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TITLE

Design and baseline characteristics of the PODOSA (Prevention of Diabetes & Obesity in South Asians) trial: a randomised lifestyle intervention in Indian and Pakistani adults with impaired glycaemia at high risk of developing type 2 diabetes

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ABSTRACT

Objectives: To describe the design and baseline characteristics of an adapted, lifestyle intervention aimed at reducing weight and increasing physical activity in people of Indian and Pakistani origin at high risk of developing type 2 diabetes.
Design: Cluster, randomised controlled trial.
Setting: Community-based in Edinburgh and Glasgow, Scotland, UK.
Participants: 156 families, comprising 171 people with impaired glycaemia, and waist sizes ≥ 90 cm (men) and ≥ 80 cm (women), plus 124 family volunteers.
Interventions: Families were randomised into either an intensive intervention of 15 dietitian visits providing lifestyle advice, or a light (control) intervention of 4 visits, over a period of 3 years.
Outcome measures: The primary outcome is change in mean weight between baseline and three years. Secondary outcomes are changes in waist, hip, Body Mass Index (BMI), plasma blood glucose and physical activity. The cost of the intervention will be measured. Qualitative work will seek to understand factors that motivated participation and retention in the trial.
Results: Between July 2007 and October 2009, 171 people with impaired glycaemia along with 124 family volunteers were randomised. 95% (171/196) of eligible participants agreed to proceed into the 3-year trial. Over half the families include family volunteers. The main participants have a mean age of 52 years and 64% are female. The average length of UK residency is 31 years. Almost half our recruits could be classified obese according to the conventional WHO cut-off point of BMI > 30 kg/m2.
Conclusions:
PODOSA is one of few randomised, intervention trials in a UK ethnic minority population. We have recruited sufficient participants to undertake an adequately powered trial to detect a mean difference in weight of 2.5 kg between the intensive and light intervention groups at the 5% significance level. The main trial results will be submitted for publication in 2013.

Trial registration: Current controlled trials ISRCTN25729565 (http://www.controlled-trials.com/isrctn/).

ARTICLE SUMMARY

Article Focus

- Randomised controlled trial
- Diabetes prevention
- South Asians

Key Messages

- The worldwide prevalence of type 2 diabetes has doubled over the past 25 years and South Asians, including those in the UK, are at particularly high risk of developing the disease,
- PODOSA is one of the first community-based lifestyle intervention trials focusing on the UK South Asian population, and is taking place in Scotland, UK.
- The dietitian led intervention is family focussed, based in the home and is culturally adapted from the Finnish Diabetes Prevention Study, for people of Indian and Pakistani origin.
- The primary outcome is weight change over 3 years, the main driver for prevention or delay of onset of type 2 diabetes. The trial is on course to report in 2013.

Strengths and Limitations of this Study

- The study is one of few trials specifically for an ethnic minority population in the UK
- The results should provide valuable information to contribute to existing evidence for tackling the high levels of diabetes in UK South Asians
- The study is not powered to examine progression to diabetes within the original timeframe, but it is planned do this in the longer term via data linkage to national health records.

BACKGROUND

Diabetes mellitus is a serious disease that reduces life expectancy by around six years from middle age,[1] and increases the risk of blindness, heart disease, stroke and kidney failure. The age-standardised prevalence of diabetes worldwide was over 9% (9.8% for men, 9.2% for women) in 2008. This translates to around 347 million people with diabetes globally, more than double the number from 1980 (153 million).[2] Estimates show that in India, the number of adults with diabetes will increase from 50 million in 2010 to at least 87 million by 2030.[3] In the UK in 2010 there were an estimated 3.4 million people with type 2 diabetes mellitus (henceforth diabetes), resulting in direct costs to the NHS of £8.8bn.[4] The adult age-standardised prevalence of diabetes in UK South Asians (defined here as UK residents with ancestral origins in the Indian Subcontinent) is about 2-6 times that of the general population with probable higher progression rates from impaired glycaemia to diabetes, although robust data are lacking.[5-7]

There is clear evidence from a number of diabetes prevention trials in adults at elevated risk for diabetes, that lifestyle intervention focusing on modest weight loss (5-10% of body weight) and increased physical activity, is effective at preventing or delaying diabetes.[8-10] Such interventions have been found to be effective in a number of ethnic groups including 'Asians' living in the US[10] and Indians living in India.[11] The evidence from randomised trials has been summarised and published by the Centres for Disease Control and Prevention Primary Prevention Working Group (2004).[12] They conclude that maintenance of moderate weight loss through diet and physical activity reduces the incidence of diabetes by 40 to 60% over 3-4 years. A review of evidence and application in a UK setting by Davies et al, showed that major benefits accrue from 5-10% body weight loss and 150 minutes per week of physical activity similar in intensity to brisk walking.[13] They suggest a need to develop and evaluate interventions that target communities and population at risk in the UK.

In the UK, the National Service Framework for Diabetes (NSFD) first standard is to reduce the number of people who develop diabetes and to reduce inequalities in this disease. The NSFD[14] and the Scottish Government Diabetes Action Plan 2010[15] place emphasis on the need to prevent and control diabetes in the UK's minority ethnic populations (highlighting the high rates in South Asians) through implementation of effective and culturally relevant interventions. The main risk factors for diabetes, principally weight gain and physical inactivity, need tackling in these populations, but there are no UK trial data to guide either practice or policy.

Therefore the current challenge is to adapt existing interventions to meet the cultural needs of South Asians, and to demonstrate efficacy in the UK context, as it has been suggested that strategies that work in some societies may not work in others, as different social, economic, political and cultural environments will affect diet and lifestyle.[13]

The PODOSA (Prevention of Diabetes and Obesity in South Asians) trial aims to reduce weight and increase physical activity in adults at high risk of diabetes indicated by Impaired Glucose Tolerance (IGT) or Impaired Fasting Glycaemia (IFG), thereby preventing or delaying diabetes. The aim of this paper is to describe the trial design and methods and baseline characteristics of participants.

METHODS / DESIGN

Study questions and design

PODOSA is a cluster, randomised controlled trial. The original protocol written in 2007 was designed to answer the primary question 'Does a family-based three-year programme promoting weight loss and increased physical activity in South Asians, modelled on interventions of proven effectiveness internationally, reduce the incidence of type 2 diabetes in South Asians?' However due to difficulties with recruitment,[16] a substantial amendment was approved by the ethics committee in 2009 to alter the primary outcome as detailed below.

The principal research questions that we are pursuing are therefore now:

- Does a family-based three-year programme promoting weight loss and increased physical activity in South Asians with IGT and/or IFG, modelled on interventions of proven effectiveness internationally, result in a clinically meaningful weight loss in the intensive intervention (15-visit) group compared to the light intervention (4-visit) group?
- What is the cost effectiveness of the intervention?
- What factors assist recruitment, adherence with advice given, and retention in the trial?

The secondary research questions which are designed to, help interpret the main outcomes, are:

- During the trial what changes occur over time among participants with IGT and/or IFG, and volunteer members of their families (analysed separately), in
    - waist circumference?
    - hip circumference?
    - fasting and 2-hour blood glucose (IGT/IFG recruits only)?
    - incidence of type 2 diabetes presently (and in the longer term, to be assessed via data linkage)?

Individual focused interventions (not family based ones) have shown the success of weight loss and increasing physical activity in preventing diabetes. PODOSA's key adaptation is to shift the emphasis from the individual to the family and from the clinic to the household. This was designed both to maximise participation and help achieve behaviour change, by recognising the fact that most health-related behaviours take place within the family or home setting and other family members may, for example, be involved in food preparation (supplementary information in the NSFDM).[14]

Our goal is weight loss of 2.5 kg more (or 2.5 kg lower weight gain) in the intensive intervention than in the light intervention group and increase in physical activity to at least 30 minutes daily. Ideally we would reduce the Body Mass Index (BMI) to at least 25 or preferably 23 (the interim World Health Organisation (WHO) recommendation for Asian populations). [17]

Ethical approval

Ethical approval was obtained from the Scotland A Research Ethics Committee. All recruits gave written, informed consent to take part in the screening stage of the study and then further written consent for participation in the three year trial. Recruitment took place between July 2007 and October 2009. Indian and Pakistani origin men and women aged 35 years and over

living in the Lothian and Greater Glasgow & Clyde Health Boards areas were invited to be screened with the Oral Glucose Tolerance Test (OGTT).

Eligibility criteria
Eligible participants for the trial were those with:

- waist sizes ≥ 90 cm for men and ≥ 80 cm for women
- IGT (i.e. fasting plasma glucose of < 7 mmol/l and, following a standard OGTT, two-hour plasma glucose of 7.8-11.0 mmol/l
- and/or IFG (ie plasma fasting glucose of 6.1 – 6.9 mmol/l)
- no previous diagnosis of diabetes
- 'family cook' agreed to cooperate (whether the main recruit, a family volunteer or another family member).

Participants on prescribed long-term oral corticosteroids, suffering from a health condition where adherence to the intervention was contraindicated or improbable, or unlikely to remain in the UK for 3 years, were excluded from trial entry.

The waist criteria correspond to the cut-off points recommended by the International Diabetes Federation Consensus Group in 2005 to identify South Asians at risk of diabetes.[18]

Sample size considerations
The target sample size for the amended trial was calculated to be 175 recruits to allow for a 10% drop-out. This would result in at least 150 recruits having complete follow up at 3 years. This sample size gives adequate (86%) power to detect a difference of 50% of the standard deviation (SD) (i.e. a mean difference of 2.5 kg between the two groups against a SD of 5 kg) at the 5% significance level (2-sided).

Randomisation and allocation of interventions
Randomisation lists were produced by the trial statistician using a random number generator program. Permuted blocks were used and block size varied randomly. Stratification is by location (Edinburgh or Glasgow), ethnic group (Indian or Pakistani), and number of IGT/IFG recruits in the family (1 or more than 1). The composition of families was established in consultation with the family itself. Criteria were defined to identify each extended family unit prior to randomisation. To minimise contamination, first degree relatives (parents, siblings, children) living in the same city could not be randomised separately All members of a 'family' gave written informed consent and completed the baseline visit prior to randomisation. Allocation of intervention group was then performed by the trial statistician or a deputy, independently from the dietitians and trial office staff. This strategy was implemented to minimise selection bias during the recruitment process.

The study has two groups for comparison, one group having more frequent and tailored contact (intensive or 15 visit intervention) with the research dietitians than the 'control' group (light or 4 visit intervention), which largely receives information. The 15 visit group of 78 families received 15 contacts over three years, monthly for 3 months and thereafter quarterly. The 4 visit group of 78 families had annual contact over three years with the dietitian. The dietitians visit the participating families at their home or community setting of their choice.

Intervention for 15 visit group
Our intervention is based on the Finnish Diabetes Prevention Study, using our experience of working with South Asian populations.[9] Our trial, in comparison, focuses on the family and is based largely in the home setting whereas the Finnish study was largely in the clinic. Research dietitians were employed to carry out the intervention.

The dietitians were trained in venepuncture, measurement, delivery of information, behaviour change, and promotion of physical activity. These contacts were, in effect, the intervention and in general each family was seen by the same dietitian for the duration of the trial. The content of the contacts were tailored, using a range of culturally adapted change management tools, to the needs of individuals and families. The dietitians motivated participating families to achieve weight loss through a calorie deficit diet in conjunction with physical activity. Verbal and written advice was provided including information on shopping, cooking (with demonstrations), and entertaining. Participants were invited to annual group sessions consisting of a food shopping tour, understanding food labels, exchange of recipes, food tasting and. brisk walking. The dietitians' toolkit contained culturally adapted resources from similar projects, on diet and physical activity, and a paper on the cultural adaptation process has been submitted for publication. Pedometers were integral to the physical activity programme, providing motivation through self-monitoring and a tool for the dietitians to assess progress. Daily food diaries and pedometer logs, body weight and waist circumference data and the Chester Step Test were used for educational and motivational purposes.

Intervention for 4 visit group

This group had a baseline and then annual contact with the research dietitian. The dietitians gave both written and verbal advice on healthy eating, diabetes prevention, promotion of physical activity and on accessing available health services for weight control and physical activity. The research team agreed which resources should be given to families in the 4-visit group at each visit, to ensure consistency. While these actions were better than routine service, it is not anticipated they will reduce weight substantially and sustainably, but they may stabilise it, and counteract the secular trend and age effects of increasing weight.[19] This level of intervention was, we judge, necessary on ethical grounds. It also offered something in return for participation and measurements.

Measurement and valuation of costs

The PODOSA trial design included an integrated cost analysis. Cost data were collected prospectively from randomisation (baseline) to the 3 year follow-up. We chose a societal perspective for the analysis which encompassed the health service costs of the intervention and the opportunity cost of time for trial participants. The programme costs included the number and length of home visits by research dietitians and self-reported health service use in primary and acute care settings. Initial screening and trial recruitment costs were excluded. We valued dietitians' time (face-to-face contact, pre- and post-visit review and travel to participants' households) using NHS salary scales inclusive of salary on-costs and overheads. Standard NHS unit costs were used to value General Practitioner visits and hospital out-patient clinic attendances. Participant time included the number and length of dietitian visits and self-reported time spent doing moderate physical activities and on household allocation of time for food shopping and meal preparation. Median hourly wages by gender and ethnicity reported by the National Equality Panel/Labour Force Survey[20] were used to value participant time. No estimate of diet costs was included. The present value of the three year cumulative costs was calculated using a 3.5% annual rate of discount following UK Treasury and NICE guidance. All costs are reported in UK pounds using 2010 pay and price levels.

