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# The importance of type 2 diabetes prevention: The Norfolk Diabetes Prevention Study

NIKKI J MURRAY, SARA ABADI, ALICEON BLAIR, MELANIE DUNK, MIKE J SAMPSON,  
On behalf of the Norfolk Diabetes Prevention Study Group\*

## Abstract

**M**any large studies have investigated the prevention of type 2 diabetes in people at high risk of the condition, usually with changes in diet and physical activity levels. It is estimated that 2.25 million people in the UK have type 2 diabetes, with significant personal and healthcare costs, and the value of preventative measures in tackling this enormous public health challenge are well described. The Norfolk Diabetes Prevention Study (Norfolk DPS) will screen 10,000 people at risk of type 2 diabetes over five years, randomising 950 people with 'pre-diabetes' into a 36-month randomised controlled trial (three-armed study) of a novel diet and lifestyle intervention. The Norfolk DPS team is multidisciplinary and the intervention will be delivered by healthcare professionals in group settings. One arm will be part delivered by lay mentors who have existing type 2 diabetes. There is no UK-validated diet and lifestyle intervention for the prevention of type 2 diabetes in high risk groups that has been tested in a controlled trial, and an intervention delivered by those with existing type 2 diabetes has not been studied. The Norfolk DPS will provide further evidence in these areas.

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**Keywords:** diabetes prevention, Norfolk Diabetes Prevention Study, type 2 diabetes

## Introduction

There are now more than 2 million people in the UK with type 2 diabetes mellitus<sup>1</sup> and the associated personal and NHS costs

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## Abbreviations and acronyms

BMI	body mass index
DPF	diabetes prevention facilitators
DPM	diabetes prevention mentor
DPP	diabetes prevention programme
DPS	diabetes prevention study
GP	general practitioner
HAPA	health action process approach
HbA <sub>1c</sub>	glycated haemoglobin A <sub>1c</sub>
NHS	National Health Service
NIHR	National Institute for Health Research
IFG	impaired fasting glucose
IGT	impaired glucose tolerance

are well described<sup>2,3</sup> with an estimated annual diabetes spend of £9 billion (much of it on complications and therapy costs). In the UK, there are 150,000–200,000 new diagnoses each year. People with type 2 diabetes pass through a 'pre-diabetes' stage of glucose intolerance where the fasting plasma glucose is elevated and identifies a group of individuals at high risk of progressing to type 2 diabetes if glucose intolerance continues to deteriorate.

Numerous large randomised controlled trials have investigated the prevention of type 2 diabetes, notably the Finnish DPS,<sup>4</sup> the US DPP,<sup>5,6</sup> the Indian DPP<sup>7</sup> and research conducted in Sweden,<sup>8</sup> China<sup>9</sup> and Japan.<sup>10</sup> All of these studies investigated the prevention of type 2 diabetes using lifestyle intervention techniques, which primarily looked at diet and exercise change. Benefits of exercise are widely recognised<sup>11</sup> and, together with weight reduction, lead to improvements in body composition, body mass index, cardiorespiratory fitness, cardiovascular risk and physical functioning. Prevention of type 2 diabetes has a positive effect on overall wellbeing and quality of life,<sup>12</sup> meaning that more focus should be given to prevention interventions for this condition. Other health benefits include improved sleeping patterns,<sup>13</sup> decreases in the severity of stress and depression<sup>14</sup> and smoking cessation.<sup>15</sup> Lifestyle changes throughout these studies incorporated weight reduction, increased physical activ-

**Table 1.** The Norfolk Diabetes Prevention Study inclusion and exclusion criteria. Participants must be > 40 years old, live in the county of Norfolk or be registered with a general practitioner in the county Norfolk, and have *at least one* of the following inclusion criteria.

