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

Alison J Dunkley,¹ Freya Tyrer,² Rebecca Spong,¹ Laura J Gray,² Mike Gillett,³ Yvonne Doherty,⁴ Lorraine Martin-Stacey,⁴ Naina Patel,¹ Thomas Yates,¹ Sabyasachi Bhaumik,⁵ Thomas Chalk,¹ Yogini Chudasama,¹ Chloe Thomas,³ Susannah Sadler,³ Sally-Ann Cooper,⁶ Satheesh K Gangadharan,⁵ Melanie J Davies¹ and Kamlesh Khunti¹* on behalf of the STOP Diabetes Team

¹Diabetes Research Centre, University of Leicester, Leicester, UK
²Department of Health Sciences, University of Leicester, Leicester, UK
³School of Health & Related Research, University of Sheffield, Sheffield, UK
⁴Leicester Diabetes Centre, University Hospitals of Leicester, Leicester, UK
⁵Learning Disabilities Service, Leicestershire Partnership NHS Trust, Leicester, UK
⁶Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

*Corresponding author kk22@le.ac.uk
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.

Published May 2017
DOI: 10.3310/pgfar05110

Scientific summary

The STOP Diabetes research project
Programme Grants for Applied Research 2017; Vol. 5: No. 11
DOI: 10.3310/pgfar05110

NIHR Journals Library www.journalslibrary.nihr.ac.uk
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 ≥ 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 ≥ 25 kg/m² 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 (≥ 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, recappping 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.

Funding
Funding for this study was provided by the Programme Grants for Applied Research programme of the National Institute for Health Research.
Programme Grants for Applied Research

ISSN 2050-4322 (Print)
ISSN 2050-4330 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full PGfAR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/pgfar. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the Programme Grants for Applied Research journal

Reports are published in Programme Grants for Applied Research (PGfAR) if (1) they have resulted from work for the PGfAR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Programme Grants for Applied Research programme

The Programme Grants for Applied Research (PGfAR) programme, part of the National Institute for Health Research (NIHR), was set up in 2006 to produce independent research findings that will have practical application for the benefit of patients and the NHS in the relatively near future. The Programme is managed by the NIHR Central Commissioning Facility (CCF) with strategic input from the Programme Director.

The programme is a national response mode funding scheme that aims to provide evidence to improve health outcomes in England through promotion of health, prevention of ill health, and optimal disease management (including safety and quality), with particular emphasis on conditions causing significant disease burden.

For more information about the PGfAR programme please visit the website: http://www.nihr.ac.uk/funding/programme-grants-for-applied-research.htm

This report

The research reported in this issue of the journal was funded by PGfAR as project number RP-PG-1209-10057. The contractual start date was in January 2012. The final report began editorial review in January 2016 and was accepted for publication in September 2016. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, NETSCC, PGfAR or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PGfAR programme or the Department of Health.

© Queen’s Printer and Controller of HMSO 2017. This work was produced by Dunkley et al. under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).
Programme Grants for Applied Research Editor-in-Chief

Professor Paul Little  Professor of Primary Care Research, University of Southampton, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley  Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein  Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May  Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key  Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck  Chair in Public Sector Management and Subject Leader (Management Group), Queen’s University Management School, Queen’s University Belfast, UK

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin  Senior Scientific Advisor, Wessex Institute, UK

Ms Tara Lamont  Scientific Advisor, NETSCC, UK

Dr Catriona McDaid  Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire  Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads  Professor of Health Sciences Research, Health and Wellbeing Research Group, University of Winchester, UK

Professor John Norrie  Chair in Medical Statistics, University of Edinburgh, UK

Professor John Powell  Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery  Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma  Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts  Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Jonathan Ross  Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks  Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton  Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood  Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk