Prevention of Diabetes & Obesity in South Asians – PODOSA Trial

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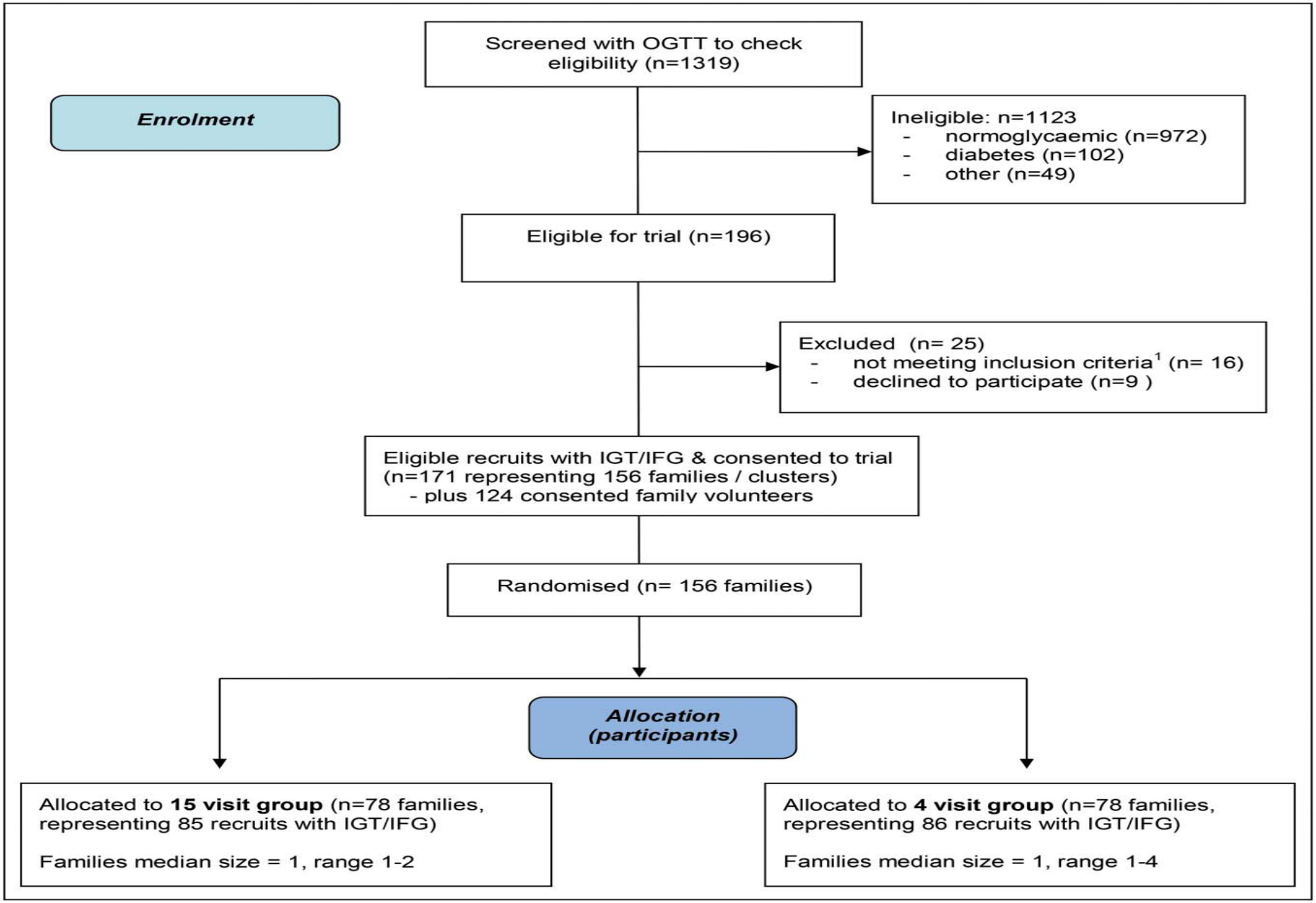


Notes:

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

Intensive intervention (15 visit group)

- Dietitian contact
- Culturally adapted tools
- Calorie deficit diet and physical activity
- Verbal and written advice
- Group sessions
- Tool kit
- Self-monitoring tool e.g. pedometers / food diaries

Light intervention (4 visit group)

- Baseline and annual contact with dietitian
- Written and verbal advice
- Family involvement

Intervention manual

- Graphical Depiction of intervention sessions
- Balance of Good Health
- Physical Activity
- Resources
- Behaviour Change
- Group Education Session
- Feedback on Intervention from dietitians
- Details of PODOSA Research Team and Investigators Group

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, socioeconomic 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 four-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.
OGTT, Oral Glucose Tolerance Test.

