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Study Protocol: Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) - a feasibility trial, with process evaluation, of a culturally-tailored diabetes self-management programme for African-Caribbean communities

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3 **1 Study Protocol: Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) - a**
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5 **2 feasibility trial, with process evaluation, of a culturally-tailored diabetes self-**
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7 **3 management programme for African-Caribbean communities**
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9

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3 **13 ABSTRACT**

4 **14 Introduction**

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6
7 15 Black-British communities are disproportionately burdened by type 2 diabetes (T2D); it
8
9 16 occurs earlier, with worse control at diagnosis, and is associated with poorer outcomes
10
11 17 compared to White-British groups. Tackling these inequalities is a priority for both healthcare
12
13 18 providers and patients. Culturally-tailored diabetes education provides long-term benefits
14
15 19 superior to standard care but to date such programmes have only been developed in the USA.
16
17 20 The Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) programme of research
18
19 21 aims to develop a culturally-tailored, evidence-based diet and lifestyle intervention for
20
21 22 managing T2D in Black-British communities; and to evaluate its acceptability and the
22
23 23 feasibility of conducting a future effectiveness trial of HEAL-D.
24
25

26 **24 Methods & analysis**

27
28 25 Informed by MRC Complex Interventions guidance this research will rigorously develop and
29
30 26 evaluate the implementation of the HEAL-D intervention. In Phase 1 the intervention will be
31
32 27 developed through co-design methods, which will seek to foster community engagement and
33
34 28 identify the intervention's underpinning programme theory and cultural adaptations. Focus
35
36 29 groups and interviews will be conducted with key stakeholders (patients, healthcare
37
38 30 professionals and community leaders). The qualitative data will be analysed using the
39
40 31 framework approach to identify priority behaviours of focus for the intervention, key barriers
41
42 32 and facilitators to behaviour change and healthcare engagement, favoured settings, and a
43
44 33 rudimentary draft of the cultural adaptations. We will map our analysis onto the Capability-
45
46 34 Opportunity-Motivation-Behaviour (COM-B) framework from the Behaviour Change Wheel
47
48 35 to ascertain appropriate behaviour change techniques for the intervention. In Phase 2 process
49
50 36 evaluation methods will evaluate the delivery and acceptability of HEAL-D, and the
51
52 37 feasibility of conducting a future effectiveness trial.
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38 **Ethics & dissemination**

39 This study is funded by a National Institute of Health Research Fellowship (CDF-2015-08-
40 006). It has been approved by the Fulham: London Research Ethics Committee (17-LO-
41 1954). Results will be disseminated at national and international conferences, in peer-
42 reviewed publications and through local and national clinical diabetes networks.

44 **Strengths and limitations of this study**

- 45 • This study employs rigorous complex intervention methodology to develop and
46 evaluate the implementation of a culturally-tailored diabetes self-management
47 intervention.
- 48 • Our intervention, HEAL-D, is designed using a ‘bottom-up’ approach, employing
49 participatory co-design methods to foster community engagement and partnership.
- 50 • We will identify the cultural adaptations of our intervention and its underpinning
51 theoretical basis through thematic analysis and the COM-B behavior change
52 framework.
- 53 • The feasibility study will provide us with key information about the feasibility of
54 running a full-scale trial of HEAL-D.
- 55 • Process evaluation methods will enable us to understand how and why the
56 intervention was effective or ineffective.

57
58 **Keywords:** African, Caribbean, ethnicity, type 2 diabetes, education, self-management, diet,
59 lifestyle

60 INTRODUCTION

61 Type 2 diabetes (T2D) affects approximately 3 million people in England and consumes
62 around 10% of the National Health Service (NHS) budget, estimated at almost £9 billion in
63 2011 (1). Diabetes and its associated complications place an illness burden on patients and
64 carers, which disproportionately affects those from ethnic minority backgrounds (2). The
65 estimated prevalence of T2D is up to 3 times higher for Black-British communities compared
66 to White Europeans (3). T2D occurs at a younger age in Black-British people, with worse
67 control at the time of diagnosis, and is associated with poorer outcomes (4, 5) thus making
68 healthcare for this community a priority (6, 7).

69 Poor access to diabetes healthcare is a significant issue for minority ethnic groups (2). First-
70 line diabetes management is situated in primary care and aims to promote patient
71 involvement and self-management (8), enabling patients to adopt a healthy lifestyle and to
72 manage their diabetes through support and education (9). To achieve this, diabetes services
73 principally aim to deliver care that is patient-centred and intended to be responsive to
74 individual culture, lifestyle and religion (10). However ethnic minority groups report finding
75 it more difficult to access primary care services (11) and are more likely to report that they
76 have not had the opportunity to attend a diabetes education course than White populations
77 (12). Specifically, African-Caribbean (AfC) communities often report a distrust of medical
78 advice and a desire for natural, non-pharmacological therapies (13). Furthermore, healthcare
79 professionals are perceived as lacking cultural understanding (14) and their advice as lacking
80 cultural relevance (15) or being poorly adapted to culture and needs (13) despite their
81 intentions; these issues may contribute to the poorer diabetes outcomes and increased
82 morbidity experienced by AfC patients.

1
2
3 83 Culturally tailored healthcare is proposed to be one of the main ways in which healthcare
4
5 84 disparities can be addressed (16-18) and is identified as a priority by patients (6). Culturally-
6
7 85 tailored diabetes education has demonstrated greater improvements in diabetes control and
8
9 86 knowledge than usual care, and the benefits are maintained long-term (17, 19). However, to
10
11 87 date, culturally tailored interventions for the African diaspora have largely been based in the
12
13 88 USA, and may not translate to UK AfC communities or healthcare structures (18).

14
15
16 89 Healthy Eating & Active Lifestyles for Diabetes (HEAL-D) is a two-phase programme of
17
18 90 research in which a culturally-tailored, evidence-based diet and lifestyle intervention for
19
20 91 managing T2D in African and Caribbean communities will be developed using co-design
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22 92 methods, and subsequently evaluated in a feasibility trial. The purpose of this article is to
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24 93 present the protocol for HEAL-D.

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3 97 **PURPOSE & AIMS**
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6 98 The overall aims of this research are to develop a culturally-tailored, evidence-based diet and
7
8 99 lifestyle intervention for managing T2D among AfC communities in primary care, called
9
10 100 HEAL-D, and to determine the feasibility of evaluating HEAL-D through a future
11
12 101 effectiveness trial.
13

14
15 102 The objectives are to:
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- 17
18 103 1. Develop a diet and lifestyle intervention appropriately tailored for AfC patients
19
20 104 through co-design methods.
21
22 105 2. Identify effective modes of sustainable engagement of key stakeholders, including
23
24 106 patients, healthcare providers, and community leaders.
25
26 107 3. Establish the feasibility of embedding delivery of a culturally-tailored programme into
27
28 108 existing care pathways.
29
30 109 4. Establish the feasibility of conducting an effectiveness trial of HEAL-D, considering
31
32 110 issues such as participation rates and reach, potential effect sizes and cost evaluation.
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112 **METHODS AND ANALYSIS**

113 Guided by the MRC Complex Interventions framework (20), HEAL-D will consist of two
114 distinct phases: phase 1 is a formative phase in which the intervention will be developed; and
115 in phase 2, the intervention will be evaluated in a feasibility trial (Figure 1).

116 **Phase 1 – Development of a culturally-tailored diet and lifestyle intervention for** 117 **managing T2D**

118 The HEAL-D intervention aims to provide a programme of self-management education and
119 behaviour change for AfC patients with T2D to achieve existing evidence-based diet and
120 lifestyle goals (21), specifically:

- 121 1. Modest weight loss (5-10%) or weight maintenance in those of healthy weight
- 122 2. 150 minutes per week of moderate-to-vigorous intensity aerobic physical activity plus
123 2 sessions per week of strength training
- 124 3. Balanced carbohydrate intakes through portion control and promotion of low
125 glycaemic index and wholegrain sources
- 126 4. Limited saturated fat intake (<10% of energy intake) and replacement with mono-
127 unsaturated fats
- 128 5. Limited salt intake (<6g per day)
- 129 6. Oily fish consumption at least twice per week

130 ***Identifying the intervention's theoretical basis***

131 Behavioural interventions are more effective if they have a theoretical under-pinning (20)
132 (REF NICE 2014) so that what changes are expected and how these will be achieved can be
133 predicted from consideration of known behaviour change techniques. The theoretical basis
134 (or programme theory) for HEAL-D will be identified through two processes; firstly an
135 evidence synthesis of key themes from published literature relating to adapting health

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2
3 136 promotion interventions for ethnic minority groups, and secondly through new primary
4
5 137 research. A number of recent systematic reviews have evaluated the evidence for designing
6
7 138 health promotion interventions for ethnic minority groups. Aside from acknowledging the
8
9 139 lack of UK-based studies, these reviews have made the following recommendations:

- 10
11
12 140 • Focus on community-level interventions rather than traditional ‘medical model’,
13
14 141 individual-centred behavioural approaches (18).
- 15
16 142 • Employ participatory methods e.g. patient involvement in intervention design, lay-led
17
18 143 delivery of interventions, and community empowerment. These are highly effective at
19
20 144 improving health behaviours and self-efficacy across a number of conditions (22).
- 21
22 145 • Use community gathering places e.g. faith institutions, which offer the benefit of
23
24 146 cultural relevancy and may reach populations who would not normally access self-
25
26 147 management education (23).
- 27
28 148 • Foster community engagement to overcome issues of deep-rooted, historical distrust
29
30 149 of medical advice and settings, develop and nurture trust between the researchers and
31
32 150 community, and nurture the strong sense of collectivism and kinship networks that are
33
34 151 evident amongst AfC communities.
- 35
36 152 • Acknowledge the powerful influence of social networks on health beliefs and
37
38 153 behaviours (24); delivering care in a social context has been shown to promote
39
40 154 engagement and be more effective than traditional individual-centred behavioural
41
42 155 approaches (18).

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47 156 HEAL-D will be grounded in these principles however, the theoretical basis of our
48
49 157 intervention will be expanded through our co-design work.

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52 158 ***Co-designing the intervention through participatory methods***

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3 159 HEAL-D will use participatory co-design methods to engage patients, healthcare providers
4
5 160 and community leaders (e.g. church leaders, community group leads), in focus groups,
6
7 161 interviews and workshops to achieve the following aims:

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9
10 162 1) understand the issues that affect healthcare engagement and delivery for AfC T2D
11
12 163 patients and thus contribute to the programme theory for our intervention, specifically
13
14 164 (along with the evidence synthesis findings):

- 15
16 165 • What are the barriers and facilitators to motivate and sustain changes in lifestyle
17
18 166 behaviours in AfC T2D patients?
19
20
21 167 • What barriers and enablers exist relating to embedding/implementation of a
22
23 168 culturally-tailored intervention in existing care pathways?

24
25 169 2) design the cultural adaptations of our intervention:

- 26
27 170 • What adaptations are needed to diet and lifestyle interventions for T2D to ensure
28
29 171 cultural sensitisation?

30
31
32 172 3) foster community engagement and support for HEAL-D, thus facilitating implementation
33
34 173 of the intervention:

- 35
36 174 • What are the processes that effectively engage AfC communities (e.g. churches,
37
38 175 community organisations) in a partnership to develop and deliver a lifestyle
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40 176 intervention for T2D management?

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43 177 *Focus groups and interviews*

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46 178 Focus groups, 8-10 groups of 6-8 participants, will be conducted with patients with T2D of
47
48 179 AfC ethnicity, recruited through local churches, mosques and community groups, as well as
49
50 180 through GP practices in Lambeth and Southwark. The focus groups will be conducted in local
51
52 181 accessible community venues e.g. church hall, library, community centre. Patients will be
53
54 182 purposively sampled to get a spread of socio-economic position, generational status and

1
2
3 183 ancestral origins, as principal factors impacting on health status, healthcare access and
4
5 184 cultural behaviours in these groups (25-27). Separate focus groups will be conducted with
6
7 185 men and women, and patients of direct African vs Caribbean ancestry, as they report different
8
9 186 cultural barriers/facilitators to lifestyle change (25, 26). A topic guide (Figure 3) based on
10
11 187 themes identified in the literature, will be used to steer discussions and ensure coverage of
12
13 188 key themes whilst encouraging free discussion of opinion/perspective. Focus groups are
14
15 189 being used to understand normative needs, as suited to the development of a community
16
17 190 intervention.

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21 191 Semi-structured interviews will be conducted with 8-10 healthcare providers, including
22
23 192 general practitioners, practice nurses, diabetes specialist nurses, diabetes specialist dietitians
24
25 193 and commissioners. The interviews will cover issues relating to healthcare needs and
26
27 194 engagement of AfC patients, experiences of delivering healthcare to AfC patients, and
28
29 195 barriers and facilitators to working in partnership with community groups to deliver care for
30
31 196 AfC communities (Figure 3). Interviews have been selected for this part of the study to
32
33 197 enable us to gather a full range of experiences and therefore optimise implementation.

34
35
36 198 Community leaders representing faith and non-faith institutions (n=4-6) will be invited to
37
38 199 participate in semi-structured interviews. Leaders will be identified initially through existing
39
40 200 networks e.g. Diabetes UK Community Champions initiative. Word-of-mouth and ‘snow-
41
42 201 balling’, techniques that are highly effective within these communities, will be used to recruit
43
44 202 a wider network. The interviews will cover issues relating to the role of community networks
45
46 203 in promoting health of AfC communities, sustaining health amongst community members,
47
48 204 and opportunities for greater impact (Figure 3).

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52 205 *Analysis*

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3 206 The focus groups and interviews will be digitally recorded and transcribed verbatim. The data
4
5 207 will be analysed using the framework approach in NVivo (QSR International), theoretically
6
7 208 driven by socio-ecological theory to identify themes relating to issues at the individual,
8
9 209 family, community and healthcare delivery levels and how these influence self-efficacy and
10
11 210 behaviour change. Our analysis will identify priority behaviours of focus for the intervention,
12
13 211 key barriers and facilitators to behaviour change and healthcare engagement, favoured
14
15 212 settings, and a rudimentary draft of the cultural adaptations. Deviant case analysis, that is
16
17 213 consideration of cases that do not fit the general picture, will be undertaken, though our
18
19 214 primary interest is in the commonalities as this is a community level intervention. Primary
20
21 215 coding and development of a coding scheme will be carried out by a single researcher; a
22
23 216 second researcher will independently use this coding scheme to code 20% of the data for
24
25 217 cross-comparison, to improve dependability. This will provide methodological rigour
26
27 218 required for confidence in the analysis of the qualitative data. The themes will be fed-back
28
29 219 and discussed with a Service User Group that will consist of representatives of patients,
30
31 220 healthcare providers, and community leaders to ensure trustworthiness of conceptualisations.
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36 221 We will divide our data into behavioural ‘barriers’ and ‘facilitators’ where possible. To
37
38 222 ascertain appropriate behaviour change techniques for our intervention (28) we will map our
39
40 223 analysis onto the Capability-Opportunity-Motivation-Behaviour (COM-B) framework from
41
42 224 the Behaviour Change Wheel (29), and thence in each case consider the outcome behaviours
43
44 225 that our intervention will aim to achieve, a worked example is shown in Figure 2. We will use
45
46 226 the COM-B framework to identify appropriate *functions* of our intervention to optimise
47
48 227 enablers and overcome barriers to achievement of planned outcomes, e.g. ‘education’ for
49
50 228 capability barriers, ‘modelling’ for opportunity and motivation barriers. Finally we will select
51
52 229 specific behaviour change techniques e.g. education, goal setting, that focus on the specific
53
54 230 functions we have identified. This will form the intervention programme theory that we draw
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3 231 on for the next stage of the study, as documented through a logic diagram. Themes that do
4
5 232 not map clearly onto the COM-B framework will also inform the programme theory e.g.
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7 233 contextual themes at the community and health system levels..
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10 234 *Stakeholder co-design workshops*

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12 235 Following evaluation of the focus groups and interviews our stakeholders, 12-15 patients,
13
14 236 healthcare providers, commissioners and community leaders, will be invited to participate in
15
16 237 a series of 2-3 half-day workshops, held in community locations. The workshops will seek to
17
18 238 gain stakeholder involvement in developing the details of the interventions, determining the
19
20 239 setting, the media channels, structure and delivery. In the first workshop the research team
21
22 240 will feed back the findings of the focus groups and interviews; anonymised interview extracts
23
24 241 will be presented to illustrate the key themes and issues that were identified. The stakeholders
25
26 242 will be asked to discuss the themes and behavioural targets in small groups, using directed
27
28 243 tasks/questions to facilitate the discussions. Following the small group discussions the
29
30 244 researchers will facilitate discussion as a whole to clarify/confirm interpretation; open
31
32 245 discussion/debate will be encouraged to examine the themes in depth and for all stakeholders
33
34 246 to agree a mutual understanding.
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39 247 In the second workshop elements of the proposed intervention will be presented for comment,
40
41 248 refining and development. Using scenarios, the stakeholders will be asked to brainstorm, in
42
43 249 small groups, key issues relating to the scenarios. For example, the moderator will present
44
45 250 scenarios relating to the intervention setting and the attendees will be asked to discuss and
46
47 251 identify the pros and cons of each, and then feed back their discussions to the other attendees.
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49 252 The research team will then facilitate cross-discussion between groups to develop the
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51 253 conclusions and a consensus.
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3 254 In the final workshop draft intervention materials, developed from workshops 1 and 2, will be
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5 255 presented. For example, media channels that could be used to promote behaviour change such
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7 256 as testimonials, story-telling, and cooking demonstrations. The stakeholders will be divided
8
9 257 into small groups to discuss and provide feedback on the acceptability of the components of
10
11 258 the intervention and identify potential barriers to engagement. Following the small group
12
13 259 discussions the researchers will facilitate feedback and encourage discussion as a whole to
14
15 260 clarify/confirm the researcher's interpretation. The intervention template may be further
16
17 261 refined, and will be developed into the detailed programme.

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20 262 The workshop discussions will be digitally audio-recorded to allow the researchers to revisit
21
22 263 the discussions as they develop the intervention details. The workshops will be analysed
23
24 264 thematically at a descriptive level in order to inform the intervention design rather than for
25
26 265 the development of conceptualisations. If the discussions are lengthy and complex they will
27
28 266 be transcribed for this, if not, the researchers will take notes as they listen to the audio-
29
30 267 recordings.

