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A community based primary prevention programme for type 2 diabetes integrating identification and lifestyle intervention for prevention: the Let's Prevent Diabetes cluster randomised controlled trial☆

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ABSTRACT

Objectives. Prevention of type 2 diabetes (T2DM) is a priority in healthcare, but there is a lack of evidence investigating how to effectively translate prevention research into a UK primary care setting. We assessed whether a structured education programme targeting lifestyle and behaviour change was effective at preventing progression to T2DM in people with pre-diabetes.

Materials and methods. Forty-four general practices were randomised to receive either standard care or a 6 hour group structured education programme with an annual refresher course, and regular phone contact. Participants were followed up for 3 years. The primary outcome was progression to T2DM.

Results. Eight hundred and eighty participants were included (36% female, mean age 64 years, 16% ethnic minority group); 131 participants developed T2DM. There was a non-significant 26% reduced risk of developing T2DM in the intervention arm compared to standard care (HR 0.74, 95% CI 0.48, 1.14, $p = 0.18$). The reduction in T2DM risk when excluding those who did not attend the initial education session was also non-significant (HR 0.65, 0.41, 1.03, $p = 0.07$). There were statistically significant improvements in HbA1c (−0.06, −0.11, −0.01), LDL cholesterol (−0.08, −0.15, −0.01), sedentary time (−26.29, −45.26, −7.32) and step count (498.15, 162.10, 834.20) when data were analysed across all time points.

Conclusions. This study suggests that a relatively low resource, pragmatic diabetes prevention programme resulted in modest benefits to biomedical, lifestyle and psychosocial outcomes, however the reduction to the risk of T2DM did not reach significance. The findings have important implications for future research and primary care.

Introduction

Type 2 diabetes mellitus (T2DM) is associated with reduced quality of life and serious complications. The life expectancy of individuals with T2DM may be shortened by as much as 10 years, with most dying of cardiovascular diseases (CVD) (Roper et al., 2001). The management of T2DM consumes around 10% of health care expenditure (Hex et al., 2012). Consequently, the prevention of T2DM is a priority and has been highlighted by the NHS, UK, as one of four priority areas (NHS, 2014).

Pre-diabetes (PDM) is a high-risk state where glucose levels are elevated but do not reach the threshold for diagnosis of T2DM. Trials have unequivocally demonstrated that lifestyle interventions, which promote moderate to vigorous-intensity physical activity, a healthy diet and weight regulation, reduce the risk of progressing to T2DM by 30%–60% in those with PDM (Gillies et al., 2007). For example, the

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Finnish Diabetes Prevention Study (DPS) found that the risk of T2DM was reduced by 58% in those referred to an intensive lifestyle intervention compared to usual care over a three-year period (Tuomilehto et al., 2001). Consistent findings have been reported from the USA Diabetes Prevention Program (DPP) (Knowler et al., 2002).

Despite the strong evidence for lifestyle interventions in the prevention of T2DM, there has been a translational gap between trial evidence and implementation into routine care. This is predominantly due to the resource-intensive nature of lifestyle interventions tested. For example, in the first year of the DPP programme, participants received 16 1 h one-to-one counselling sessions followed by an average of eight additional contacts and two telephone consultations. The participants were also offered supervised exercise classes (Knowler et al., 2002). This intensity of care is incompatible with routine care pathways. Therefore, the emphasis needs to be shifted to examining the effectiveness of approaches designed for implementation within routine primary care. As healthcare services have differences in funding, organisation and infrastructure, programmes cannot be assumed to be generalisable across contexts. To date there has been a dearth of evidence concerning T2DM prevention in the UK, with small-scale projects showing mixed results (Yates et al., 2009; Dyson et al., 1997; Oldroyd et al., 2006; Bhopal et al., 2014).

This study assesses whether the Let's Prevent T2DM programme is effective at preventing progression to T2DM in people with PDM identified through a systematic screening pathway within primary care. Let's Prevent is a pragmatic, relatively low resource, group-based structured-education programme targeting lifestyle behaviour change specifically designed for implementation within a community setting.

Methods

The study had two phases. The first was a screening phase which identified people at risk of PDM/T2DM through the use of a screening tool that had been developed and validated for use within primary care (Gray et al., 2012a; Gray et al., 2012b). In the second phase, the participants who had been screened and found to have PDM progressed to the cluster RCT. The cluster RCT design has been described in detail elsewhere (Gray et al., 2012c). The trial randomised practices to avoid the risk of contamination. Ethical approval was sought and the study involved practice level and individual level informed consent. The recruitment took place between May 2009 and June 2011, with follow-up data collected up to July 2014.