Inclusion	Exclusion
BMI $\geq$ 30kg/m <sup>2</sup>	Not able to provide GP details, i.e. not registered with a GP or unwilling for their GP to be contacted
Parent, sibling or child with type 2 diabetes	Unable to give informed consent due to lack of capacity through severe mental health, learning difficulties or significant cognitive impairment
Personal history of coronary disease	Self-reported conditions which could adversely affect the trial results or patient clinical well-being
Previous history of gestational diabetes	Taking part in any research study which involves a dietary or lifestyle change intervention
Known impaired fasting glucose or impaired glucose tolerance	Inability to attend or comply with the interventions or follow-up scheduling Living with, or related to, someone in the programme team GP advice on health grounds that participant should not take part or be contacted
BMI, body mass index; GP, general practitioner.	

ity and changes to diet (decreasing fat intake) through goal setting. It has been shown that the more goals achieved, the better the health outcomes for the participants as they were shown not to progress to type 2 diabetes.<sup>16</sup> The dominant diabetes prevention randomised controlled trial using a lifestyle intervention is the US DPP<sup>5</sup> which was conducted in 27 centres with 3,234 IGT participants, of which 1,079 were randomised to a lifestyle intervention for a mean of 2.8 years. The lifestyle intervention had a target weight loss of 7%, largely through a reduced fat intake and increased walking, underpinned with intense structured contact and interventions. The US DPP was exceptionally well resourced with one-to-one coaching and intensive telephone contact from healthcare professionals.<sup>5</sup> The staffing resources required to achieve this result would be an estimated 188 salaried full-time lifestyle trainers per 100,000 UK adults; an unlikely level of investment in the current NHS. The translational costs from a research setting to the US healthcare system has also been recognised as unaffordable, and the US DPP investigators recognised that their intervention would need to be delivered in groups settings,<sup>17</sup> perhaps by community health workers potentially decreasing costs by > 70%.<sup>18</sup> This is an important point, as there is no validated diet and lifestyle intervention for the prevention of type 2 diabetes in the UK that involves the use of lay mentors that has been tested in controlled trials, and the research interventions that have been used elsewhere to reduce risk cannot be applied in a general UK population at risk.

As mentioned, to address the issue of cost for successful intervention programmes the idea of community health workers has been raised. The role of peer mentors has also been investigated with older adults participating in a physical fitness intervention<sup>19</sup> but this model has not been examined in disease prevention where the mentors themselves have the disease in question. Kennedy *et al.* (2008) have reviewed these roles in the UK and proposed the term 'lay food and health worker' for a role in improving community food and health awareness.<sup>20</sup> As stated, there will never be enough healthcare professionals to

support the ever growing numbers of people being diagnosed with type 2 diabetes in the UK, so a solution must be found to provide support to those at risk of developing the condition. People with existing type 2 diabetes are the obvious choice to train in this role as they are demographically similar to those with glucose intolerance, are a large enough element in any UK population to develop sufficient mentors, share a common experience of being diabetes aware, and face identical lifestyle challenges. Peers play a different, yet complimentary role to that of healthcare professionals and the unique lived and shared experience is absent in generic lay trainer support programmes and will be a novel element tested in the Norfolk DPS

### The Norfolk Diabetes Prevention Study

The Norfolk DPS is a five-year funded NIHR programme grant (£2.029 million, [www.norfolkdiabetespreventionstudy.nhs.uk](http://www.norfolkdiabetespreventionstudy.nhs.uk)) which began in 2011 following a two-year NIHR feasibility and development programme (The University of East Anglia – Impaired Fasting Glucose Study). The Norfolk DPS will screen 10,000 people at risk of type 2 diabetes and randomise 950 people with 'pre-diabetes' into a 36-month randomised controlled trial of a novel diet and lifestyle intervention. This will in part be delivered by lay mentors who have existing type 2 diabetes (DPMs), rooted in the NHS practicalities of delivering diabetes prevention in UK primary care.

### Recruitment

The Norfolk DPS inclusion and exclusion criteria are set out in table 1. Established recruitment strategies and new recruitment strategies that have benefitted from recent NHS developments will be used to identify potential participants for the study. These strategies include:

- general practice database searches and mailshots, where a member of practice staff will search their database for patients who fit the Norfolk DPS criteria and mail a letter on

the study's behalf to those patients. Patients are invited to phone the study line to register their interest

- self-referral through a structured media campaign including television, radio, local newspapers and general poster advertising
- the use of the NHS retinal screening programmes in Norfolk to recruit the friends and family of patients with type 2 diabetes
- pharmacist and NHS health checks.

### Study targets

Norfolk DPS participants who are randomised into the lifestyle intervention are required to work towards four main study targets. These goals are based on the behaviour goals that were set in other major diabetes prevention trials such as the US DPP<sup>5</sup> and the Finish DPS.<sup>4</sup> The Norfolk DPS study goals are:

- where initial BMI  $\geq 30$ , obtain a 7% weight loss within first six months and maintain to study end
- eat more healthily by eating less fat, in particular saturated fat
- build up to 30 minutes of moderate physical activity five days per week. This can be achieved by increasing step count, building up to 10,000 steps per day
- perform resistance training two to three times per week.

