Screening for glucose intolerance and development of a lifestyle education programme for prevention of type 2 diabetes in a population with intellectual disabilities: the STOP Diabetes research project

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Declared competing interests of authors: Mike Gillett has undertaken consultancy work for NHS England and Public Health England (PHE), for the National Diabetes Prevention Programme. Thomas Yates has been a member of National Institute for Health and Care Excellence (NICE) public health guidance on preventing type 2 diabetes. Sabyasachi Bhaumik has been a member of the Health Services and Delivery Research (researcher-led) panel for the last 3 years and before that he was a member of the Community and Psychological Therapies panel of the National Institute for Health Research (NIHR) for 3 years. He is the chairperson of the Diaspora Committee of the Royal College of Psychiatrists and was the chairperson of the Faculty of Psychiatry of Learning Disability for 4 years. He is also a co-editor of the only prescribing guidelines in intellectual disability nationally, and the third edition of this book, *The Frith Prescribing Guidelines for People with Intellectual Disability*, was published in 2015 by Wiley. Chloe Thomas has undertaken consultancy work for NHS England and PHE, for the National Diabetes Prevention Programme. Susannah Sadler has undertaken consultancy work for NHS England and PHE, for the National Diabetes Prevention Programme. Sally-Ann Cooper has received grants from NIHR during the conduct of the study, and grants from NIHR and from the Scottish Government outside the submitted work. Melanie Davies is a member of NICE public health guidance on preventing type 2 diabetes and an advisor to the UK Department of Health for the NHS Health Check Programme. She has acted as a consultant, an advisory board member and a speaker for Novo Nordisk, Sanofi Aventis, Eli Lilly and Company, Merck Sharp & Dohme Corp., Boehringer Ingelheim, AstraZeneca and Janssen Pharmaceutica, and as a speaker for Mitsubishi Tanabe Pharma Corp. She has received grants in support of investigator and investigator-initiated trials from Novo Nordisk, Sanofi Aventis and Eli Lilly and Company. She received grants and support from NIHR during the conduct of this study. Kamlesh Khunti (chairperson) is a member of the NICE public health guidance on preventing type 2 diabetes and an advisor to the UK Department of Health for the NHS Health Check Programme. He has acted as a consultant, served on advisory boards and been a speaker for Novartis, Novo Nordisk, Sanofi Aventis, Eli Lilly and Company, Janssen Pharmaceutica, Boehringer Ingelheim and Merck Sharp & Dohme. He has received grants in support of investigator and investigator-initiated trials from Novartis, Novo Nordisk, Sanofi Aventis, Eli Lilly and Company, Roche, Boehringer Ingelheim and Merck Sharp & Dohme. He also received grants and support from NIHR during the conduct of this study.

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Scientific summary

The STOP Diabetes research project

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Scientific summary

Background

Type 2 diabetes mellitus (T2DM) is a serious chronic condition that is associated with an increased risk of cardiovascular disease (CVD) and affects approximately 6% of the UK adult population. Impaired glucose regulation (IGR), whereby blood glucose level is elevated above the normal range, is a precursor to T2DM and affects approximately 12% of the UK adult population. T2DM can be prevented through changes to lifestyle, and lifestyle education interventions have been shown to be cost-effective in delaying or preventing the transition to T2DM in people with IGR in the general population.

Intellectual disability (ID), also known as learning disability, is a lifelong condition with onset before adulthood, characterised by a reduced ability to understand new or complex information and to learn new skills, and a reduced ability to cope independently. The prevalence of T2DM is believed to be higher among people with ID owing to the increased prevalence of a number of risk factors, including obesity and lack of exercise. However, there has been very little research in this area, and the evidence base for detection and prevention of T2DM has not yet been applied in a population with ID.

The focus of this research programme was to conduct a diabetes screening programme among people with ID and to develop a lifestyle multicomponent education programme for the prevention of T2DM and CVD, suitable for use in this population.

Objectives

The objectives of the programme were to:

- establish a programme of research that significantly enhances the knowledge and understanding of IGR and T2DM in people with ID
- test strategies for the early identification of IGR and T2DM in people with ID
- develop a lifestyle education programme and educator training protocol to promote behaviour change in a population with ID and IGR [or high risk of T2DM/CVD based on elevated body mass index (BMI) score].

To achieve these objectives, three distinct work packages (WPs) were developed:

1. WP1 – development and assessment of the feasibility of a structured screening programme to determine the prevalence and demographic risk factors for T2DM and IGR in people with ID. This WP also included the validation of the Leicester Self-Assessment diabetes risk score in people with ID, a cost-effectiveness analysis and the establishment of data linkage mechanisms.
2. WP2 – development of a lifestyle education programme for people with ID and IGR (or at high risk of T2DM/CVD based on elevated BMI).
3. WP3 – development of an intervention fidelity process for the assessment of the educators delivering the intervention.

Service user involvement

Service users were integral to the research programme. People with ID helped to promote the programme, develop study documentation and research processes, recruit and train staff, test procedures and disseminate the findings.

Methods

Work package 1: screening programme

We recruited adults with ID from community settings, including residential homes and family homes. Potential participants were approached through general practices, specialist ID services (using the Leicestershire Learning Disability Register) and specialist ID clinics, and through direct contact with the research team. We collected information on demographics, medical and family history, depression, behaviour problems, lifestyle factors and activity levels. We also collected biomedical measures (plasma glucose, glycated haemoglobin, lipids, urea and electrolytes, liver function tests, thyroid function and albumin), anthropometric measures (height, weight, BMI, and waist and hip circumference) and blood pressure (BP).

