

## Let's Prevent Diabetes: From idea to implementation

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### Abstract

The prevention of Type 2 Diabetes Mellitus (T2DM) is a global health care priority. We describe a programme of work, which developed a method for identifying those with Non Diabetic Hyperglycaemia (NDH) (a high risk group in which T2DM is preventable) in primary care and developed and tested a prevention programme suitable for delivery within the NHS. The subsequent implementation of this programme as part of the NHS Diabetes Prevention Programme, which was launched in 2016, is then described.

### Introduction

The prevention of Type 2 Diabetes Mellitus (T2DM) is a global health care priority and was highlighted as a national priority in the NHS 'Five Year Forward View' which outlined the NHS's ambition to become the first country to implement at scale an evidence-based T2DM prevention programme (1). T2DM is preceded by a high risk state called NDH, also known as prediabetes, where glucose levels are elevated but do not cross the diagnostic threshold for T2DM. In England, 5 million people are estimated to have NDH (2), a number which is expected to increase over the coming decades.

Once identified with NDH, there is robust evidence that T2DM can be prevented or delayed. Pivotal trials conducted globally have shown that lifestyle modification programmes that promote a healthy diet, weight loss, and increased physical activity could reduce the incidence of T2DM by up to 58% and are at least if not more effective than pharmacological intervention (3). These programmes were very resource intensive (for example the USA programme included 16 one-hour one-to-one counselling sessions followed by an average of eight additional contacts and two telephone consultations) (4); thus it has been challenging to replicate these findings in programmes suitable for mass delivery within settings such as the NHS (5).

### Development and validation of a risk score for identifying those at risk

NICE recommend a two-stage approach for identifying those with NDH - using a non-invasive risk score followed by a blood test in those with a high risk score (6). This method has been shown to be cost saving compared to using a blood test alone (7). Risk scores calculate an individual's risk of having or developing a condition based on their risk factors. Risk scores not only target blood testing, they also engage individuals with their risk factors and help to explain why someone is at high risk in a way a result from a blood test cannot. Initially we developed a risk score which was designed to be completed by members of the public to see if they were at risk of having undiagnosed NDH or T2DM (8). This score is calculated by assessing age, sex, ethnicity, body mass index, waist circumference, family history of diabetes and high blood pressure. This score is available at <https://riskscore.diabetes.org.uk/>.

As part of this programme we wanted to adapt this score for use in primary care. We wanted to develop and validate a score which could be calculated using data stored in primary care medical records. This score would be able to identify all those at risk of NDH within a practice who could then be invited for screening. The score was adapted in a number of ways: (1) waist circumference was removed as this is not well recorded in primary care; (2) we used a more sophisticated scoring

method as this would be calculated by a piece of software; (3) we developed software to run the score in practice and output a spreadsheet of those at risk to be used for inviting people for screening. This score was developed using data from the ADDITION-Leicester study and validated using data from the STAR study (9, 10). It was shown to have acceptable levels of discrimination and calibration (11).

### **Development of the Let's Prevent Diabetes programme**

This Let's Prevent Diabetes structured education intervention was developed to meet the need for an evidence based diabetes prevention programme which adheres NICE recommendations and that can be implemented within the NHS.

The Let's Prevent Diabetes intervention encourages self-management of NDH, using simple, non-technical language and visual aids. The Diabetes Education and Self-Management for On-going and Newly Diagnosed (DESMOND) programme which was the first national education programme for people with T2DM that met NICE criteria was used as a basis for the development of the Let's Prevent Diabetes programme. The development process was informed by the Medical Research Council (MRC) framework. An iterative cycle (including initial development, piloting, collecting and collating qualitative and quantitative data, reflection and modification of the intervention) was used to inform and refine the intervention until it was considered to be fit for purpose for evaluation (12).

The Let's Prevent Diabetes programme is a six hour structured group education session, with three hour refresher sessions at 12 and 24 months after the initial session. These group based sessions were complemented by telephone calls every three months from nursing staff, trained to offer on-going support in behaviour change and encourage participants in achieving their individual goals. The programme was underpinned by a theoretical basis with a philosophy centred on patient empowerment. The key goals within the curriculum were based on those from the international pivotal trials and included: (1) Sustained weight reduction of >5% body weight; (2) Moderate reduction in total fat intake to <30% of energy intake; (3) Low saturated fat intake to <10% of energy intake; (4) Higher fibre intake of >15 g per 1000 kcals; and (5) Increase step count (all participants are provided with a pedometer).

### **Cluster randomised trial of the Let's Prevent Diabetes programme**

This Let's Prevent Diabetes programme was evaluated in a cluster randomised trial. Forty four general practices were randomised to receive either standard care (n=21) or the Let's Prevent Diabetes programme (n=23). Within each practice the risk score was used to identify people at high risk of having NDH who were then invited for screening. Of the 17,972 identified as high risk and invited for screening, 3,449 attended (19.2%). Of those screened, 880 were found to have NDH and were included in the trial (13). Participants either attended the Let's Prevent Diabetes programme or received standard care depending on the allocation of their practice. Participants were followed up for three years and the primary outcome was progression to T2DM (14).