TABLE OF PODOSA INTERVENTION VISITS

VISIT	PLANNED ACTION	VERBAL ADVICE GIVEN	RESOURCES GIVEN
1	Visit 1 is the Baseline visit. This visit occurs prior to randomisation into the control or intervention group. All measurements and interaction are exactly the same for all trial recruits at this visit. Carry out the Chester Step Test (CST) to determine the recruit's aerobic fitness. This is then done annually and results are discussed and compared to previous years.	• Explanation of impaired glycaemia (IGT/IFG) and diabetes risk and associated long term complications. • Discussion of weight - overweight, obesity, central fat deposition and health consequences. • Lifestyle changes – diet and PA contribute to weight loss and benefits of weight loss. Discussion around recruit's weight, BMI and waist, and need for reduction as appropriate. • Target weight discussed and realistic interim target set as appropriate. • Discussion of healthy balanced diet by using the BOGH, food groups, proportions of food groups to be consumed and portion sizes. Advised low fat, low sugar, high fibre options. Refer to Appendix B for further details on BOGH. • Recommendations for PA, explanation and discussion around different intensities (light, moderate, vigorous) of PA using the WOF. Advice given appropriate to individual e.g. aim to increase PA slowly to meet recommendations if no previous PA carried out (Appendix C). • Explain and discuss results of the CST and motivate to improve results over the next year as appropriate.	• IFG/IGT info leaflet • SA BOGH • WOF Folder provided for recruit to store all resources in.
2	The intervention visits start here. Visit 2 is conducted 4 weeks after the 1st visit.	• Recap of what was discussed at first visit and if any changes made; answer any questions. • Review BOGH and WOF and go into more detail as appropriate for recruit. • Give praise if changes attempted and encouragement to continue. • Assign appropriate stage of change according to Trans-theoretical Model (TTM). • Discussion of healthy weight loss of 1-2lbs per week.	• DLD •Yamax Digi-walker SW-200 pedometer • Pedometer recording sheet • Healthy Eating quiz

VISIT	PLANNED ACTION	VERBAL ADVICE GIVEN	RESOURCES GIVEN
		• Target weight – discussion around achievable and realistic target and period over which weight is to be lost. • Discussion of waist, and BMI (use BMI chart to show recruit). • Go over the DLD with explanation on how to record at least 3 days food intake. Follow the information as specified in the daily living diary. • Discussion around pedometer and recording sheet – how to use and wear and number of steps to aim for. Recommendation of 10,000 steps mentioned and aim to gradually increase to this as appropriate. • Aim to achieve at least 30 minutes moderate intensity physical activity per day. • Discussion around activity pattern – frequency, intensity and engagement. • Provide information on various physical activity classes, yoga classes, exercise referral scheme or any other NHS or local authority services and how to go about accessing these services. • 2-3 realistic and appropriate targets agreed jointly with recruit (and FV) for diet and PA, aim to try and achieve these targets in the time between visits e.g. eat less fat, try semi-skimmed milk instead of whole milk, use spray oil in cooking, walk up and downstairs 10 times per day etc. If FV(s) is present when visit is conducted, he/she is encouraged to sit in and take part in the above discussions. This is encouraged at every visit. The behavioural change approach is used at each visit using the TTM (Refer to Appendix E).	*Other resources were given as appropriate in the relevant language (All counterweight leaflets are available in English, Punjabi and Urdu). (see Appendix D)

VISIT	PLANNED ACTION	VERBAL ADVICE GIVEN	RESOURCES GIVEN
3	Visit 3 occurs 2 months after the Baseline visit	• Review the targets as agreed at the last visit. Congratulate and motivate if achieved. Discuss how they feel and what helped in achieving the target. What is the main change they made? Reinforce the importance of this change. Agree new targets for diet and physical activity. • Collect the DLD and discuss it in detail i.e. description of food consumed, quantity, type of food, home-made, carry out or eating out. Also focus on and discuss meal patterns, portion size, cooking methods, hidden fats, fibre containing foods, snacks and drinks. • Use the DLD as an educational tool, engaging the recruit to identify where their eating pattern may be improved. Provide guidance to self–monitor the food diaries to make preferred changes to achieve an energy deficit of 500-600kcals/day. • Collect the pedometer log sheet. Discuss the number of steps taken and a staged approach to achieve recommended 10,000 steps/day. NB - When the food diary or pedometer log sheet are not completed, record why this has not been possible.	Provision of appropriate resources

