

## Title Page

### **Development of a multi-component lifestyle intervention for preventing Type 2 diabetes and cardiovascular risk factors in adults with intellectual disabilities**

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**Short title:** Development of a lifestyle intervention for adults with intellectual disabilities

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# **Abstract**

## **Background**

We report on the development of the 'STOP Diabetes' education programme, a multi-component lifestyle behaviour change intervention for the prevention of Type 2 diabetes and cardiovascular risk factors in adults with intellectual disabilities (ID).

## **Methods**

We combined qualitative stakeholder interviews with evidence reviews to develop the intervention, guided by the MRC Framework and informed by intervention mapping and two existing diabetes prevention programmes. We conducted two pilot cycles drawing on additional stakeholder interviews to inform and refine the intervention.

## **Results**

The STOP Diabetes education programme employed a theoretical framework, using sound learning and behavioural principles and concrete kinaesthetic methods, to provide the grounding for innovative games and activities to promote health behaviour change in adults with ID. Qualitative data also suggested that two educators and one support person delivering a programme of one carer session followed by seven 2.5 hour sessions over seven weeks was acceptable to service users, carers and educators and appeared to benefit the participants.

## **Conclusions**

The STOP Diabetes education programme was successfully developed and is suitable for a definitive randomised controlled trial (RCT).

## **Key Words**

|                |              |                           |
|----------------|--------------|---------------------------|
| Development    | Intervention | Diabetes                  |
| Cardiovascular | Lifestyle    | Intellectual disabilities |

## **Background**

People with intellectual disabilities (ID) face considerable health inequalities (1, 2). In the UK, there is a current focus on modifiable health conditions such as Type 2 diabetes (T2DM) and obesity (3, 4) in this population because it is assumed that preventive strategies that benefit the general population (5-7) are transferrable. People with ID often have poorer diet (8), exercise less (9-11) and are more likely to be obese (1, 12, 13) than the general population. It therefore seems logical that strategies to modify these risk factors will also reduce the risk of developing T2DM and cardiovascular risk factors in the longer term. However, people with ID learn and develop differently, so it is important that preventive strategies take account of these differences.

Both UK and international guidelines recommend that lifestyle interventions to prevent T2DM should be multi-component, incorporating both dietary and physical activity advice, and behaviour change techniques (14-17). However, none of the national prevention programmes are suitable for people with ID. Previous systematic reviews of lifestyle interventions in this population (18-20) have highlighted inadequacies in study design, conduct, lack of theory basis for the intervention and/or unclear reporting, and have called for robust multi-component behaviour change interventions that are informed by current guidance (18). It is important that lifestyle interventions for people with ID are adapted to allow for their increased physical and mental health needs (21-24), as these can impede understanding and ability to take up such interventions.

There is an urgent need to develop and test preventive strategies to lessen the health inequality gap and optimise resource allocation in this population. The purpose of this study was to develop a lifestyle education programme for people with ID with impaired glucose regulation (IGR) or at high-risk of developing T2DM and/or cardiovascular disease based on increased body mass index (BMI).

## **Methods**

### **Design**

The STOP Diabetes education programme was developed in Leicestershire, UK, as part of a broader programme of work, which included a region-wide diabetes screening programme (25). Development work took place over 27 months, commencing in October 2012 and ending in January 2015 when the final refinements were made to the curriculum (ready for feasibility testing). Development followed a systematic process based on the current Medical Research Council (MRC) framework for developing and evaluating complex interventions (26) and intervention mapping (27) led by the core multidisciplinary team members and additional experts in ID and intervention development.

The first phase of development combined a review of existing interventions and behaviour change literature with qualitative interviews with service users, carers and health professionals (Figure 1). The second phase involved testing and refining the procedures, and assessing acceptability; the initial programme was piloted and refined based on observation and stakeholder interviews (first pilot cycle) and tested once more using interviews with service users and carers (second pilot cycle).

[Figure 1 about here]

## **Phase 1: Review of the evidence and stakeholder interviews**

### Review of the evidence

We reviewed key ID-specific research, behaviour change literature, existing prevention programmes, relevant published guidance, consensus statements and service evaluations (28). Part of this work also involved a systematic review of existing multi-component behaviour change interventions for modifying risk factors for T2DM and CVD in people with ID. The systematic review, described in full elsewhere (29), considered studies published between 01/01/2000 and 21/04/2015, and was conducted following Centre for Reviews and Dissemination guidance (30). The findings from all components of the evidence review were collated and summarised for discussion at the subsequent framework and curriculum development meeting (see later).

## Interviews with stakeholders

A provisional quota of up to 25 interviews for service user and health professional interviews was identified in advance. Interviews were held between June 2013 and June 2014 by a qualitative researcher, with support from an ID research nurse for the service user interviews.

Service users were participants of the STOP diabetes screening programme (25) who had consented to be contacted again, had mild to moderate ID, and had either screened positive for IGR or were overweight ( $BMI \geq 25$ ). After taking written informed consent, semi-structured interviews were conducted with these individuals and their carers. Topic guides and open questions were used to explore issues around knowledge, understanding and experience of T2DM and modifiable risk factors, perceived barriers to behaviour change, support needs of people with ID and practical aspects, such as inclusion of follow-up sessions and optimal programme length. Additional communication tools were used when interviewing services users to facilitate communication. Interviews were conducted in a convenient setting for the participant, which included family homes, residential homes and community clinics.

Health professionals were identified through ID services at Leicestershire Partnership NHS Trust, UK. Purposive sampling was used to ensure inclusion of a range of health care professionals with experience of working with adults with ID who could offer diverse perspectives based on their occupational/professional background. Topic guides focused on the process and delivery aspects of the programme, exploring and identifying challenges, physical and intellectual needs, reasonable adjustments, style of delivery and the role of carers.

## Analysis

Interviews for Phase 1 of the study were audio-recorded and transcribed verbatim. Data-driven thematic analysis was conducted using NVivo version 7 QSR (qualitative software programme) (31). Themes relevant to the development of the intervention were identified and recorded (32).

## Development of initial curriculum and theoretical framework

The overarching framework, content, process and learning methods for the initial curriculum were formed at a large curriculum development meeting of multidisciplinary team members, including experts in intervention development and ID. Findings from Phase 1 were presented, discussed and assessed, and a consensus was reached on necessary components (“needs”) to include in the initial curriculum and actions taken to incorporate these components into the programme.

### **Phase 2: Pilot testing and curriculum refinement**

The pilot phase involved two cycles of testing, evaluation, modification and re-testing. Potential participants in the chosen geographical location (based on a pragmatic decision of the number of people in that locality who were identified as high risk and had previously agreed to assist with later phases of the programme, at the time of the pilot testing) were invited to attend the sessions on the dates agreed by the researchers and educators in advance and a maximum of 8 attendees for the sessions was stipulated in advance. The first pilot cycle was conducted between April and July 2014; the second was conducted between October and December 2014. None of the participants had taken part in the previous phase.

#### First pilot cycle

Carers of participants were invited to an initial session, held one week before the delivery of the main education sessions, to give an overview of the programme and explore their role in supporting the participant. The initial curriculum (7 weeks, 2.5 hours held weekly) was then delivered to the participants by a registered ID nurse, a diabetes specialist with an educational background, and an additional ID nurse or health care assistant.

The sessions were evaluated using notes from an experienced researcher who observed the sessions, interviews with programme educators and qualitative interviews with participants (and carers) who had attended the programme. Educator interviews explored content and style of delivery, experiences of delivering the

programme and practical issues. Participant interviews covered content and style of delivery, experiences of receiving the programme, ease of understanding, usefulness, relevance and practical issues.

### Second pilot cycle

The curriculum was refined in response to feedback from the first pilot cycle and then delivered to a separate group. The same process of evaluation and modification was repeated to derive a third and final curriculum (Figure I). Interviews for this, and the previous pilot cycle, were conducted and analysed by the same qualitative researcher as for Phase 1. During this second cycle, a quality development process was also developed for assessing intervention fidelity of the STOP Diabetes education programme (not reported here).

## **Results**

### **Phase 1**

#### Review of the evidence

Only one intervention in the evidence review provided a description of their theoretical underpinning (33). However, some studies recommended the employment of social cognition models such as the Theory of Planned Behaviour (34) and Reasoned Action (34, 35). Key aspects identified were the need to use vicarious, observational and concrete kinaesthetic methods of learning, alongside social support and peer norms (33-37), intrinsic motivation (i.e. people actively choosing healthy lifestyles and sticking with them) and reinforcing feedback loops (providing people with information about their healthy eating behaviours and giving them a chance to change those behaviours) (37). Self-efficacy (i.e. a person's belief that they can perform the behaviour) was identified as an established aspect of behaviour change (37), but it was acknowledged that people's disabilities may preclude them from having complete control over their own activities, such as buying and cooking their own food.

#### Service users and carer interviews

Seven service users agreed to be interviewed (of 18 approached); their characteristics are shown in Supplementary Table S1. The participants generally had some knowledge of diabetes and could describe basic health messages, such as eating vegetables and a high fibre diet and doing exercise. Similarly, they were able to describe the types of food they enjoyed and the degree of choice and control available in relation to foods consumed. The additional use of prompt cards enabled useful discussion around the types of physical activities undertaken; for the more independent, walking appeared to be the most preferred and accessible form of physical activity.

Participants spoke about going to some form of group activity sessions, at local day centres or colleges for example, but it proved difficult to establish whether they preferred group or individual sessions. Most participants said that they preferred photographs to pictorial images on educational resources. More practical considerations related to holding the education sessions locally for familiarity and accessibility. Participants also expressed a preference for carers to be included in the sessions to provide support, make them feel at ease and help them to make lifestyle changes outside the session.

#### Health professional interviews

Fourteen health care professionals were interviewed (of 20 approached), covering a range of specialities (Supplementary Table S1). Most felt that a pre-assessment before delivering the education programme was necessary to assess ability, verbal communication and to prepare people to work in a group setting. It was emphasised that participants had to be in the 'right frame of mind' (the "best place to learn"; HCP 07; Supplementary Table S2) and that this could be enhanced by building in regular short breaks, watching videos or taking part in activities. The use of visual aids to deliver information about dietary choices and practical activities such as preparing healthy foods were considered important. Similarly, when promoting physical activity, suggested strategies included giving participants the opportunity to take part in physical activity during the education sessions.