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34 268 **Phase 2 – Evaluation of HEAL-D; a culturally-tailored diet and lifestyle intervention for**
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36 269 **managing T2D in African and Caribbean communities**

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39 270 In phase 2 a feasibility study, with an embedded process evaluation, will be conducted to
40
41 271 address the following objectives:

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43
44 272 1. Estimate the effect of the intervention on a range of diabetes-related outcomes
45
46 273 including HbA1c, weight, waist circumference, blood pressure, dietary intake,
47
48 274 physical activity levels, diabetes knowledge, quality of life to inform an effectiveness
49
50 275 trial.
- 51
52 276 2. Evaluate the acceptability of the intervention.
- 53
54 277 3. Evaluate implementation of the intervention, including fidelity and contextual factors.
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3 278 4. Evaluate the feasibility of trial procedures.
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6 279 *Study Design*
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8 280 The feasibility study will use a randomised controlled design (Figure 1), with individual
9
10 281 patients as the unit of randomisation, evaluating HEAL-D against usual care. In addition
11
12 282 there will be a cohort of phase 1 co-design patients who will be allocated to the intervention
13
14 283 arm (not randomised) because their involvement in the intervention design phase would
15
16 284 contaminate the control arm. These patients are included in the feasibility study to allow us to
17
18 285 evaluate the impact of former involvement on intervention engagement, acceptability and
19
20 286 ownership. The RCT design has been chosen to [a] test the feasibility of recruiting and
21
22 287 retaining a control arm, [b] define what constitutes ‘usual care’ and the variability within that,
23
24 288 [c] determine the feasibility of using individual randomisation in a full-scale trial, looking
25
26 289 particularly at issues of sample size and contamination between study arms, and [d] evaluate
27
28 290 the impact of intervention development involvement on subsequent uptake and acceptability.
29
30

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32
33 291 *Participants*
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35 292 Participants will principally be recruited from General Practice in the London Boroughs of
36
37 293 Lambeth and Southwark through screening of referrals for structured education and letters of
38
39 294 invitation to patients with established T2D. In addition participants from the phase 1 co-
40
41 295 design study will be invited to participate, and self-referral methods will also be used, for
42
43 296 example posters and advertisements in community locations.
44
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47 297 Patients with diagnosed T2D who are of African or Caribbean ethnicity and with capacity to
48
49 298 provide fully informed consent to participation in research will be eligible to participate in the
50
51 299 trial. Ethnicity will be self-declared using the standard NHS ethnicity categorisation
52
53 300 questionnaire. Patients who are unable to communicate in English and patients with complex
54
55 301 therapeutic dietary needs may be ineligible to participate if their individual needs are deemed
56
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2
3 302 incompatible with the aims of the intervention. This is because the intervention will provide
4
5 303 general diet and lifestyle advice for the self-management of T2D in a group setting; in cases
6
7 304 of patients with certain comorbidities e.g. advanced renal disease, the intervention may be
8
9 305 inappropriate for the individual, and the group nature of the intervention will prevent their
10
11 306 individual needs from being addressed.

12
13
14 307 A pragmatic sample size of 120 patients is anticipated to be sufficient to evaluate the
15
16 308 programme, allowing for 20% drop-out/non-completion; 80 patients will be randomised, 40
17
18 309 in each arm, and a further cohort of patients (n=40) from phase 1 will be allocated to the
19
20 310 intervention arm without randomisation. As this is a feasibility trial it is not powered to detect
21
22 311 statistically significant intervention effects. A primary objective of the study is to provide
23
24 312 estimates of key parameters such as potential effect sizes, recruitment and retention rates of
25
26 313 the trial and participation rates of the programme, so that the optimal design of a full-scale
27
28 314 trial can be determined.

31 315 *Intervention and control arms*

32
33 316 Participants in the control arm will continue with usual care deemed appropriate and
34
35 317 delivered by their primary care team, which may include referral to group structured
36
37 318 education and/or one-to-one consultations with healthcare professionals.

38
39
40 319 Participants in the intervention arm will be offered the HEAL-D programme, which will
41
42 320 deliver a curriculum of culturally-tailored, evidence-based diet and physical activity
43
44 321 education and behavior change in a group setting. The details of each session, particularly the
45
46 322 behavior change techniques and corresponding activities will be identified through the phase
47
48 323 1 co-design work.

49
50
51 324 The proposed curriculum is as follows:

- 52
53
54
55 325 1. *'Diabetes: it's in your hands'*: an introduction to self-management principles.

- 326 2. *'Get moving!'*: the role of physical activity in type 2 diabetes management.
- 327 3. *'Taking control'*: understanding carbohydrates & portion sizes.
- 328 4. *'Shape up!'*: weight management for diabetes.
- 329 5. *'Drop the pressure'*: managing cardiovascular health.
- 330 6. *'Plans for life: yes you can!'*: long-term maintenance of healthy lifestyles.

331 The sessions will consist of group-based education and behavior change techniques/activities,
332 and participation in instructor-led physical activity.

333 The education sessions will be delivered through educator-led interactive discussion,
334 however support materials will be provided to reinforce the learning e.g. videos and written
335 information booklets detailing evidence-based diet and physical activity guidance, which is
336 culturally tailored for the African and Caribbean communities.

337 *Data Collection*

338 Participants will attend a baseline and post-intervention follow-up assessment visit at 26-32
339 weeks. Data collection will focus on the following:

- 340 A. Estimating the effect of the intervention on potential trial outcomes
 - 341 • HbA1c, total- HDL- & LDL-cholesterol, triglycerides: a 5ml venous blood sample
342 will be taken for analysis of HbA1c & lipids.
 - 343 • Body weight, height and body mass index (BMI): body weight will be measured
344 using digital scales, with the patient wearing light clothing (without shoes), to the
345 nearest 0.1 kg. Height will be measured, using a stadiometer, without shoes.
 - 346 • Waist circumference: measured using a flexible tape, with the patient wearing
347 only light clothing, at the mid-point between the lowest rib and the iliac crest.
 - 348 • Systolic and diastolic blood pressure: the mean of three seated readings, taken
349 using an automated sphygmomanometer.

- 1
2
3 350 • Diet & physical activity behaviours: dietary intake will be assessed through
4
5 351 completion of a 24-hour diet recall, using the structured multiple pass interview
6
7 352 method, and physical activity through 3-day Actiwatch accelerometer assessment
8
9 353 and completion of the International Physical Activity Questionnaire (IPAQ).

10
11 354

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14 355 B. Evaluating intervention mechanisms

15
16 356 The following validated self-complete questionnaires will be administered:

- 17
18 357 • Perceived Diabetes & Dietary Competence (PDDC) questionnaire
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20 358 • Short Diabetes Knowledge Instrument (SDKI)
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22 359 • Diabetes Empowerment Scale- Short Form (DEC-SF)
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24 360 • Social support: Multidimensional Scale of Perceived Social Support (PSS)
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26 361 • Quality of life: EQ-5D-3L & PAID-5

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31 363 C. Evaluating acceptability & implementation of the intervention, and feasibility of trial
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33 364 procedures

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35 365 Process evaluation is an essential part of testing complex interventions, allowing researchers
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37 366 to refine the theory by which the intervention brings about change, understand how the
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39 367 multiple components of the intervention may interact and how the intervention is
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41 368 implemented in the 'real world' setting (30). Our process evaluation will assess
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43 369 implementation and acceptability of the intervention. In terms of implementation, we will
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45 370 assess: 1) the reach of the intervention; 2) completion of the intervention (dose); 3) fidelity of
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47 371 the intervention, this includes coverage of core materials and learning objectives during
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49 372 delivery, and the extent to which the programme is delivered in accordance with the delivery
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51 373 manual; 4) quality of delivery; 5) barriers and facilitators to the uptake of the intervention in
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53 374 current care pathways.

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3 375 Intervention acceptability will be explored by assessing participants' perceptions and
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5 376 experiences of the intervention, and how this varies across different settings and across the
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7 377 course of the programme. Acceptability of HEAL-D will be assessed through quantitative
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9 378 and qualitative data. Quantitative measures will include attendance records. Qualitative data
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11 379 will explore the experiences of participating in the sessions and the activities. Sustainability
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13 380 will be considered by assessing the scope for the intervention to be embedded within current
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15 381 care pathways, and contextual factors that may determine decision-making around
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17 382 continuance. Table 1 presents the research questions addressed by the process evaluation, and
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19 383 how they map onto the key domains being examined. The process evaluation data types and
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21 384 how they relate to the research questions is summarised in Table 2; details of our process
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23 385 evaluation data collection is provided in Table 3.
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3 387 **ETHICS & DISSEMINATION**
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6 388 This paper presents the protocol for the design and feasibility testing of HEAL-D, a
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8 389 culturally-tailored diet and physical activity intervention for the self-management of type 2
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10 390 diabetes in UK African and Caribbean communities. In this work we will use rigorous
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12 391 complex intervention methodology to develop our intervention and evaluate its
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14 392 implementation prior to the design of a definitive trial of HEAL-D. The study protocol has
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16 393 been approved by the Fulham: London Research Ethics Committee (17-LO-1954); all
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18 394 participants will provide written consent prior to participation. All data will be anonymised
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21 395 and data protection protocols followed.
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24 396 The study findings will be disseminated to the scientific community via conference
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26 397 presentations and peer-reviewed manuscripts, and to healthcare professionals via national and
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28 398 local clinical networks. The findings of the study will be communicated to our participants
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30 399 and local communities via the community networks and figureheads who we have engaged in
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32 400 our participatory methods; we will give presentations at church events and publish a
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34 401 newsletter via our study website (www.heal-d.co.uk).
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3 403 **Abbreviations**
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6 404 AfC African-Caribbean
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9 405 COM-B Capability Opportunity Motivation Behaviour
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12 406 HEAL-D Healthy Eating & Active Lifestyles for Diabetes
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15 407 MRC Medical Research Council
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18 408 NHS National Health Service
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21 409 T2D Type 2 diabetes
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26 411 **Declarations**
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28
29 412 The study protocol has been approved by the Health Research Authority (London Fulham
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31 413 Research Ethics Committee; 17/LO/1954); all participants will provide written consent prior
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34 414 to participation.
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36 415 **Consent for publication**
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39 416 Not applicable.
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42 417 **Availability of data and materials**
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45 418 Not applicable.
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48 419 **Competing interests**
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50
51 420 The authors declare that they have no competing interests.
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53
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4
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6
7 424 views expressed in this publication are those of the author(s) and not necessarily those of the
8
9 425 NHS, the National Institute for Health Research or the Department of Health.

12 426 **Author contributions**

15 427 All authors have made substantial contributions to this study. LMG, CR and SH were
16
17 428 responsible for the conception and design of the study. LMG, CR, SH and AM developed the
18
19 429 protocol and study approach. LMG drafted the manuscript. All authors read, revised and
20
21 430 approved the final manuscript. LMG is guarantor.

24 431 **Acknowledgements**

27 432 Not applicable.

30 433

33 434 **Figure legends**

36 435 **Figure 1.** Overview of HEAL-D: development (phase 1) and feasibility evaluation (phase 2)
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38 436 of a culturally-tailored diet and lifestyle intervention for type 2 diabetes in African and
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40 437 Caribbean communities

43 438 **Figure 2.** Applying the COM-B behaviour change framework to the development of the
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45 439 HEAL-D intervention; identifying theory of change

48 440 **Figure 3.** Topic guides for patient focus groups & stakeholder interviews

Table 1. HEAL-D process evaluation domains and research questions

Process Evaluation Domain	Research Question
Mechanisms of Change	Are the intervention's mechanisms of change operationalised as hypothesised?
	How is the operationalisation of the mechanisms of change influenced by contextual factors?
	Does the interaction of the mechanisms of change with contextual factors give rise to unintended effects?
Programme Differentiation and Usual Practice	Is the HEAL-D intervention differentiable from 'usual practice'?
Implementation	Is there contamination of usual practice in control patients by receipt of the HEAL-D intervention?
	What is the reach of the HEAL-D intervention?
	How many patients complete the HEAL-D intervention?
	Are the HEAL-D components and sessions delivered with fidelity and what is the nature of any adaptations undertaken?
	Are there differences in the delivery of the HEAL-D sessions between sites, and what gives rise to any differences?
	How well are the HEAL-D components and sessions delivered?
Acceptability	What are the barriers and facilitators to the implementation of the HEAL-D programme?
Acceptability	Is the HEAL-D intervention acceptable to commissioners, healthcare professionals, and patients?
Sustainability	How likely is the HEAL-D intervention to be sustainable and what factors might ensure sustainability?

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Table 2. Mapping of research questions, process evaluation measures and data sources in HEAL-D feasibility study

Research Domain	Research Question	Data Source	Informant	Procedure of Data Collection	Time of Data Collection
Mechanisms of Change	Operationalisation of intervention mechanisms. Contextual factors. Unintended effects.	A. Patient questionnaires	Patients (n≈120)	Self-assessment; completion of paper questionnaire	Baseline & 26-32 week follow-up
		B. Observation of interventions sessions	HEAL-D educators (n≈4); HEAL-D patients	Independent assessment of intervention by research team (n=2); completion of observation schedules	During programme delivery
		C. HEAL-D course fidelity checklist and record of activities & materials	HEAL-D educators (n≈4); HEAL-D attendees	Self-assessment; completion of checklists and materials logs	During programme delivery
		D. HEAL-D evaluation forms	HEAL-D patients	Self-assessment; completion of evaluation forms	During programme delivery
		E. HEAL-D educator interview	HEAL-D educators	Interview led by study team	At the end of each delivery
		F. Patient interview	Patients	Interview led by study team	During & at the end of programme delivery
		G. Patient focus group	HEAL-D patients	Focus group led by study team	At the end of programme delivery
Programme Differentiation and Usual Practice	Differentiation.	A. Patient questionnaires	Patients (n≈120)	Self-assessment; completion of paper questionnaire	Baseline & 26-32 week follow-up
	Contamination.	F. Patient interview	Patients	Interview led by study team	26-32 wks follow-up
Implementation	Reach.	H. Attendance records	Patients	Participant completion; programme registers	During programme

	Completion.				delivery
	Fidelity.	A. Patient questionnaires	Patients (n≈120)	Self-assessment; completion of paper questionnaire	Baseline & 26-32 week follow-up
	Quality.	B. Observation of intervention sessions.	HEAL-D educators (n≈4); HEAL-D patients	Independent assessment of intervention by research team (n=2); completion of observation schedules	During programme delivery
	Barriers and facilitators.	E. HEAL-D educator interview	HEAL-D educators	Interview led by study team	At the end of programme delivery
		I. Healthcare professional interview	Healthcare professionals	Interview led by study team	At the end of programme delivery
Acceptability	Acceptability.	J. Commissioner interview	Commissioners	Interview led by study team	At the end of programme delivery
		G. Patient focus group	HEAL-D patients	Focus group led by study team	At the end of programme delivery
		I. Healthcare professional interview	Healthcare professionals	Interview led by study team	At the end of programme delivery
		E. HEAL-D educator interview	HEAL-D educators	Interview led by study team	At the end of programme delivery
Sustainability	Sustainability.	J. Commissioner interview	Commissioners	Interview led by study team	At the end of programme delivery
		G. Patient focus group	HEAL-D patients	Focus group led by study team	At the end of programme delivery
		I. Healthcare professional interview	Healthcare professionals	Interview led by study team	At the end of programme delivery
		E. HEAL-D educator			At the end of programme

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interview	HEAL-D educators	Interview led by study team	delivery At the end of programme delivery
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Table 3. Details of process evaluation data collection methods***A. Patient questionnaires***

Questionnaire data will test the proposed theory of change underpinning the intervention through measurement of knowledge, motivation, and social support.

B. Observation of intervention sessions

The research team will observe the HEAL-D sessions to quantitatively assess: coverage of curriculum; use of supporting materials and behaviour change techniques; quality of delivery; and participant engagement (binary score or a five-point Likert scale). Observers will qualitatively document any information relevant for understanding the quantitative assessment, and other issues of importance e.g. course adaptations and general contextual observations. Observations will inform the focus group and interview topic guides for educators, patients and healthcare professionals.

C. HEAL-D course fidelity checklist and record of activities & materials

Educators will list any resources, activities, examples or discussions that were additional to the standardised schedule. These data will be used to assess fidelity, and compare intervention deliveries and contextual impacts.

D. HEAL-D evaluation forms

Evaluation forms will use five-point Likert scales to record self-reported increase in knowledge, motivation, social support, and views on quality of course content, structure, format and delivery.

E. HEAL-D educator interviews

Semi-structured interviews will be conducted with the intervention educators to explore: mechanisms underpinning the behaviour change processes; preparedness to deliver the intervention components; experiences of delivery, including barriers and facilitators; fidelity and motivations for any adaptations undertaken; and perceived acceptability.

F. Patient interviews

Semi-structured interviews will be conducted with patients from both arms of the study, purposively sampled to ensure representation from all deliveries of the intervention and a spread of gender, age, ethnicity and employment status. Data will explore: experiences of intervention and control; perceived acceptability of sessions and session components; reasons for attendance and non-attendance, including contextual factors; impact of sessions on behaviour, including any behaviour change that has occurred. Among control patients issues of contamination will be explored and perceptions of 'usual care' will be discussed.

G. Patient focus groups

Focus groups will be conducted with patients from the intervention arm to explore views of the intervention, including: acceptability; effectiveness at promoting behaviour change, and perceived barriers and facilitators to this.

H. Attendance records

Attendance records will assess reach (numbers completing the intervention), and retention in the programme and patterns in these according to gender, age, ethnicity and employment status.

I. Healthcare professional interviews

Semi-structured interviews will be conducted with healthcare professionals involved in the

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3 primary care management of diabetes to assess intervention awareness, acceptability and
4 effectiveness.