Over the three years, 131 participants developed T2DM (15). There was a 26% reduced risk of developing T2DM in the intervention arm compared to standard care, but this did not reach statistical significance (HR 0.74, 95% CI 0.48, 1.14, p=0.18). The reduction was larger in a per protocol analysis which excluded those from the intervention arm who did not attend the education (HR 0.65 [95% CI 0.41, 1.03]). There were statistically significant improvements in HbA1c, LDL cholesterol, psychosocial wellbeing, sedentary time and step count in the intervention group compared to the standard care.

The intervention was found to result in a net gain of 0.046 QALYs over three years at an overall cost of £168 per patient, with an incremental cost effectiveness ratio of £3,643 and a probability of 86% of being cost-effective at a willingness to pay threshold of £20,000 (16).

### **Engagement and retention**

Twenty two percent of participants in the intervention arm did not attend the initial six hour session and only 29% attend the initial session and the two refresher sessions. We conducted a secondary analysis of the trial data to assess if outcome was related to the amount of the intervention received (17). Participants who attended the initial session and at least one refresher session were 62% less likely to develop T2DM compared to those in the standard care arm (HR 0.38 [95% CI 0.24, 0.62]). This was increased an 88% reduction in participants who attended all sessions (HR 0.12 [95% CI 0.05, 0.28]).

### **NHS Diabetes Prevention Programme**

In 2015 the NHS outlined its intention to be the first country to deliver a national evidence-based diabetes prevention programme. The specification for the NHS programme was based on an evidence review of real-world prevention programmes conducted globally which had aimed to translate the findings of the pivotal trials into a routine health care setting (18). This review found that better outcomes were associated with programmes which adhered to NICE guidelines, were delivered over 9-18 months with over 13 sessions, covered both diet and physical activity, used social support, had supervised physical activity, recommended a calorie restricted diet and included 10-15 participants.

In 2016, the NHS commissioned four providers to deliver a National Diabetes Programme. One of the providers (Ingeus UK Ltd) worked in collaboration with the Let's Prevent Diabetes team to adapt the programme to meet the NHS specifications (based on the results of the systematic review). This adapted programme (called Healthier You) will run across 13 shorter sessions over a nine-month period. To date (Dec 2016), the adapted Let's Prevent Diabetes programme is being delivered in Leeds, Leicestershire and South East England (19). Public Health England and NHS England have commissioned evaluations of this initial roll-out. The NIHR have commissioned a larger scale national evaluation.

### **Conclusions**

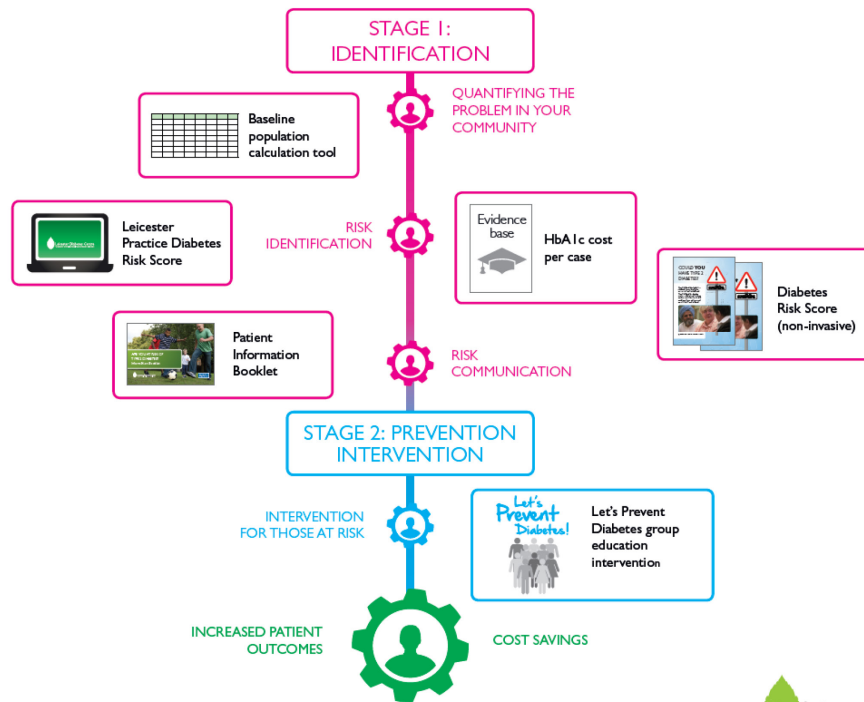
We have developed a prevention pathway for T2DM which includes a risk score for use in primary care which can be used as part of a two-stage screening programme to identify those with NDH (See Figure 1). This score is freely available for health care practitioners to use across the UK. Once identified at risk, we have developed a pragmatic cost-effective diabetes prevention programme which leads to improvements in metabolic health, psychological wellbeing and health behaviour over three years, with significant reductions in the progression to T2DM in those who attend the entire programme. An adapted version of this programme is now being delivered nationally by one of the four providers of the NHS Diabetes Prevention Programme.

**Figure 1. Leicester Diabetes Prevention Pathway**

Additional information on each of the aspects is available at

<http://leicesterdiabetescentre.org.uk/Leicester-Diabetes-Centre-Prevention-Pathway>

## Leicester Diabetes Centre Prevention Pathway



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