VISIT	PLANNED ACTION	VERBAL ADVICE GIVEN	RESOURCES GIVEN
4	3 months after Baseline visit	• Review the targets as agreed at the last visit. Congratulate and motivate if achieved. Discuss how they feel, what helped in achieving the target. What is the main change they made? Reinforce the importance of this change. Agree new targets for diet and physical activity. • If targets not achieved, discuss why, identify barriers and how to overcome them. • If the recruit has reached the target weight discuss weight maintenance strategies, Encouraging the recruit to continue self-monitoring of weight and food intake. • If the recruit gains weight, review food intake and the pedometer log, stage of change and have a problem solving discussion using motivational strategies. • Relapse: Coping strategies, discuss and acknowledge the difficulties of food temptations and how to deal with such situations. Involve family members for support. Provide information on future group sessions/shopping tours. (See Appendix F)	Provision of appropriate resources
5 + 6	Visit 5 is 6 months after Baseline and visit 6 is 9 months after Baseline	• As above, a lot of the advice provided at subsequent visits is similar to previous visits where targets are discussed in relation to diet and PA modification to achieve weight loss, appropriate tailored advice provided, any difficulties highlighted and discussed. • Aim is to achieve continual weight loss.	Appropriate resources

VISIT	PLANNED ACTION	VERBAL ADVICE GIVEN	RESOURCES GIVEN
7	Visit 7 is 12 months after the Baseline visit. Carry out CST. Any change in health status over the past 12 months is recorded. If a diagnosis of diabetes has been made since the participant was last reviewed, then details will be collected by the dietitians (consisting of approximate date of diagnosis, where they were treated, any medications prescribed).	• As above • Discussion of progress over past year – achievements and difficulties, motivation provided and encouragement of behaviour change as appropriate. • Discuss results of the CST and motivate to improve results over the next year as appropriate.	BHF Recipe booklet DLD Other resources as appropriate
	Annual group session – Refer to Appendix F for more details		
8, 9, 10		• As above	Appropriate resources provided
	Annual group session		
11	Visit 11 is 24 months after the Baseline visit. Carry out CST. Any change in health status over the past 12 months is recorded. Details of a diagnosis of diabetes are recorded.	• As above • Discussion of progress over past year – achievements and difficulties/challenges of making changes. Provide motivation and encouragement of behaviour change as appropriate. • Discuss results of Chester Step Test (CST) and motivate to improve results over the next year as appropriate.	DVD 'Meethi Baatein' DLD Other resources as appropriate
12, 13, 14		As above	Appropriate resources provided
	Annual group session		

VISIT	PLANNED ACTION	VERBAL ADVICE GIVEN	RESOURCES GIVEN
15 FINAL VISIT	Visit 15 is 36 months after the Baseline visit. OGTT carried out. Carry out CST.	• Discussion on how progressed over past year and over the 3 years. • Weight change from Baseline visit. • Dietary and PA modification advice, if appropriate. • Discussion of CST results and comparison to previous years.	Laminated BOGH

Resources

- Physical activity, Pedometer
- IGT
- Ways to burn calories
- Alcohol information
- Weight loss
- BMI
- Food labels
- DVD’s
- Exercise group classess

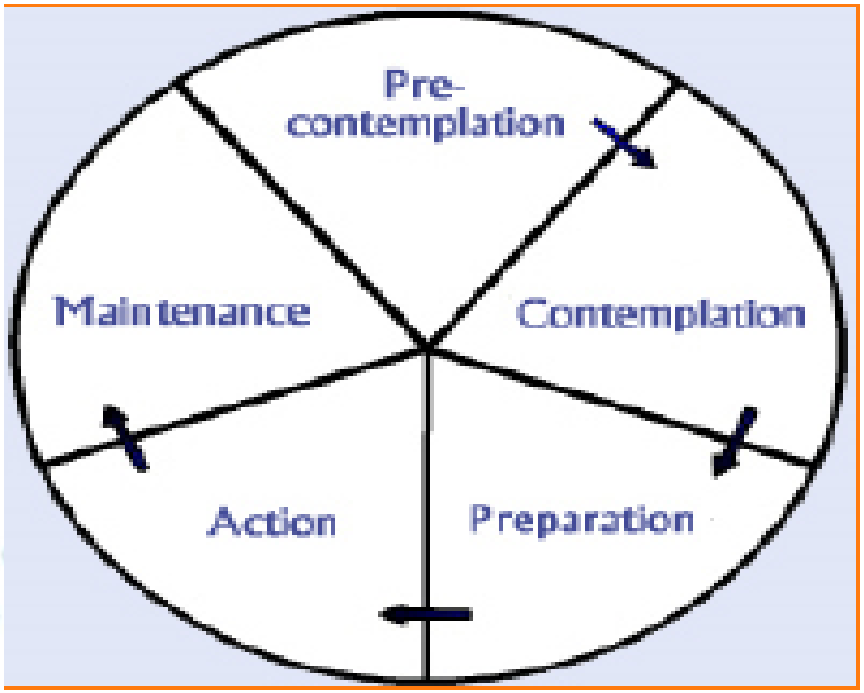
- Food groups- practical advice
- Portion control
- Recipes
- Fibre facts
- Healthy eating on a plate
- Glycemic Index