5 ***J. Commissioner interviews***

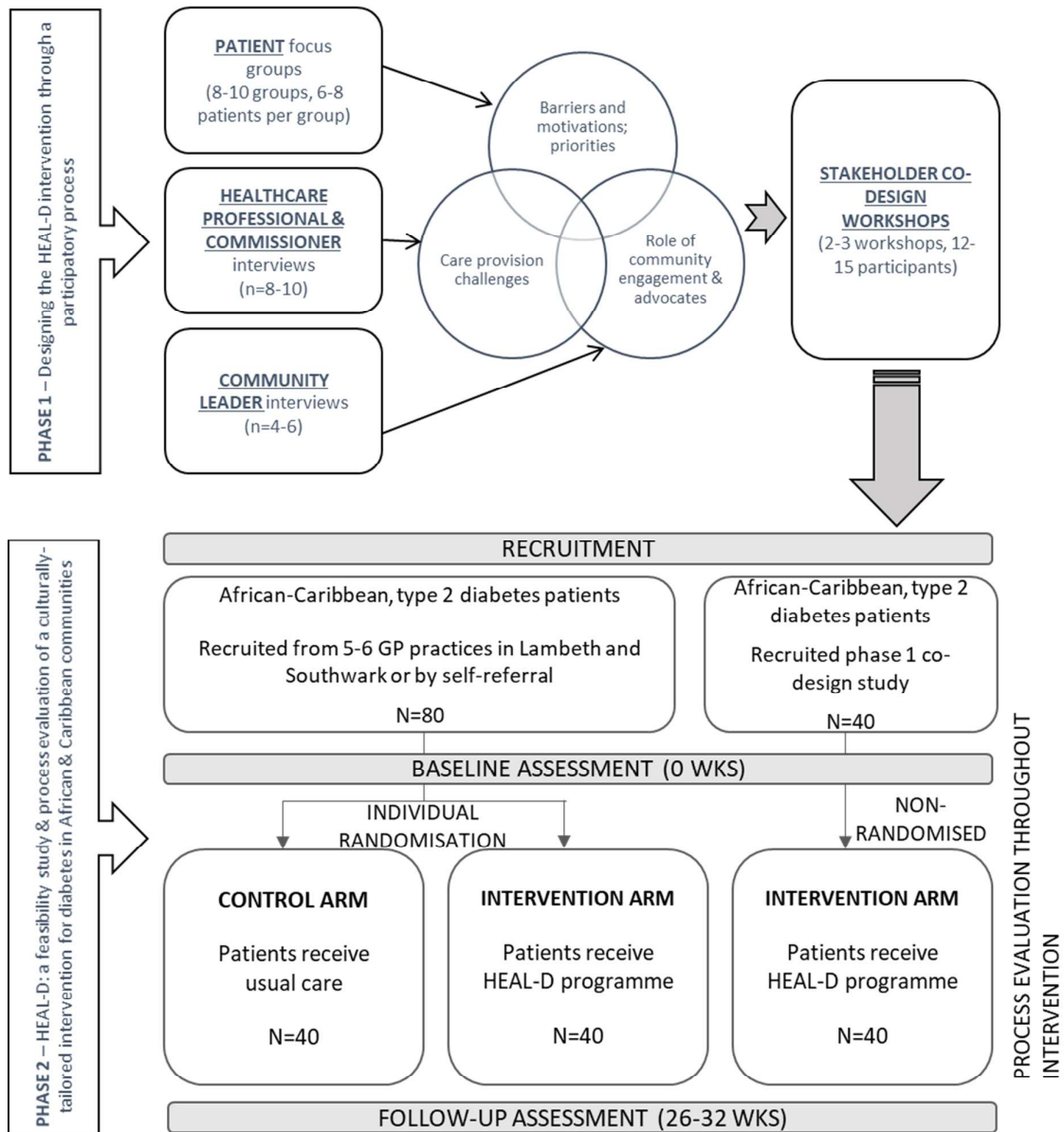
6 Semi-structured interviews will be conducted with commissioner representatives to assess
7 intervention acceptability, fit with organisational priorities, and the feasibility of sustained
8 resource allocation to the HEAL-D intervention if found to be successful.
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Behaviour goal: Walk 10,000 steps per day at moderate intensity	
Capability	<p>Knowledge: Does the target group know:</p> <ul style="list-style-type: none"> - Why walking 10,000 steps would help diabetes management? - What moderate intensity is and how to measure it? <p>Behavioural regulation: Does the target group know how to:</p> <ul style="list-style-type: none"> - Plan to fit the activity in to their daily life? - Remember to do the activity? - Prioritise this activity over others? - Record & measure and self-monitor their activity? <p>Physical skills: Does the target group:</p> <ul style="list-style-type: none"> - Have the physical stamina to walk 10,000 steps at this intensity?
Opportunity	<p>Environmental context & resources:</p> <ul style="list-style-type: none"> - Is there somewhere safe to walk in the neighbourhood? - Do the patients have appropriate equipment e.g. suitable trainers or walking shoes? - Can they afford a pedometer or some means of measuring their steps? <p>Social influences (what interpersonal influences cause individuals to change their thoughts, feelings or behaviours?)</p> <ul style="list-style-type: none"> - It is culturally acceptable to walk for exercise? - What is the social norm amongst immediate friends and family? - What positive or negative views do others have that may influence activity? - Are there any positive role models? - Are there competing demands e.g. pressure to spend leisure time with family or at church? - Would group support be motivating?
Motivation	<p>Reflective (conscious) motivation:</p> <ul style="list-style-type: none"> - How optimistic do the patients feel they can achieve the goal? - Do they intend to do the behaviour (stages of change model)? - What emotions may help or hinder? e.g. do they fear injury? - What other emotions may conflict? e.g. tiredness, depression, stress <p>Automatic (innate drivers):</p> <ul style="list-style-type: none"> - What are established habit patterns? - What are routines/thought/behaviours set up by previous experience?

Patient focus groups

- Knowledge and perceptions of diabetes, and diet and lifestyle advice for managing diabetes
- Current practices relating to diabetes self-care, and diet and lifestyle
- Health concerns/priorities in relation to diabetes
- Motivations and barriers/difficulties relating to diabetes self-care, weight management and diet and lifestyle
- Experiences and perceptions of diabetes care/education, and barriers to accessing care
- Experiences of behaviour change in relation to diabetes, weight, diet and lifestyle – successes and failures
- Role of family/friends/communities in influencing and shaping knowledge and behaviours in relation to diabetes, diet and lifestyle

Community leader interviews (including religious leaders)

- Health problems affecting the community and diabetes impact on health within this context
- Attitude of the community towards health, medicines, doctors
- Role of community leaders in promoting health and community activities
- Diabetes health promotion activities within the community. What worked and what didn't?
- Barriers and facilitators to positive diabetes behaviours within the community
- Advice about engaging the community: Who are the role models? What will engage and help people? How can healthcare & community work together?

Healthcare professional interviews

- Experience of supporting African & Caribbean patients – what happens? What are the issues? How could things be improved? What factors make successful T2D management likely?
- Patient beliefs and motivations
- Involvement in community activities and experience of working with community leaders and lay educators and suggestions to improve partnerships
- Difficulties & challenges with offering a tailored lifestyle intervention

BMJ Open

**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**

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-023733.R1
Article Type:	Protocol
Date Submitted by the Author:	05-Nov-2018
Complete List of Authors:	Goff, Louise; Kings College Lonodn, Diabetes and Nutritional Sciences Moore, Amanda; Kings College Lonodn, Diabetes and Nutritional Sciences Rivas, Carol; University of Southampton, Faculty of Health Sciences Harding, Seeromanie; King\'s College London Division of Diabetes and Nutritional Sciences, Diabetes & Nutritional Sciences Division
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Nutrition and metabolism
Keywords:	type 2 diabetes, ethnicity, culture, diet, lifestyle, education

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Manuscripts

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3 1 **Healthy Eating and Active Lifestyles for Diabetes (HEAL-D): study protocol for the**
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5 2 **design and feasibility trial, with process evaluation, of a culturally-tailored diabetes self-**
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7 3 **management programme for African-Caribbean communities**
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10 4 Louise M. Goff^{1#}, Amanda P. Moore¹, Carol Rivas², Seeromanie Harding¹
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13 **ABSTRACT**

14 **Introduction**

15 Black-British communities are disproportionately burdened by type 2 diabetes (T2D) and its
16 complications. Tackling these inequalities is a priority for both healthcare providers and
17 patients. Culturally-tailored diabetes education provides long-term benefits superior to
18 standard care but to date such programmes have only been developed in the USA. The Healthy
19 Eating and Active Lifestyles for Diabetes (HEAL-D) programme of research aims to develop
20 a culturally-tailored T2D self-management programme for Black-British communities; and to
21 evaluate its delivery, acceptability and the feasibility of conducting a future effectiveness trial
22 of HEAL-D.

23 **Methods & analysis**

24 Informed by Medical Research Council (MRC) Complex Interventions guidance this research
25 will rigorously develop and evaluate the implementation of the HEAL-D intervention to
26 understand the feasibility of conducting a full-scale effectiveness trial. In Phase 1 the
27 intervention will be developed. The intervention curriculum will be based on existing evidence-
28 based guidelines for diet and lifestyle management of T2D; co-design methods will be used to
29 foster community engagement, identify the intervention's underpinning theory; identify the
30 optimal structure, format and methods of delivery, ascertain adaptations that are needed to
31 ensure cultural sensitivity of the content, and understand issues of implementation. In Phase 2
32 process evaluation methods will evaluate the delivery and acceptability of HEAL-D; the
33 feasibility of conducting a future effectiveness trial will also be evaluated, particularly
34 feasibility of randomisation, recruitment, retention, and contamination, and identify potential
35 primary outcomes for a future trial.

36 **Ethics & dissemination**

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3 37 This study is funded by a National Institute of Health Research Fellowship (CDF-2015-08-
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5 38 006). It has been approved by the Fulham: London Research Ethics Committee (17-LO-1954).
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8 39 Results will be disseminated at national and international conferences, in peer-reviewed
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10 40 publications and through local and national clinical diabetes networks.

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12 41 **Trial Registration:** this trial is registered with www.clinicaltrials.gov, identifier:
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14 42 NCT03531177.
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19 44 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 21 45 • This study will employ rigorous complex intervention methodology to develop and
22 46 evaluate the implementation of a culturally-tailored diabetes self-management
23 47 intervention.
- 24 48 • Our intervention, HEAL-D, will be designed using a ‘bottom-up’ approach, employing
25 49 participatory co-design methods to foster community engagement and partnership.
- 26 50 • We will identify the cultural adaptations of our intervention and its underpinning
27 51 theoretical basis through thematic analysis and the COM-B behavior change
28 52 framework.
- 29 53 • The feasibility study will provide us with key information about the feasibility of
30 54 running a full-scale trial of HEAL-D.
- 31 55 • Process evaluation methods will enable us to understand how and why the intervention
32 56 is effective or ineffective.

33 57

34 58 **Keywords:** African, Caribbean, ethnicity, type 2 diabetes, education, self-management, diet,
35 59 lifestyle
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60 INTRODUCTION

61 Type 2 diabetes (T2D) affects approximately 3 million people in England and consumes around
62 10% of the National Health Service (NHS) budget, estimated at almost £9 billion in 2011 and
63 predicted to rise to 17% of the NHS budget by 2035 (1). Diabetes and its associated
64 complications place an illness burden on patients and carers, which disproportionately affects
65 those from ethnic minority backgrounds (2). The estimated prevalence of T2D is up to 3 times
66 higher for Black-British communities compared to White Europeans (3). T2D occurs, on
67 average, 10 years earlier in Black-British people, the mean age of diagnosis is 48 years and
68 approximately 25% of patients are under the age of 40 years (4). Furthermore, glycaemic
69 control is worse at the time of diagnosis, requires greater medical management, and poorer
70 outcomes are evident (5-7). The reasons for these disparities are not fully understood; while
71 biological factors are involved, it is understood that a range of behavioural, lifestyle and health
72 system factors play a role. Tackling these inequalities is a healthcare priority (8, 9).

73 Individuals of Black-British ethnicity form the second largest ethnic minority population in the
74 United Kingdom (UK); around 4% of the population self-identify from this ethnic background
75 (10). Around half of individuals are of Black African ancestry and a third of Black Caribbean
76 ancestry (10). Growth in the Black-British communities is relatively recent, beginning mainly
77 in response post-second world war appeals to citizens of the Commonwealth regions to assist
78 with gaps in its labour market. This prompted a large influx of migrants in the 1950s from the
79 Caribbean islands, particularly Jamaica. Migration from the African continent has been more
80 recent, peaking around the 1980s; migrants from African nations currently form the largest
81 growing ethnic minority group in the UK population (11). In some regions, such as London,
82 Black-British communities may represent 30-40% of the local population and are therefore a
83 'majority-minority' community. Other demographic patterns are recognised; the age
84 distribution of the Black African and Black Caribbean communities differs, with a larger

1
2
3 85 proportion of Black Caribbeans being aged 65 years and over, while in the Black African
4
5 86 population a greater proportion are children and young adults. High rates of unemployment are
6
7 87 evident, averaging around 12% compared to 4% in the White British population (11).
8
9

10 88 Poor access to diabetes healthcare is a significant issue for minority ethnic groups (2). In the
11
12 89 UK the NHS provides care to all UK residents that is free at the point of delivery. First-line
13
14 90 diabetes management is situated in primary care and aims to promote patient involvement and
15
16 91 self-management (12), enabling patients to adopt a healthy lifestyle and to manage their
17
18 92 diabetes through support and education (13). To achieve this, UK T2D management guidelines
19
20 93 recommend that all patients attend a structured education course to teach them the principals
21
22 94 of T2D self-management and that this be offered annually from the time of diagnosis (14).
23
24 95 Courses are recommended to use a group structure; typically they use face-to-face delivery by
25
26 96 a diabetes specialist nurse or dietitian, with lay educator co-delivery in some cases (14).
27
28 97 Referral to such courses is audited and incentivised through the Quality Outcomes Framework
29
30 98 (15). Ethnic minority groups report finding it more difficult to access primary care services
31
32 99 (16) and are more likely to report that they have not had the opportunity to attend a diabetes
33
34 100 education course than White populations (17). Specifically, African-Caribbean (AfC)
35
36 101 communities often report a distrust of medical advice and a desire for natural, non-
37
38 102 pharmacological therapies (18). Furthermore, healthcare professionals are perceived as lacking
39
40 103 cultural understanding (19) and their advice as lacking cultural relevance (20) or being poorly
41
42 104 adapted to culture and needs (18) despite their intentions; these issues may contribute to the
43
44 105 poorer diabetes outcomes and increased morbidity experienced by AfC patients.
45
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51
52 106 Culturally tailored healthcare is proposed to be one of the main ways in which healthcare
53
54 107 disparities can be addressed (21-23) and is identified as a priority by patients (8). Culturally-
55
56 108 tailored diabetes education has demonstrated greater improvements in diabetes control and
57
58 109 knowledge than usual care, and the benefits are maintained long-term (22, 24). Culture is a
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1
2
3 110 concept that is notoriously difficult to define but generally within healthcare it is thought of as
4
5 111 'a set of attitudes, values, beliefs and behaviours shared by a group of people, communicated
6
7
8 112 from one generation to the next' (25). In their model for understanding cultural sensitivity in
9
10 113 healthcare, Resnicow *et al.* (1999) described two dimensions in culture: surface and deep
11
12 114 structures. Tailoring interventions to surface structures involves matching materials and
13
14 115 messages to observable, "superficial" characteristics of a target population e.g. language and
15
16 116 food, familiar to, and preferred by, the target audience. Deep structure involves incorporating
17
18 117 the cultural, social, historical, environmental and psychological forces that influence the target
19
20 118 health behaviours in the proposed target population. Whereas surface structure generally
21
22 119 increases the "receptivity" or "acceptance" of messages, deep structure conveys salience (26).
23
24 120 Culture is ever evolving for any group and it is important to recognise the diversity that exists
25
26 121 within any one 'cultural group', which is particularly evident in migrant populations where
27
28 122 second/third generations may have undergone significant acculturation. To date, culturally
29
30 123 tailored interventions for the African diaspora have largely been based in the USA, and may
31
32 124 not translate to UK healthcare structures or UK AfC communities whose cultural needs may
33
34 125 be different (23).
35
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39
40 126 Healthy Eating & Active Lifestyles for Diabetes (HEAL-D) is a two-phase programme of
41
42 127 research focusing on the co-design of a culturally-tailored, evidence-based self-management
43
44 128 programme for T2D in African and Caribbean communities, followed by a feasibility trial. The
45
46 129 intervention curriculum will be based on existing evidence-based guidelines for T2D (14, 27)
47
48 130 to enable it to have potential to be embedded into clinical practice; co-design methods will be
49
50 131 used to identify the optimal structure, format and methods of delivery and to ascertain
51
52 132 appropriate adaptations that are needed to ensure cultural sensitivity of the content. The
53
54 133 purpose of this article is to present the protocol for HEAL-D.
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3 135 **PURPOSE & AIMS**
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6 136 The overall aims of this research are to develop a culturally-tailored, evidence-based self-
7
8 137 management programme for managing T2D among AfC communities in primary care, called
9
10 138 HEAL-D, and to determine the feasibility of evaluating HEAL-D through a future effectiveness
11
12
13 139 trial.
14
15

16 140 The objectives are to:
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18

- 19 141 1. Develop a self-management programme, based on existing evidence-based diet and
20
21 142 lifestyle guidelines, appropriately tailored for AfC patients through co-design methods.
22
23 143 2. Establish the feasibility of conducting an effectiveness trial of HEAL-D, considering
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25
26 144 issues such as participation rates and potential effect sizes.
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146 **METHODS AND ANALYSIS**

147 Guided by the Medical Research Council's Complex Interventions framework (28) (Figure 1),
148 HEAL-D will consist of two distinct phases: phase 1 is a formative phase in which the
149 intervention will be developed; and in phase 2, the intervention will be evaluated in a feasibility
150 trial. Study recruitment will begin in April 2018; the study duration will be 36 months.

151 **Phase 1 – Development of a culturally-tailored T2D self-management programme**

152 The process for the development of HEAL-D is outlined in Figure 2. Firstly, to ensure its
153 potential to be embedded into future clinical practice, the HEAL-D curriculum will align with
154 existing management recommendations and guidelines (14, 27):

155 Guidelines for diet and lifestyle management of T2D (27):

- 156 1. Achieve 5-10% weight loss or weight maintenance in those of healthy weight.
- 157 2. Undertake 150 minutes/week of moderate-to-vigorous intensity aerobic physical
158 activity plus 2 sessions/week of strength training.
- 159 3. Balance carbohydrate intakes through portion control and promotion of low
160 glycaemic index and wholegrain sources.
- 161 4. Limit saturated fat intake (<10% of energy intake), replace with mono-unsaturated
162 fats.
- 163 5. Limit salt intake (<6g per day).
- 164 6. Consume oily fish at least twice per week.

165 Guidelines for T2D self-management education (14):

- 166 1. Offer structured education to adults with T2D and/or their family members or
167 carers.
- 168 2. Offer group education programmes as the preferred option.

