PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A mixed methods implementation study of a virtual culturally tailored diabetes self-management programme for African and Caribbean communities (HEAL-D) in south London and its scaling up across NHS regions in England: study protocol
AUTHORS	Lowry, Sophie; Goff, Louise; Irwin, Sally; Brady, Oliver; Curran, Natasha; Lelliott, Zoe; Sevdalis, Nick; Walker, Andrew

VERSION 1 – REVIEW

REVIEWER	Freya MacMillan Western Sydney University
REVIEW RETURNED	21-Sep-2022

GENERAL COMMENTS	This is a well written manuscript that describes the protocol for an implementation science study of a diabetes self-management program for African and Caribbean people in England. The methodology has been detailed sufficiently in the text and associated tables, to make it clear for replication of a similar evaluation of a similar intervention. I only have minor suggestions that are mostly focused on the writing of this manuscript: Abstract - Write NIHR out in full before the abbreviation in the opening paragraph - Pg 2, line 41, insert 'in' before South London - Pg 2, line 44, 'inequities' rather than inequalities would be more appropriate here (it is an inequity issue as ethnic minority groups are not starting in the same place health wise – their health is worse to begin with because they have lower health access than other groups). - Pg 2 line 47: co-developed with whom? Community? Main manuscript: - Pg 4 line 91: insert 'the' before NHS Reset…. - Pg 5 line 122: Inequities - Page 13 line 46: purposive sampling will be used. What will this purposive sampling consider? What characteristics or considerations will be used to guide this sampling strategy? - Page 14, first paragraph. How many adult members of the African and Caribbean communities will be recruited for this element of the evaluation? - Page 14, line 44: inequities - Page 15, line 35: this sentence is missing 'delivered as' before the word 'intended' - Page 16, line 3: the comma should be after 'checklist'

REVIEWER	Alok Kumar Indiab Foundation/MK Diabetes Clinic
REVIEW RETURNED	22-Sep-2022

GENERAL COMMENTS	With reference to submitted protocol titled "A mixed methods implementation study of a virtual culturally tailored diabetes self-management programme for African and Caribbean communities (HEAL-D) in south London and its scaling up across NHS regions in England: study protocol" submitted by Lowry eta al., I have following comments and suggestions: 1-Methods and Analysis Data collection methods and sources on page 14 - 16 Authors should justify the sample size chosen to study various groups i.e n=20 (One-to-one semi-structured interviews with HEAL-D for online service users); n= 10 (One-to-one semi-structured interviews for service delivery staff) Scaling-up of HEAL-D online n=6 (One-to-one semi-structured interviews) and focus groups (n=16, 2 focus groups of 8 people each) with members of the public from African and Caribbean and n=15 (semi-structured interviews with commissioners) Are these arbitrary numbers or based on any other evidence. Will all participants in current study be those who had earlier participated in face-to-face evaluation? Please clarify in the protocol 2-Also, how would authors assess benefit/outcome of a particular method? Authors should clearly describe the "benefit" variables that they intend to investigate to consider a particular method as beneficial.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

Comment	**Response**	**Location (on unmarked copy)**
Abstract: Write NIHR out in full before the abbreviation in the opening paragraph	Corrected	Page 2, lines 40-41
Abstract: Pg 2, line 41, insert 'in' before South London	Corrected	Page 2, line 41
Abstract: Pg 2, line 44, 'inequities' rather than inequalities would be more appropriate here (it is an inequity issue as ethnic minority groups are not starting in the same place health wise – their health is worse to begin with because they have lower health access than other groups).	Thank you for this comment, we agree that this is a more appropriate term and have corrected this.	Page 2, line 45
Abstract: Pg 2 line 47: co-developed with whom? Community?	HEAL-D was co-designed with a variety of people in south London who have lived experience of Type 2 Diabetes, and more detail about this process is available in	Page 2, line 48

	previous literature[1]. To make this clearer, without adding too much detail within the abstract we have added the text 'with people with lived experience'. We hope this helps to clarify the co-development process.	
Main manuscript: Pg 4 line 91: insert 'the' before NHS Reset….	Corrected	Page 4, line 92
Main manuscript: Pg 5 line 122: Inequities	Corrected	Page 5, line 123
Main manuscript: Page 13 line 46: purposive sampling will be used. What will this purposive sampling consider? What characteristics or considerations will be used to guide this sampling strategy?	Thank you for highlighting this omission, we have added details around the sampling characteristics which will be used to guide this strategy.	Page 14, lines 240-242
Main manuscript: Page 14, first paragraph. How many adult members of the African and Caribbean communities will be recruited for this element of the evaluation?	We had included this information at a later point in the paper but have now added this information into this section for further clarity.	Page 14, line 247
Main manuscript: Page 14, line 44: inequities	Corrected	Page 15, line 266
Main manuscript: Page 15, line 35: this sentence is missing 'delivered as' before the word 'intended'	Corrected	Page 16, line 287
Main manuscript: Page 16, line 3: the comma should be after 'checklist'	Corrected	Page 16, line 300

Reviewer 2

Comment	**Response**	**Location (on unmarked copy)**
Methods and Analysis: Data collection methods and sources on page 14 - 16 Authors should justify the sample size chosen to study various groups i.e n=20 (One-to-one semi-structured interviews with HEAL-D for online service users); n= 10 (One-to-one semi-structured interviews for service delivery staff) Scaling-up of HEAL-D online n=6 (One-to-one semi-structured interviews) and focus groups (n=16, 2 focus groups of 8 people each) with	Thank you for your comment. All sample sizes have been chosen based on feasibility considering the total sample available and the principle of saturation that we expect to observe in what participants will report. For the latter, we have used established guidance that suggests that early themes may appear in interview analysis of approx. 6 individuals, and stabilise within 12 interviews[2] taken together, our sampling framework establishes these recommended numbers	Page 13, lines 215-222

members of the public from African and Caribbean and n=15 (semi-structured interviews with commissioners). Are these arbitrary numbers or based on any other evidence.	within a feasible timescale and resource available to carry out the evaluation. We have also added details on how if the initial target size is not sufficient to reach saturation, then the sample size will be increased.	
Will all participants in current study be those who had earlier participated in face-to-face evaluation? Please clarify in the protocol	A majority of participants in this study will not be the same as those who have participated in the earlier face-to-face evaluation. We have added in details around this, confirming where participants who had experienced the face-to-face intervention will be contributing.	Page 13, lines 213-214 Page 14, lines 237-238
Also, how would authors assess benefit/outcome of a particular method? Authors should clearly describe the “benefit” variables that they intend to investigate to consider a particular method as beneficial.	Thank you for this comment, unfortunately we are slightly unclear about the scope of this query. We understand it to mean a comparison between face to face and virtual delivery of HEAL- and would like to clarify that this is not the variable of interest for this study and that a direct comparison of delivery methodology is beyond the scope of the current descriptive project where the aims are to explore the: 1. feasibility and acceptability of a virtual delivery model for HEAL-D in south London and 2. factors affecting its scale-up across other areas in England. The scope of this study is to explore the virtual delivery of an evidenced intervention, in the form of HEAL-D, which was originally designed to be delivered face-to-face. Therefore, this study is an exploration of implementation aspects as opposed to a direct comparison of different delivery formats. As part of our study, we will draw some indirect comparisons and comment on the current evidence of HEAL-D as delivered face-to-face (based on the original research which supports the intervention). And we will articulate the need for a direct formal comparison of delivery methodology (face to face vs. virtual) in a subsequent large, and adequately powered, study which will ideally include clinical, implementation and cost effectiveness elements.	N/A

	We hope this explanation addresses your comment.	