Other resources

Counterweight booklet
Daily Living Diary
Healthy Eating Quiz
Making Changes
Shopping, Cooking & Eating out
Getting the Balance Right
Goals to Help you Lose Weight and Eat Healthily
My Personal Weight Loss Plan
Physical Activity

Snack Attack
Eating Behaviour
Maintaining Change
Managing Difficult Times

TTM of behaviour change



Group Sessions

The following are covered in the session:

- Balance of Good health
- Energy balance
- Types of fat and ways to cut down on fat
- Healthy cooking methods
- Menu planning
- Ways to increase fibre
- Portion control
- Weight management
- Physical activity – types, duration, recommendations, speakers e.g. 'Live Active' staff.
- Recipe ideas and ways to adapt existing recipes to enc
- Prevention of diabetes

- Practical information on recipes
- Visual aids
- Walking sessions
- Supermarket tours
- Evaluation feedback

Qualitative study

- Obtain a rich and multifaceted understanding of the main motivations for participation in an intervention study of 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.

Laboratory assessments

- Plasma glucose

  - overnight fast
  - 2 hours after OGTT

- Samples were obtained at:

  - Baseline
  - At 3 years

Results

- 1319 participants
- OGTT
- 27-month period
- n = 102 (8%) – diabetes
- n = 196 (15.4%) – impaired glycaemic control
- 95% agreed to 3-year trial
- 156 family clusters – 171 eligible volunteers
- 15-visit or 4-visit intervention group

Baseline characteristics

- Gender - 45.6% Males
- Mean age – 52.3 years (35-80)
- Ethnic group – Pakistanis (66.7% ; Indian 33.3%)
- Education – 32.7% - no educational qualifications
- Smoking 6.4%
- Alcohol 11.1%
- Physical activity n= 51 - moderate vigorous activity (60mins/day)
- Mean BMI 30.5
  - < 25 – 11.7%
  - 25-30 – 39.2%
  - > 30 -49.1%

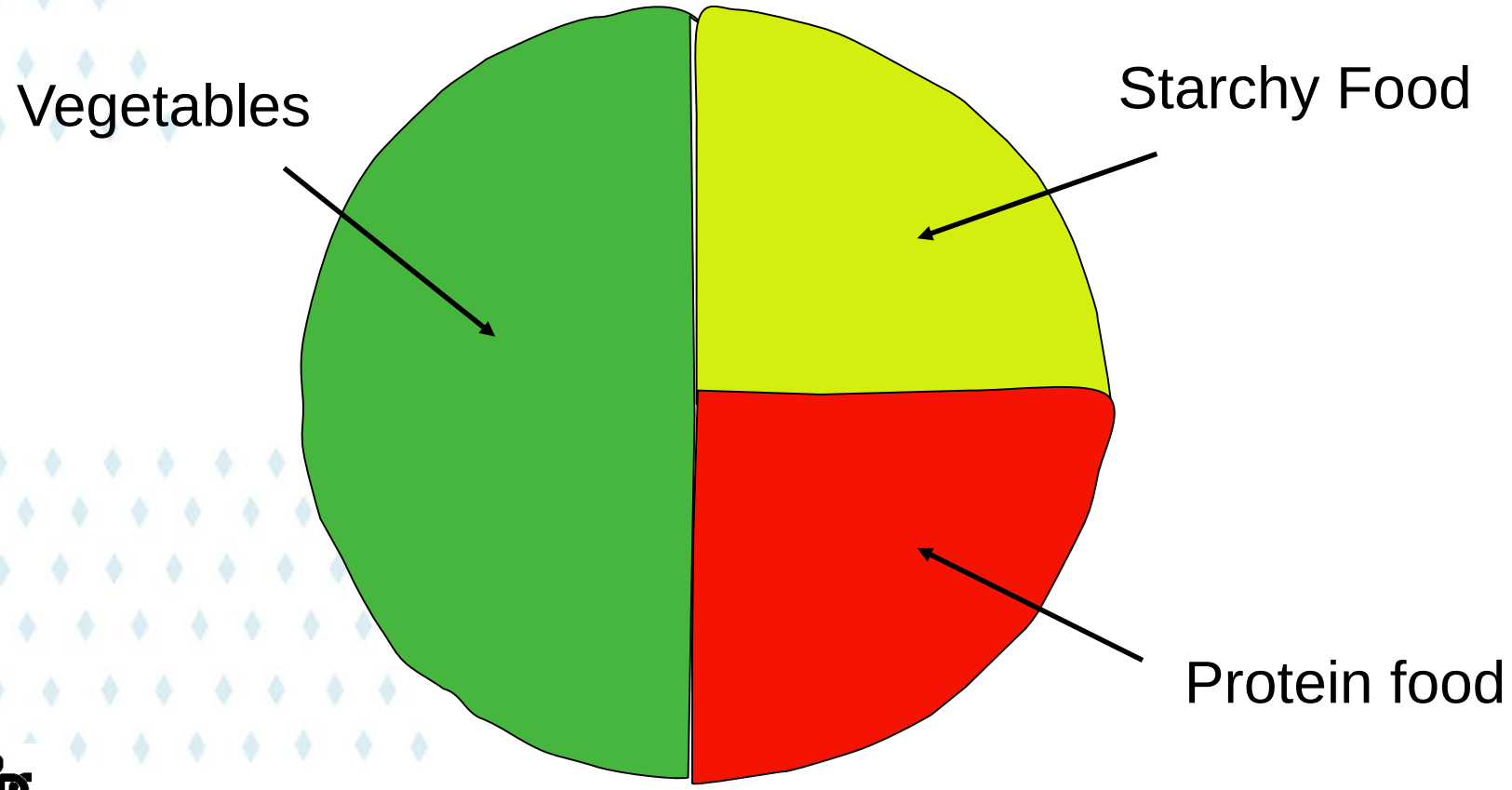
Biomedical measures (values are given as mean and SD)