1
2
3 169 2. Ensure the education programme is theory-driven, evidence-based and meets the
4
5 170 cultural, linguistic, cognitive and literacy needs of the population.
6
7

8 171 **Drawing on the existing evidence base**
9

10
11 172 Secondly it will draw on key themes reported in published literature relating to methodologies
12
13 173 for adapting health promotion interventions for ethnic minority groups. These have been
14
15 174 evaluated in a number of recent systematic reviews; aside from acknowledging the lack of UK-
16
17 175 based studies, these reviews have made the following recommendations:
18
19

- 20
21 176 • Acknowledge the powerful influence of social networks on health beliefs and
22
23 177 behaviours (29). Focus on community-level interventions; delivering care in a social
24
25 178 context has been shown to promote engagement and be more effective than traditional
26
27 179 individual-centred behavioural approaches (23).
28
29 180 • Foster community engagement to overcome issues of deep-rooted, historical distrust of
30
31 181 medical advice and settings, develop and nurture trust between the researchers and
32
33 182 community, and nurture the strong sense of collectivism and kinship networks that are
34
35 183 evident amongst AfC communities.
36
37 184 • Employ participatory methods (e.g. patient involvement in intervention design, lay-led
38
39 185 delivery of interventions), which are highly effective at improving health behaviours
40
41 186 and self-efficacy across a number of conditions (30).
42
43 187 • Use community gathering places (e.g. faith institutions), which offer the benefit of
44
45 188 cultural relevancy and may reach populations who would not normally access self-
46
47 189 management education (31).
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54 190 **Identifying the intervention's theoretical basis**
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56
57 191 Behavioural interventions should have a theoretical under-pinning (28, 32) so that the changes
58
59 192 that are expected, and how these will be achieved, can be predicted from consideration of
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1
2
3 193 known behaviour change techniques. While there have been a number of interventions tailored
4
5 194 to support diet and lifestyle behaviour change in AfC communities, their theoretical
6
7
8 195 underpinning has rarely been drawn out or clearly presented. The theoretical underpinning of
9
10 196 HEAL-D will be developed through a combination of key themes from the published literature
11
12 197 and new primary research.

13
14
15 198 In the literature collectivism and the importance of social interaction for people of AfC ancestry
16
17 199 is well reported (29), and the provision of a social support group, or inclusion of a family
18
19 200 member, has been shown to be particularly effective in lifestyle interventions in African-
20
21 201 American communities (33, 34). In USA interventions, researchers have proposed that a focus
22
23 202 on facilitating/nurturing social support may be a particularly ‘therapeutic and cost-effective
24
25 203 public health strategy’ for AfC communities (33). Notably, the majority of literature that
26
27 204 identifies the drivers of health behaviours in AfC communities and may, therefore, inform the
28
29 205 theoretical basis of an intervention, comes from the USA and it is not known to what extent
30
31 206 these findings apply to AfC in other regions. One of the reasons we will use co-design methods
32
33 207 will be to understand the relevance of these existing themes to the UK context and enable us to
34
35 208 identify themes that are important to Black-British communities.

36 37 38 39 40 41 209 **Co-designing the intervention through participatory methods**

42
43
44 210 HEAL-D will use participatory co-design methods to engage patients, healthcare providers and
45
46 211 community leaders (e.g. church leaders, community group leads) in focus groups, interviews
47
48 212 and workshops in order to achieve the following:

- 49
50
51 213 1. Foster community engagement.
- 52
53 214 2. Identify the theoretical under-pinning of HEAL-D.
- 54
55 215 3. Identify appropriate cultural adaptations for the intervention.
- 56
57 216 4. Understand issues of intervention implementation.
- 58
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1
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3 217 ***Focus groups and interviews***
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5

6 218 Focus groups, 8-10 groups of 6-8 participants, will be conducted with patients with T2D of
7
8 219 AfC ethnicity, recruited through local churches, mosques and community groups, as well as
9
10 220 through GP practices in London. The focus groups will be conducted in local accessible
11
12 221 community venues e.g. church hall, library, community centre. Patients will be purposively
13
14 222 sampled to get a spread of socio-economic position, generational status and ancestral origins,
15
16 223 as principal factors impacting on health status, healthcare access and cultural behaviours in
17
18 224 these groups (35-37). Separate focus groups will be conducted with men and women, and
19
20 225 patients of direct African *versus* Caribbean ancestry, as they report different cultural
21
22 226 barriers/facilitators to lifestyle change (35, 36). A topic guide (Table 1) based on themes
23
24 227 identified in the literature, will be used to steer discussions and ensure coverage of key themes
25
26 228 whilst encouraging free discussion of opinion/perspective. Focus groups have been selected to
27
28 229 enable us to understand normative needs, as suited to the development of a community
29
30 230 intervention.
31
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36 231 Semi-structured interviews will be conducted with 8-10 healthcare providers, including general
37
38 232 practitioners, practice nurses, diabetes specialist nurses, diabetes specialist dietitians and
39
40 233 commissioners. The interviews will cover issues relating to healthcare needs and engagement
41
42 234 of AfC patients, experiences of delivering healthcare to AfC patients, and barriers and
43
44 235 facilitators to working in partnership with community groups to deliver care for AfC
45
46 236 communities (Table 1). Interviews have been selected for this part of the study to enable us to
47
48 237 gather a full range of experiences and therefore optimise implementation.
49
50
51
52

53 238 Community leaders representing faith and non-faith institutions (n=4-6) will be invited to
54
55 239 participate in semi-structured interviews. Leaders will be identified initially through existing
56
57 240 networks e.g. Diabetes UK Community Champions initiative. Word-of-mouth and ‘snow-
58
59
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1
2
3 241 balling' techniques that are highly effective within these communities, will be used to recruit a
4
5 242 wider network. The interviews will cover issues relating to the role of community networks in
6
7 243 promoting health of AfC communities, sustaining health amongst community members, and
8
9 244 opportunities for greater impact (Table 1).
10
11
12

13 245 *Analysis*

14
15
16 246 The focus groups and interviews will be digitally recorded and transcribed verbatim. The data
17
18 247 will be analysed using the framework approach in NVivo (QSR International), theoretically
19
20 248 driven by socio-ecological theory to identify themes relating to issues at the individual, family,
21
22 249 community and healthcare delivery levels and how these influence self-efficacy and behaviour
23
24 250 change. Our analysis will identify priority behaviours of focus for the intervention, key barriers
25
26 251 and facilitators to behaviour change and healthcare engagement, favoured settings, and a
27
28 252 rudimentary draft of the cultural adaptations. Deviant case analysis, that is consideration of
29
30 253 cases that do not fit the general picture, will be undertaken, though our primary interest is in
31
32 254 the commonalities as this is a community level intervention. Primary coding and development
33
34 255 of a coding scheme will be carried out by a single researcher; a second researcher will
35
36 256 independently use this coding scheme to code 20% of the data for cross-comparison, to improve
37
38 257 dependability. This will provide methodological rigour required for confidence in the analysis
39
40 258 of the qualitative data. The themes will be fed-back and discussed with a Service User Group
41
42 259 (SUG), which will consist of representatives of patients, healthcare providers, and community
43
44 260 leaders. The SUG will be set up to inform and guide each stage of the research plan and will
45
46 261 be a forum through which the research team can seek the opinion of key stakeholders, in this
47
48 262 case particularly relating to interpretation of the qualitative data and to ensure trustworthiness
49
50 263 of conceptualisations. The SUG will also review research documents, such as patient
51
52 264 information sheets and questionnaires, and provide feedback on their content and suitability
53
54 265 for the communities of focus.
55
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3 266 We will divide our data into behavioural ‘barriers’ and ‘facilitators’ where possible. To
4
5 267 ascertain appropriate behaviour change techniques for our intervention (32) we will map our
6
7 268 analysis onto the Capability-Opportunity-Motivation-Behaviour (COM-B) framework from
8
9
10 269 the Behaviour Change Wheel (38) (Figure 3), and thence in each case consider the outcome
11
12 270 behaviours that our intervention will aim to achieve, a worked example is shown in Figure 4.
13
14 271 We will use the COM-B framework to identify appropriate *functions* of our intervention to
15
16 272 optimise facilitators and overcome barriers to achievement of planned outcomes, e.g.
17
18 273 ‘education’ for capability barriers, ‘modelling’ for opportunity and motivation barriers. Finally
19
20 274 we will select specific behaviour change techniques e.g. education, goal setting, that focus on
21
22 275 the specific functions we have identified. This will form the intervention theory that we will
23
24 276 draw on for the next stage of the study, as documented through a logic diagram. We will also
25
26 277 look to identify other themes that arise from the data, which might not map clearly onto the
27
28 278 COM-B framework (e.g. contextual themes relating to the health system) but which may
29
30 279 inform our intervention theory as well as help us to understand issues of implementation (e.g.
31
32 280 favoured settings and timings).

281 ***Stakeholder co-design workshops***

33
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36
37
38
39 282 Following evaluation of the focus groups and interviews our stakeholders, 12-15 patients,
40
41 283 healthcare providers, commissioners and community leaders, will be invited to participate in a
42
43 284 series of 2-3 half-day workshops, held in community locations. The workshops will seek to
44
45 285 gain stakeholder involvement in developing the details of the interventions. This will include
46
47 286 determining the setting, the media channels, structure and delivery, as well as steering the
48
49 287 research team to understand and respond to literacy and numeracy needs. The workshops will
50
51 288 endeavour to reach a consensus opinion from attendees but where stakeholders have different
52
53 289 needs and a consensus cannot be reached the research team will consult with the SUG to make
54
55 290 decisions on the way forward and consider where there is scope for the intervention to be

1
2
3 291 structured to meet these different needs e.g. delivery in a range of settings. In the first workshop
4
5 292 the research team will feed back the findings of the focus groups and interviews; anonymised
6
7
8 293 interview extracts will be presented to illustrate the key themes and issues that were identified.
9
10 294 The stakeholders will be asked to discuss the themes and behavioural targets in small groups,
11
12 295 using directed tasks/questions to facilitate the discussions. Following the small group
13
14 296 discussions the researchers will facilitate discussion as a whole to clarify/confirm
15
16 297 interpretation; open discussion/debate will be encouraged to examine the themes in depth and
17
18
19 298 for all stakeholders to agree a mutual understanding.

22 299 In the second workshop elements of the proposed intervention will be presented for comment,
23
24 300 refining and development. Using scenarios, the stakeholders will be asked to brainstorm, in
25
26
27 301 small groups, key issues relating to the scenarios. For example, the moderator will present
28
29 302 scenarios relating to the intervention setting and the attendees will be asked to discuss and
30
31 303 identify the pros and cons of each, and then feed back their discussions to the other attendees.
32
33 304 The attendees will be asked to review existing educational/support materials e.g. leaflets and
34
35 305 videos and provide feedback on, for example, language/phrasing, content, pitch and
36
37 306 understanding. The research team will then facilitate cross-discussion between groups to
38
39
40 307 develop the conclusions and a consensus.

43 308 In the final workshop draft intervention materials, developed from workshops 1 and 2, will be
44
45 309 presented. For example, media channels that could be used to promote behaviour change such
46
47
48 310 as testimonials, story-telling, and cooking demonstrations. The stakeholders will be divided
49
50 311 into small groups to discuss and provide feedback on the acceptability of the components of
51
52 312 the intervention and identify potential barriers to engagement. Following the small group
53
54 313 discussions the researchers will facilitate feedback and encourage discussion as a whole to
55
56 314 clarify/confirm the researcher's interpretation. The intervention template may be further
57
58
59 315 refined, and will be developed into the detailed programme.

316

317 **Phase 2 – Evaluation of HEAL-D; a culturally-tailored T2D self-management**
318 **programme for African and Caribbean communities**

319 In phase 2 a feasibility study, with an embedded process evaluation, will be conducted to
320 address the following objectives:

- 321 1. Evaluate the HEAL-D intervention, particularly its theoretical under-pinning,
322 acceptability, fidelity, issues of implementation and sustainability.
- 323 2. Evaluate the feasibility of trial procedures, considering issues such as rates of
324 recruitment, retention, completion and contamination.
- 325 3. Estimate the effect size of potential trial outcomes including HbA1c, weight, waist
326 circumference, blood pressure, dietary intake, physical activity levels, diabetes
327 knowledge, and quality of life, to inform an effectiveness trial.

328 **Study Design**

329 The feasibility study will use a randomised controlled design (RCT), with individual patients
330 as the unit of randomisation, evaluating HEAL-D against usual care. In addition there will be
331 a cohort of phase 1 co-design patients who will be allocated to the intervention arm (not
332 randomised) because their involvement in the intervention design phase would contaminate the
333 control arm. These patients will be included in the feasibility study to enable us to evaluate the
334 impact of former involvement on intervention engagement, acceptability and ownership.

335 **Participants**

336 Participants will principally be recruited from General Practice in the London Boroughs of
337 Lambeth and Southwark through screening of referrals for structured education and letters of
338 invitation to patients with established T2D. In addition participants from the phase 1 co-design

1
2
3 339 study will be invited to participate, and self-referral methods will also be used, for example
4
5 340 posters and advertisements in community locations.
6
7

8 341 Patients with diagnosed T2D who are of African or Caribbean ethnicity and with capacity to
9
10 342 provide fully informed consent to participation in research will be eligible to participate in the
11
12 343 trial. Ethnicity will be self-declared using the standard NHS ethnicity categorisation
13
14 344 questionnaire. Patients who are unable to communicate in English and patients with complex
15
16 345 therapeutic dietary needs may be ineligible to participate if their individual needs are deemed
17
18 346 incompatible with the aims of the intervention. This is because the intervention will provide
19
20 347 general diet and lifestyle advice for the self-management of T2D in a group setting; in cases of
21
22 348 patients with certain comorbidities e.g. advanced renal disease, the intervention may be
23
24 349 inappropriate for the individual, and the group nature of the intervention will prevent their
25
26 350 individual needs from being addressed.
27
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31
32 351 A pragmatic sample size of 120 patients is anticipated to be sufficient to evaluate the
33
34 352 programme, allowing for 20% drop-out/non-completion; 80 patients will be randomised, 40 in
35
36 353 each arm, and a further cohort of patients (n=40) from phase 1 will be allocated to the
37
38 354 intervention arm without randomisation. As this is a feasibility trial it will not be powered to
39
40 355 detect statistically significant intervention effects. A primary objective of the study is to
41
42 356 provide estimates of key parameters such as potential effect sizes, recruitment and retention
43
44 357 rates of the trial and participation rates of the programme, to enable the optimal design of a
45
46 358 full-scale trial to be determined.
47
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49

50 359 **Intervention and control arms**

51
52 360 Participants in the control arm will continue with usual care deemed appropriate and delivered
53
54 361 by their primary care team, which may include referral to group structured education and/or
55
56 362 one-to-one consultations with healthcare professionals.
57
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3 363 Participants in the intervention arm will be offered the HEAL-D programme, which will deliver
4
5 364 a curriculum of culturally-tailored, evidence-based diet and physical activity education and
6
7
8 365 behavior change in a group setting. In line with clinical guidelines, the programme will be
9
10 366 delivered by trained educators (external to the research team); favoured educators (e.g. lay
11
12 367 educators *versus* healthcare professionals) will be identified in the co-design process. The
13
14 368 details of each session, particularly the behavior change techniques and corresponding
15
16 369 activities/materials will be identified through the co-design work.

17
18
19
20 370 The proposed curriculum will map to evidence-based guidelines, and will be as follows:

- 21
22
23 371 1. An introduction to T2D self-management principles.
24
25 372 2. Physical activity in T2D management.
26
27 373 3. Carbohydrates & portion sizes.
28
29 374 4. Weight management for T2D.
30
31 375 5. Managing cardiovascular health.

32
33
34 376 In line with clinical guidelines for diabetes structured education, the education sessions will be
35
36 377 delivered through educator-led interactive discussion, however support materials will be
37
38 378 provided to reinforce the learning, detailing evidence-based diet and physical activity guidance,
39
40 379 which is culturally tailored for the African and Caribbean communities.

41 42 43 44 380 **Data Collection**

45
46
47 381 We will use a mixed methods approach, collecting a range of quantitative and qualitative data,
48
49 382 to evaluate the intervention and the feasibility of trial procedures.

50 51 52 383 ***Estimating the effect of the intervention on potential trial outcomes***

53
54 384 Participants will attend a baseline and post-intervention follow-up assessment visit, conducted
55
56 385 by a research technician, at 26-32 weeks to collect the following potential trial outcomes and
57
58 386 estimate effect sizes:
59
60

- 1
2
3 387 • HbA1c, total- HDL- & LDL-cholesterol, triglycerides: a 5ml venous blood sample will be
4
5 388 taken for analysis of HbA1c & lipids.
6
7
8 389 • Body weight, height and body mass index (BMI): body weight will be measured using
9
10 390 digital scales, with the patient wearing light clothing (without shoes), to the nearest 0.1 kg.
11
12 391 Height will be measured, using a stadiometer, without shoes.
13
14
15 392 • Waist circumference: measured using a flexible tape, with the patient wearing only light
16
17 393 clothing, at the mid-point between the lowest rib and the iliac crest.
18
19
20 394 • Systolic and diastolic blood pressure: the mean of three seated readings, taken using an
21
22 395 automated sphygmomanometer.
23
24 396 • Diet & physical activity behaviours: dietary intake will be assessed through completion of
25
26 397 a 24-hour diet recall, using the structured multiple pass interview method, and physical
27
28 398 activity through 3-day Actiwatch accelerometer assessment and completion of the
29
30 399 International Physical Activity Questionnaire (IPAQ).

31
32
33 400 The following validated self-complete questionnaires will be administered:

- 34
35
36 401 • Short Diabetes Knowledge Instrument (SDKI).
37
38 402 • Perceived Diabetes & Dietary Competence (PDDC).
39
40 403 • Diabetes Empowerment Scale- Short Form (DEC-SF).
41
42 404 • Multidimensional Scale of Perceived Social Support (PSS).
43
44 405 • Quality of life: EQ-5D-3L and PAID-5 questionnaires.
45
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49

50 ***Evaluation of the HEAL-D intervention***

51
52 408 Process evaluation is an essential part of testing complex interventions (39) and will be used in
53
54 409 our feasibility trial to evaluate the HEAL-D intervention and the feasibility of trial procedures.
55
56
57 410 Our process evaluation aims to achieve the following:
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- 1
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3 411 1. Test the intervention theory and whether the mechanisms of change operationalise as
4
5 412 hypothesised.
- 6
7
8 413 2. Understand how the multiple components of the intervention interact.
- 9
10 414 3. Evaluate contextual factors that influence operationalisation of the intervention's
11
12 415 theory/mechanisms of change, and any unintended effects of these factors.
- 13
14 416 4. Evaluate whether the intervention is differentiable from 'usual practice'.
- 15
16
17 417 5. Evaluate implementation of the intervention, particularly 'reach' (e.g. who receives the
18
19 418 intervention), 'dose' and completion rates, and intervention fidelity (e.g. coverage of
20
21 419 core materials and learning objectives during delivery, and the extent to which the
22
23 420 programme is delivered in accordance with the delivery manual, what adaptations are
24
25 421 undertaken and why).
- 26
27
28 422 6. Evaluate acceptability of the intervention to patients, healthcare professionals and
29
30 423 commissioners.
- 31
32
33 424 7. Evaluate intervention embedding and sustainability e.g. what are the barriers and
34
35 425 facilitators to the uptake of the intervention in current care pathways.