Work package 1: physical activity substudy

Adults who consented to take part in the screening programme and who were able to walk unassisted were asked if they would be willing to wear the ActiGraph (Pensacola, FL, USA) waist-worn accelerometer or the GENEActiv (Activinsights Ltd, Cambridge, UK) wrist-worn accelerometer to assess physical activity and sedentary behaviour.

Work package 1: validation of the Leicester Self-Assessment risk score

The Leicester Self-Assessment risk score for detecting those at risk of undiagnosed IGR/T2DM was validated using the data from the screening programme. The sensitivity, specificity, positive predictive value and negative predictive value were calculated with 95% confidence intervals (CIs) for a cut-off point of $\geq$ 16 points.

Work package 1: cost-effectiveness study

Economic work was undertaken to estimate the cost-effectiveness of the STOP Diabetes lifestyle education programme (see *Work package 2: lifestyle education programme*), compared with current routine care, in reducing cardiometabolic comorbidities among individuals with ID.

Work package 2: lifestyle education programme

Adults with mild to moderate ID with a BMI of $\geq$ 25 kg/m^2 and/or IGR were invited to take part in the STOP Diabetes lifestyle education programme. This involved initial intervention and curriculum development, two cycles of testing and evaluation, and a final refinement of the programme, and included interviews with adults with ID, carers and health professionals.

Feasibility was assessed by collecting primary outcomes (physical activity and sedentary behaviour) and secondary outcomes (weight, height, BMI, waist circumference, BP and dietary intake) before delivering the education programme and 3 months after delivering the programme.

Work package 3: intervention fidelity

We conducted preliminary work towards developing an intervention fidelity process and tool that was specifically tailored to people with ID.

Results

Work package 1: screening programme

In total, 930 (29% of those originally approached) took part in the screening programme. Their mean age was 43.3 years. Fifty-eight per cent were men, 80% were white and most were overweight (31%) or obese (37%). Anthropometric measures were available for at least 86% of participants. Bloods were available for 675 participants (73%) to assess the prevalence of IGR/T2DM.

Among people with ID, the overall prevalence of screen-detected (undiagnosed) T2DM was 1.3% (95% CI 0.5% to 2%) and of IGR was 5% (95% CI 4% to 7%). Abnormal glucose regulation was almost four times more common in those from non-white ethnic groups [odds ratio (OR) 3.93, 95% CI 2.10 to 7.33] and over three times more common among those with first-degree history of diabetes (OR 3.35, 95% CI 1.64 to 6.86). Similarly, increasing weight, waist circumference, BMI, diastolic BP and triglycerides and decreasing high-density lipoprotein cholesterol were all associated with an increased risk of abnormal glucose regulation.

Work package 1: physical activity substudy

Of 203 people approached, 97 (48%) agreed to wear the waist-worn accelerometer. Valid data ($\geq$ 8 hours per day for 3 days) were obtained for 55 participants (57%). Similarly, of 76 people approached, 47 (62%) agreed to wear the wrist-worn accelerometer. Valid data were obtained for 39 of these participants (83%). Thus, compliance could be improved by wearing wrist-worn accelerometers.

Work package 1: validation of the Leicester Self-Assessment risk score

Of 88% of adults with data available, 82% of people with abnormal glucose regulation were correctly identified as being at high or very high risk (sensitivity). Ninety-eight per cent of participants with low/medium risk scores were correctly identified as being at low risk.

Work package 1: cost-effectiveness

The findings from the health economic component of the analysis showed that, in its current form, the STOP Diabetes education programme that we developed in WP2 would not be cost-effective at a £20,000 cost per quality-adjusted life-year (QALY) threshold. However, there were scenarios in which the intervention may be effective if commissioners/payers were willing to fund the intervention up to a threshold of £30,000 per QALY.

Work package 2: lifestyle education programme

The interviews carried out at the initial curriculum development revealed that people with ID liked to use visual aids to help them to learn. Health professionals also highlighted the importance of allowing for the diverse ability levels of people with ID, such as different attention spans and ability levels. Important considerations included the need to use recall and repetition to support learning, ensuring familiarity and consistency, and allowing generalised behaviour change goals to allow for different levels of physical ability. For the testing cycles, we found that learning was facilitated by the group dynamic, recapping main messages, using concrete examples and walking exercises. However, conceptual exercises, abstract examples and giving too many messages did not work so well.

The preliminary findings suggest that it was both acceptable and feasible to collect outcome measures, including physical activity and sedentary behaviour, at baseline and 3 months post intervention delivery for this study. In this small sample ($n = 5$), all of the anthropometric outcome measures, 80% of BP data and 60% (three out of four individuals who agreed at baseline) of accelerometer data were available at 3 months' follow-up.

Work package 3: intervention fidelity

We completed the first step in developing a tool for assessing intervention fidelity of the education programme. The preliminary findings suggest some variance among educators. The new tool involved focusing on educators' teaching at the group's pace; avoiding abstract concepts, abbreviations and jargon; and engaging the learners without asking them to summarise key messages.

Conclusions

This programme of work has significantly enhanced the existing knowledge and understanding of T2DM and IGR in people with ID. It has also allowed us to test strategies for the early identification of IGR and T2DM in this population. Further work is needed to evaluate the intervention that we have developed and to identify cost-effective strategies for its implementation.

Trial registration

This trial is registered as NCT02513277.

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This report

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