All analyses will be conducted on an intention-to-treat basis. The conditional mean cost comparison between 15-visit and 4-visit groups will be modelled using linear regression and generalised linear parametric methods. The mean cost difference between the groups will also be assessed using a non-parametric bootstrap. Quantile regression will be used to examine and compare the median cost differences. The relatively small sample size precludes assessment of heterogeneous treatment effects or sub-group differences in costs.

The robustness of results will be investigated using a strategy of comparing different specifications within the generalised linear model and conducting a series of one-way sensitivity analyses, where we will alter key assumptions on programme intensity and frequency as measured by the number, length and duration of visits. The cost implications arising from moving away from a one-to-one programme towards a group based intervention will also be considered.

Qualitative study

A qualitative study will utilise experience-centred, culturally-orientated narrative methods to capture the experiences of PODOSA from those who have recently completed the trial. The objective is to try to understand what factors motivate ethnic minority people to engage with research and to understand more about the facilitators to participation through understanding the perspectives and experiences of those who chose to participate in the trial. The main aims are to:

- Obtain a rich and multi-faceted understanding of the main motivations for participation in an intervention study of Indian and Pakistani adults who are at high risk of developing diabetes.
- Investigate participants' perceptions of fidelity and faithfulness to the interventions offered both during and after participation.
- Understand the factors that may help promote retention of participants once enrolled.

Measurements for volunteer members of the family

Height and weight for BMI, and waist and hip circumferences, were measured annually in adult family volunteers with and without diabetes (no blood tests were done).

Laboratory assessments

The 75 g OGTT followed standardised procedures, with venous blood samples taken after an overnight fast of 10–16 hours and 2 hours after ingestion of 75 g glucose. Samples were then transported to a central hospital laboratory (Glasgow Royal Infirmary or Western General Hospital, Edinburgh) where plasma glucose concentration was determined using the Ortho clinical diagnostics, Fusion dry ice method (Edinburgh), or the Abbott Architect, hexokinase/glucose-6-phosphate dehydrogenase method (Glasgow). Both laboratories participate in the UK National External Quality Assessment Service (UK NEQAS) scheme. In addition, an EDTA sample was obtained from all recruits at baseline and at three years, and with the participant's specific informed consent, plasma and DNA aliquots stored at -80˚C. The frozen samples will be analysed to examine the effect of the intervention on cardio-metabolic risk factors, which will be the subject of a subsequent paper.

Data collection and handling

Standard operating procedures were written for all the main study procedures including anthropometric measurements and the oral glucose tolerance test. Two measurements for height, weight, waist and hip were performed and if the difference was more than a specified value (height, waist and hip > 1cm, weight > 0.2kg), a third measurement was carried out. To counteract any potential observer bias when recording the key endpoint variables at the 3-year visits, an independent set of anthropometric measures were recorded by trained research nurses, blinded to study group.

Anthropometric measurements, and demographic, socio-economic, self-reported medical history, physical activity and diet data were collected by the dietitians in the case record forms at baseline and at each annual visit. A subset of these data was collected at the interim visits

in the 15-visit group to help deliver the intervention. Data on costs to deliver the intervention, opportunity costs of the time of the recruits and health resource use were collected at all visits. Physical activity was assessed annually for recruits in both groups. Time spent sitting, walking, and undertaking moderate and vigorous activities, was extracted from the short form of the International Physical Activity Questionnaire (IPAQ),[21] with time spent walking and in moderate and vigorous activities truncated at 180 min per day in line with the published IPAQ data processing guidelines (www.ipaq.ki.se).

Data were entered by the study assistant into a Microsoft Access database which has inbuilt validity and consistency checks. Subsequent data cleaning was performed by further manual and statistical checking. Double data entry was carried out for the key variables relating to the main trial outcomes, including randomisation criteria, all anthropometric and biomedical measures, and demographic and health economics data.

Statistical analysis

Analyses will be performed on an intention-to-treat basis, i.e. participants will be analysed in the group that they were randomised to regardless of how much of the intervention they received, unless specified otherwise.

Due to the clustering inherent in the design, the primary outcome will be analysed using a random effects linear regression model (to accommodate the clustering of individuals within families) with maximum likelihood estimation. The model will be adjusted for the stratification variables (ethnicity and location). Change over time will be incorporated into the model using an extension to the analysis of covariance (ANCOVA) approach, adjusting for baseline value. Treatment group will be included in the model as a fixed effect. Results will be reported as an adjusted (for ethnicity and location) mean difference in weight between baseline and three years, with a 95% confidence interval and corresponding p-value.

Analyses of secondary/tertiary outcomes will mirror those for the primary outcome, where the distribution of the relevant outcome is continuous. Where the outcome is a proportion, the approach will be to fit a generalised linear mixed model with terms for stratification variables and treatment group as above and adjusting for baseline value where applicable. Results will be reported as an adjusted odds ratio with a 95% confidence interval and corresponding p-value.

RESULTS

Baseline characteristics of the trial population

Baseline characteristics are shown in Table 1. The families range from single participants to a family comprising 4 IGT/IFG recruits with 5 family volunteers. Only 13 of the 156 trial families have more than one recruit with IGT/IFG. Family volunteers were recruited to 85 families. The trial population are well established in the UK with mean residency time of around 31 years. Approximately 33% of the participants have no formal educational qualifications.

Table 1 shows that approximately 84% of family cooks are either the IGT/IFG person or a family volunteer. The remainder all agreed to cooperate. Over a third of the participants had a close family history of diabetes.

Part (c) of Table 1 describes lifestyle characteristics of participants. Average total activity time (comprising vigorous, moderate and brisk walking) for the trial population was 51 minutes per day. Mean sitting time was 6.5 hours per day.

Mean BMI for all recruits was 30.5 kg/m^2 and overall 49% of participants had BMI > 30 kg/m^2.

Table 2 shows demographic and anthropometric characteristics of the 124 family volunteers. Most volunteers are female (77%) and 64/124 (52%) were the spouse or partner of the index recruit. Over 90% of the family volunteers were recruited in Glasgow. The mean BMI of family volunteers was 27.4 kg/m^2.

Recruitment

As shown in Figure 1, 1319 participants were screened with an OGTT over a 27 month period between July 2007 and October 2009. 102 recruits (8%) had OGTT results indicative of diabetes and 196 (15.4%) were found to have impaired glycaemia. 16 participants did not meet eligibility criteria to proceed into the full trial and nine declined to participate further. Thus, 95% (171/196) agreed to continue into the three year trial. 156 families comprising the 171 eligible participants with IGT and/or IFG, along with 124 family volunteers, were randomised into either the intensive or light intervention groups.

DISCUSSION

Principal findings

The PODOSA trial's key achievements include: establishing the infrastructure for the trial; recruiting, training and forging a multi-ethnic team to implement the trial; and the very high level of support from within the wider South Asian community. Although recruitment to the screening stage of the trial was challenging,[16] it is encouraging that 95% of eligible recruits consented to participate in the 3 year trial (171/196). We emphasised the need for family involvement as a means of motivating behaviour change and set the complex intervention in the home setting. Our only entry criterion relating to the family was that the main cook participated and this was always achieved. We consider this a major success. It proved harder to recruit family volunteers in Edinburgh than in Glasgow. It was difficult to identify clear reasons for this but the dietitians reported that, in many instances, potential volunteers were either unavailable or did not interact or eat with the main recruits with sufficient frequency.

The proportion of Pakistani to Indian recruits (2:1) in PODOSA closely reflects the wider resident South Asian population as reported in the 2001 Scottish census where those of Pakistani origin represented 31% of the total minority ethnic population and 15% were of Indian origin.[22]

Strengths and weaknesses

PODOSA is one of the first culturally adapted randomised intervention trials in South Asians in the UK. PODOSA is important for weight control and diabetes specifically, however, its long-term legacy will be the experience, lessons and example of the evaluation of complex interventions in ethnic minority populations set in the community in the UK multi-ethnic society.

Although we were unable to recruit sufficient numbers to examine, with sufficient power, progression to diabetes within the life of the trial, we have participants' consent to link trial data to Scottish national morbidity and diabetes register data during a 10 year follow up period. This may allow analysis of this outcome in the longer term. However weight loss, our new primary outcome, is the main driver for diabetes prevention.

Putting the study in context

Based on available evidence at the design stage of the trial,[5,18] we set eligibility criteria for waist circumference (≥ 90 cm for men and ≥ 80 cm for women) as those with central obesity are more likely to have impaired glycaemia. We estimated that we would identify IGT in around 30% of such volunteers screened for trial eligibility.[5] Within PODOSA the prevalence rate for IGT **and/or** IFG was approximately 15%, much lower than expected. The Leicester (UK) Addition study reported finding 19.8% IGT or IFG in South Asians aged 40-75 years, with no minimum waist size.[23] A recent systematic review[24] of cross-sectional studies in South Asians also suggests a stable or falling IGT prevalence, although the natural history of pre-diabetes and its progression to diabetes still remains unclear. Our lower prevalence rate of impaired glycaemia was one of the contributory factors to our difficulty in achieving the original intended sample size. However we have recruited adequate numbers to have sufficient statistical power to detect a significant effect in the amended primary outcome.

Within the UK, the case for national screening programmes for both diabetes and impaired glycaemia remains equivocal.[25] Recent research has suggested that the case is stronger than it was, although evidence from good quality trials showing a subsequent reduction in morbidity and mortality is still required.[26] Hanif et al argue that a stepwise screening strategy aimed at the South Asian population could be effective although further work is needed to examine implementation within primary care.[27] The Addition Leicester trial,[6] a community screening programme and cardiovascular risk intervention, includes a significant South Asian population and is due to report in 2013. The results from PODOSA, also expected in 2013, will contribute to urgently needed evidence about the effectiveness of prevention interventions in a UK ethnic minority population at high risk of developing diabetes.

Implications

South Asians are at high risk of developing type 2 diabetes and effectiveness data for culturally tailored health care interventions are urgently required in order to help prevent this epidemic and to help inform health care services and policy in the UK. The trial intervention will finish in October 2012 and the main results, including cost-effectiveness and qualitative findings, will be submitted for publication in 2013. In particular, this study has focussed on

the family rather than the individual and moved from the traditional clinic, to a home setting. More generally, PODOSA will also contribute to the evidence base for conducting randomised lifestyle intervention trials in ethnic minority populations in the UK and contribute to future meta-analyses with on-going diabetes prevention trials in other South Asian populations.

Table 1. Recruits with IFG and/or IGT
Demographic, social, lifestyle, anthropometric, biochemical and other background characteristics of trial participants. Figures are numbers and column percentages unless otherwise stated

Variables	All participants No.	(column %)
a) Demographic		
No. of families with-		
1 IGT/IFG recruit	143	(91.7)
2 IGT/IFG recruits	12	(7.7)
4 IGT/IFG recruits	1	(0.6)
No. of families with-		
with family volunteer(s)	85	(54.5)
No. of IGT/IFG individuals	171	(100)
No. family volunteers	124	(100)
Individual IGT/IFG recruits		
Sex – male	78	(45.6)
Age – mean (SD)	52.3	(10.1)
Age – range	35-80	
Location		
– Glasgow	132	(77.2)
– Edinburgh	39	(22.8)
Ethnic group		
– Indian	57	(33.3)
– Pakistani	114	(66.7)
Religion		
– Muslim	114	(66.7)
– Hindu	15	(8.8)
– Sikh	39	(22.8)
– Other	3	(1.8)
b) Social circumstances		
Cook was a participant	85	(49.7)
Cook was a family volunteer	59	(34.5)
Cook was simply cooperating	27	(15.8)
Blood relative with diabetes	118	(69.0)
Years lived in UK (mean, SD)	31.4	(13.1)
Education:		
no qualifications	56	(32.7)
school level	49	(28.7)
further or higher education	66	(38.6)

continued

Table 1. Continued

Variables	All participants No.	(column %)
c) Lifestyle		
Current smoking/chewing tobacco	11	(6.4)
Currently drinks alcohol	19	(11.1)
Vegetarian	26	(15.2)
Physical activity (**mean minutes per day, SD**)		
– Total (moderate, vigorous, walking)	51.0	(61.0)
– Moderate and vigorous only	23.3	(44.7)
– Walking only	27.7	(37.1)
– Sitting time (mean hours per day, SD)	6.5	(3.0)
d) Anthropometric (Values are given as mean and SD)		
Height (cm)	161.9	(9.3)
Weight (kg)	80.2	(15.6)
BMI (kg/m^2)	30.5	(4.8)
Waist (cm)	103.0	(11.1)
Hip (cm)	107.1	(9.5)
Waist/hip ratio	0.96	(0.07)
BMI < 25 (n,%)	20	(11.7)
BMI ≥ 25 and <30 (n,%)	67	(39.2)
BMI ≥ 30 (n,%)	84	(49.1)
e) Biomedical measures (Values are given as mean and SD)		
Systolic BP (mmHg)	136.9	(20.6)
Diastolic BP (mmHg)	83.0	(11.5)
Fasting plasma glucose (mmol/l)	5.8	(0.6)
2-hr post OGTT plasma glucose (mmol/l)	8.3	(1.6)
Current medications (n,%)		
– Antihypertensives	48	(28.1)
– Cholesterol lowering	39	(22.8)

Table 2 Family volunteers
Demographic, anthropometric and other background characteristics of family volunteers. Figures are numbers and column percentages unless otherwise stated

	All family volunteers No.	(column %)
a) Demographic		
Sex – male	28	(22.6)
Age – mean (SD)	41.9	(14.9)
Age – range	18 – 75	
Location		
– Glasgow	114	(91.9)
– Edinburgh	10	(8.1)
Ethnic group		
– Indian	42	(33.9)
– Pakistani	79	(63.7)
– Other	3	(2.4)
Relationship to main recruit		
– Spouse/partner	64	(51.6)
– Parent	2	(1.6)
– son/daughter	26	(21.0)
– brother/sister	5	(4.0)
– other	27	(21.7)
b) Anthropometric (Values are given as mean and SD)		
Height (cm)	161.7	(8.5)
Weight (kg)	71.4	(13.9)
BMI (kg/m^2)	27.4	(5.3)
Waist (cm)	92.7	(12.4)
Hip (cm)	104.7	(8.6)
Waist/hip ratio	0.89	(0.08)
c) Biomedical		
No. with diabetes (self-reported)	15	(12.1)

Authors' contributions

AD and RSB drafted the manuscript and are joint guarantors. SW, RuB and AS are research dietitians carrying out the study recruitment, screening and interventions. RSB, SW, JFF, JMG, JMcK, GM, NS, SWild, ASheikh and AD helped plan the trial. All authors contributed to the interpretation of the data and writing of the manuscript. Prof Mike J E Lean and Prof Jaakko Tuomilehto contributed to planning the trial but are not authors on this paper.