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37 426 A range of quantitative and qualitative data will be collected, as detailed in Table 2. Attendance
38
39 427 records, observation checklists, session/programme evaluation forms completed by patients
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41 428 and records of session activities completed by educators will provide quantitative data and will
42
43 429 be used to evaluate a number of process domains, as indicated in Table 2. Our process
44
45 430 evaluation will mainly focus on qualitative evaluations, with which we will use inductive
46
47 431 reasoning to determine whether the intervention requires further development and adaptation.
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49 432 Patient interviews and focus groups, and interviews with educators, healthcare professionals
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51 433 and commissioners, and session observation notes will provide qualitative data for the
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53 434 evaluation of a number of process domains, as detailed in Table 2.

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3 436 ***Evaluation of trial procedures***
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5 437 The feasibility of trial procedures will be evaluated, particularly rates and methods of
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7 438 recruitment, retention, completion, contamination between study arms and the proposed data
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9 collection methods:
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12 440 Recruitment: a number of different pathways of recruitment will be implemented e.g. screening
13
14 441 of primary care databases and letters of invitation, face-to-face referral during medical
15
16 442 appointments, self-referral via posters, word-of-mouth referral. We will assess uptake rates
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18 443 from these different pathways to enable us to identify the most effectiveness methods and
19
20 444 assess the feasibility of recruiting for a full-scale trial.
21

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23 445 Retention & completion: we will assess the rate of retention both within the HEAL-D
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25 446 intervention (i.e. numbers completing each session and the full programme) and the feasibility
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27 447 trial (i.e. numbers completing baseline and endpoint assessment visits). We will evaluate the
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29 448 feasibility of randomising and retaining a control arm by assessing drop-out rates and
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31 449 comparing these between the study arms; we will also interview control arm patients to explore
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33 450 the acceptability of being assigned to the control arm.
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37 451 Data collection methods: we will assess the frequency of missing data and any trends in which
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39 452 data is missing e.g. self-complete questionnaires, blood measures, to assess the feasibility of
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41 453 our data collection methods.
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44 454 Contamination: we will interview patients from the control arm to explore issues of
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46 455 contamination e.g. did their participation in the trial promote change in self-management
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48 456 behaviours or motivate information-seeking behaviours, did they know anybody in the
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50 457 intervention arm or discuss the intervention with anybody.
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459 **PATIENT AND PUBLIC INVOLVEMENT**

460 Service user involvement is intrinsic to this proposed research, which utilises participatory
461 methods to engage patients and other stakeholders in the intervention design. The protocol
462 provides extensive detail of how patients will be involved in the design, recruitment, conduct
463 and dissemination of the research.

464 **ETHICS & DISSEMINATION**

465 The study protocol has been approved by the Fulham: London Research Ethics Committee (17-
466 LO-1954); all participants will provide written consent prior to participation. All data will be
467 anonymised and data protection protocols followed.

468 The study findings will be disseminated to the scientific community via conference
469 presentations and peer-reviewed manuscripts, and to healthcare professionals via national and
470 local clinical networks. The findings of the study will be communicated to our participants and
471 local communities via the community networks and figureheads who we will engage in our
472 participatory methods; we will give presentations at church events and publish a newsletter via
473 our study website (www.heal-d.co.uk).

474 **DISCUSSION**

475 This paper presents the protocol for the design and feasibility testing of HEAL-D, a culturally-
476 tailored T2D self-management programme for UK African and Caribbean communities. This
477 study will employ rigorous complex intervention methodology to develop and evaluate the
478 implementation of a culturally-tailored T2D self-management intervention. The intervention's
479 curriculum will be based on existing evidence-based guidelines for diet and lifestyle
480 management of T2D, participatory co-design methods will be employed to foster community
481 engagement and partnership. We will use a 'bottom-up' approach to identify the cultural

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3 482 adaptations of our intervention, and identify its theoretical basis through thematic analysis and
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5 483 the COM-B behavior change framework. The feasibility study will provide us with key
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7 484 information about the feasibility of running a full-scale trial of HEAL-D and process evaluation
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9 485 methods will enable us to understand how and why the intervention is effective or ineffective.
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13 486 Culturally-tailored T2D education has been found to be more effective than standard education
14
15 487 (40) but to date there have been no tailored education programmes for Black-British
16
17 488 communities. A number of culturally-tailored diabetes education programmes have been
18
19 489 developed for African-American communities; these have mainly used participatory methods
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21 490 to foster community engagement and have largely drawn on faith-based partnerships for their
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23 491 delivery (41, 42). It is not known to what extent these approaches and the content of these
24
25 492 education programmes translates to the UK context, in which there are differences in both the
26
27 493 healthcare systems and AfC culture to that of the USA. Indeed it is not known to what extent
28
29 494 culturally-tailored care is needed for Black-British communities as little work has been
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31 495 undertaken with these communities. To date in the UK, culturally-tailored education
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33 496 programmes have been developed only for South Asian populations and other communities for
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35 497 whom English is not their first language, and ‘tailoring’ has focused on translating the delivery
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37 498 and resources into relevant languages. This type of adaptation would be considered a ‘surface
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39 499 structure’ in Resnicow’s model of cultural tailoring (26). Our co-design work is intended to
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41 500 identify deeper levels of adaptation by exploring the socio-cultural barriers and facilitators to
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43 501 behaviour change and structuring HEAL-D accordingly. We acknowledge that we are likely to
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45 502 find huge diversity within our Black-British communities and *culture* will likely be only one
46
47 503 of many important factors that affects their health behaviours. However, our co-design work
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49 504 will provide a more comprehensive theoretical under-pinning for the content of our programme
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51 505 than that which currently exists and will provide us with a framework upon which to evaluate
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506 the effectiveness of our programme. This work will provide essential information and
507 evaluation to inform the design of a future definitive trial.

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3 509 **ABBREVIATIONS**
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6 510 AfC African-Caribbean
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9 511 COM-B Capability Opportunity Motivation Behaviour
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12 512 HEAL-D Healthy Eating & Active Lifestyles for Diabetes
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15 513 MRC Medical Research Council
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18 514 NHS National Health Service
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21 515 T2D Type 2 diabetes
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28 517 **DECLARATIONS**
29
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31 518 The study protocol has been approved by the Health Research Authority (London Fulham
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33

34 519 Research Ethics Committee; 17/LO/1954); all participants will provide written consent prior
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36

37 520 to participation.
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39 521 **CONSENT FOR PUBLICATION**
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42 522 Not applicable.
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45 523 **AVAILABILITY OF DATA AND MATERIALS**
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48 524 Not applicable.
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51 525 **COMPETING INTERESTS**
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54 526 The authors declare that they have no competing interests.
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4
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6
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8 530 expressed in this publication are those of the author(s) and not necessarily those of the NHS,
9
10 531 the National Institute for Health Research or the Department of Health.
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13 532 **AUTHOR CONTRIBUTIONS**

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15
16 533 All authors have made substantial contributions to this study. LMG, CR and SH were
17
18 534 responsible for the conception and design of the study. LMG, CR, SH and AM developed the
19
20 535 protocol and study approach. LMG drafted the manuscript. All authors read, revised and
21
22 536 approved the final manuscript. LMG is guarantor.
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29 538 Not applicable.
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3 541 **FIGURE LEGENDS**
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6 542 **Figure 1.** Medical Research Council's framework for the development and evaluation of
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8 543 complex interventions. Reproduced from Craig P. *et al.* British Medical Journal. 2008;
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10 544 337:a1655.
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13 545 **Figure 2.** Schematic diagram of Phase I: Development of HEAL-D using evidence synthesis
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15 546 and co-design methodology to design a culturally-tailored self-management programme for
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17 547 T2D in African and Caribbean communities
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21 548 **Figure 3.** The Capability-Opportunity-Motivation (COM-B) Framework and Behaviour
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23 549 Change Wheel; a framework for developing behavioural interventions. Reproduced from
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25 550 Michie S., van Stralen M.M. and West R. Implementation Science. 2011; 6:42.
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29 551 **Figure 4.** Applying the COM-B behaviour change framework to the development of the
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31 552 HEAL-D intervention; identifying theory of change.
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Table 1. Topic guides for patient focus groups and stakeholder interviews**Patient focus groups**

Knowledge and perceptions of diabetes, and diet and lifestyle advice for managing diabetes.

Current practices relating to diabetes self-care, and diet and lifestyle.

Health concerns/priorities in relation to diabetes.

Motivations and barriers/difficulties relating to diabetes self-care, weight management and diet and lifestyle.

Experiences and perceptions of diabetes care/education, and barriers to accessing care.

Experiences of behaviour change in relation to diabetes, weight, diet and lifestyle – successes and failures.

Role of family/friends/communities in influencing and shaping knowledge and behaviours in relation to diabetes, diet and lifestyle.

Community leader interviews (including religious leaders)

Health problems affecting the community and diabetes impact on health within this context.

Attitude of the community towards health, medicines, doctors.

Role of community leaders in promoting health and community activities.

Diabetes health promotion activities within the community. What worked and what didn't.

Barriers and facilitators to positive diabetes behaviours within the community.

Advice about engaging the community: Who are the role models; What will engage and help people; How can healthcare & community work together.

Healthcare professional interviews

Experience of supporting African & Caribbean patients. What are the issues. How could things be improved. What factors make successful T2D management likely.

Patient beliefs and motivations.

Involvement in community activities and experience of working with community leaders and lay educators and suggestions to improve partnerships.

Difficulties & challenges with offering a tailored lifestyle intervention.

Table 2. Mapping of the HEAL-D feasibility study research questions, process evaluation data sources and evaluation methods

PROCESS EVALUATION DOMAIN & RESEARCH QUESTIONS	DATA SOURCES										EVALUATION METHOD
	Patient questionnaires	Session observations	Session record of activities	Patient evaluation forms	Educator interviews	Patient interviews	Patient focus groups	Attendance records	HCP interviews	Commissioner interviews	
TESTING INTERVENTION THEORY & MECHANISMS OF CHANGE											
Are the intervention's mechanisms of change operationalised as hypothesised?	X	X	X	X	X	X	X				Qualitative data collected through interviews/focus groups with patients and educators, and session observation notes will be used to evaluate how the theory of the intervention operationalises and interacts with contextual factors.
How is the operationalisation of the mechanisms of change influenced by contextual factors?		X	X		X	X	X				
Does the interaction of the mechanisms of change with contextual factors give rise to unintended effects?		X	X		X	X	X				
ASSESSING USUAL PRACTICE & CONTAMINATION											
Is HEAL-D differentiable from 'usual practice'?						X					Interviews will be conducted with patients from both arms. Experiences of the intervention and control will be explored. With control patients issues of contamination and perceptions of 'usual care' will be discussed.
Is there contamination in control patients?							X				
ASSESSING IMPLEMENTATION											
What is the intervention reach and dose?	X							X			Questionnaire data will assess who receives the intervention and how representative they are e.g. age, gender, ethnicity, working status. Attendance records will be used to quantify the proportion of patients receiving the full vs part intervention.

priorities, and the feasibility of sustained resource allocation to the HEAL-D intervention if found to be successful.

HCP, Healthcare professionals

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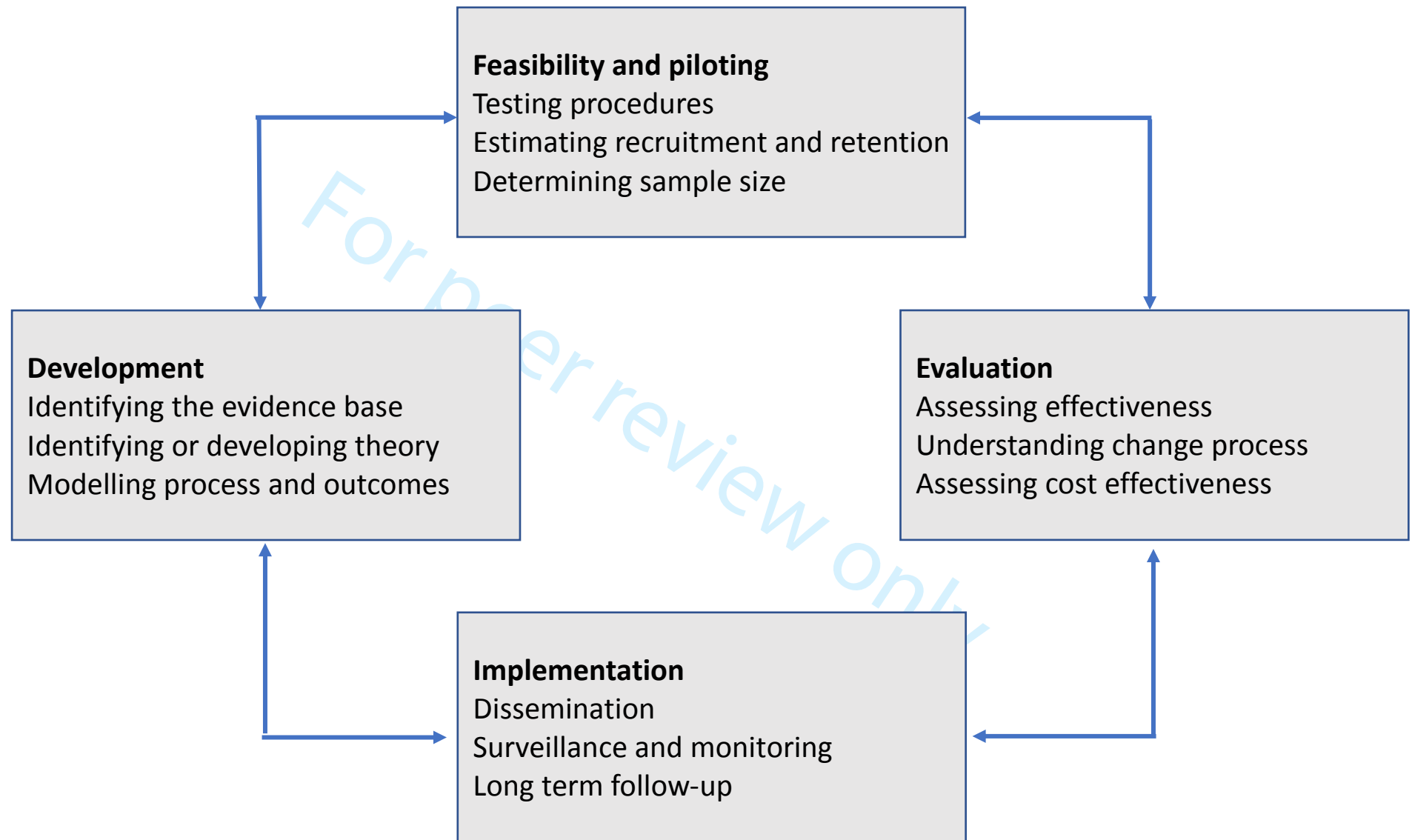
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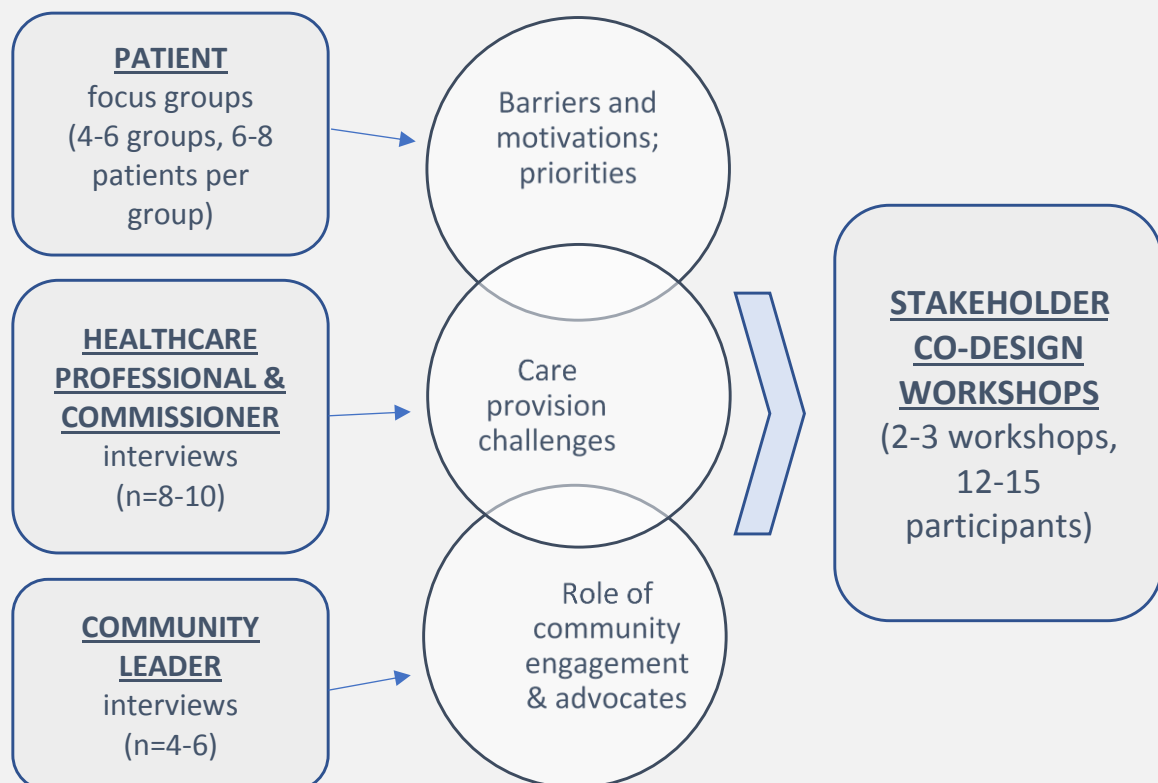


DEVELOPMENT OF HEAL-D, A CULTURALLY-TAILORED T2D SELF-MANAGEMENT PROGRAMME FOR AFRICAN & CARIBBEAN COMMUNITIES

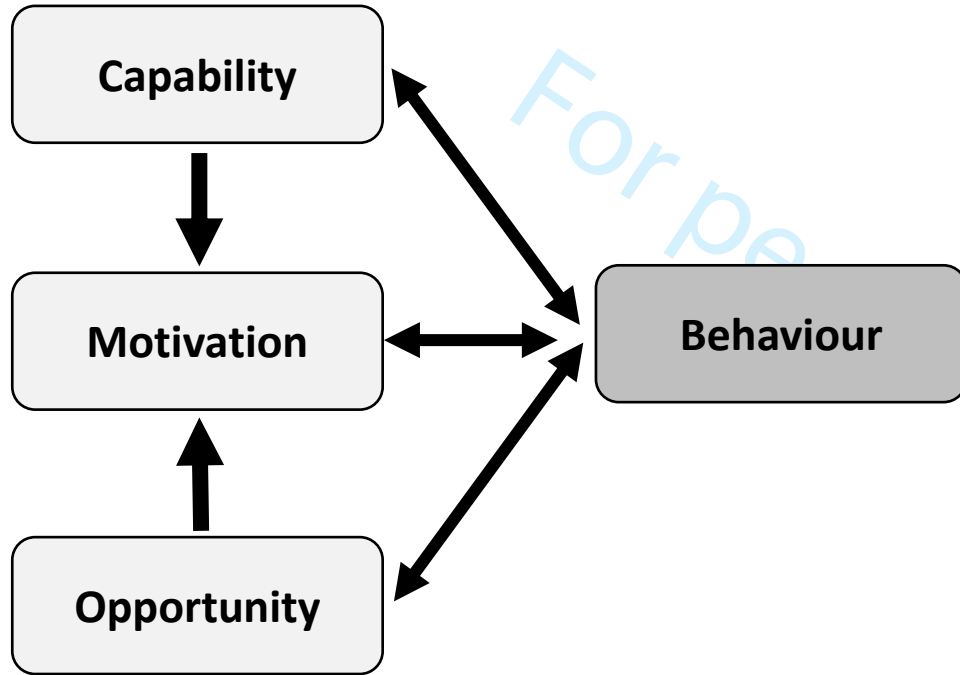
1. INCORPORATE EXISTING RECOMMENDATIONS INTO DRAFT STRUCTURE & ALIGN WITH CLINICAL GUIDELINES

2. DRAW ON THE EXISTING EVIDENCE BASE FOR ADAPTING HEALTH PROMOTION INTERVENTIONS FOR ETHNIC MINORITY GROUPS

3. IDENTIFY THE INTERVENTION'S THEORETICAL BASIS & CULTURAL ADAPTATIONS THROUGH CO-DESIGN METHODS



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COM-B analysis of the behaviour goal: performing 30 minutes moderate intensity physical activity per day

CAPABILITY

Knowledge: Does the target group know:

- Why moderate intensity physical activity would help diabetes management?
- What moderate intensity is and how to measure it?