Practices and participants

Practices in Leicestershire, UK, were recruited and randomised using a computer-generated list 1:1 to either the standard-care or intervention arm by an independent researcher, using stratification by list size (<6000, ≥6000), and ethnicity (percentage South Asian <21%, ≥21% — taken from ADDITION-Leicester study; Webb et al., 2010) with a block size of four. Practices and participants were informed of their allocation in the result letters after the screening/baseline measurements were complete. Eligible participants were identified from recruited practices via a two-stage screening process. The Leicester Diabetes Practice Risk Score was used in each practice to identify people at high-risk of PDM/T2DM for invitation to screening (Gray et al., 2012a). The top 10% of patients with the highest score fulfilling the inclusion criteria were invited. The inclusion criteria for screening were ages 40 to 75 if White European, or 25–75 years if South Asian. Participants were excluded if they were unable to give informed consent, pregnant or lactating, had established diabetes or a terminal illness, or if they required an interpreter for a language other than one of the locally used South Asian languages accommodated within this study. All those agreeing to take part received an oral glucose tolerance test (OGTT). Only participants who were identified as having PDM (IFG and/or IGT WHO 1999 criteria; World Health Organization, 1999) during screening took part in the RCT. In one small practice (list size = 1650) no participants were identified with PDM and this practice was excluded.

The screening–visit data formed the baseline assessment for the RCT; the participants were followed up at 6, 12, 24 and 36 months.

Interventions

All participants received an information booklet which included information on risk factors for T2DM, and how dietary and lifestyle changes and increased physical activity can prevent progression to T2DM.

The participants in the intervention practices were invited to attend the Let's Prevent programme (Gray et al., 2012c), which tailors the widely delivered DESMOND structured-education programme into a prevention context (Davies et al., 2008; Gillett et al., 2010).

Let's Prevent was delivered to groups of ten over 6 h, either over a full-day or two half-days, by two trained educators. The programme was underpinned by a theoretical basis with a philosophy centred on patient empowerment. The aim was to increase knowledge and promote realistic perceptions of PDM, and to promote healthy behaviour, with the aims of reducing body weight by 5%, limiting total and saturated fat intake to 30% and 10% of total energy intake respectively, increasing fibre intake and promoting physical activity. The physical activity section incorporated the successful PREPARE structured-education programme (Yates et al., 2009), based on providing participants with a pedometer and enabling the formation of personalised step-per-day goals. The content and educational resources used within the programme were further tailored to the need of local South Asian populations, including delivery through interpreters where required. The educators were trained using an accredited pathway, and received ongoing support and quality development to ensure consistent delivery.

The participants were invited to 3 h refresher sessions at 12 and 24 months to reinforce key messages, review risk factors and update action plans. In addition, the participants received a 15-minute telephone call every 3 months from healthcare professionals trained to offer ongoing support in behaviour change. Those who did not attend the initial session were not invited to the refresher sessions, but continued to be followed up.

Outcome measures

All outcomes were measured at the participant level. The primary outcome was progression to T2DM during 3 years. T2DM diagnosis was defined according to WHO 1999 criteria/guidelines (World Health Organization, 1999), Participants without symptoms of diabetes in whom the initial OGTT showed T2DM were recalled for a second test to confirm the diagnosis. Participants found to have T2DM at baseline were excluded. Following the update of the WHO diagnostic criteria to include HbA1c (World Health Organization, 2011) we obtained a protocol amendment in January 2013 allowing HbA1c ≥ 6.5% to become part of the diagnostic criteria for T2DM within this study. Therefore T2DM was diagnosed using OGTT prior to January 2013, and with either an OGTT or HbA1c post January 2013. The participants and their GP were informed of the results. The diagnosis of T2DM within primary care was also captured by self-report followed by confirmation through GP records. Participants diagnosed with T2DM after baseline remained in the study to complete the questionnaires and other biomedical data, but did not undertake further OGTTs.

A full list of the secondary outcomes assessed at each time point is described elsewhere (Gray et al., 2012c), these included: lipid levels, HbA1c, medical and medication history, blood pressure, weight, waist and body mass index (BMI). The participants also completed a questionnaire containing a number of validated questionnaires which assessed total self-reported physical activity, subsequently reported as metabolic equivalent minutes per week (METS.mins/week) (Craig et al., 2003), diet reported as a unitless fibre, total fat and unsaturated fat score (Roe et al., 1994), illness beliefs (Broadbent et al., 2006), anxiety and depression (Zigmond and Snaith, 2006), quality of life (Sintonen and Pekurinen, 1993) and sleep pattern; resource usage data and EQ-5D responses were also collected for the cost-effectiveness analysis (Gusi et al., 2010). The participants also wore a sealed pedometer (NL-800, New Lifestyles, Inc., Lees Summit, MO, USA) with a seven-day memory during waking hours to provide habitual ambulatory activity (average daily step count derived by summing total accumulated steps and dividing by days worn). For the purposes of this study, at least three valid days of data were required; a valid day constituted at least 10 h of wear time (Tudor-Locke and Bassett, 2004).

Other secondary outcomes included change in cardiovascular risk as calculated by the Framingham risk calculator, and presence of metabolic syndrome as defined by NCEP ATP III.