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Competing Interests None

Provenance and peer review Not commissioned; externally peer reviewed

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Ethics approval Ethical approval was obtained from the Scotland A Research Ethics Committee (reference number 07-MRE10-2)

Data sharing statement No additional data available

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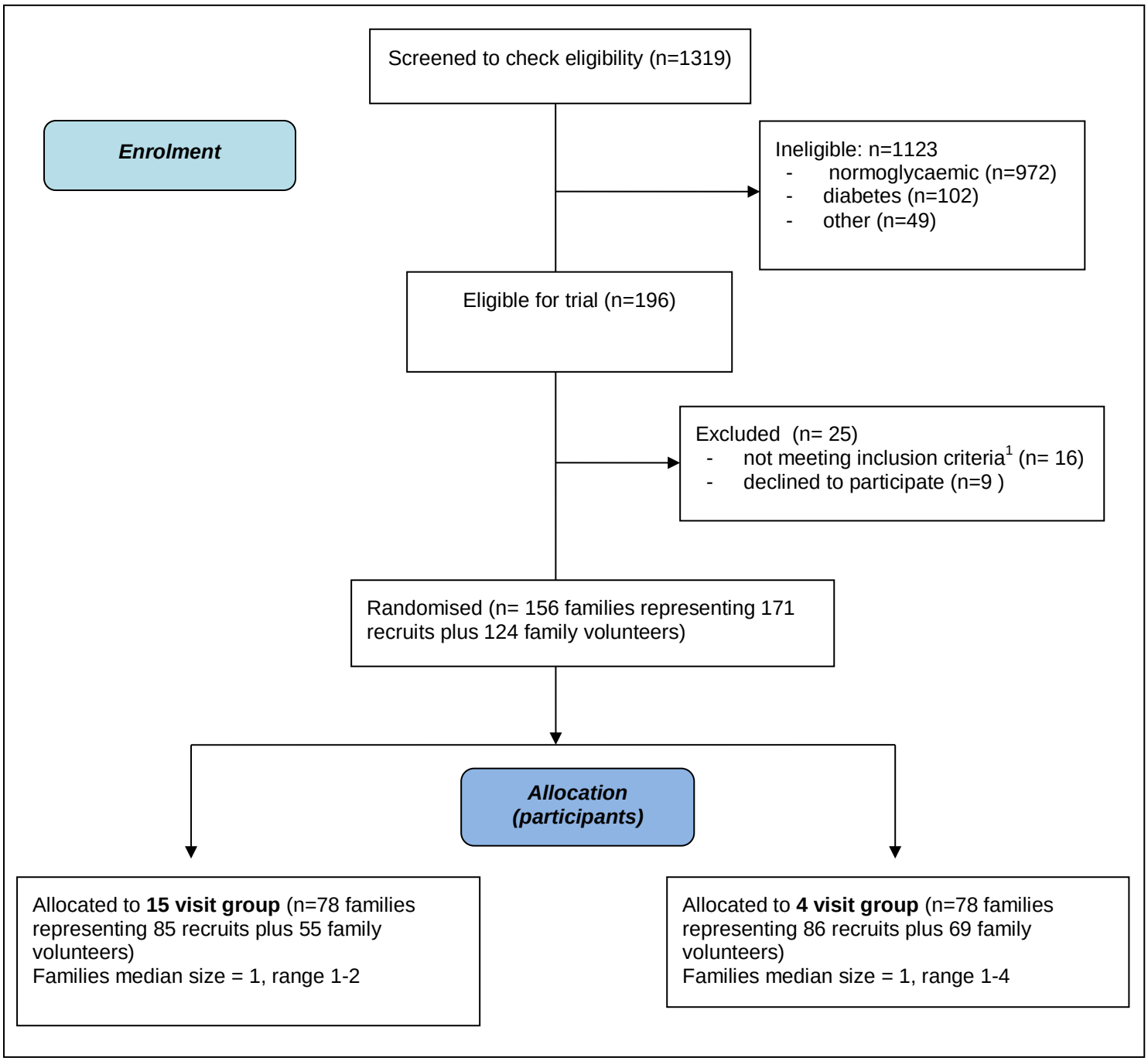
Figures

Figure 1 PODOSA TRIAL CONSORT FLOWCHART



Notes:

[1] Main reasons were, unavailable for baseline visit within timeframe, or close family members already in the trial.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	5
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7-8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 &2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	n/a
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	n/a
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	n/a
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	na
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ open

Design and baseline characteristics of the PODOSA (Prevention of Diabetes & Obesity in South Asians) trial: a cluster, randomised lifestyle intervention in Indian and Pakistani adults with impaired glycaemia at high risk of developing type 2 diabetes

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Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Public health, Health economics
Keywords:	randomised controlled trial, PREVENTION, diabetes mellitus, Type 2, ethnic groups

TITLE

Design and baseline characteristics of the PODOSA (Prevention of Diabetes & Obesity in South Asians) trial: a cluster, randomised lifestyle intervention in Indian and Pakistani adults with impaired glycaemia at high risk of developing type 2 diabetes

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ABSTRACT

Objectives: To describe the design and baseline population characteristics of an adapted, lifestyle intervention trial aimed at reducing weight and increasing physical activity in people of Indian and Pakistani origin at high risk of developing type 2 diabetes.
Design: Cluster, randomised controlled trial.
Setting: Community-based in Edinburgh and Glasgow, Scotland, UK.
Participants: 156 families, comprising 171 people with impaired glycaemia, and waist sizes ≥ 90 cm (men) and ≥ 80 cm (women), plus 124 family volunteers.
Interventions: Families were randomised into either an intensive intervention of 15 dietitian visits providing lifestyle advice, or a light (control) intervention of 4 visits, over a period of 3 years.
Outcome measures: The primary outcome is change in mean weight between baseline and three years. Secondary outcomes are changes in waist, hip, Body Mass Index (BMI), plasma blood glucose and physical activity. The cost of the intervention will be measured. Qualitative work will seek to understand factors that motivated participation and retention in the trial and families' experience of adhering to the interventions.
Results: Between July 2007 and October 2009, 171 people with impaired glycaemia, along with 124 family volunteers were randomised. 95% (171/196) of eligible participants agreed to proceed into the 3-year trial. Only 13 of the 156 families contained more than one recruit with impaired glycaemia. We have recruited sufficient participants to undertake an adequately powered trial to detect a mean difference in weight of 2.5 kg between the intensive and light intervention groups at the 5% significance level. Over half the families include family volunteers. The main participants have a mean age of 52 years and 64% are female.
Conclusions:
PODOSA is one of the first community-based, randomised, lifestyle intervention trials in a UK South Asian population. The main trial results will be submitted for publication during 2013.

Trial registration: Current controlled trials ISRCTN25729565 (http://www.controlled-trials.com/isrctn/).

ARTICLE SUMMARY

Article Focus

- Randomised controlled trial.
- Diabetes prevention via weight loss and physical activity.
- South Asians living in Scotland, UK.

Key Messages

- The worldwide prevalence of type 2 diabetes has doubled over the past 25 years and South Asians, including those in the UK, are at particularly high risk of developing the disease,
- PODOSA is one of the first community-based randomised, lifestyle intervention trials focusing on the UK South Asian population, and is taking place in Scotland, UK.
- The dietitian led intervention is family focussed, based in the home and is culturally adapted from the Finnish Diabetes Prevention Study, for people of Indian and Pakistani origin.
- The primary outcome is weight change over 3 years, the main driver for prevention or delay of onset of type 2 diabetes. The trial is on course to report in 2013.

Strengths and Limitations of this Study

- The study is one of few randomised trials specifically for an ethnic minority population in the UK
- The results should provide valuable evidence for tackling the high levels of diabetes in UK South Asians
- The study could not recruit sufficient people to examine progression to diabetes within the original timeframe, but it is planned do this over the longer term via data linkage to national health records.

BACKGROUND

Diabetes mellitus is a serious disease that reduces life expectancy by around six years from middle age,[1] and increases the risk of blindness, heart disease, stroke and kidney failure. The age-standardised prevalence of diabetes worldwide was over 9% (9.8% for men, 9.2% for women) in 2008. This translates to around 347 million people with diabetes globally, more than double the number from 1980 (153 million).[2] Estimates show that in India, the number of adults with diabetes will increase from 50 million in 2010 to at least 87 million by 2030.[3] In the UK in 2010 there were an estimated 3.4 million people with type 2 diabetes mellitus (henceforth diabetes), resulting in direct costs to the NHS of £8.8bn.[4] The adult age-standardised prevalence of diabetes in UK South Asians (defined here as UK residents with ancestral origins in the Indian Subcontinent) is about 2-6 times that of the general population with probable higher progression rates from impaired glycaemia to diabetes, although robust data are lacking.[5-7]

There is clear evidence from a number of diabetes prevention trials in adults at elevated risk for diabetes, that lifestyle intervention focusing on modest weight loss (5-10% of body weight) and increased physical activity, is effective at preventing or delaying diabetes.[8-10] Such interventions have been found to be effective in a number of ethnic groups including 'Asians' living in the US[10] and Indians living in India.[11] The evidence from randomised trials has been summarised and published by the Centres for Disease Control and Prevention Primary Prevention Working Group (2004).[12] They conclude that maintenance of moderate weight loss through diet and physical activity reduces the incidence of diabetes by 40 to 60% over 3-4 years. A review of evidence and application in a UK setting by Davies et al, showed that major benefits accrue from 5-10% body weight loss and 150 minutes per week of physical activity similar in intensity to brisk walking.[13] They suggest a need to develop and evaluate interventions that target communities and populations at risk in the UK.

In the UK, the National Service Framework for Diabetes' (NSFD) first standard is to reduce the number of people who develop diabetes and to reduce inequalities in this disease. The NSFD[14] and the Scottish Government Diabetes Action Plan 2010[15] place emphasis on the need to prevent and control diabetes in the UK's minority ethnic populations (highlighting the high rates in South Asians) through implementation of effective and culturally relevant interventions. The main risk factors for diabetes, principally weight gain and physical inactivity, need tackling in these populations, but there are no UK trial data to guide either practice or policy.

The current challenge is to adapt existing interventions to meet the cultural needs of South Asians, and to demonstrate efficacy in the UK context, as it has been suggested that strategies that work in some societies may not work in others, as different social, economic, political and cultural environments will affect diet and lifestyle.[13] We based the Prevention of Diabetes and Obesity in South Asians (PODOSA) trial on the Finnish Diabetes Prevention study, which demonstrated the effectiveness of an individual focused behavioural intervention that promoted weight loss and increased physical activity in preventing diabetes in a general population.[9] PODOSA's key adaptations are to shift the emphasis from the individual to the family and from the clinic to the household. A cluster design was chosen firstly to maximise participation and help achieve behaviour change, by recognising the fact that most health-related behaviours take place within the family or home setting and other family members

may, for example, be involved in food preparation (supplementary information in the NSFD).[14] Secondly, this design would limit potential 'contamination' where close members of a family were in different arms of the trial, but sharing information. For reasons already described[16,17] recruitment proved difficult and the primary aim was changed from a reduction in the incidence of diabetes, to weight loss, as this needed a smaller sample size.

The PODOSA trial thus aims to test the effectiveness and cost-effectiveness of an intervention designed to reduce weight and increase physical activity in adults at high risk of diabetes indicated by Impaired Glucose Tolerance (IGT) or Impaired Fasting Glycaemia (IFG), thereby preventing or delaying diabetes. The aim of this paper is to describe the trial design and methods and baseline characteristics of participants and family volunteers.

METHODS / DESIGN

Study design and questions

PODOSA is a cluster, randomised controlled trial, the 'cluster' represented by a family. The original protocol written in 2007 was designed to answer the primary question 'Does a family-based three-year programme promoting weight loss and increased physical activity in South Asians, modelled on interventions of proven effectiveness internationally, reduce the incidence of type 2 diabetes in South Asians?' However due to recruitment challenges,[16] a substantial amendment was approved by the ethics committee in 2009 to alter the primary outcome as detailed above.

The principal research questions that we are pursuing are therefore now:

- Does a family-based three-year programme promoting weight loss and increased physical activity in South Asians with IGT and/or IFG, modelled on interventions of proven effectiveness internationally, result in a clinically meaningful weight loss in the intensive intervention (15-visit) group compared to the light intervention (4-visit) group?
- What is the cost effectiveness of the intervention?
- What factors assist recruitment, adherence with advice given, and retention in the trial?

In addition to participants with impaired glycaemia, we invited adult members of their families to take part, mainly to support the trial participants in the process of lifestyle change. We made limited measurements on the family volunteers both to motivate them in changing their own lifestyles and to help assess the potential benefits to family members outside the main intervention groups.

The secondary research questions which are designed to help interpret the main outcomes, are:

- During the trial what changes occur over time among participants with IGT and/or IFG, and volunteer members of their families (analysed separately), in
    - waist circumference?
    - hip circumference?
    - fasting and 2-hour blood glucose (IGT/IFG recruits only)?
    - incidence of type 2 diabetes presently (and in the longer term, to be assessed via data linkage)?

The primary outcome is mean weight change between baseline and three years. Our goal is weight loss of 2.5 kg more (or 2.5 kg lower weight gain) in the intensive intervention than in the light intervention group and increase in physical activity to at least 30 minutes daily. Ideally we would reduce the Body Mass Index (BMI) to at least 25 or preferably 23 (the interim World Health Organisation (WHO) recommendation for Asian populations). [18]

Secondary outcome measures of interest are:

- Mean changes between baseline and 3 years in waist and hip circumference, BMI, fasting and 2-hour post- Oral Glucose Tolerance Test (OGTT) glucose
- Cost effectiveness of the intervention (focusing on health service costs of the intervention and the opportunity cost of time for trial participants)
- Progression to type 2 diabetes in the longer term

For volunteer members of the family these are:

- Mean changes between baseline and 3 years in weight, BMI, and waist and hip circumference

Ethical approval

Ethical approval was obtained from the Scotland A Research Ethics Committee. All recruits gave written, informed consent to take part in the screening stage of the study and then further written consent for participation in the three year trial.

Setting and Recruitment

Recruitment took place between July 2007 and October 2009. Indian and Pakistani origin men and women aged 35 years and over living in the Lothian and Greater Glasgow & Clyde Health Boards areas were invited to be screened with the (OGTT).

Eligibility criteria

Eligible participants for the trial were those with:

- waist sizes ≥ 90 cm for men and ≥ 80 cm for women
- IGT (i.e. fasting plasma glucose of < 7 mmol/l and, following a standard OGTT, two-hour plasma glucose of 7.8-11.0 mmol/l)
- and/or IFG (ie plasma fasting glucose of 6.1 – 6.9 mmol/l)
- no previous diagnosis of diabetes
- 'family cook' agreed to cooperate (whether the main recruit, a family volunteer or another family member).

Participants on prescribed long-term oral corticosteroids, suffering from a health condition where adherence to the intervention was contraindicated or improbable, or unlikely to remain in the UK for 3 years, were excluded from trial entry.

The waist criteria correspond to the cut-off points recommended by the International Diabetes Federation Consensus Group in 2005 to identify South Asians at risk of diabetes.[19]

Eligibility family volunteers were:

- ≥ 18 years of age
- Close relative of the IGT/IFG participant either living within the same household, or living nearby and interacting with main recruit(s) on at least a weekly basis

Definition of a family (cluster)
The composition of families was established in consultation with the family itself. Criteria were defined to identify each extended family unit prior to randomisation. To minimise contamination, first degree relatives (parents, siblings, children) living in the same city could not be randomised separately. The cluster is 'the core family' consisting of the participant(s) with IGT/IFG, plus any family volunteer(s). In practice, given the relatively low prevalence of IGT or IFG (15%), compared to 30% expected, clustering was less common than predicted.

Sample size considerations
In the original study design it was anticipated that there would often be at least two eligible individuals per family (i.e. per cluster), so the fact that we were using a cluster randomised design was critical in the power calculation. However when the primary endpoint was amended to weight change, it was clear that the vast majority of 'clusters' would comprise a single individual. Thus, in practice, the impact of clustering will be negligible, and the modified power calculation did not take this into account. The target sample size for the amended trial was calculated to be 175 recruits to allow for a 10% drop-out. This would result in at least 150 recruits having complete follow up at 3 years. This sample size gives adequate (86%) power to detect a difference of 50% of the standard deviation (SD) (i.e. a mean difference in weight change of 2.5 kg between the two groups against a common background SD of 5 kg, derived using nQuery Advisor Version 7.0) at the 5% significance level (2-sided).

Randomisation and allocation of interventions
Randomisation lists were produced by the trial statistician using a random number generator program. Permuted blocks were used and block size varied randomly. Stratification was by location (Edinburgh or Glasgow), ethnic group (Indian or Pakistani), and number of IGT/IFG recruits in the family (1 or more than 1). All members of a 'family' gave written informed consent and completed the baseline visit prior to randomisation. Allocation of intervention group was then performed centrally, by the trial statistician or a deputy, independently from the dietitians and trial office staff. This strategy was implemented to minimise selection bias during the recruitment process and meant that both the dietitians and the families did not know the allocated intervention until enrolment and baseline measurements had been completed. As in other lifestyle prevention trials, blinding of the intervention was not feasible.

The study has two groups for comparison, one group having more frequent and tailored contact (intensive or 15 visit intervention) with the research dietitians than the 'control' group (light or 4 visit intervention), which largely receives information. The 15 visit group of 78 families received 15 contacts over three years, monthly for 3 months and thereafter quarterly. The 4 visit group of 78 families had annual contact over three years with the dietitian. The dietitians visited the participating families at their home or community setting of their choice.

Measurements and data collection
Prior to recruitment commencing, pilot work was carried out for the main trial procedures, covering consent, measurements and OGTT, and the screening and baseline visits. Table 1 outlines the time-points for consent, randomisation and collection of data for the main trial outcomes for all trial participants. Anthropometric measurements, background and outcome data were collected by the dietitians in the case record forms at each visit. Standard operating procedures were written for all the main study procedures including anthropometric measurements and the oral glucose tolerance test. Two measurements for height, weight, waist and hip were performed and if the difference was more than a specified value (height, waist and hip > 1cm, weight > 0.2kg), a third measurement was carried out. Physical activity was assessed by the short form of the International Physical Activity Questionnaire (IPAQ).[20] Time spent sitting, walking, and undertaking moderate and vigorous activities, was extracted

from the IPAQ with time spent walking and in moderate and vigorous activities truncated at 180 min per day in line with the published IPAQ data processing guidelines (www.ipaq.ki.se).

Data were entered by the study assistant into a Microsoft Access database which has inbuilt validity and consistency checks. Subsequent data cleaning was performed by further manual and statistical checking. Double data entry was carried out for the key variables relating to the main trial outcomes, including randomisation criteria, all anthropometric and biomedical measures, and demographic and health economics data.

Three of four research dietitians were employed throughout the full study period and followed up the families for the full three years. The fourth dietitian left the research team in 2009 and her families were distributed amongst the remaining three dietitians. To counteract any potential observer bias when recording the key endpoint variables at the 3-year visits, an independent set of anthropometric measures (in addition to those recorded by the dietitians) were recorded by trained research nurses, blinded to study group.

Measurements for volunteer members of the family

As shown in Table 1, weight and waist and hip circumferences, were measured annually in adult family volunteers with and without diabetes (no blood tests were done).

Intervention for 15 visit group

The research dietitians were trained in venepuncture, measurement, delivery of information, behaviour change, and promotion of physical activity. The contacts with the families were, in effect, the intervention and in general each family was seen by the same dietitian for the duration of the trial. The content of the contacts were tailored, using a range of culturally adapted change management tools, to the needs of individuals and families. The dietitians motivated participating families to achieve weight loss through a calorie deficit diet in conjunction with physical activity. Verbal and written advice was provided including information on shopping, cooking (with demonstrations), and entertaining. Participants were invited to annual group sessions consisting of a food shopping tour, understanding food labels, exchange of recipes, food tasting and. brisk walking. The dietitians' toolkit (which will be published on the PODOSA website, www.podosa.org, by the end of March 2013, contained culturally adapted and translated existing resources on diet and physical activity such as Counterweight.[21] A paper on the cultural adaptation process of the study materials has been accepted for publication (subject to minor revisions) by Health Promotion International. Pedometers were integral to the physical activity programme, providing motivation through self-monitoring and a tool for the dietitians to assess progress. Daily food diaries and pedometer logs, body weight and waist circumference data and the Chester Step Test[22] were used as educational and motivational tools by the dietitians.

Intervention for 4 visit group

This group had a baseline and then annual contact with the research dietitian. The dietitians gave both written and verbal advice on healthy eating, diabetes prevention, promotion of physical activity and on accessing available health services for weight control and physical activity. The research team agreed which resources should be given to families in the 4-visit group at each visit, to ensure consistency. While these actions were better than routine service, it is not anticipated they will reduce weight substantially and sustainably, but they may stabilise it, and counteract the secular trend and age effects of increasing weight.[23] This level of intervention was, we judge, necessary on ethical grounds. It also offered something in return for participation and measurements.

Measurement and valuation of costs

The PODOSA trial design included an integrated cost analysis. Cost data were collected prospectively from randomisation (baseline) to the 3 year follow-up. We chose a societal perspective for the analysis which encompassed the health service costs of the intervention and the opportunity cost of time for trial participants. The programme costs included the number and length of home visits by research dietitians and self-reported health service use in primary and acute care settings. Initial screening and trial recruitment costs were excluded. We valued dietitians' time (face-to-face contact, pre- and post-visit review and travel to participants' households) using NHS salary scales inclusive of salary on-costs and overheads. Standard NHS unit costs were used to value General Practitioner visits and hospital out-patient clinic attendances. Participant time included the number and length of dietitian visits and self-reported time spent doing moderate physical activities and on household allocation of time for food shopping and meal preparation. Median hourly wages by gender and ethnicity reported by the National Equality Panel/Labour Force Survey[24] were used to value participant time. No estimate of diet costs was included. The present value of the three year cumulative costs was calculated using a 3.5% annual rate of discount following UK Treasury and NICE guidance. All costs are reported in UK pounds using 2010 pay and price levels.

All analyses will be conducted on an intention-to-treat basis. The conditional mean cost comparison between 15-visit and 4-visit groups will be modelled using linear regression and generalised linear parametric methods. The mean cost difference between the groups will also be assessed using a non-parametric bootstrap. Quantile regression will be used to examine and compare the median cost differences. The relatively small sample size precludes assessment of heterogeneous treatment effects or sub-group differences in costs.

The robustness of results will be investigated using a strategy of comparing different specifications within the generalised linear model and conducting a series of one-way sensitivity analyses, where we will alter key assumptions on programme intensity and frequency as measured by the number, length and duration of visits. The cost implications arising from moving away from a one-to-one programme towards a group based intervention will also be considered.

Qualitative study

An embedded qualitative study was undertaken to:

- Obtain a rich and multi-faceted understanding of the main motivations for participation in an intervention study of Indian and Pakistani adults who are at high risk of developing diabetes.
- Investigate participants' perceptions of fidelity and faithfulness to the interventions offered both during and after participation.
- Understand the factors that may help promote retention of participants once enrolled.

We utilised storytelling to collect narratives describing the lived experiences of participation in PODOSA from families at completion of the trial. The objective was to try to understand what factors motivate ethnic minority people to engage with research and to understand more about the facilitators to participation through understanding the perspectives and experiences of those who chose to participate in the trial.

A detailed description of our methods will be reported in due course, but in summary, we undertook purposeful sampling on the basis of age, sex, ethnicity, faith group, geographical location, and trial arm to ensure recruitment of a maximum diversity sample. We also sought to include family volunteers when possible. Biographical narrative interviews were

undertaken usually in participants' homes and in their preferred language, with the aid of a translator, if necessary. These interviews were digitally recorded, translated (if necessary) and then transcribed together with accompanying field notes. Analysis was undertaken in an iterative fashion, thus informing further data collection. Thematic and performance analysis[25] of the data utilised the constant comparison method[26] concurrent to data generation, utilising NVivo9 software to code data during analysis.

Laboratory assessments

The 75 g OGTT followed standardised procedures, with venous blood samples taken after an overnight fast of 10–16 hours and 2 hours after ingestion of 75 g glucose. Samples were then transported to a central hospital laboratory (Western General Hospital, Edinburgh or Glasgow Royal Infirmary) where plasma glucose concentration was determined using the Ortho clinical diagnostics, Fusion dry ice method (Edinburgh), or the Abbott Architect, hexokinase/glucose-6-phosphate dehydrogenase method (Glasgow). Both laboratories participate in the UK National External Quality Assessment Service (UK NEQAS) scheme. In addition, an EDTA sample was obtained from all recruits at baseline and at three years, and with the participant's specific informed consent, plasma and DNA aliquots stored at -80˚C, for future analyses outwith the remit of the current trial.