Behavioural regulation: Does the target group know how to:

- Plan to fit the activity in to their daily life?
- Remember to do the activity?
- Prioritise this activity over others?
- Record & measure and self-monitor their activity?

Physical skills: Does the target group: Have the physical stamina to be active at this intensity?

OPPORTUNITY

Environmental context & resources:

- Is it safe to exercise in the neighbourhood?
- Do patients have suitable footwear?
- Can they afford a pedometer or some means of measuring their activity?

Social influences (what interpersonal influences cause individuals to change their thoughts, feelings or behaviours?)

- It is culturally acceptable to exercise?
- What is the social norm among immediate friends and family?
- What positive or negative views do others have that may influence activity?
- Are there any positive role models?
- Are there competing demands e.g. pressure to spend leisure time with family or at church?

Would group support be motivating?

MOTIVATION

Reflective (conscious) motivation:

- How optimistic do the patients feel they can achieve the goal?
- Do they intend to do the behaviour (stages of change model)?
- What emotions may help or hinder? e.g. fear of injury.
- What other emotions may conflict? e.g. tiredness, depression, stress.

Automatic (innate drivers):

- What are established habit patterns?
- What are routines/thought/behaviours set up by previous experience

BMJ Open

**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**

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-023733.R2
Article Type:	Protocol
Date Submitted by the Author:	18-Dec-2018
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Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Nutrition and metabolism
Keywords:	type 2 diabetes, ethnicity, culture, diet, lifestyle, education

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Manuscripts

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3 1 **Healthy Eating and Active Lifestyles for Diabetes (HEAL-D): study protocol for the**
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5 2 **design and feasibility trial, with process evaluation, of a culturally-tailored diabetes self-**
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7 3 **management programme for African-Caribbean communities**
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12 **ABSTRACT**

13 **Introduction**

14 Black-British communities are disproportionately burdened by type 2 diabetes (T2D) and its
15 complications. Tackling these inequalities is a priority for healthcare providers and patients.
16 Culturally-tailored diabetes education provides long-term benefits superior to standard care but
17 to date such programmes have only been developed in the USA. The current programme of
18 research aims to develop the Healthy Eating and Active Lifestyles for Diabetes (HEAL-D)
19 culturally-tailored T2D self-management programme for Black-British communities; and to
20 evaluate its delivery, acceptability and the feasibility of conducting a future effectiveness trial
21 of HEAL-D.

22 **Methods & analysis**

23 Informed by Medical Research Council Complex Interventions guidance this research will
24 rigorously develop and evaluate the implementation of the HEAL-D intervention to understand
25 the feasibility of conducting a full-scale effectiveness trial. In Phase 1 the intervention will be
26 developed. The intervention curriculum will be based on existing evidence-based T2D
27 guidelines for diet and lifestyle management; co-design methods will be used to foster
28 community engagement, identify the intervention's underpinning theory; identify the optimal
29 structure, format and delivery methods, ascertain adaptations that are needed to ensure cultural
30 sensitivity, and understand issues of implementation. In Phase 2 the intervention will be
31 delivered and compared to usual care in a feasibility trial. Process evaluation methods will
32 evaluate the delivery and acceptability of HEAL-D. The effect size of potential primary
33 outcomes, such as HbA1c and body weight will be estimated. The feasibility of conducting a
34 future effectiveness trial will also be evaluated, particularly feasibility of randomisation,
35 recruitment, retention, and contamination.

36 **Ethics & dissemination**

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2
3 37 This study is funded by a National Institute of Health Research Fellowship (CDF-2015-08-
4
5 38 006), and approved by NHS Research Ethics Committee (17-LO-1954). Dissemination will be
6
7 39 through national and international conferences, peer-reviewed publications and local and
8
9 national clinical diabetes networks.
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12 41 **Trial Registration:** this trial is registered with www.clinicaltrials.gov, identifier:
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14 42 NCT03531177.
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19 44 **STRENGTHS AND LIMITATIONS OF THIS STUDY**

- 21 45 • This study employs rigorous complex intervention methodology to develop and
22 46 evaluate a culturally-tailored diabetes self-management intervention.
- 23
24 47 • Participatory co-design methods are being used to foster stakeholder engagement in
25
26 48 intervention development.
- 27
28 49 • The COM-B behaviour change framework is being used to identify appropriate
29
30 50 intervention behaviour change techniques.
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32 51 • Process evaluation measures are being collected to assess the feasibility of evaluating
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34 52 the intervention in a full-scale trial.
- 35
36 53 • The feasibility trial is designed to estimate the effect size of the intervention rather than
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38 54 efficacy, which will be the focus of a future definitive trial.
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48 56 **Keywords:** African, Caribbean, ethnicity, type 2 diabetes, education, self-management, diet,
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58 INTRODUCTION

59 Type 2 diabetes (T2D) affects approximately 3 million people in England and consumes around
60 10% of the National Health Service (NHS) budget, estimated at almost £9 billion in 2011 and
61 predicted to rise to 17% of the NHS budget by 2035 (1). Diabetes and its associated
62 complications place an illness burden on patients and carers, which disproportionately affects
63 those from ethnic minority backgrounds (2). The estimated prevalence of T2D is up to 3 times
64 higher for Black-British communities compared to White Europeans (3). T2D occurs, on
65 average, 10 years earlier in Black-British people, the mean age of diagnosis is 48 years and
66 approximately 25% of patients are under the age of 40 years (4). Furthermore, glycaemic
67 control is worse at the time of diagnosis, requires greater medical management, and poorer
68 outcomes are evident (5-7). The reasons for these disparities are not fully understood; while
69 biological factors are involved, it is understood that a range of behavioural, lifestyle and health
70 system factors play a role. Tackling these inequalities is a healthcare priority (8, 9).

71 Individuals of Black-British ethnicity form the second largest ethnic minority population in the
72 United Kingdom (UK); around 4% of the population self-identify from this ethnic background
73 (10). Around half of individuals are of Black African ancestry and a third of Black Caribbean
74 ancestry (10). Growth in the Black-British communities is relatively recent, beginning mainly
75 in response post-second world war appeals to citizens of the Commonwealth regions to assist
76 with gaps in its labour market. This prompted a large influx of migrants in the 1950s from the
77 Caribbean islands, particularly Jamaica. Migration from the African continent has been more
78 recent, peaking around the 1980s; migrants from African nations currently form the largest
79 growing ethnic minority group in the UK population (11). In some regions, such as London,
80 Black-British communities may represent 30-40% of the local population and are therefore a
81 'majority-minority' community. Other demographic patterns are recognised; the age
82 distribution of the Black African and Black Caribbean communities differs, with a larger

1
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3 83 proportion of Black Caribbeans being aged 65 years and over, while in the Black African
4
5 84 population a greater proportion are children and young adults. High rates of unemployment are
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8 85 evident, averaging around 12% compared to 4% in the White British population (11).
9
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11 86 Poor access to diabetes healthcare is a significant issue for minority ethnic groups (2). In the
12
13 87 UK the NHS provides care to all UK residents that is free at the point of delivery. First-line
14
15 88 diabetes management is situated in primary care and aims to promote patient involvement and
16
17 89 self-management (12), enabling patients to adopt a healthy lifestyle and to manage their
18
19 90 diabetes through support and education (13). To achieve this, UK T2D management guidelines
20
21 91 recommend that all patients attend a structured education course to teach them the principals
22
23 92 of T2D self-management and that this be offered annually from the time of diagnosis (14).
24
25 93 Courses are recommended to use a group structure; typically they use face-to-face delivery by
26
27 94 a diabetes specialist nurse or dietitian, with lay educator co-delivery in some cases (14).
28
29 95 Referral to such courses is audited and incentivised through the Quality Outcomes Framework
30
31 96 (15). Ethnic minority groups report finding it more difficult to access primary care services
32
33 97 (16) and are more likely to report that they have not had the opportunity to attend a diabetes
34
35 98 education course than White populations (17). Specifically, African-Caribbean (AfC)
36
37 99 communities often report a distrust of medical advice and a desire for natural, non-
38
39 100 pharmacological therapies (18). Furthermore, healthcare professionals are perceived as lacking
40
41 101 cultural understanding (19) and their advice as lacking cultural relevance (20) or being poorly
42
43 102 adapted to culture and needs (18), despite their intentions; these issues may contribute to the
44
45 103 poorer diabetes outcomes and increased morbidity experienced by AfC patients.
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53 104 Culturally tailored healthcare is proposed to be one of the main ways in which healthcare
54
55 105 disparities can be addressed (21-23) and is identified as a priority by patients (8). Culturally-
56
57 106 tailored diabetes education has demonstrated greater improvements in diabetes control and
58
59 107 knowledge than usual care, and the benefits are maintained long-term (22, 24). Culture is a

1
2
3 108 concept that is notoriously difficult to define but generally within healthcare it is thought of as
4
5 109 'a set of attitudes, values, beliefs and behaviours shared by a group of people, communicated
6
7
8 110 from one generation to the next' (25). In their model for understanding cultural sensitivity in
9
10 111 healthcare, Resnicow *et al.* (1999) described two dimensions in culture: surface and deep
11
12 112 structures. Tailoring interventions to surface structures involves matching materials and
13
14 113 messages to observable, "superficial" characteristics of a target population e.g. language and
15
16 114 food, familiar to, and preferred by, the target audience. Deep structure involves incorporating
17
18 115 the cultural, social, historical, environmental and psychological forces that influence the target
19
20 116 health behaviours in the proposed target population. Whereas surface structure generally
21
22 117 increases the "receptivity" or "acceptance" of messages, deep structure conveys salience (26).
23
24 118 Culture is ever evolving for any group and it is important to recognise the diversity that exists
25
26 119 within any one 'cultural group', which is particularly evident in migrant populations where
27
28 120 second/third generations may have undergone significant acculturation. To date, culturally
29
30 121 tailored interventions for the African diaspora have largely been based in the USA, and may
31
32 122 not translate to UK healthcare structures or UK AfC communities whose cultural needs may
33
34 123 be different (23).

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40 124 A two-phase programme of research is proposed in which a culturally-tailored, evidence-based
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42 125 self-management programme for T2D in African and Caribbean communities, called Healthy
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44 126 Eating & Active Lifestyles for Diabetes (HEAL-D), is developed, followed by a feasibility
45
46 127 trial. The intervention curriculum will be based on existing evidence-based guidelines for T2D
47
48 128 (14, 27) to enable it to have potential to be embedded into clinical practice; co-design methods
49
50 129 will be used to identify the optimal structure, format and methods of delivery and to ascertain
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52 130 appropriate adaptations that are needed to ensure cultural sensitivity of the content. The
53
54 131 purpose of this article is to present the protocol for the development and feasibility trial of
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56 132 HEAL-D.
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3 133 **PURPOSE & AIMS**
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6 134 The overall aims of this research are to develop a culturally-tailored, evidence-based self-
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8 135 management programme for managing T2D among AfC communities in primary care, called
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10 136 HEAL-D, and to determine the feasibility of evaluating HEAL-D through a future effectiveness
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12
13 137 trial.
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16 138 The objectives are to:
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- 19 139 1. Develop a self-management programme, based on existing evidence-based diet and
20
21 140 lifestyle guidelines, appropriately tailored for AfC patients through co-design methods.
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23 141 2. Establish the feasibility of conducting an effectiveness trial of HEAL-D, considering
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26 142 issues such as participation rates and potential effect sizes.
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144 **METHODS AND ANALYSIS**

145 Guided by the Medical Research Council's Complex Interventions framework (28) (Figure 1),
146 two distinct phases of research are proposed: phase 1 is a formative phase in which the HEAL-
147 D intervention will be developed; and phase 2 will evaluate the HEAL-D intervention in a
148 feasibility trial. Study recruitment began in April 2017; the study duration will be 36 months.

149 **Phase 1 – Development of a culturally-tailored T2D self-management programme**

150 The process for the development of HEAL-D is outlined in Figure 2. Firstly, to ensure its
151 potential to be embedded into future clinical practice, the HEAL-D curriculum will align with
152 existing UK management recommendations and guidelines published by the National Institute
153 of Clinical Excellence and Diabetes UK (14, 27):

154 Guidelines for diet and lifestyle management of T2D (27):

- 155 1. Achieve 5-10% weight loss or weight maintenance in those of healthy weight.
- 156 2. Undertake 150 minutes/week of moderate-to-vigorous intensity aerobic physical
157 activity plus 2 sessions/week of strength training.
- 158 3. Balance carbohydrate intakes through portion control and promotion of low
159 glycaemic index and wholegrain sources.
- 160 4. Limit saturated fat intake (<10% of energy intake), replace with mono-unsaturated
161 fats.
- 162 5. Limit salt intake (<6g per day).
- 163 6. Consume oily fish at least twice per week.

164 Guidelines for T2D recommend that self-management structured education is offered to
165 adults with T2D and/or their family members or carers, with group education as the preferred
166 option, and that the education programmes are theory-driven, evidence-based and meet the
167 cultural, linguistic, cognitive and literacy needs of the population (14).

168 **Drawing on the existing evidence base**

169 Secondly it will draw on key themes reported in published literature relating to methodologies
170 for adapting health promotion interventions for ethnic minority groups. These have been
171 evaluated in a number of recent systematic reviews; aside from acknowledging the lack of UK-
172 based studies, these reviews make several recommendations. The powerful influence of social
173 networks on health beliefs and behaviours should be acknowledged (29), and a focus on
174 community-level interventions should be taken; delivering care in a social context promotes
175 engagement and has been shown to be more effective than traditional individual-centred
176 behavioural approaches (23). Community engagement should be promoted to overcome issues
177 of deep-rooted, historical distrust of medical advice and settings, to develop and nurture trust
178 between the researchers and community, and to nurture the strong sense of collectivism and
179 kinship networks that are evident amongst AfC communities. Participatory methods (e.g.
180 patient involvement in intervention design, lay-led delivery of interventions) should be
181 employed as they are highly effective at improving health behaviours and self-efficacy across
182 a number of conditions (30). Using community gathering places (e.g. faith institutions) as
183 intervention settings offers the benefit of cultural relevancy and may reach populations who
184 would not normally access self-management education (31).

185 **Identifying the intervention's theoretical basis**

186 Behavioural interventions should have a theoretical under-pinning (28, 32) so that the changes
187 that are expected, and how these will be achieved, can be predicted from consideration of
188 known behaviour change techniques. While there have been a number of interventions tailored
189 to support diet and lifestyle behaviour change in AfC communities (33), their theoretical
190 underpinning has rarely been drawn out or clearly presented. The theoretical underpinning of

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3 191 HEAL-D will be developed through a combination of key themes from the published literature
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5 192 and new primary research.
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8 193 In the literature collectivism and the importance of social interaction for people of AfC ancestry
9
10 194 is well reported (29), and the provision of a social support group, or inclusion of a family
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12 195 member, has been shown to be particularly effective in lifestyle interventions in African-
13
14 196 American communities (34, 35). These findings suggest social learning theory, which focuses
15
16 197 on promoting behaviour change through social interaction, role modelling and social
17
18 198 comparison, may be a relevant behaviour change theory for our intervention. Notably, much of
19
20 199 literature that identifies the drivers of health behaviours in AfC communities and may,
21
22 200 therefore, inform the theoretical basis of an intervention, comes from the USA and it is not
23
24 201 known to what extent these findings apply to AfC in other regions. One of the reasons we will
25
26 202 use co-design methods will be to understand the relevance of these existing themes to the UK
27
28 203 context and enable us to identify themes that are important to Black-British communities.
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34 204 **Co-designing the intervention through participatory methods**

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37 205 HEAL-D will use participatory co-design methods to engage patients, healthcare providers and
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39 206 community leaders (e.g. church leaders, community group leads) in focus groups, interviews
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41 207 and workshops to achieve the following:
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- 45 208 1. Foster community engagement.
- 46
47 209 2. Identify the theoretical under-pinning of HEAL-D and its mechanisms of action.
- 48
49 210 3. Identify appropriate cultural adaptations for the intervention.
- 50
51 211 4. Understand issues of intervention implementation.
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55 212 ***Focus groups and interviews***

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58 213 Focus groups, 8-10 groups of 6-8 participants, will be conducted with patients with T2D of
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60 214 AfC ethnicity, recruited through local churches, mosques and community groups, as well as

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3 215 through GP practices in London. The focus groups will be conducted in local accessible
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5 216 community venues e.g. church hall, library, community centre. Patients will be purposively
6
7 217 sampled to get a spread of socio-economic position, generational status and ancestral origins,
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9 218 as principal factors impacting on health status, healthcare access and cultural behaviours in
10
11 219 these groups (36-38). Separate focus groups will be conducted with men and women, and
12
13 220 patients of direct African *versus* Caribbean ancestry, as they report different cultural
14
15 221 barriers/facilitators to lifestyle change (36, 37). A topic guide (Table 1) based on themes
16
17 222 identified in the literature, will be used to steer discussions and ensure coverage of key themes
18
19 223 whilst encouraging free discussion of opinion/perspective. Focus groups have been selected to
20
21 224 enable us to understand normative needs, as suited to the development of a community
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23 225 intervention.

