Healthy Eating & Active Lifestyles for Diabetes: proposal for a randomised controlled trial evaluation of clinical and cost effectiveness

BACKGROUND. Healthy Eating & Active Lifestyles for Diabetes ('HEAL-D') is a diabetes self-management education and support (DSMES) programme, culturally tailored for black-British adults with type 2 diabetes (T2D). HEAL-D was developed through a co-design project in which black-British adults living with T2D, healthcare practitioners and community leaders were engaged in designing and developing the content, format and structure of the intervention [1].

HEAL-D consists of 14 hours of group-based culturally-tailored education, behaviour change support, and participatory physical activity. Seven sessions, each of 2 hours, are delivered by a trained diabetes specialist registered dietitian and a trained lay educator. Sessions are delivered during either working hours, evening or weekend and a 'flexible attendance schedule' allows for switching between programmes where needed/desired e.g. missed sessions. Sessions are delivered on either a weekly or fortnightly schedule. The sessions focus on evidence-based diet and lifestyle goals; the curriculum is delivered using a range of behaviour change techniques, the selection of which was informed by the co-design study [2]. Culturally-tailored materials, including information booklets, games and videos are used in the delivery [1]. HEAL-D was originally evaluated as a face-to-face programme, delivered in community settings. In response to the COVID pandemic, it has been adapted for remote delivery using video conferencing and evaluated in a small pilot.

HEAL-D has been evaluated in a feasibility RCT, funded by a NIHR Advanced Fellowship. The feasibility trial aimed to evaluate acceptability, fidelity and trial feasibility of the HEAL-D intervention. Participants were recruited from primary and intermediate care and assigned to control (usual care) or intervention (HEAL-D), in a ratio of 1:1. Primary outcomes were rates of recruitment and retention, intervention attendance and completion. Intervention fidelity was assessed through observations and qualitative evaluation of the intervention was undertaken with participants and educators. Sixty-three black-British adults with T2D consented and were randomised (8 were withdrawn after randomisation due to high baseline HbA1c values requiring intensive medical management). Of the remaining 55 participants (27 intervention, 28 control), 69% were female, 47% were of African and 51% were of Caribbean ethnicity. Baseline HbA1c of the participants was 60.6 (SD 11.4) and 59.1 (SD 11.2) mmol/mol in the intervention and control groups, respectively. The adjusted mean difference between intervention and control at endpoint was -2.8 (95% CI -9.5, 3.9) mmol/mol. 93% of participants completed the trial, providing endpoint data. Intervention attendance was high; 85% of participants completed the programme, which was considered as attendance at 5 or more sessions, and 74% attended 6 or more sessions. Overall, the educator interview and patient focus group data showed that HEAL-D was acceptable and successfully implemented. It was clear from numerous statements that participants had taken the advice and information on board and made real changes in their life. The intervention was delivered with acceptable fidelity, although the qualitative evaluations identified some areas of structure and format that are need of refinement.

[1] Goff LM, Moore AP, Harding S, Rivas C. Development of Healthy Eating and Active Lifestyles for Diabetes (HEAL-D), a culturally-tailored diabetes self-management education and support programme for black-British adults: a participatory research approach. Under review.

[2] Moore AP, Rivas CA, Stanton-Fay S, Harding S, Goff LM. Designing the Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) self-management and support programme for UK African and Caribbean communities: a culturally tailored, complex intervention under-pinned by behaviour change theory. BMC Public Health. 2019. Aug 20;19(1):1146.