Statistical analysis

Analyses will be performed on an intention-to-treat basis, i.e. participants will be analysed in the group that they were randomised to regardless of how much of the intervention they received, unless specified otherwise.

Due to the clustering inherent in the design, the primary outcome will be analysed using a random effects linear regression model (to accommodate the clustering of individuals within families) with maximum likelihood estimation. The model will be adjusted for the stratification variables (ethnicity and location). Change over time will be incorporated into the model using an extension to the analysis of covariance (ANCOVA) approach, adjusting for baseline value. Treatment group will be included in the model as a fixed effect. Results will be reported as an adjusted (for ethnicity and location) mean difference in weight between baseline and three years, with a 95% confidence interval and corresponding p-value. The intra-class correlation coefficient will be reported.

Analyses of secondary outcomes will mirror those for the primary outcome, where the distribution of the relevant outcome is continuous. Where the outcome is a proportion, the approach will be to fit a generalised linear mixed model with terms for stratification variables and treatment group as above and adjusting for baseline value where applicable. Results will be reported as an adjusted odds ratio with a 95% confidence interval and corresponding p-value.

RESULTS

Recruitment

As shown in Figure 1, 1319 participants were screened with an OGTT over a 27 month period between July 2007 and October 2009. 102 recruits (8%) had OGTT results indicative of diabetes and 196 (15.4%) were found to have impaired glycaemia. 16 participants did not meet eligibility criteria to proceed into the full trial and nine declined to participate further. Thus, 95% (171/196) agreed to continue into the three year trial. 156 family clusters comprising the 171 eligible participants with IGT and/or IFG, along with 124 family volunteers, were randomised into either the 15 visit or 4 visit intervention groups.

Baseline characteristics of the trial population

Baseline characteristics are shown in Table 2. The families range from single participants to a family comprising 4 IGT/IFG recruits with 5 family volunteers. Only 13 of the 156 trial families have more than one recruit with IGT/IFG. Family volunteers were recruited to 85 families. The trial population are well established in the UK with mean residency time of around 31 years. Approximately 33% of the participants have no formal educational qualifications.

Table 2 shows that approximately 84% of family cooks are either the IGT/IFG person or a family volunteer. The remainder all agreed to cooperate. Over a third of the participants had a close family history of diabetes.

Part (c) of Table 2 describes lifestyle characteristics of participants. Average total activity time (comprising vigorous, moderate and brisk walking) for the trial population was 51 minutes per day. Mean sitting time was 6.5 hours per day.

Mean BMI for all recruits was 30.5 kg/m^2 and overall 49% of participants had BMI > 30 kg/m^2.

Table 3 shows demographic and anthropometric characteristics of the 124 family volunteers. Most volunteers were female (77%) and 64/124 (52%) were the spouse or partner of the index recruit. Over 90% of the family volunteers were recruited in Glasgow. The mean BMI of family volunteers was 27.4 kg/m^2.

DISCUSSION

Principal achievements

The PODOSA trial's key achievements include: establishing the infrastructure for the trial; recruiting, training and forging a multi-ethnic team to implement the trial; and the involvement and support from within the wider South Asian community, particularly in the recruitment phase.[17] It was encouraging that 95% of eligible recruits consented to participate in the 3 year trial (171/196). We emphasised the need for family involvement as a means of motivating behaviour change and set the complex intervention in the home setting. Our only entry criterion relating to the family was that the main cook agreed to co-operate and this was always achieved. We consider this a major success. It proved harder to recruit family volunteers in Edinburgh than in Glasgow. It was difficult to identify clear reasons for this but the dietitians reported that, in many instances, potential volunteers were either unavailable or did not interact or eat with the main recruits with sufficient frequency.

The proportion of Pakistani to Indian recruits (2:1) in PODOSA closely reflects the wider resident South Asian population as reported in the 2001 Scottish census where those of Pakistani origin represented 31% of the total minority ethnic population and 15% were of Indian origin.[27]

Strengths and weaknesses

PODOSA, to our knowledge, is one of the first culturally adapted, community based, randomised intervention trials on lifestyle and health issues in South Asians in the UK. PODOSA will contribute evidence for weight control and diabetes specifically, however, its long-term legacy will be the experience, lessons and example of the evaluation of complex interventions in ethnic minority populations set in the community in the UK multi-ethnic society.

Although we were unable to recruit sufficient numbers to examine, with sufficient power, progression to diabetes within the life of the trial, we have participants' consent to link trial data to Scottish national morbidity and diabetes register data during a 10 year follow up period. This may allow analysis of this outcome in the longer term. However weight loss, our new primary outcome, is the main driver for diabetes prevention, and physical activity, a secondary outcome, is also important.

Putting the study in context

Based on available evidence in 2005 at the design stage of the trial,[5,19] we set eligibility criteria for waist circumference (≥ 90 cm for men and ≥ 80 cm for women) as those with central obesity are more likely to have impaired glycaemia. We estimated that we would identify IGT in around 30% of such volunteers screened for trial eligibility.[5] Within PODOSA the prevalence rate for IGT and/or IFG was approximately 15%, much lower than expected. The Leicester (UK) Addition study reported finding 19.8% IGT or IFG in South Asians aged 40-75 years, with no minimum waist size.[28] A recent systematic review[29] of cross-sectional studies in South Asians also suggests a stable or falling IGT prevalence, although the natural history of pre-diabetes and its progression to diabetes still remains unclear. Our lower prevalence rate of impaired glycaemia was one of the contributory factors to our difficulty in achieving the original intended sample size.

Within the UK, the case for national screening programmes for both diabetes and impaired glycaemia remains equivocal.[30] Recent research has suggested that the case is stronger than it was, although evidence from good quality trials showing a subsequent reduction in morbidity and mortality is still required.[31] Hanif et al argue that a stepwise screening strategy aimed at the South Asian population could be effective although further work is needed to examine implementation within primary care.[32] The Addition Leicester trial,[6] a community screening programme and cardiovascular risk intervention, includes a significant South Asian population and is due to report in 2013. The results from PODOSA, also expected in 2013, will contribute to urgently needed evidence about the effectiveness of prevention interventions in a UK ethnic minority population at high risk of developing diabetes.

Implications

South Asians are at high risk of developing type 2 diabetes and effectiveness data for culturally tailored health care interventions are urgently required in order to help prevent this epidemic and to help inform health care services and policy in the UK. The trial results, including cost-effectiveness and qualitative findings, will be submitted for publication in

2013. In particular, this study has focussed on the family rather than the individual and moved from the traditional clinic, to a home setting. This kind of approach has been promoted in guidance from NSFD and the National Institute for Health and Clinical Excellence (NICE),[14,33] so evidence from PODOSA will be pertinent to this line of argument. More generally, PODOSA will also contribute to the evidence base for conducting randomised lifestyle intervention trials in ethnic minority populations in the UK and contribute to future meta-analyses with on-going diabetes prevention trials in other South Asian populations.

Table 1 Time points of outcome measures and data collection

Time Point (Months)	Name of Visit	Informed consent	OGTT & blood sample for storage	Anthropometric measurements	Demographic, socio-economic self-reported medical history	Costs and health resource use	Physical activity data	Delivery of Intervention (intensive or light)
-1*	Screen	✓	✓		✓			
0* +	**Baseline**	✓ +		✓ +	✓	✓	✓	General information on diabetes, diet and physical activity to all participants
0*+ (plus 1 week)	**Family (as the cluster) randomised to 15 or 4 visit group**							
1	Interim			✓		✓		✓
2	Interim			✓		✓		✓
3	Interim			✓		✓		✓
6	Interim			✓		✓		✓
9	Interim			✓		✓		✓
12* +	**Annual**			✓ +	✓	✓	✓	**Intensive or light**
15	Interim			✓		✓		✓
18	Interim			✓		✓		✓
21	Interim			✓		✓		✓
24* +	**Annual**			✓ +	✓	✓	✓	**Intensive or light**
				✓		✓		✓
27	Interim			✓		✓		✓
30	Interim			✓		✓		✓
33	Interim			✓		✓		✓
36* +	**Annual**		✓ (OGTT repeated if positive for diabetes)	✓ +	✓	✓	✓	**Intensive or light**

* Measurements and data collected similarly for participants in intervention and control groups – or prior to randomisation

+ Indicates time points and data collection for Family Volunteers

Table 2. Recruits with IFG and/or IGT

Demographic, social, lifestyle, anthropometric, biochemical and other background characteristics of trial participants. Figures are numbers and column percentages unless otherwise stated

Variables	All participants No.	(column %)
a) Demographic		
No. of families with-		
1 IGT/IFG recruit	143	(91.7)
2 IGT/IFG recruits	12	(7.7)
4 IGT/IFG recruits	1	(0.6)
No. of families with-		
with family volunteer(s)	85	(54.5)
No. of IGT/IFG individuals	171	(100)
No. family volunteers	124	(100)
Individual IGT/IFG recruits		
Sex – male	78	(45.6)
Age – mean (SD)	52.3	(10.1)
Age – range	35-80	
Location		
– Glasgow	132	(77.2)
– Edinburgh	39	(22.8)
Ethnic group		
– Indian	57	(33.3)
– Pakistani	114	(66.7)
Religion		
– Muslim	114	(66.7)
– Hindu	15	(8.8)
– Sikh	39	(22.8)
– Other	3	(1.8)
b) Social circumstances		
Cook was a participant	85	(49.7)
Cook was a family volunteer	59	(34.5)
Cook was simply cooperating	27	(15.8)
Blood relative with diabetes	118	(69.0)
Years lived in UK (mean, SD)	31.4	(13.1)
Education:		
no qualifications	56	(32.7)
school level	49	(28.7)
further or higher education	66	(38.6)

continued

Table 2. Continued

Variables	All participants No.	(column %)
c) Lifestyle		
Current smoking/chewing tobacco	11	(6.4)
Currently drinks alcohol	19	(11.1)
Vegetarian	26	(15.2)
Physical activity (**mean minutes per day, SD**)		
– Total (moderate, vigorous, walking)	51.0	(61.0)
– Moderate and vigorous only	23.3	(44.7)
– Walking only	27.7	(37.1)
– Sitting time (mean hours per day, SD)	6.5	(3.0)
d) Anthropometric (Values are given as mean and SD)		
Height (cm)	161.9	(9.3)
Weight (kg)	80.2	(15.6)
BMI (kg/m^2)	30.5	(4.8)
Waist (cm)	103.0	(11.1)
Hip (cm)	107.1	(9.5)
Waist/hip ratio	0.96	(0.07)
BMI < 25 (n,%)	20	(11.7)
BMI ≥ 25 and <30 (n,%)	67	(39.2)
BMI ≥ 30 (n,%)	84	(49.1)
e) Biomedical measures (Values are given as mean and SD)		
Systolic BP (mmHg)	136.9	(20.6)
Diastolic BP (mmHg)	83.0	(11.5)
Fasting plasma glucose (mmol/l)	5.8	(0.6)
2-hr post OGTT plasma glucose (mmol/l)	8.3	(1.6)
Current medications (n,%)		
– Antihypertensives	48	(28.1)
– Cholesterol lowering	39	(22.8)

Table 3 Family volunteers
Demographic, anthropometric and other background characteristics of family volunteers. Figures are numbers and column percentages unless otherwise stated

	All family volunteers No.	(column %)
a) Demographic		
Sex – male	28	(22.6)
Age – mean (SD)	41.9	(14.9)
Age – range	18 – 75	
Location		
– Glasgow	114	(91.9)
– Edinburgh	10	(8.1)
Ethnic group		
– Indian	42	(33.9)
– Pakistani	79	(63.7)
– Other	3	(2.4)
Relationship to main recruit		
– Spouse/partner	64	(51.6)
– Parent	2	(1.6)
– son/daughter	26	(21.0)
– brother/sister	5	(4.0)
– other	27	(21.7)
b) Anthropometric (Values are given as mean and SD)		
Height (cm)	161.7	(8.5)
Weight (kg)	71.4	(13.9)
BMI (kg/m^2)	27.4	(5.3)
Waist (cm)	92.7	(12.4)
Hip (cm)	104.7	(8.6)
Waist/hip ratio	0.89	(0.08)
c) Biomedical		
No. with diabetes (self-reported)	15	(12.1)

Authors' contributions

AD and RSB drafted the manuscript and are joint guarantors. SW, RuB and AS are research dietitians carrying out the study recruitment, screening and interventions. RSB, SW, JFF, JMG, JMcK, GM, NS, SWild, ASheikh and AD helped plan the trial. All authors contributed to the interpretation of the data and writing of the manuscript. Prof Mike J E Lean and Prof Jaakko Tuomilehto contributed to planning the trial but are not authors on this paper.

