things did you expect to get out of the course?	
2b	To what extent were these expectations met? Were your expectations exceeded, met, partially met or not met?	Exceeded met partially met not met
3	For the following questions, on a scale of 1-5 where 1 is not a problem and 5 is a serious problem, please can you rate the following statements:	
3a	Feeling scared when you think about living with diabetes	1 Not a problem 2 Minor Problem 3 Moderate problem 4 Somewhat a serious problem 5 Serious problem
3b	Feeling depressed when you think about living with diabetes	
3c	Worrying about the future and the possibility of serious complications	
3d	Feeling that diabetes is taking up too much of your mental & physical energy every day	
3e	Coping with the complication of diabetes	
4	For the following questions, please rate the following statements about HEAL-D on a	

		scale of 1 – 5 where 1 is strongly agree and 5 is strongly disagree	
4a	HEAL-D has helped me learn to manage my diabetes		1 Strongly agree
4b	I have learnt practical skills that I will apply to my daily life		2 Agree
4c	I feel motivated to follow the HEAL-D advice		3 Neither agree nor disagree
4d	HEAL-D has helped me feel supported in living with diabetes		4 Disagree
4e	It has helped me to feel confident in managing my diabetes		5 Strongly disagree
4f	It was helpful to meet other people with diabetes		
5	For the next questions, please rate the following aspects of HEAL-D on a scale of excellent, good, average or poor. And can you please let me know why you have given this rating?		
5a	Initial phone call with HEAL-D team		Excellent
5b	HEAL-D starter pack		Good
5c	Exercise classes		Average
5d	Cooking session		Poor
5e	Delivery by the facilitators		
5f	Interaction with the facilitators		
5g	Interaction with other people on your cohort		
6	Thinking about the video calling facilities,		
6a	How easy did you find it to use? On a scale of 1—5 where 1 is very easy and 5 is very difficult		1. Very Easy 2. Easy 3. Neither easy nor difficult 4. Difficult 5. Very difficult
6b	How did you find the instructions for using bluejeans? Excellent, good, average or poor?		Excellent Good

			Average
			Poor
7a	Have you lost any weight since you started the course?		
7b	Have you noticed a reduction in your waist measurements?		
8	If HEAL-D was available face-to-face or remote, which would you prefer?		Face to face Remote No preference
9	When would be your preferred timing for attending HEAL-D?		No preference Weekday daytime Weekday evening Saturday morning
10	Overall - Please tell us what went well		
11	Overall - Please tell us if there is anything that you believe would enhance the course		
12	Overall - Would you recommend HEAL-D to family/friends		Yes No
13	Do you have any other comments/feedback?		
14	We are currently completing an evaluation of the HEAL-D programme, and we are asking people to complete a telephone / video interview in order to find out their experiences. It will be similar to this questionnaire, and will take approx. 30 minutes. You will also be offered £15 for your time. If you would be interested in taking part, can you please confirm that you are happy for me to share		Yes No

	your details with the project team?	
15	HEAL-D is currently only delivered in South London, but we are looking to develop it further. Would you be interested in hearing about HEAL-D in the future?	Yes No

Appendix 2. Key lines of enquiry to inform the interview guide development for the evaluation of HEAL-D online in south London

Service users

- What is your experience of and perceptions about the acceptability of HEAL-D online?

- What implications does a digital model of delivery have on participation?

- What impacts (positive and negative) have you gained from participating in HEAL-D online?

- How could the model be improved?

Service delivery staff

- What is the feasibility and acceptability of HEAL-D online for African and Caribbean people with diabetes?

- What perceived impacts (positive and negative) does the model have for patients, the service and health system?

- What implications does a digital model of delivery have on participation?

- What factors affect the implementation and delivery of HEAL-D online in south London?

- How could the model be improved?

Appendix 3. Key lines of enquiry to inform interview guide development for the scale up HEAL-D study

Public members topics guide

- What are your preferences around accessing a self-management course online versus face to face, and why?

- Describe the potential challenges of attending an online course?

- Describe the potential benefits of attending an online course?

Commissioners of diabetes services topic guide

- What evidence would be required for you to commission a HEAL-D online course?

- What are the barriers and facilitators to commissioning HEAL-D?

Service providers and professionals delivering diabetes topic guide

- What are the potential challenges you may face when implementing and delivering a virtual course?

- What benefits can you see to delivering a virtual course?

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Standards for Reporting Implementation Studies: the StaRI checklist for completion

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

| The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. | The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations. |

The StaRI standards refers to the broad range of study designs employed in implementation science.   Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	1	1-2	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	2-3	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	3	4-7	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale*	4	8, 12	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	5-6	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Please note: the STaRI checklist is most appropriate checklist, however as this is a protocol of an evaluation (guided by implementation science and theory) not all items are applicable. Where highlighted (by ''), information has been included in the protocol about the checklist item but it does not directly correlate with the StaRI description.*

1

Aims and objectives*	**5**	7	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Design	**6**	8	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context*	**7**	12-13	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	N/A	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	13-14	The population targeted by the intervention and any eligibility criteria.
Description	**9**	N/A	A description of the implementation strategy	5-6	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Outcomes	**11**	9-11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	9-11	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	9-11	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	N/A	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	13-16	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	17	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	N/A	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Please note: the STaRI checklist is most appropriate checklist, however as this is a protocol of an evaluation (guided by implementation science and theory) not all items are applicable. Where highlighted (by ''), information has been included in the protocol about the checklist item but it does not directly correlate with the STaRI description.*

2

Results *(all N/A as this is a protocol)*					
Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	3-4, 17-18	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	N/A	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	N/A	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	22-23	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

Please note: the STaRI checklist is most appropriate checklist, however as this is a protocol of an evaluation (guided by implementation science and theory) not all items are applicable. Where highlighted (by ''), information has been included in the protocol about the checklist item but it does not directly correlate with the STaRI description.

3