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29 226 Semi-structured interviews will be conducted with 8-10 healthcare providers, including general
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31 227 practitioners, practice nurses, diabetes specialist nurses, diabetes specialist dietitians and
32
33 228 commissioners. The interviews will cover issues relating to healthcare needs and engagement
34
35 229 of AfC patients, experiences of delivering healthcare to AfC patients, and barriers and
36
37 230 facilitators to working in partnership with community groups to deliver care for AfC
38
39 231 communities (Table 1). Interviews have been selected for this part of the study to enable us to
40
41 232 gather a full range of experiences and therefore optimise implementation.

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46 233 Community leaders representing faith and non-faith institutions (n=4-6) will be invited to
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48 234 participate in semi-structured interviews. Leaders will be identified initially through existing
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50 235 networks e.g. Diabetes UK Community Champions initiative. Word-of-mouth and ‘snow-
51
52 236 balling’ techniques that are highly effective within these communities, will be used to recruit a
53
54 237 wider network. The interviews will cover issues relating to the role of community networks in
55
56 238 promoting health of AfC communities, sustaining health amongst community members, and
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58 239 opportunities for greater impact (Table 1).

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3 240 *Analysis*
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6 241 The focus groups and interviews will be digitally recorded and transcribed verbatim. The data
7
8 242 will be analysed using the framework approach in NVivo (QSR International), theoretically
9
10 243 driven by socio-ecological theory to identify themes relating to issues at the individual, family,
11
12 244 community and healthcare delivery levels and how these influence self-efficacy and behaviour
13
14 245 change. Our analysis will identify priority behaviours of focus for the intervention, key barriers
15
16 246 and facilitators to behaviour change and healthcare engagement, favoured settings, and a
17
18 247 rudimentary draft of the cultural adaptations. Deviant case analysis, that is consideration of
19
20 248 cases that do not fit the general picture, will be undertaken, though our primary interest is in
21
22 249 the commonalities as this is a community level intervention. Primary coding and development
23
24 250 of a coding scheme will be carried out by a single researcher; a second researcher will
25
26 251 independently use this coding scheme to code 20% of the data for cross-comparison, to improve
27
28 252 dependability. This will provide methodological rigour required for confidence in the analysis
29
30 253 of the qualitative data. The themes will be fed-back and discussed with a Service User Group
31
32 254 (SUG), which will consist of representatives of patients, healthcare providers, and community
33
34 255 leaders. The SUG will be set up to inform and guide each stage of the research plan and will
35
36 256 be a forum through which the research team can seek the opinion of key stakeholders, in this
37
38 257 case particularly relating to interpretation of the qualitative data and to ensure trustworthiness
39
40 258 of conceptualisations. The SUG will also review research documents, such as patient
41
42 259 information sheets and questionnaires, and provide feedback on their content and suitability
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44 260 for the communities of focus.
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53 261 We will divide our data into behavioural ‘barriers’ and ‘facilitators’ where possible. To
54
55 262 ascertain appropriate behaviour change techniques for our intervention (32) we will map our
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57 263 analysis onto the Capability-Opportunity-Motivation-Behaviour (COM-B) framework from
58
59 264 the Behaviour Change Wheel (39) (Figure 3), and thence in each case consider the outcome
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3 265 behaviours that our intervention will aim to achieve, a worked example is shown in Figure 4.
4
5 266 We will use the COM-B framework to identify appropriate *functions* of our intervention to
6
7
8 267 optimise facilitators and overcome barriers to achievement of planned outcomes, e.g.
9
10 268 ‘education’ for capability barriers, ‘modelling’ for opportunity and motivation barriers. Finally,
11
12 269 we will select specific behaviour change techniques e.g. education, goal setting, that focus on
13
14 270 the specific functions we have identified. We will also look to identify other themes that arise
15
16 271 from the data, which might not map clearly onto the COM-B framework (e.g. contextual
17
18 272 themes relating to the health system) but which may inform our intervention theory as well as
19
20 273 help us to understand issues of implementation (e.g. favoured settings and timings). Through
21
22 274 this analysis we will identify our intervention theory that we will draw on for the next stage of
23
24 275 the study, as documented through a logic diagram.

26 276 ***Stakeholder co-design workshops***

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32 277 Following evaluation of the focus groups and interviews our stakeholders, 12-15 patients,
33
34 278 healthcare providers, commissioners and community leaders, will be invited to participate in a
35
36 279 series of 2-3 half-day workshops, held in community locations. The workshops will seek to
37
38 280 gain stakeholder involvement in developing the details of the interventions. This will include
39
40 281 determining the setting, the media channels, structure and delivery, as well as steering the
41
42 282 research team to understand and respond to literacy and numeracy needs. The workshops will
43
44 283 endeavour to reach a consensus opinion from attendees but where stakeholders have different
45
46 284 needs and a consensus cannot be reached the research team will consult with the SUG to make
47
48 285 decisions on the way forward and consider where there is scope for the intervention to be
49
50 286 structured to meet these different needs e.g. delivery in a range of settings. In the first workshop
51
52 287 the research team will feed back the findings of the focus groups and interviews; anonymised
53
54 288 interview extracts will be presented to illustrate the key themes and issues that were identified.
55
56 289 The stakeholders will be asked to discuss the themes and behavioural targets in small groups,
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3 290 using directed tasks/questions to facilitate the discussions. Following the small group
4
5 291 discussions the researchers will facilitate discussion as a whole to clarify/confirm
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7 292 interpretation; open discussion/debate will be encouraged to examine the themes in depth and
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9 293 for all stakeholders to agree a mutual understanding.
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13 294 In the second workshop elements of the proposed intervention will be presented for comment,
14
15 295 refining and development. Using scenarios, the stakeholders will be asked to brainstorm, in
16
17 296 small groups, key issues relating to the scenarios. For example, the moderator will present
18
19 297 scenarios relating to the intervention setting and the attendees will be asked to discuss and
20
21 298 identify the pros and cons of each, and then feedback their discussions to the other attendees.
22
23 299 The attendees will be asked to review existing educational/support materials e.g. leaflets and
24
25 300 videos and provide feedback on, for example, language/phrasing, content, pitch and
26
27 301 understanding. The research team will then facilitate cross-discussion between groups to
28
29 302 develop the conclusions and a consensus.
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34 303 In the final workshop draft intervention materials, developed from workshops 1 and 2, will be
35
36 304 presented. For example, media channels that could be used to promote behaviour change such
37
38 305 as testimonials, story-telling, and cooking demonstrations. The stakeholders will be divided
39
40 306 into small groups to discuss and provide feedback on the acceptability of the components of
41
42 307 the intervention and identify potential barriers to engagement. Following the small group
43
44 308 discussions the researchers will facilitate feedback and encourage discussion as a whole to
45
46 309 clarify/confirm the researcher's interpretation. The intervention template may be further
47
48 310 refined, and will be developed into the detailed programme.
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56 312 **Phase 2 – Evaluation of HEAL-D; a culturally-tailored T2D self-management**
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58 313 **programme for African and Caribbean communities**
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3 314 In phase 2 a feasibility study, with an embedded process evaluation, will be conducted to
4
5 315 address the following objectives:

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8 316 1. Evaluate the HEAL-D intervention, particularly its theoretical under-pinning,
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10 317 acceptability, fidelity, issues of implementation and sustainability.
11
12 318 2. Evaluate the feasibility of trial procedures, considering issues such as rates of
13
14 319 recruitment, retention, completion and contamination.
15
16 320 3. Estimate the effect size of potential trial outcomes including HbA1c, weight, waist
17
18 321 circumference, blood pressure, dietary intake, physical activity levels, diabetes
19
20 322 knowledge, and quality of life, to inform an effectiveness trial.
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24 323 **Study Design**

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27 324 The feasibility study will use a randomised controlled design (RCT), with individual patients
28
29 325 as the unit of randomisation, evaluating HEAL-D against usual care. In addition, there will be
30
31 326 a cohort of phase 1 co-design patients who will be allocated to the intervention arm (not
32
33 327 randomised) because their involvement in the intervention design phase would contaminate the
34
35 328 control arm. These patients will be included in the feasibility study to enable us to evaluate the
36
37 329 impact of former involvement on intervention engagement, acceptability and ownership.
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41 330 **Participants**

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44 331 Participants will principally be recruited from General Practice in the London Boroughs of
45
46 332 Lambeth and Southwark through screening of referrals for structured education and letters of
47
48 333 invitation to patients with established T2D. In addition, participants from the phase 1 co-design
49
50 334 study will be invited to participate, and self-referral methods will also be used, for example
51
52 335 posters and advertisements in community locations.
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57 336 Patients with diagnosed T2D who are of African or Caribbean ethnicity and with capacity to
58
59 337 provide fully informed consent to participation in research will be eligible to participate in the
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3 338 trial. Ethnicity will be self-declared using the standard NHS ethnicity categorisation
4
5 339 questionnaire. Patients who are unable to communicate in English and patients with complex
6
7 340 therapeutic dietary needs may be ineligible to participate if their individual needs are deemed
8
9 341 incompatible with the aims of the intervention. This is because the intervention will provide
10
11 342 general diet and lifestyle advice for the self-management of T2D in a group setting; in cases of
12
13 343 patients with certain comorbidities e.g. advanced renal disease, the intervention may be
14
15 344 inappropriate for the individual, and the group nature of the intervention will prevent their
16
17 345 individual needs from being addressed.
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22 346 A pragmatic sample size of 120 patients is anticipated to be sufficient to evaluate the
23
24 347 programme, allowing for 20% drop-out/non-completion; 80 patients will be randomised, 40 in
25
26 348 each arm, and a further cohort of patients (n=40) from phase 1 will be allocated to the
27
28 349 intervention arm without randomisation. As this is a feasibility trial it will not be powered to
29
30 350 detect statistically significant intervention effects. A primary objective of the study is to
31
32 351 provide estimates of key parameters such as potential effect sizes, recruitment and retention
33
34 352 rates of the trial and participation rates of the programme, to enable the optimal design of a
35
36 353 full-scale trial to be determined.
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41 354 **Intervention and control arms**

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43 355 Participants in the control arm will continue with usual care deemed appropriate and delivered
44
45 356 by their primary care team, which may include referral to group structured education and/or
46
47 357 one-to-one consultations with healthcare professionals.
48
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50 358 Participants in the intervention arm will be offered the HEAL-D programme, which will deliver
51
52 359 a curriculum of culturally-tailored, evidence-based diet and physical activity education and
53
54 360 behavior change in a group setting. In line with clinical guidelines, the programme will be
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56 361 delivered by trained educators (external to the research team); favoured educators (e.g. lay
57
58 362 educators *versus* healthcare professionals) will be identified in the co-design process. The
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3 363 details of each session, particularly the behavior change techniques and corresponding
4
5 364 activities/materials will be identified through the co-design work.
6
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8 365 The proposed curriculum will map to evidence-based guidelines, and will be as follows:
9

10
11 366 1. An introduction to T2D self-management principles.

12
13 367 2. Physical activity in T2D management.

14
15 368 3. Carbohydrates & portion sizes.

16
17 369 4. Weight management for T2D.

18
19 370 5. Managing cardiovascular health.
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22

23 371 In line with clinical guidelines for diabetes structured education, the education sessions will be
24
25 372 delivered through educator-led interactive discussion, however support materials will be
26
27 373 provided to reinforce the learning, detailing evidence-based diet and physical activity guidance,
28
29 374 which is culturally tailored for the African and Caribbean communities.
30
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32 33 375 **Data Collection** 34 35

36 376 We will use a mixed methods approach, collecting a range of quantitative and qualitative data,
37
38 377 to evaluate the intervention and the feasibility of trial procedures.
39

40 378 *Estimating the effect of the intervention on potential trial outcomes* 41 42

43 379 Participants will attend a baseline and post-intervention follow-up assessment visit, conducted
44
45 380 by a research technician, at 26-32 weeks to collect the following potential trial outcomes and
46
47 381 estimate effect sizes:
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50 382 Biomedical outcomes: a 5ml venous blood sample will be taken for analysis of HbA1c and
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52 383 total- HDL- & LDL-cholesterol, triglycerides. Systolic and diastolic blood pressure will be
53
54 384 measured using an automated sphygmomanometer.
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57 385 Anthropometric outcomes: body weight will be measured using digital scales, with the patient
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59 386 wearing light clothing (without shoes); height will be measured, using a stadiometer, without
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3 387 shoes; body mass index (BMI) will be calculated as [weight kg/height m²]. Waist
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5 388 circumference will be measured with the patient wearing only light clothing, at the mid-point
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7 389 between the lowest rib and the iliac crest.

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10 390 Diet & physical activity behaviour outcomes: dietary intake will be assessed through
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12 391 completion of a 24-hour diet recall, using the structured multiple pass interview method, and
13
14 392 physical activity through 3-day Actiwatch accelerometer assessment and completion of the
15
16 393 International Physical Activity Questionnaire (IPAQ).

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18 394 The following validated self-complete questionnaires will be administered to assess: diabetes
19
20 395 knowledge (Short Diabetes Knowledge Instrument (40)); diabetes and diet knowledge and
21
22 396 competence (Perceived Diabetes & Dietary Competence (37)); empowerment (Diabetes
23
24 397 Empowerment Scale- Short Form (41)); social support (Multidimensional Scale of Perceived
25
26 398 Social Support (42)); diabetes distress (PAID-5 (43)) and quality of life (EQ-5D-3L (44)).
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32
33 400 Statistical analysis: Given that this is a feasibility study with a small sample size, descriptive
34
35 401 statistics will be used (Chi-Square test, Fisher's exact test). Differences between the groups in
36
37 402 all outcomes will be estimated with 95% confidence intervals. The descriptive data will provide
38
39 403 stable estimates of the variability of continuous outcomes by group, and provide estimates of
40
41 404 differences between the groups in means and proportions for the key outcomes. The standard
42
43 405 deviations of the mean change in HbA1c will be estimated by arms and used to derive the
44
45 406 sample size calculation for a subsequent trial.
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50 51 408 ***Evaluation of the HEAL-D intervention***

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53 409 Process evaluation is an essential part of testing complex interventions (45) and will be used in
54
55 410 our feasibility trial to evaluate the HEAL-D intervention and the feasibility of trial procedures.
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58 411 Our process evaluation aims to achieve the following:
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3 412 1. Test the intervention theory and whether the mechanisms of change operationalise as
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5 413 hypothesised.
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8 414 2. Understand how the multiple components of the intervention interact.
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10 415 3. Evaluate contextual factors that influence operationalisation of the intervention's
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12 416 theory/mechanisms of change, and any unintended effects of these factors.
- 13
14 417 4. Evaluate whether the intervention is differentiable from 'usual practice'.
- 15
16
17 418 5. Evaluate implementation of the intervention, particularly 'reach' (e.g. who receives the
18
19 419 intervention), 'dose' and completion rates, and intervention fidelity (e.g. coverage of
20
21 420 core materials and learning objectives during delivery, and the extent to which the
22
23 421 programme is delivered in accordance with the delivery manual, what adaptations are
24
25 422 undertaken and why).
- 26
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28 423 6. Evaluate acceptability of the intervention to patients, healthcare professionals and
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30 424 commissioners.
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33 425 7. Evaluate intervention embedding and sustainability e.g. what are the barriers and
34
35 426 facilitators to the uptake of the intervention in current care pathways.

37 427 A range of quantitative and qualitative data will be collected, as detailed in Table 2. Attendance
38
39 428 records, observation checklists, session/programme evaluation forms completed by patients
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41 429 and records of session activities completed by educators will provide quantitative data and will
42
43 430 be used to evaluate a number of process domains, as indicated in Table 2. Our process
44
45 431 evaluation will mainly focus on qualitative evaluations, with which we will use inductive
46
47 432 reasoning to determine whether the intervention requires further development and adaptation.

48
49 433 Patient interviews and focus groups, and interviews with educators, healthcare professionals
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51 434 and commissioners, and session observation notes will provide qualitative data for the
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53 435 evaluation of a number of process domains, as detailed in Table 2.

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3 437 ***Evaluation of trial procedures***
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5 438 The feasibility of trial procedures will be evaluated, particularly rates and methods of
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7 439 recruitment, retention, completion, contamination between study arms and the proposed data
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9 collection methods:
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12 441 Recruitment: several different pathways of recruitment will be implemented e.g. screening of
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14 442 primary care databases and letters of invitation, face-to-face referral during medical
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16 443 appointments, self-referral via posters, word-of-mouth referral. We will assess uptake rates
17
18 444 from these different pathways to enable us to identify the most effective methods and assess
19
20 445 the feasibility of recruiting for a full-scale trial.
21

22
23 446 Retention & completion: we will assess the rate of retention both within the HEAL-D
24
25 447 intervention (i.e. numbers completing each session and the full programme) and the feasibility
26
27 448 trial (i.e. numbers completing baseline and endpoint assessment visits). We will evaluate the
28
29 449 feasibility of randomising and retaining a control arm by assessing drop-out rates and
30
31 450 comparing these between the study arms; we will also interview control arm patients to explore
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33 451 the acceptability of being assigned to the control arm.
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37 452 Data collection methods: we will assess the frequency of missing data and any trends in which
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39 453 data is missing e.g. self-complete questionnaires, blood measures, to assess the feasibility of
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41 454 our data collection methods.
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44 455 Contamination: we will interview patients from the control arm to explore issues of
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46 456 contamination e.g. did their participation in the trial promote change in self-management
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48 457 behaviours or motivate information-seeking behaviours, did they know anybody in the
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50 458 intervention arm or discuss the intervention with anybody.
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460 **PATIENT AND PUBLIC INVOLVEMENT**

461 Service user involvement is intrinsic to this proposed research, which utilises participatory
462 methods to engage patients and other stakeholders in the intervention design. The protocol
463 provides extensive detail of how patients will be involved in the design, recruitment, conduct
464 and dissemination of the research.

465 **ETHICS & DISSEMINATION**

466 The study protocol has been approved by the Fulham: London Research Ethics Committee (17-
467 LO-1954); all participants will provide written consent prior to participation. All data will be
468 anonymised and data protection protocols followed.

469 The study findings will be disseminated to the scientific community via conference
470 presentations and peer-reviewed manuscripts, and to healthcare professionals via national and
471 local clinical networks. The findings of the study will be communicated to our participants and
472 local communities via the community networks and figureheads who we will engage in our
473 participatory methods; we will give presentations at church events and publish a newsletter via
474 our study website (www.heal-d.co.uk).