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Competing Interests None

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Ethics approval Ethical approval was obtained from the Scotland A Research Ethics Committee (reference number 07-MRE10-2)

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TITLE

Design and baseline characteristics of the PODOSA (Prevention of Diabetes & Obesity in South Asians) trial: a cluster, randomised lifestyle intervention in Indian and Pakistani adults with impaired glycaemia at high risk of developing type 2 diabetes

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ABSTRACT

Objectives: To describe the design and baseline population characteristics of an adapted, lifestyle intervention trial aimed at reducing weight and increasing physical activity in people of Indian and Pakistani origin at high risk of developing type 2 diabetes.
Design: Cluster, randomised controlled trial.
Setting: Community-based in Edinburgh and Glasgow, Scotland, UK.
Participants: 156 families, comprising 171 people with impaired glycaemia, and waist sizes ≥ 90 cm (men) and ≥ 80 cm (women), plus 124 family volunteers.
Interventions: Families were randomised into either an intensive intervention of 15 dietitian visits providing lifestyle advice, or a light (control) intervention of 4 visits, over a period of 3 years.
Outcome measures: The primary outcome is change in mean weight between baseline and three years. Secondary outcomes are changes in waist, hip, Body Mass Index (BMI), plasma blood glucose and physical activity. The cost of the intervention will be measured. Qualitative work will seek to understand factors that motivated participation and retention in the trial and families' experience of adhering to the interventions.
Results: Between July 2007 and October 2009, 171 people with impaired glycaemia, along with 124 family volunteers were randomised. 95% (171/196) of eligible participants agreed to proceed into the 3-year trial. Only 13 of the 156 families contained more than one recruit with impaired glycaemia. We have recruited sufficient participants to undertake an adequately powered trial to detect a mean difference in weight of 2.5 kg between the intensive and light intervention groups at the 5% significance level. Over half the families include family volunteers. The main participants have a mean age of 52 years and 64% are female. ~~Almost half our recruits could be classified obese according to the conventional WHO cut-off point of BMI > 30 kg/m2.~~
Conclusions:
PODOSA is one of ~~few~~ the first community-based, randomised, lifestyle intervention trials in a UK ~~ethnic minority~~South Asian population. ~~We have recruited sufficient participants to undertake an adequately powered trial to detect a mean difference in weight of 2.5 kg between the intensive and light intervention groups at the 5% significance level.~~ The main trial results will be submitted for publication ~~in~~ during 2013.

Trial registration: Current controlled trials ISRCTN25729565 (http://www.controlled-trials.com/isrctn/).

ARTICLE SUMMARY

Article Focus

- Randomised controlled trial.
- Diabetes prevention via weight loss and physical activity.
- South Asians living in Scotland, UK.

Key Messages

- The worldwide prevalence of type 2 diabetes has doubled over the past 25 years and South Asians, including those in the UK, are at particularly high risk of developing the disease,
- PODOSA is one of the first community-based randomised, lifestyle intervention trials focusing on the UK South Asian population, and is taking place in Scotland, UK.
- The dietitian led intervention is family focussed, based in the home and is culturally adapted from the Finnish Diabetes Prevention Study, for people of Indian and Pakistani origin.
- The primary outcome is weight change over 3 years, the main driver for prevention or delay of onset of type 2 diabetes. The trial is on course to report in 2013.

Strengths and Limitations of this Study

- The study is one of few randomised trials specifically for an ethnic minority population in the UK
- The results should provide valuable ~~information to contribute to existing~~ evidence for tackling the high levels of diabetes in UK South Asians
- The study ~~is not powered~~could not recruit sufficient people to examine progression to diabetes within the original timeframe, but it is planned do this ~~in~~ over the longer term via data linkage to national health records.

BACKGROUND

Diabetes mellitus is a serious disease that reduces life expectancy by around six years from middle age,[1] and increases the risk of blindness, heart disease, stroke and kidney failure. The age-standardised prevalence of diabetes worldwide was over 9% (9.8% for men, 9.2% for women) in 2008. This translates to around 347 million people with diabetes globally, more than double the number from 1980 (153 million).[2] Estimates show that in India, the number of adults with diabetes will increase from 50 million in 2010 to at least 87 million by 2030.[3] In the UK in 2010 there were an estimated 3.4 million people with type 2 diabetes mellitus (henceforth diabetes), resulting in direct costs to the NHS of £8.8bn.[4] The adult age-standardised prevalence of diabetes in UK South Asians (defined here as UK residents with ancestral origins in the Indian Subcontinent) is about 2-6 times that of the general population with probable higher progression rates from impaired glycaemia to diabetes, although robust data are lacking.[5-7]

There is clear evidence from a number of diabetes prevention trials in adults at elevated risk for diabetes, that lifestyle intervention focusing on modest weight loss (5-10% of body weight) and increased physical activity, is effective at preventing or delaying diabetes.[8-10] Such interventions have been found to be effective in a number of ethnic groups including 'Asians' living in the US[10] and Indians living in India.[11] The evidence from randomised trials has been summarised and published by the Centres for Disease Control and Prevention Primary Prevention Working Group (2004).[12] They conclude that maintenance of moderate weight loss through diet and physical activity reduces the incidence of diabetes by 40 to 60% over 3-4 years. A review of evidence and application in a UK setting by Davies et al, showed that major benefits accrue from 5-10% body weight loss and 150 minutes per week of physical activity similar in intensity to brisk walking.[13] They suggest a need to develop and evaluate interventions that target communities and populations at risk in the UK.

In the UK, the National Service Framework for Diabetes' (NSFD) first standard is to reduce the number of people who develop diabetes and to reduce inequalities in this disease. The NSFD[14] and the Scottish Government Diabetes Action Plan 2010[15] place emphasis on the need to prevent and control diabetes in the UK's minority ethnic populations (highlighting the high rates in South Asians) through implementation of effective and culturally relevant interventions. The main risk factors for diabetes, principally weight gain and physical inactivity, need tackling in these populations, but there are no UK trial data to guide either practice or policy.

~~Therefore t~~The current challenge is to adapt existing interventions to meet the cultural needs of South Asians, and to demonstrate efficacy in the UK context, as it has been suggested that strategies that work in some societies may not work in others, as different social, economic, political and cultural environments will affect diet and lifestyle.[13] We based the Prevention of Diabetes and Obesity in South Asians (PODOSA) trial on the Finnish Diabetes Prevention study, which demonstrated the effectiveness of an individual focused behavioural intervention that promoted weight loss and increased physical activity in preventing diabetes in a general population.[9] PODOSA's key adaptations are to shift the emphasis from the individual to the family and from the clinic to the household. A cluster design was chosen firstly to maximise participation and help achieve behaviour change, by recognising the fact that most health-related behaviours take place within the family or home setting and other family members

may, for example, be involved in food preparation (supplementary information in the NSFD).[14] Secondly, this design would limit potential 'contamination' where close members of a family were in different arms of the trial, but sharing information. For reasons already described[16,17] recruitment proved difficult and the primary aim was changed from a reduction in the incidence of diabetes, to weight loss, as this needed a smaller sample size.

The PODOSA ~~(Prevention of Diabetes and Obesity in South Asians)~~ trial thus aims to test the effectiveness and cost-effectiveness of an intervention designed to reduce weight and increase physical activity in adults at high risk of diabetes indicated by Impaired Glucose Tolerance (IGT) or Impaired Fasting Glycaemia (IFG), thereby preventing or delaying diabetes. The aim of this paper is to describe the trial design and methods and baseline characteristics of participants and family volunteers.

METHODS / DESIGN

Study design and questions ~~and design~~

PODOSA is a cluster, randomised controlled trial, the 'cluster' represented by a family. The original protocol written in 2007 was designed to answer the primary question 'Does a family-based three-year programme promoting weight loss and increased physical activity in South Asians, modelled on interventions of proven effectiveness internationally, reduce the incidence of type 2 diabetes in South Asians?' However due to recruitment challenges,[16] a substantial amendment was approved by the ethics committee in 2009 to alter the primary outcome as detailed ~~below~~above.

The principal research questions that we are pursuing are therefore now:

- Does a family-based three-year programme promoting weight loss and increased physical activity in South Asians with IGT and/or IFG, modelled on interventions of proven effectiveness internationally, result in a clinically meaningful weight loss in the intensive intervention (15-visit) group compared to the light intervention (4-visit) group?
- What is the cost effectiveness of the intervention?
- What factors assist recruitment, adherence with advice given, and retention in the trial?

In addition to participants with impaired glycaemia, we invited adult members of their families to take part, mainly to support the trial participants in the process of lifestyle change. We made limited measurements on the family volunteers both to motivate them in changing their own lifestyles and to help assess the potential benefits to family members outside the main intervention groups.

The secondary research questions which are designed to~~,~~ help interpret the main outcomes, are:

- During the trial what changes occur over time among participants with IGT and/or IFG, and volunteer members of their families (analysed separately), in
    - waist circumference?
    - hip circumference?
    - fasting and 2-hour blood glucose (IGT/IFG recruits only)?
    - incidence of type 2 diabetes presently (and in the longer term, to be assessed via data linkage)?

~~Individual focused interventions (not family based ones) have shown the success of weight loss and increasing physical activity in preventing diabetes. PODOSA's key adaptation is to shift the emphasis from the individual to the family and from the clinic to the household. This was designed both to maximise participation and help achieve behaviour change, by recognising the fact that most health-related behaviours take place within the family or home setting and other family members may, for example, be involved in food preparation (supplementary information in the NSFDM).~~[14]

The primary outcome is mean weight change between baseline and three years. Our goal is weight loss of 2.5 kg more (or 2.5 kg lower weight gain) in the intensive intervention than in the light intervention group and increase in physical activity to at least 30 minutes daily. Ideally we would reduce the Body Mass Index (BMI) to at least 25 or preferably 23 (the interim World Health Organisation (WHO) recommendation for Asian populations). [18]

Secondary outcome measures of interest are:

- Mean changes between baseline and 3 years in waist and hip circumference, BMI, fasting and 2-hour post- Oral Glucose Tolerance Test (OGTT) glucose
- Cost effectiveness of the intervention (focusing on health service costs of the intervention and the opportunity cost of time for trial participants)
- Progression to type 2 diabetes in the longer term

For volunteer members of the family these are:

- Mean changes between baseline and 3 years in weight, BMI, and waist and hip circumference

Ethical approval

Ethical approval was obtained from the Scotland A Research Ethics Committee. All recruits gave written, informed consent to take part in the screening stage of the study and then further written consent for participation in the three year trial.

Setting and Recruitment

Recruitment took place between July 2007 and October 2009. Indian and Pakistani origin men and women aged 35 years and over living in the Lothian and Greater Glasgow & Clyde Health Boards areas were invited to be screened with the (OGTT).

Eligibility criteria

Eligible participants for the trial were those with:

- waist sizes ≥ 90 cm for men and ≥ 80 cm for women
- IGT (i.e. fasting plasma glucose of < 7 mmol/l and, following a standard OGTT, two-hour plasma glucose of 7.8-11.0 mmol/l)
- and/or IFG (ie plasma fasting glucose of 6.1 – 6.9 mmol/l)
- no previous diagnosis of diabetes
- 'family cook' agreed to cooperate (whether the main recruit, a family volunteer or another family member).

Participants on prescribed long-term oral corticosteroids, suffering from a health condition where adherence to the intervention was contraindicated or improbable, or unlikely to remain in the UK for 3 years, were excluded from trial entry.

The waist criteria correspond to the cut-off points recommended by the International Diabetes Federation Consensus Group in 2005 to identify South Asians at risk of diabetes.[19]

Eligibility family volunteers were:

- ≥ 18 years of age
- Close relative of the IGT/IFG participant either living within the same household, or living nearby and interacting with main recruit(s) on at least a weekly basis

Definition of a family (cluster)

The composition of families was established in consultation with the family itself. Criteria were defined to identify each extended family unit prior to randomisation. To minimise contamination, first degree relatives (parents, siblings, children) living in the same city could not be randomised separately. The cluster is 'the core family' consisting of the participant(s) with IGT/IFG, plus any family volunteer(s). In practice, given the relatively low prevalence of IGT or IFG (15%), compared to 30% expected, clustering was less common than predicted.

Sample size considerations

In the original study design it was anticipated that there would often be at least two eligible individuals per family (i.e. per cluster), so the fact that we were using a cluster randomised design was critical in the power calculation. However when the primary endpoint was amended to weight change, it was clear that the vast majority of 'clusters' would comprise a single individual. Thus, in practice, the impact of clustering will be negligible, and the modified power calculation did not take this into account. The target sample size for the amended trial was calculated to be 175 recruits to allow for a 10% drop-out. This would result in at least 150 recruits having complete follow up at 3 years. This sample size gives adequate (86%) power to detect a difference of 50% of the standard deviation (SD) (i.e. a mean difference in weight change of 2.5 kg between the two groups against a common background SD of 5 kg, derived using nQuery Advisor Version 7.0) at the 5% significance level (2-sided).

Randomisation and allocation of interventions

Randomisation lists were produced by the trial statistician using a random number generator program. Permuted blocks were used and block size varied randomly. Stratification wasis by location (Edinburgh or Glasgow), ethnic group (Indian or Pakistani), and number of IGT/IFG recruits in the family (1 or more than 1). ~~The composition of families was established in consultation with the family itself. Criteria were defined to identify each extended family unit prior to randomisation. To minimise contamination, first degree relatives (parents, siblings, children) living in the same city could not be randomised separately~~ All members of a 'family' gave written informed consent and completed the baseline visit prior to randomisation. Allocation of intervention group was then performed centrally, by the trial statistician or a deputy, independently from the dietitians and trial office staff. This strategy was implemented to minimise selection bias during the recruitment process and meant that both the dietitians and the families did not know the allocated intervention until enrolment and baseline measurements had been completed. As in other lifestyle prevention trials, blinding of the intervention was not feasible.