The lifestyle intervention is delivered by DPFs whose role is to monitor and support the participants, deliver the intervention sessions and assist with goal setting and progress review in order to help participants meet specific targets set to help attain the four specified study goals.

### Randomisation

Volunteers diagnosed with IFG on screening by the Norfolk DPS will be offered randomisation into the Norfolk DPS intervention. Participants have a 1:1:1 opportunity of being randomised into one of three study arms; 2:1 to intervention versus control.

### Control arm

The first is the control arm; participants randomised into this arm will receive a single two-hour education session on the effects of physical activity and healthy diet on diabetes prevention.

### Intervention arm

The second is the intervention arm. The intervention comprises of six education sessions for the first 12 weeks of the intervention, each of two hours duration with varying content which provides information to:

- encourage decision making about behaviour change
- increase motivation to change; support lifestyle changes in relation to physical activity and diet
- aid individual goal setting, action planning and self-monitoring.

The intervention then comprises of up to 15 maintenance sessions held eight weeks apart, commencing four weeks after the final education session until intervention end. These maintenance sessions include facilitated discussion and physical activity circuits carried out by DPFs and physiotherapists respectively.

### Intervention plus the DPM arm

The third arm consists of intervention plus DPM. In this arm, the participants will receive the same programme as the intervention arm but will additionally receive motivational telephone calls from lay volunteers with existing type 2 diabetes. To enhance retention rates, all participants will have the continuity of a DPF and DPM if randomised into that arm of the study.

### Approaches

The Norfolk DPS intervention provides many strategies and tools for facilitating initial behaviour change by supporting maintenance of change and addressing the need for individual tailoring. The approach throughout will be interactive rather than didactic, with all the sessions and one-to-one feedback components allowing for interaction and discussion. Reviews suggest the use of psychological theories and techniques in the development of effective interventions.<sup>21</sup> Cognitive behavioural therapy principles are acknowledged by recognising the importance of interactions between thoughts, emotions, behaviours and identifying automatic negative thoughts as potentially important barriers to behaviour change.<sup>22</sup> Final maintenance sessions will focus more heavily on the maintenance of health behaviours and the model of self-regulation.

Recently published literature on diabetes prevention programmes, such as the Greater Green Triangle programme<sup>23</sup> and the GOAL lifestyle implementation programme,<sup>24</sup> highlight the HAPA model<sup>25</sup> as a basis for these interventions. With this in mind, greater health psychology input will be drawn on to ensure that the Norfolk DPS intervention adopts a similar theoretical underpinning. The two-stage HAPA model has been found to be successful when focusing on initial behaviour change and also maintenance of behaviour change.<sup>26,27</sup> The two stages comprise a motivation stage and a volition (action) stage, with the importance of maintaining behavioural changes. The intervention was developed in line with the Medical Research Council framework for the development and evaluation of randomised controlled trials for complex health interventions. Existing evidence on DPPs and relevant theories guided initial development of the intervention content, structure and techniques

Basing the structure of the education sessions on the HAPA model, the Norfolk DPS also covers participants' ideas about risks and progression to type 2 diabetes, perceptions and attitudes towards diabetes and 'pre-diabetes'. The sessions further address participants' outcome expectancies related to the intervention and what participants feel are their main goals. Implementation intentions<sup>28</sup> are further utilised to translate decisions and motivation to change behaviours into actions by

providing participants with the knowledge to set themselves 'if-then' action plans, i.e. in line with the planning phase of the HAPA approach. 'If-then' plans specify when, where and how a person will perform goal-directed behaviours. 'If situation **y** arises **then** I will perform behaviour **x**'.<sup>29</sup> Subsequent education and maintenance sessions combine the use of health education models to provide information relating to nutrition and physical activity; with an emphasis on enhancing individual self-efficiency, goal planning, self-monitoring in the form of diaries and increasing skills to perform health behaviours. The intervention and process evaluation were developed through a process similar to intervention mapping. Stages included: 1) needs assessment; 2) 'mapping' theorised processes against their modifiable determinants; 3) selection of intervention methods to modify identified determinants, drawing on taxonomies of behaviour change techniques; 4) organising intervention methods into a coherent programme; 5) a detailed specification informed by the design of process evaluation for testing the process model and intervention fidelity.

