

Healthy Living Diabetes - Long-term Independent National Evaluation (HED-LINE)

Investigators:

Sarah Cotterill (PI), Peter Bower, David French, Evangelos Kontopantelis, Rachel Elliot, Paul Wilson, Brian McMillan, Martin Rutter, Caroline Sanders, Sally Giles, Eric Lowndes.

Scientific abstract

Background

Type 2 diabetes (T2DM) has serious health implications and is costly for the NHS. Appropriate glycaemic and blood pressure control, and changes in lifestyle to reduce weight can decrease these risks. People often find it difficult to make (and maintain) changes. Structured T2DM education programmes are available but attending groups is not suitable for everyone. Healthy-Living is a web-based self-management programme offering information, behaviour-change content and support for emotional well-being. An RCT has shown it is feasible, acceptable, effective and cost-effective. Now the NHS wants to see if there are similar benefits from a roll-out across England.

Aim: Evaluate the real world implementation of Healthy-Living.

Objectives:

- 1) Examine the extent to which people with T2DM start Healthy-Living and continue to use it, and whether engagement varies by patient characteristics;
- 2) Determine the effectiveness of Healthy-Living in changing clinical outcomes;
- 3) Assess the barriers and facilitators affecting the implementation of Healthy-Living at clinical and organisational levels, the fidelity of implementation and acceptability to patients and the NHS;
- 4) Establish the cost-effectiveness of Healthy-Living compared with usual care when rolled out across England, from an NHS and personal and social services perspective.

Methods

Uptake: using data from the Healthy-Living programme linked to a primary-care dataset, the National Diabetes Audit (the Linked Data) we will use multiple logistic regression and linear regression to estimate the association between patient demographics, baseline clinical measures, T2DM-treatments, co-morbidities, referral-type and various measures of participation in the programme.

Effectiveness: Matched cohort study using two years of Linked Data (baseline and follow-up). Referred people will be matched 1:5 to non-referred using demographic and health characteristics. Multiple and logistic regression models will estimate the association between being referred and HbA1c (primary) and other clinical outcomes. Sub-group analyses will explore population characteristics that potentially benefit most/least from the intervention. A “dose-response” approach will model exposure to Healthy-Living and its association with outcomes.

Implementation: Barriers, challenges and enablers to implementation of Healthy-Living, and its integration within existing NHS T2DM management care pathways will be explored using semi-structured interviews with local NHS implementation leads and general practices, and documentary analysis.

Service Delivery and Fidelity. We will provide an estimate of what “dose” of intervention participants received, how they received it, and consider how this impacts differently on diverse populations. Methods: coding of online content for behaviour change techniques and self-management tasks, compared to plans; analysis of Linked Data to examine exposure to online content; semi-structured interviews with patients to understand engagement, enactment and acceptability.

Budget Impact Analysis. An economic evaluation informed by modelling to estimate longer-term benefits and costs. We will use an existing validated simulation model, the UKPDS OM2 model to extrapolate T2DM risk factors and predict long-term outcomes expressed as life expectancy, quality-adjusted life-years (QALYs), and NHS/PSS costs.

Impact and Dissemination

We will share early findings with the Healthy-Living team to shape future implementation and seek opportunities for wider dissemination to patients and clinicians, involving patients to ensure the most important findings are disseminated clearly.