The study has two groups for comparison, one group having more frequent and tailored contact (intensive or 15 visit intervention) with the research dietitians than the 'control' group (light or 4 visit intervention), which largely receives information. The 15 visit group of 78 families received 15 contacts over three years, monthly for 3 months and thereafter quarterly. The 4 visit group of 78 families had annual contact over three years with the dietitian. The dietitians visited the participating families at their home or community setting of their choice.

Measurements and data collection

Prior to recruitment commencing, pilot work was carried out for the main trial procedures, covering consent, measurements and OGTT, and the screening and baseline visits. Table 1 outlines the time-points for consent, randomisation and collection of data for the main trial outcomes for all trial participants. Anthropometric measurements, background and outcome data were collected by the dietitians in the case record forms at each visit. Standard operating procedures were written for all the main study procedures including anthropometric measurements and the oral glucose tolerance test. Two measurements for height, weight, waist and hip were performed and if the difference was more than a specified value (height, waist and hip > 1cm, weight > 0.2kg), a third measurement was carried out. Physical activity was assessed by the short form of the International Physical Activity Questionnaire (IPAQ).[20] Time spent sitting, walking, and undertaking moderate and vigorous activities, was extracted from the IPAQ with time spent walking and in moderate and vigorous activities truncated at 180 min per day in line with the published IPAQ data processing guidelines (www.ipaq.ki.se).

Data were entered by the study assistant into a Microsoft Access database which has inbuilt validity and consistency checks. Subsequent data cleaning was performed by further manual and statistical checking. Double data entry was carried out for the key variables relating to the main trial outcomes, including randomisation criteria, all anthropometric and biomedical measures, and demographic and health economics data.

Three of four research dietitians were employed throughout the full study period and followed up the families for the full three years. The fourth dietitian left the research team in 2009 and her families were distributed amongst the remaining three dietitians. To counteract any potential observer bias when recording the key endpoint variables at the 3-year visits, an independent set of anthropometric measures (in addition to those recorded by the dietitians) were recorded by trained research nurses, blinded to study group.

Measurements for volunteer members of the family

As shown in Table 1, weight and waist and hip circumferences, were measured annually in adult family volunteers with and without diabetes (no blood tests were done).

Intervention for 15 visit group

The research dietitians were trained in venepuncture, measurement, delivery of information, behaviour change, and promotion of physical activity. The~~se~~ contacts with the families were, in effect, the intervention and in general each family was seen by the same dietitian for the duration of the trial. The content of the contacts were tailored, using a range of culturally adapted change management tools, to the needs of individuals and families. The dietitians motivated participating families to achieve weight loss through a calorie deficit diet in conjunction with physical activity. Verbal and written advice was provided including information on shopping, cooking (with demonstrations), and entertaining. Participants were invited to annual group sessions consisting of a food shopping tour, understanding food labels, exchange of recipes, food tasting and. brisk walking. The dietitians' toolkit (which will be published on the PODOSA website, www.podosa.org, by the end of March 2013, contained culturally adapted and translated existing resources ~~from similar projects ,~~ on diet and physical activity such as Counterweight.[21] A~~and a~~ paper on the cultural adaptation process of the study materials has been ~~submitted~~ accepted for publication (subject to minor revisions) by Health Promotion International. Pedometers were integral to the physical activity programme, providing motivation through self-monitoring and a tool for the dietitians to assess progress. Daily food diaries and pedometer logs, body weight and waist circumference data and the Chester Step Test[22] were used ~~for~~ as educational and motivational ~~purposes.~~tools by the dietitians.

Intervention for 4 visit group

This group had a baseline and then annual contact with the research dietitian. The dietitians gave both written and verbal advice on healthy eating, diabetes prevention, promotion of physical activity and on accessing available health services for weight control and physical activity. The research team agreed which resources should be given to families in the 4-visit group at each visit, to ensure consistency. While these actions were better than routine service, it is not anticipated they will reduce weight substantially and sustainably, but they may stabilise it, and counteract the secular trend and age effects of increasing weight.[23] This level of intervention was, we judge, necessary on ethical grounds. It also offered something in return for participation and measurements.

Measurement and valuation of costs

The PODOSA trial design included an integrated cost analysis. Cost data were collected prospectively from randomisation (baseline) to the 3 year follow-up. We chose a societal perspective for the analysis which encompassed the health service costs of the intervention and the opportunity cost of time for trial participants. The programme costs included the number and length of home visits by research dietitians and self-reported health service use in primary and acute care settings. Initial screening and trial recruitment costs were excluded. We valued dietitians' time (face-to-face contact, pre- and post-visit review and travel to participants' households) using NHS salary scales inclusive of salary on-costs and overheads. Standard NHS unit costs were used to value General Practitioner visits and hospital out-patient clinic attendances. Participant time included the number and length of dietitian visits and self-reported time spent doing moderate physical activities and on household allocation of time for food shopping and meal preparation. Median hourly wages by gender and ethnicity reported by the National Equality Panel/Labour Force Survey[24] were used to value participant time. No estimate of diet costs was included. The present value of the three year cumulative costs was calculated using a 3.5% annual rate of discount following UK Treasury and NICE guidance. All costs are reported in UK pounds using 2010 pay and price levels.

All analyses will be conducted on an intention-to-treat basis. The conditional mean cost comparison between 15-visit and 4-visit groups will be modelled using linear regression and generalised linear parametric methods. The mean cost difference between the groups will also be assessed using a non-parametric bootstrap. Quantile regression will be used to examine and compare the median cost differences. The relatively small sample size precludes assessment of heterogeneous treatment effects or sub-group differences in costs.

The robustness of results will be investigated using a strategy of comparing different specifications within the generalised linear model and conducting a series of one-way sensitivity analyses, where we will alter key assumptions on programme intensity and frequency as measured by the number, length and duration of visits. The cost implications arising from moving away from a one-to-one programme towards a group based intervention will also be considered.

Qualitative study

An embedded qualitative study was undertaken to:

- Obtain a rich and multi-faceted understanding of the main motivations for participation in an intervention study of Indian and Pakistani adults who are at high risk of developing diabetes.
- Investigate participants' perceptions of fidelity and faithfulness to the interventions offered both during and after participation.
- Understand the factors that may help promote retention of participants once enrolled.

~~will~~ We utilise~~d experience centred,~~ storytelling to collect narratives describing the lived experiences of ~~culturally orientated narrative methods to capture the experiences of~~ participation in PODOSA from ~~those who have recently~~families at completion of the trial. The objective wa~~i~~s to try to understand what factors motivate ethnic minority people to engage with research and to understand more about the facilitators to participation through understanding the perspectives and experiences of those who chose to participate in the trial. ~~The main aims are to:~~

- ~~Obtain a rich and multi-faceted understanding of the main motivations for participation in an intervention study of Indian and Pakistani adults who are at high risk of developing diabetes.~~
- ~~Investigate participants' perceptions of fidelity and faithfulness to the interventions offered both during and after participation.~~
- ~~Understand the factors that may help promote retention of participants once enrolled.~~

A detailed description of our methods will be reported in due course, but in summary, we undertook purposeful sampling on the basis of age, sex, ethnicity, faith group, geographical location, and trial arm to ensure recruitment of a maximum diversity sample. We also sought to include family volunteers when possible. Biographical narrative interviews were undertaken usually in participants' homes and in their preferred language, with the aid of a translator, if necessary. These interviews were digitally recorded, translated (if necessary) and then transcribed together with accompanying field notes. Analysis was undertaken in an iterative fashion, thus informing further data collection. Thematic and performance analysis[25] of the data utilised the constant comparison method[26] concurrent to data generation, utilising NVivo9 software to code data during analysis.

~~**Measurements for volunteer members of the family**~~
~~Height and weight for BMI, and waist and hip circumferences, were measured annually in adult family volunteers with and without diabetes (no blood tests were done).~~

Laboratory assessments
The 75 g OGTT followed standardised procedures, with venous blood samples taken after an overnight fast of 10–16 hours and 2 hours after ingestion of 75 g glucose. Samples were then transported to a central hospital laboratory (Western General Hospital, Edinburgh or Glasgow Royal Infirmary) where plasma glucose concentration was determined using the Ortho clinical diagnostics, Fusion dry ice method (Edinburgh), or the Abbott Architect, hexokinase/glucose-6-phosphate dehydrogenase method (Glasgow). Both laboratories participate in the UK National External Quality Assessment Service (UK NEQAS) scheme. In addition, an EDTA sample was obtained from all recruits at baseline and at three years, and with the participant's specific informed consent, plasma and DNA aliquots stored at -80˚C, for future analyses outwith the remit of the current trial. ~~The frozen samples will be analysed to examine the effect of the intervention on cardio-metabolic risk factors, which will be the subject of a subsequent paper.~~

~~**Data collection and handling**~~
~~Standard operating procedures were written for all the main study procedures including anthropometric measurements and the oral glucose tolerance test. Two measurements for height, weight, waist and hip were performed and if the difference was more than a specified value (height, waist and hip > 1cm, weight > 0.2kg), a third measurement was carried out. To counteract any potential observer bias when recording the key endpoint variables at the 3-year~~

~~visits, an independent set of anthropometric measures were recorded by trained research nurses, blinded to study group.~~

~~Anthropometric measurements, and demographic, socio-economic, self-reported medical history, physical activity and diet data were collected by the dietitians in the case record forms at baseline and at each annual visit. A subset of these data was collected at the interim visits in the 15-visit group to help deliver the intervention. Data on costs to deliver the intervention, opportunity costs of the time of the recruits and health resource use were collected at all visits. Physical activity was assessed annually for recruits in both groups. Time spent sitting, walking, and undertaking moderate and vigorous activities, was extracted from the short form of the International Physical Activity Questionnaire (IPAQ),[21] with time spent walking and in moderate and vigorous activities truncated at 180 min per day in line with the published IPAQ data processing guidelines (www.ipaq.ki.se).~~

~~Data were entered by the study assistant into a Microsoft Access database which has inbuilt validity and consistency checks. Subsequent data cleaning was performed by further manual and statistical checking. Double data entry was carried out for the key variables relating to the main trial outcomes, including randomisation criteria, all anthropometric and biomedical measures, and demographic and health economics data.~~

Statistical analysis

Analyses will be performed on an intention-to-treat basis, i.e. participants will be analysed in the group that they were randomised to regardless of how much of the intervention they received, unless specified otherwise.

Due to the clustering inherent in the design, the primary outcome will be analysed using a random effects linear regression model (to accommodate the clustering of individuals within families) with maximum likelihood estimation. The model will be adjusted for the stratification variables (ethnicity and location). Change over time will be incorporated into the model using an extension to the analysis of covariance (ANCOVA) approach, adjusting for baseline value. Treatment group will be included in the model as a fixed effect. Results will be reported as an adjusted (for ethnicity and location) mean difference in weight between baseline and three years, with a 95% confidence interval and corresponding p-value. The intra-class correlation coefficient will be reported.

Analyses of secondary~~/tertiary~~ outcomes will mirror those for the primary outcome, where the distribution of the relevant outcome is continuous. Where the outcome is a proportion, the approach will be to fit a generalised linear mixed model with terms for stratification variables and treatment group as above and adjusting for baseline value where applicable. Results will be reported as an adjusted odds ratio with a 95% confidence interval and corresponding p-value.

RESULTS

Recruitment

As shown in Figure 1, 1319 participants were screened with an OGTT over a 27 month period between July 2007 and October 2009. 102 recruits (8%) had OGTT results indicative of diabetes and 196 (15.4%) were found to have impaired glycaemia. 16 participants did not meet eligibility criteria to proceed into the full trial and nine declined to participate further. Thus, 95% (171/196) agreed to continue into the three year trial. 156 family clusters comprising the 171 eligible participants with IGT and/or IFG, along with 124 family volunteers, were randomised into either the 15 visit or 4 visit intervention groups.

Baseline characteristics of the trial population

Baseline characteristics are shown in Table 21. The families range from single participants to a family comprising 4 IGT/IFG recruits with 5 family volunteers. Only 13 of the 156 trial families have more than one recruit with IGT/IFG. Family volunteers were recruited to 85 families. The trial population are well established in the UK with mean residency time of around 31 years. Approximately 33% of the participants have no formal educational qualifications.

Table 21 shows that approximately 84% of family cooks are either the IGT/IFG person or a family volunteer. The remainder all agreed to cooperate. Over a third of the participants had a close family history of diabetes.

Part (c) of Table 21 describes lifestyle characteristics of participants. Average total activity time (comprising vigorous, moderate and brisk walking) for the trial population was 51 minutes per day. Mean sitting time was 6.5 hours per day.

Mean BMI for all recruits was 30.5 kg/m^2 and overall 49% of participants had BMI > 30 kg/m^2.

Table 32 shows demographic and anthropometric characteristics of the 124 family volunteers. Most volunteers weare female (77%) and 64/124 (52%) were the spouse or partner of the index recruit. Over 90% of the family volunteers were recruited in Glasgow. The mean BMI of family volunteers was 27.4 kg/m^2.