475 **DISCUSSION**

476 This paper presents the protocol for the design and feasibility testing of HEAL-D, a culturally-
477 tailored T2D self-management programme for UK African and Caribbean communities. This
478 study will employ rigorous complex intervention methodology to develop and evaluate the
479 implementation of a culturally-tailored T2D self-management intervention. The intervention's
480 curriculum will be based on existing evidence-based guidelines for diet and lifestyle
481 management of T2D, participatory co-design methods will be employed to foster community
482 engagement and partnership. We will use a 'bottom-up' approach to identify the cultural

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3 483 adaptations of our intervention, and identify its theoretical basis through thematic analysis and
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5 484 the COM-B behavior change framework. The feasibility study will provide us with key
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8 485 information about the feasibility of running a full-scale trial of HEAL-D and process evaluation
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10 486 methods will enable us to understand how and why the intervention is effective or ineffective.
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13 487 To date there have been no tailored education programmes for Black-British communities.
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15 488 Indeed it is not known to what extent culturally-tailored care is needed for Black-British
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17 489 communities as little work has been undertaken with these communities. Our co-design work
18
19
20 490 is intended to explore the socio-cultural barriers and facilitators to behaviour change and
21
22 491 structure HEAL-D accordingly. We acknowledge that we are likely to find huge diversity
23
24 492 within our Black-British communities and *culture* will likely be only one of many important
25
26 493 factors that affects their health behaviours. However, our co-design work will provide a more
27
28 494 comprehensive theoretical under-pinning for the content of our programme than that which
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30 495 currently exists and will provide us with a framework upon which to evaluate the effectiveness
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32 496 of our programme. This work will provide essential information and evaluation to inform the
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34 497 design of a future definitive trial.
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3 499 **ABBREVIATIONS**
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6 500 AfC African-Caribbean
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9 501 COM-B Capability Opportunity Motivation Behaviour
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12 502 HEAL-D Healthy Eating & Active Lifestyles for Diabetes
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15 503 MRC Medical Research Council
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18 504 NHS National Health Service
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21 505 T2D Type 2 diabetes
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28 507 **DECLARATIONS**
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31 508 The study protocol has been approved by the Health Research Authority (London Fulham
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33 509 Research Ethics Committee; 17/LO/1954); all participants will provide written consent prior
34
35 510 to participation.
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39 511 **CONSENT FOR PUBLICATION**
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42 512 Not applicable.
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45 513 **AVAILABILITY OF DATA AND MATERIALS**
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47

48 514 Not applicable.
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50

51 515 **COMPETING INTERESTS**
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53

54 516 The authors declare that they have no competing interests.
55
56
57

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6
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8 520 expressed in this publication are those of the author(s) and not necessarily those of the NHS,
9
10 521 the National Institute for Health Research or the Department of Health.
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13 522 **AUTHOR CONTRIBUTIONS**

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16 523 All authors have made substantial contributions to this study. LMG, CR and SH were
17
18 524 responsible for the conception and design of the study. LMG, CR, SH and AM developed the
19
20 525 protocol and study approach. LMG drafted the manuscript. All authors read, revised and
21
22 526 approved the final manuscript. LMG is guarantor.
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26 527 **ACKNOWLEDGEMENTS**

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3 531 **FIGURE LEGENDS**
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6 532 **Figure 1.** Medical Research Council's framework for the development and evaluation of
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8 533 complex interventions. Reproduced from Craig P. *et al.* British Medical Journal. 2008;
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10 534 337:a1655.

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13 535 **Figure 2.** Schematic diagram of Phase I: Development of HEAL-D using evidence synthesis
14
15 536 and co-design methodology to design a culturally-tailored self-management programme for
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17 537 T2D in African and Caribbean communities

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21 538 **Figure 3.** The Capability-Opportunity-Motivation (COM-B) Framework and Behaviour
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23 539 Change Wheel; a framework for developing behavioural interventions. Reproduced from
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25 540 Michie S., van Stralen M.M. and West R. Implementation Science. 2011; 6:42.

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29 541 **Figure 4.** Applying the COM-B behaviour change framework to the development of the
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31 542 HEAL-D intervention; identifying theory of change.
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Table 1. Topic guides for patient focus groups and stakeholder interviews**Patient focus groups**

- Knowledge and perceptions of diabetes, and diet and lifestyle advice for managing diabetes.
- Current practices relating to diabetes self-care, and diet and lifestyle.
- Health concerns/priorities in relation to diabetes.
- Motivations and barriers/difficulties relating to diabetes self-care, weight management and diet and lifestyle.
- Experiences and perceptions of diabetes care/education, and barriers to accessing care.
- Experiences of behaviour change in relation to diabetes, weight, diet and lifestyle – successes and failures.
- Role of family/friends/communities in influencing and shaping knowledge and behaviours in relation to diabetes, diet and lifestyle.

Community leader interviews (including religious leaders)

- Health problems affecting the community and diabetes impact on health within this context.
- Attitude of the community towards health, medicines, doctors.
- Role of community leaders in promoting health and community activities.
- Diabetes health promotion activities within the community. What worked and what didn't.
- Barriers and facilitators to positive diabetes behaviours within the community.
- Advice about engaging the community: Who are the role models; What will engage and help people; How can healthcare & community work together.

Healthcare professional interviews

- Experience of supporting African & Caribbean patients. What are the issues. How could things be improved. What factors make successful T2D management likely.
- Patient beliefs and motivations.
- Involvement in community activities and experience of working with community leaders and lay educators and suggestions to improve partnerships.
- Difficulties & challenges with offering a tailored lifestyle intervention.

Table 2. Mapping of the HEAL-D feasibility study research questions, process evaluation data sources and evaluation methods

PROCESS EVALUATION DOMAIN & RESEARCH QUESTIONS	DATA SOURCES										EVALUATION METHOD
	Patient questionnaires	Session observations	Session record of activities	Patient evaluation forms	Educator interviews	Patient interviews	Patient focus groups	Attendance records	HCP interviews	Commissioner interviews	
TESTING INTERVENTION THEORY & MECHANISMS OF CHANGE											
Are the intervention's mechanisms of change operationalised as hypothesised?	X	X	X	X	X	X	X				Qualitative data collected through interviews/focus groups with patients and educators, and session observation notes will be used to evaluate how the theory of the intervention operationalises and interacts with contextual factors.
How is the operationalisation of the mechanisms of change influenced by contextual factors?		X	X		X	X	X				
Does the interaction of the mechanisms of change with contextual factors give rise to unintended effects?		X	X		X	X	X				
ASSESSING USUAL PRACTICE & CONTAMINATION											
Is HEAL-D differentiable from 'usual practice'?						X					Interviews will be conducted with patients from both arms. Experiences of the intervention and control will be explored. With control patients issues of contamination and perceptions of 'usual care' will be discussed.
Is there contamination in control patients?							X				
ASSESSING IMPLEMENTATION											
What is the intervention reach and dose?	X							X			Questionnaire data will assess who receives the intervention and how representative they are e.g. age, gender, ethnicity, working status. Attendance records will be used to quantify the proportion of patients receiving the full vs part intervention.

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2									
3	Are the HEAL-D components/sessions delivered with fidelity and what is the nature of any adaptations?	X	X	X					
4	Does the delivery of HEAL-D differ between sites, and what gives rise to differences?	X	X	X					
5	How well are the HEAL-D components/sessions delivered?								
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13		X	X						
14									
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18									
19	ASSESSING INTERVENTION ACCEPTABILITY								
20	Is HEAL-D acceptable to patients, commissioners and healthcare professionals?								
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22									
23									
24									
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26									
27		X	X	X	X	X	X		
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34	ASSESSING INTERVENTION SUSTAINABILITY								
35	How likely is the HEAL-D intervention to be sustainable and what factors might ensure sustainability?								
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priorities, and the feasibility of sustained resource allocation to the HEAL-D intervention if found to be successful.

HCP, Healthcare professionals

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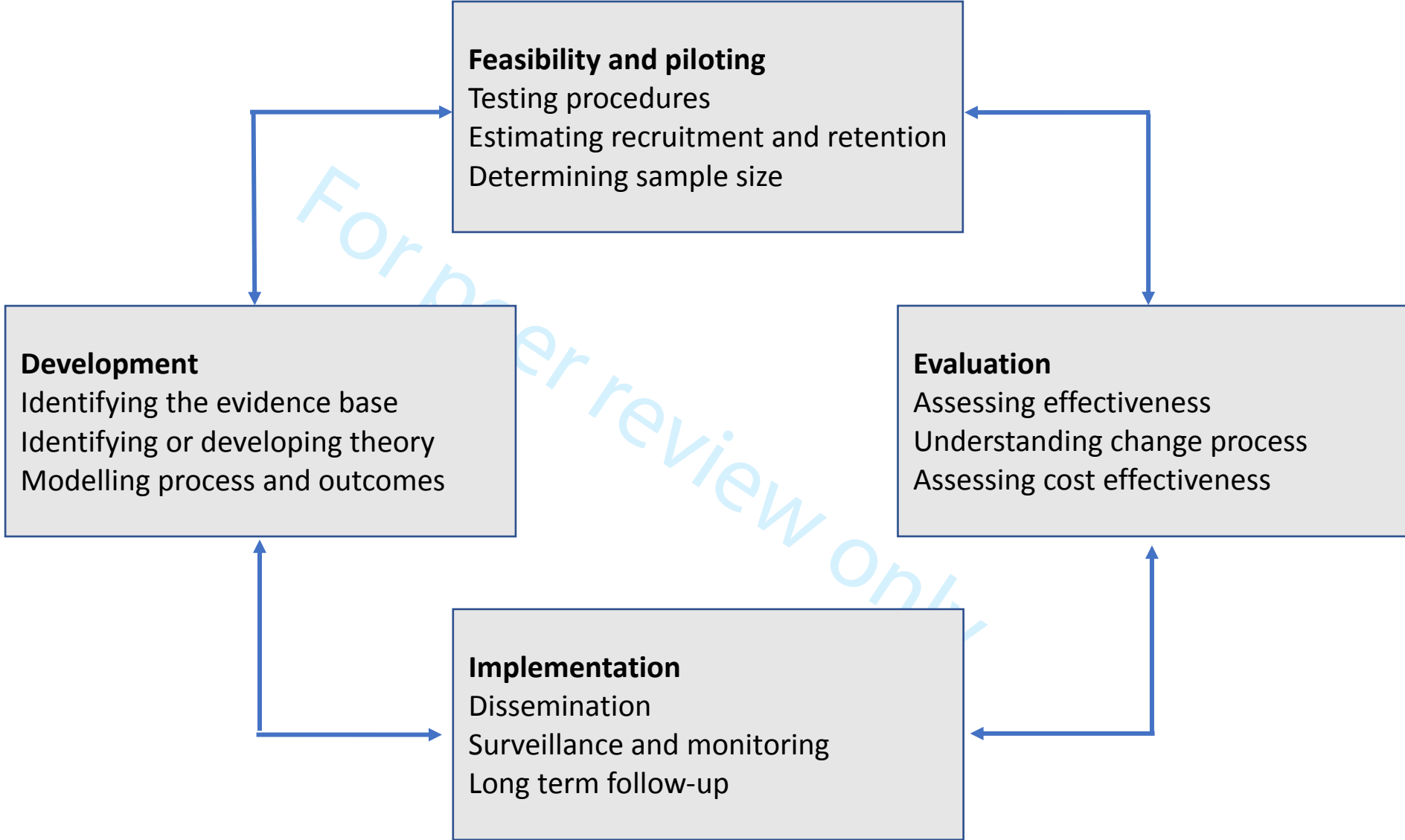
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DEVELOPMENT OF HEAL-D, A CULTURALLY-TAILORED T2D SELF-MANAGEMENT PROGRAMME FOR AFRICAN & CARIBBEAN COMMUNITIES

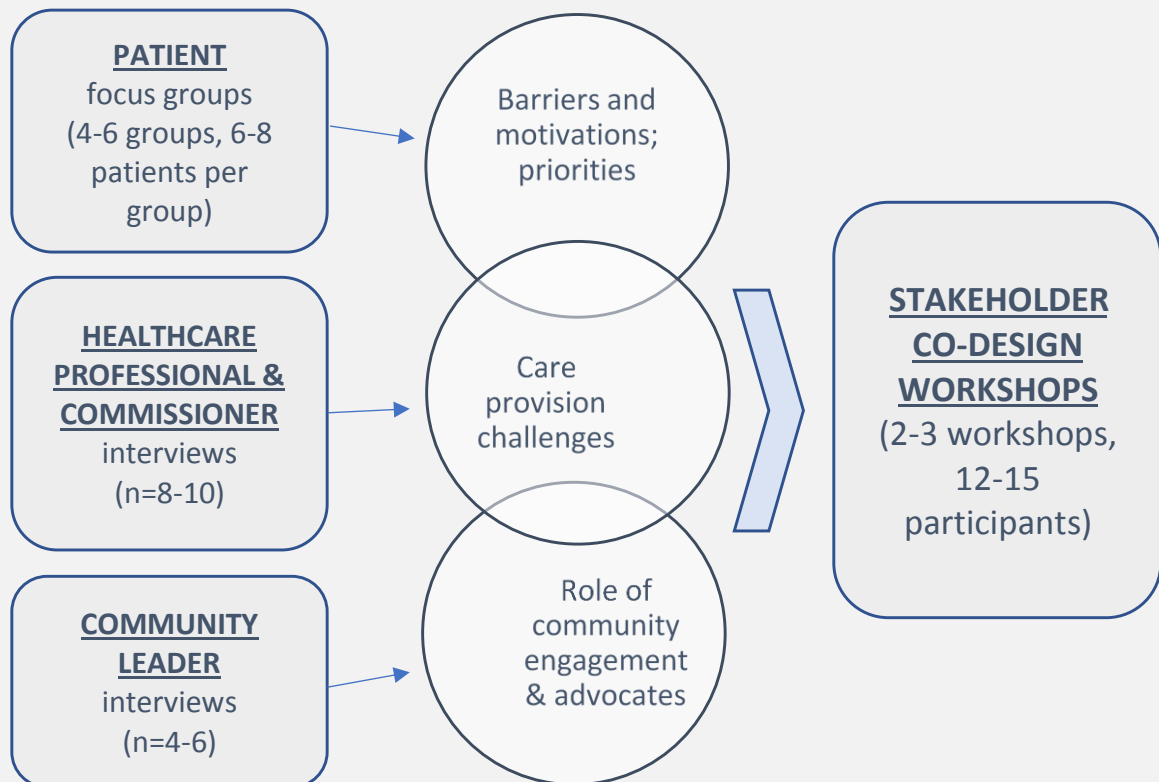
1. INCORPORATE EXISTING RECOMMENDATIONS INTO DRAFT STRUCTURE & ALIGN WITH CLINICAL GUIDELINES



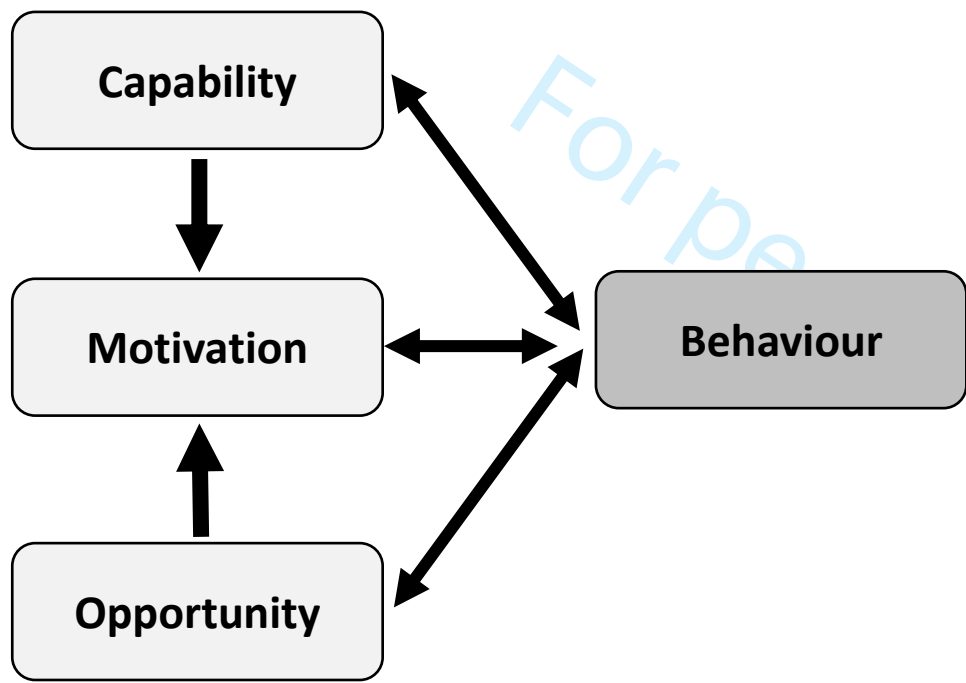
2. DRAW ON THE EXISTING EVIDENCE BASE FOR ADAPTING HEALTH PROMOTION INTERVENTIONS FOR ETHNIC MINORITY GROUPS



3. IDENTIFY THE INTERVENTION'S THEORETICAL BASIS & CULTURAL ADAPTATIONS THROUGH CO-DESIGN METHODS



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COM-B analysis of the behaviour goal: performing 30 minutes moderate intensity physical activity per day

CAPABILITY

Knowledge: Does the target group know:

- Why moderate intensity physical activity would help diabetes management?
- What moderate intensity is and how to measure it?

Behavioural regulation: Does the target group know how to:

- Plan to fit the activity in to their daily life?
- Remember to do the activity?
- Prioritise this activity over others?
- Record & measure and self-monitor their activity?

Physical skills: Does the target group:
Have the physical stamina to be active at this intensity?

OPPORTUNITY

Environmental context & resources:

- Is it safe to exercise in the neighbourhood?
- Do patients have suitable footwear?
- Can they afford a pedometer or some means of measuring their activity?

Social influences (what interpersonal influences cause individuals to change their thoughts, feelings or behaviours?)

- It is culturally acceptable to exercise?
- What is the social norm among immediate friends and family?
- What positive or negative views do others have that may influence activity?
- Are there any positive role models?
- Are there competing demands e.g. pressure to spend leisure time with family or at church?

Would group support be motivating?

MOTIVATION

Reflective (conscious) motivation:

- How optimistic do the patients feel they can achieve the goal?
- Do they intend to do the behaviour (stages of change model)?
- What emotions may help or hinder? e.g. fear of injury.
- What other emotions may conflict? e.g. tiredness, depression, stress.

Automatic (innate drivers):

- What are established habit patterns?
- What are routines/thought/behaviours set up by previous experience