Systolic BP (mm Hg)	136.9 (20.6)
Diastolic BP (mm Hg)	83.0 (11.5)
Fasting plasma glucose (mmol/l)	5.8 (0.6)
2 h post-OGTT plasma glucose (mmol/l)	8.3 (1.6)
Current medications (n, %)	
Antihypertensives	48 (28.1)
Cholesterol lowering	39 (22.8)

Key achievements of the trial

- PODOSA – first culturally adapted, community-based randomised intervention trials on lifestyle and health issues in south Asians in the UK
- Contribute to the evidence for weight control and diabetes, long term emphasis on lessons learnt and evaluation of a complex intervention in ethnic minorities set in the multi-ethnic society in the UK
- Establishing an infrastructure – recruiting, training and forging a multi-ethnic team to implement the trial
- Encouraging family involvement as a means of motivating behaviour change and setting complex intervention in a home setting

Healthy Plate model



Cultural beliefs

- Food is a family's way of meeting -Late Dinners
- 3 meal patterns and beverage consumption
- Seasonal inactivity
- Healthy cooking NOT a traditional concept
- Fasting days
- Lack of awareness of right nutrients E.g. calcium
- High salt savouries
- Myth foods – pregnancy

Why things change !!!

- Migration
- Western world
- Accessibility to food, cost ?
- Nuclear family, single
- Change in lifestyle
- Less traditional cooking
- Easy Eats /processed-cheap and quick

Eating Patterns

Food Issues

- Junk food – availability and cost
- Convenience foods
- Supermarket choices – specials, low cost, freebies
- Lack of awareness of healthy foods
- Illiteracy – unable to read or interpret label
- No time to cooking

Ideas for programmes

Programmes in settings:

- Indian grocery stores
  - promotion of healthy choices e.g. signage
- Restaurants
  - modification of food prep – “target foods”
- Places of worship – Temples, Mosques
  - availability of healthy food at events

‘Train the trainer’

- Many community organisations
- Nominate members to receive training to bring back information to their communities
- Model used for tuberculosis awareness

Raise awareness of the link

- Key food habits:
  - low vegetable and fruit intake
  - high fat intake through use of ghee, cream, coconut cream
  - large portions of 2-3 types of carbohydrate at one meal e.g. rice and potato and chapatti

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Implications

- South Asians are at high risk of developing type 2 diabetes.
- Culturally tailored healthcare interventions
  - prevention care
  - inform healthcare services
  - policy making
- PODOSA Trial results
  - Cost-effectiveness and qualitative findings
  - Focus on family rather than individual
  - Traditional setting to home setting
- PODOSA will also contribute to the evidence base
  - randomised lifestyle intervention trials in the future.
  - future meta-analyses with ongoing diabetes prevention
  - trials in other South Asian populations