### The Norfolk DPS, novel aspect – DPMs

Patients >18 years old who have been diagnosed with type 2 diabetes for > 2 and who are living in the county of Norfolk will be eligible to apply for the role of DPM. Recruitment of DPMs will be primarily identified from GP surgery databases and potential DPMs will be sent invitation letters on behalf of the Norfolk DPS. A general media campaign will also run alongside the GP recruitment strategy. Those wishing to know more about the role, including commitment required as a volunteer, can enter the recruitment process which includes a pre-recruitment questionnaire and an informal interview with senior study staff.

Successful DPMs (of which the Norfolk DPS requires 50) will be fully trained in all aspects of the study using various learning techniques in interactive group sessions. From weeks 1 to 7, training sessions will cover (in order):

- Introduction and getting started
- Healthy eating – fats
- Active listening skills
- Getting active
- Portion control and food labels
- Getting stronger
- Maintaining change.

Throughout the training, behaviour change techniques and theoretical concepts, including goal setting, motivation, problem solving and progress review, will be covered in relation to each topic. To maximise the convenience and access to training, sessions will be held in the evenings at weekly intervals between 1800 and 2000. Interaction and communications will be encouraged throughout.

DPMs will be provided with a folder containing PowerPoint slides for each session, confidentiality protocol and information on key skills for behaviour change including eliciting techniques. A specifically designed manual containing written information on all



### Key messages

The Norfolk DPS is investigating lifestyle prevention strategies:

- in an at-risk impaired fasting glucose UK population
- running the lifestyle intervention in groups as opposed to one-to-one
- plus telephone peer mentoring by a lay volunteer with existing type 2 diabetes

aspects of being a DPM, such as support, supervision, intervention structure, difficult situations, tips for successful telephone conversations and instructions and reference information, will also be provided.

DPMs will make motivational phone calls to the participants throughout the intervention if a participant is randomised to the intervention plus DPM arm. During the education sessions (the first 12 weeks of the study) participants will receive phone calls from their assigned DPM every four weeks to review progress and assist in support and motivation to meet healthy eating and physical activity goals. Following this, during the maintenance sessions of the study (four weeks after the final education session to the end of the study) the participants will receive phone calls every eight weeks to coincide with the maintenance sessions run every eight weeks by study staff. Phone calls will last approximately 15 minutes.

The DPMs well being and body measurements will also be monitored to see if being a mentor itself has health benefits. We know that those being mentored do receive benefits, but the literature is sparse in this population as to whether the benefits of mentoring are effective on diabetes control. Body measurements include weight, height, BMI, body fat percentage/mass and visceral fat (a Tanita Body Composition machine was used to measure total body fat and visceral fat) as well as HbA<sub>1c</sub> at baseline and at 6-, 12-, 24- and 40-month time points.

### Conclusion

To discuss the importance and relevance of diabetes prevention at this time is beyond the scope of this text and this topic has been recently (July–August 2011) considered in a themed issue of this journal.<sup>30</sup> Increasing incidence of type 2 diabetes is also having major cost implications for health providers.<sup>31</sup> The cost effectiveness of preventing type 2 diabetes using lifestyle interventions has been looked at in a number of clinical trials outside the UK.<sup>32,33</sup> Gillies (2008) concluded that implementing appropriate lifestyle intervention for those with pre-diabetes is a cost-effective strategy.<sup>32</sup> Herman *et al.* (2005) concurred with this conclusion by stating that from a healthcare perspective, the lifestyle intervention was highly cost effective compared with the control intervention. Within the UK, costs were calculated using the feasibility study

(UEA-IFG Study) conducted prior to the Norfolk DPS, at £226 per participant over a short intervention period.<sup>34</sup>

Increasing levels of obesity, prolonged periods of sedentary behaviour and lack of physical activity or moderate exercise are well known independent risk factors for type 2 diabetes<sup>11</sup> and these need to be a continued focus of diabetes prevention interventions. The Norfolk DPS is investigating additional elements of group-based interventions and using these in association with DPMs who have existing type 2 diabetes as a novel approach to prevent those at high risk developing the condition over a five-year period.

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## Declaration of Conflicting Interests

The study has no conflicting interest to report.

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