~~**Recruitment**~~

~~As shown in Figure 1, 1319 participants were screened with an OGTT over a 27 month period between July 2007 and October 2009. 102 recruits (8%) had OGTT results indicative of diabetes and 196 (15.4%) were found to have impaired glycaemia. 16 participants did not meet eligibility criteria to proceed into the full trial and nine declined to participate further. Thus, 95% (171/196) agreed to continue into the three year trial. 156 families comprising the 171 eligible participants with IGT and/or IFG, along with 124 family volunteers, were randomised into either the intensive or light intervention groups.~~

DISCUSSION

Principal ~~findings~~achievements

The PODOSA trial's key achievements include: establishing the infrastructure for the trial; recruiting, training and forging a multi-ethnic team to implement the trial; and the involvement and ~~very high level of~~ support from within the wider South Asian community.

particularly in the recruitment phase.[17] ~~Although recruitment to the screening stage of the trial was challenging,~~[16] ~~I~~it ~~is~~ was encouraging that 95% of eligible recruits consented to participate in the 3 year trial (171/196). We emphasised the need for family involvement as a means of motivating behaviour change and set the complex intervention in the home setting. Our only entry criterion relating to the family was that the main cook ~~participated~~ agreed to co-operate and this was always achieved. We consider this a major success. It proved harder to recruit family volunteers in Edinburgh than in Glasgow. It was difficult to identify clear reasons for this but the dietitians reported that, in many instances, potential volunteers were either unavailable or did not interact or eat with the main recruits with sufficient frequency. The proportion of Pakistani to Indian recruits (2:1) in PODOSA closely reflects the wider resident South Asian population as reported in the 2001 Scottish census where those of Pakistani origin represented 31% of the total minority ethnic population and 15% were of Indian origin.[27]

Strengths and weaknesses

PODOSA, to our knowledge, is one of the first culturally adapted, community based, randomised intervention trials on lifestyle and health issues in South Asians in the UK. PODOSA ~~is important for~~will contribute evidence for weight control and diabetes specifically, however, its long-term legacy will be the experience, lessons and example of the evaluation of complex interventions in ethnic minority populations set in the community in the UK multi-ethnic society.

Although we were unable to recruit sufficient numbers to examine, with sufficient power, progression to diabetes within the life of the trial, we have participants' consent to link trial data to Scottish national morbidity and diabetes register data during a 10 year follow up period. This may allow analysis of this outcome in the longer term. However weight loss, our new primary outcome, is the main driver for diabetes prevention, and physical activity, a secondary outcome, is also important.

Putting the study in context

Based on available evidence in 2005 at the design stage of the trial,[5,19] we set eligibility criteria for waist circumference (≥ 90 cm for men and ≥ 80 cm for women) as those with central obesity are more likely to have impaired glycaemia. We estimated that we would identify IGT in around 30% of such volunteers screened for trial eligibility.[5] Within PODOSA the prevalence rate for IGT and/or IFG was approximately 15%, much lower than expected. The Leicester (UK) Addition study reported finding 19.8% IGT or IFG in South Asians aged 40-75 years, with no minimum waist size.[28] A recent systematic review[29] of cross-sectional studies in South Asians also suggests a stable or falling IGT prevalence, although the natural history of pre-diabetes and its progression to diabetes still remains unclear. Our lower prevalence rate of impaired glycaemia was one of the contributory factors to our difficulty in achieving the original intended sample size. ~~However we have recruited adequate numbers to have sufficient statistical power to detect a significant effect in the amended primary outcome.~~

Within the UK, the case for national screening programmes for both diabetes and impaired glycaemia remains equivocal.[30] Recent research has suggested that the case is stronger than it was, although evidence from good quality trials showing a subsequent reduction in morbidity and mortality is still required.[31] Hanif et al argue that a stepwise screening strategy aimed at the South Asian population could be effective although further work is needed to examine implementation within primary care.[32] The Addition Leicester trial,[6] a community screening programme and cardiovascular risk intervention, includes a significant South Asian

population and is due to report in 2013. The results from PODOSA, also expected in 2013, will contribute to urgently needed evidence about the effectiveness of prevention interventions in a UK ethnic minority population at high risk of developing diabetes.

Implications

South Asians are at high risk of developing type 2 diabetes and effectiveness data for culturally tailored health care interventions are urgently required in order to help prevent this epidemic and to help inform health care services and policy in the UK. The trial ~~intervention will finish in October 2012 and the main~~ results, including cost-effectiveness and qualitative findings, will be submitted for publication in 2013. In particular, this study has focussed on the family rather than the individual and moved from the traditional clinic, to a home setting. This kind of approach has been promoted in guidance from NSFD and the National Institute for Health and Clinical Excellence (NICE),[14,33] so evidence from PODOSA will be pertinent to this line of argument. More generally, PODOSA will also contribute to the evidence base for conducting randomised lifestyle intervention trials in ethnic minority populations in the UK and contribute to future meta-analyses with on-going diabetes prevention trials in other South Asian populations.

Table 1 Time points of outcome measures and data collection

Time Point (Months)	Name of Visit	Informed consent	OGTT & blood sample for storage	Anthropometric measurements	Demographic, socio-economic self-reported medical history	Costs and health resource use	Physical activity data	Delivery of Intervention (intensive or light)
-1*	Screen	✓	✓		✓			
0* +	**Baseline**	✓ +		✓ +	✓	✓	✓	General information on diabetes, diet and physical activity to all participants
0*+ (plus 1 week)	**Family (as the cluster) randomised to 15 or 4 visit group**							
1	Interim			✓		✓		✓
2	Interim			✓		✓		✓
3	Interim			✓		✓		✓
6	Interim			✓		✓		✓
9	Interim			✓		✓		✓
12* +	**Annual**			✓ +	✓	✓	✓	**Intensive or light**
15	Interim			✓		✓		✓
18	Interim			✓		✓		✓
21	Interim			✓		✓		✓
24* +	**Annual**			✓ +	✓	✓	✓	**Intensive or light**
				✓		✓		✓
27	Interim			✓		✓		✓
30	Interim			✓		✓		✓
33	Interim			✓		✓		✓
36* +	**Annual**		✓ (OGTT repeated if positive for diabetes)	✓ +	✓	✓	✓	**Intensive or light**

***** Measurements and data collected similarly for participants in intervention and control groups – or prior to randomisation

+ Indicates time points and data collection for Family Volunteers

Table 24. Recruits with IFG and/or IGT

Demographic, social, lifestyle, anthropometric, biochemical and other background characteristics of trial participants. Figures are numbers and column percentages unless otherwise stated

Variables	All participants No.	(column %)
a) Demographic		
No. of families with-		
1 IGT/IFG recruit	143	(91.7)
2 IGT/IFG recruits	12	(7.7)
4 IGT/IFG recruits	1	(0.6)
No. of families with-		
with family volunteer(s)	85	(54.5)
No. of IGT/IFG individuals	171	(100)
No. family volunteers	124	(100)
Individual IGT/IFG recruits		
Sex – male	78	(45.6)
Age – mean (SD)	52.3	(10.1)
Age – range	35-80	
Location		
– Glasgow	132	(77.2)
– Edinburgh	39	(22.8)
Ethnic group		
– Indian	57	(33.3)
– Pakistani	114	(66.7)
Religion		
– Muslim	114	(66.7)
– Hindu	15	(8.8)
– Sikh	39	(22.8)
– Other	3	(1.8)
b) Social circumstances		
Cook was a participant	85	(49.7)
Cook was a family volunteer	59	(34.5)
Cook was simply cooperating	27	(15.8)
Blood relative with diabetes	118	(69.0)
Years lived in UK (mean, SD)	31.4	(13.1)
Education:		
no qualifications	56	(32.7)
school level	49	(28.7)
further or higher education	66	(38.6)

continued

Table 24. Continued

Variables	All participants No.	(column %)
c) Lifestyle		
Current smoking/chewing tobacco	11	(6.4)
Currently drinks alcohol	19	(11.1)
Vegetarian	26	(15.2)
Physical activity (**mean minutes per day, SD**)		
– Total (moderate, vigorous, walking)	51.0	(61.0)
– Moderate and vigorous only	23.3	(44.7)
– Walking only	27.7	(37.1)
– Sitting time (mean hours per day, SD)	6.5	(3.0)
d) Anthropometric (Values are given as mean and SD)		
Height (cm)	161.9	(9.3)
Weight (kg)	80.2	(15.6)
BMI (kg/m^2)	30.5	(4.8)
Waist (cm)	103.0	(11.1)
Hip (cm)	107.1	(9.5)
Waist/hip ratio	0.96	(0.07)
BMI < 25 (n,%)	20	(11.7)
BMI ≥ 25 and <30 (n,%)	67	(39.2)
BMI ≥ 30 (n,%)	84	(49.1)
e) Biomedical measures (Values are given as mean and SD)		
Systolic BP (mmHg)	136.9	(20.6)
Diastolic BP (mmHg)	83.0	(11.5)
Fasting plasma glucose (mmol/l)	5.8	(0.6)
2-hr post OGTT plasma glucose (mmol/l)	8.3	(1.6)
Current medications (n,%)		
– Antihypertensives	48	(28.1)
– Cholesterol lowering	39	(22.8)

Table 32 Family volunteers

Demographic, anthropometric and other background characteristics of family volunteers. Figures are numbers and column percentages unless otherwise stated

	All family volunteers No.	(column %)
a) Demographic		
Sex – male	28	(22.6)
Age – mean (SD)	41.9	(14.9)
Age – range	18 – 75	
Location		
– Glasgow	114	(91.9)
– Edinburgh	10	(8.1)
Ethnic group		
– Indian	42	(33.9)
– Pakistani	79	(63.7)
– Other	3	(2.4)
Relationship to main recruit		
– Spouse/partner	64	(51.6)
– Parent	2	(1.6)
– son/daughter	26	(21.0)
– brother/sister	5	(4.0)
– other	27	(21.7)
b) Anthropometric (Values are given as mean and SD)		
Height (cm)	161.7	(8.5)
Weight (kg)	71.4	(13.9)
BMI (kg/m^2)	27.4	(5.3)
Waist (cm)	92.7	(12.4)
Hip (cm)	104.7	(8.6)
Waist/hip ratio	0.89	(0.08)
c) Biomedical		
No. with diabetes (self-reported)	15	(12.1)

Authors' contributions

AD and RSB drafted the manuscript and are joint guarantors. SW, RuB and AS are research dietitians carrying out the study recruitment, screening and interventions. RSB, SW, JFF, JMG, JMcK, GM, NS, SWild, ASheikh and AD helped plan the trial. All authors contributed to the interpretation of the data and writing of the manuscript. Prof Mike J E Lean and Prof Jaakko Tuomilehto contributed to planning the trial but are not authors on this paper.

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Competing Interests None

Provenance and peer review Not commissioned; externally peer reviewed

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Ethics approval Ethical approval was obtained from the Scotland A Research Ethics Committee (reference number 07-MRE10-2)

Data sharing statement No additional data available

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

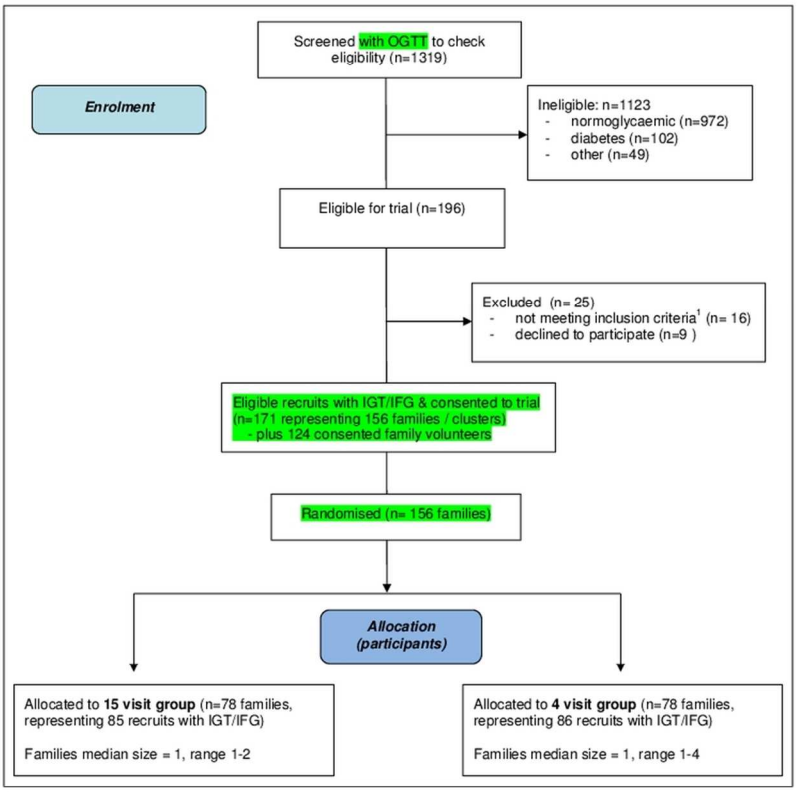
Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	5
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	7-8
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	n/a
Recruitment	14a	Dates defining the periods of recruitment and follow-up	10
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 &2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	n/a
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	n/a
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	n/a
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	na
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Figures

Figure 1 PODOSA TRIAL CONSORT FLOWCHART



Notes:

[1] Main reasons were, unavailable for baseline visit within timeframe, or close family members already in the trial.

Figure 1 PODOSA TRIAL CONSORT FLOWCHART
90x127mm (300 x 300 DPI)