## Curriculum development

Figure II shows the conceptual framework for the STOP diabetes programme. The framework was informed by that reported by Bazzano and colleagues (33), the qualitative findings and all aspects of the literature highlighted in the evidence review, including 'actual behaviour control' to account for differences that people with ID experience in relation to controlling their own activities (28).

[Figure I about here]

Key needs identified at the curriculum development meeting and incorporated into the programme are shown in Table I. The needs included using a concrete kinaesthetic style, making learning resources available for different levels of ID, preparatory work with individuals before sessions, reflection of personal risks, self-monitoring (through pedometers and/or food diaries), and exploring barriers and solutions to lifestyle behaviour change. Carers were perceived to be crucial to the success of the programme by providing support and advice.

[Table I about here]

Behavioural goals and lifestyle messages were based on those of the 'Let's Prevent' (38) and PREPARE programmes (39, 40), which are two existing prevention programmes developed for the general adult population. Although the programme incorporated specific nutritional and physical activity goals, the emphasis in the curriculum was on more generalised behaviour goals rather than prescriptive targets. These included losing weight, reducing consumption of dietary fat and increasing physical activity and/or sedentary behaviour (Table II).

[Table II about here]

## **Phase 2**

### Pilot testing and evaluation

The first pilot cycle was held in a community resource centre and was attended by four individuals (and three supporting carers) of 21 people approached. Two attendees (50%) were male; the median age was 35 years (range 29–60); three (75%) lived in a supported living environment with carers and one lived independently. None of the participants were in paid employment. Overall attendance at the education sessions was good, with all carers attending the initial carer session, one participant (and carer) attending all seven days and three participants attending six days (n=1 missed the 2<sup>nd</sup> session; n=2 missed the 4<sup>th</sup> session). The most common reason given for not attending sessions was an existing commitment, such as an appointment or holiday. Subsequently, all of the participants and carers who attended the programme were interviewed (see Supplementary Table S3 for key themes and comments). Five educators (out of 6 approached) were also interviewed (see Supplementary Table S4 for key themes and comments).

The second pilot cycle was held in a residential home with seven residents (of 9 approached). Three participants (43%) were male and the median age was 43 years (range 29–50). One participant was in paid employment and two did voluntary work. Attendance at the education sessions was generally good, with three participants attending all seven days, one attending six and the remainder attending at least four days (n=1 missed the 2<sup>nd</sup> session; n=2 missed the 4<sup>th</sup> and 6<sup>th</sup> session; n=3 missed the 5<sup>th</sup> session); care workers attended some or part of the sessions. As before, the most common reason given for not attending sessions was an existing commitment. Five participants were interviewed along with two members of staff (carers) after the final education session (see Supplementary Table S5 for key themes and comments).

### Implications

Taken together, findings from the first and second pilot cycles suggested that participants enjoyed the programme and that it helped them to make and sustain changes to their diet and physical activity levels. Carers felt that attending the programme helped them to facilitate behaviour changes and their input was valued by the educators. However, for the first pilot cycle, the sessions were sometimes perceived to be over-complicated, with numerous resources and messages, confusing images and pictures, and overly conceptualised messages and activities.

For the first pilot cycle, changes to the programme included simplifying the resources and session content, and changing images and symbols to make them more visible and understandable (Table III). Realistic images and/or photographs (checked by our service user groups), and communication aids were introduced to manage discussions. The programme built in further opportunities for movement during the sessions (e.g. a walk around the room) to help the participants to stay focused and to monitor their own activity and steps.

For the second pilot cycle, resources were further personalised, educators had a more flexible approach to the timetable to fit the needs of the group, and seating and positioning of participants were built into the programme to support engagement and one-to-one support (if required). Further, in response to the positive feedback, more interactive games and activities were included. Service users were also provided with more options to prompt them towards their goals; for example, fridge magnets could be used as prompts, but were not used by people who shared their fridges.

[Table III about here]

### Final curriculum

Supplementary tables S6 and S7 outline the final curriculum of the STOP diabetes programme for carers and participants. The carer session provided information about the programme, content, role of the educators and provided an opportunity to ask questions or raise concerns. It allowed carers to reflect on the learning needs of the participants, how they might be supported, and the potential health benefits of attending the sessions.

The curriculum for the seven participant (and carer) sessions included a description of the sessions, review of previous sessions and a discussion or reflection of two topics each week. Topics broadly covered health, nutrition and physical activity. They included health checks, types of physical activity, healthy foods, current physical activity levels, current eating habits and realistic goals to increase physical activity

levels and eat healthily. The curriculum built in flexible breaks to be taken on request or when educators perceived there to be a decrease in engagement levels.

## **Discussion**

### **Main findings of this study**

This study describes the development of a lifestyle behaviour change programme for adults with ID informed by the MRC framework for the development of complex interventions (26), intervention mapping (27), evidence reviews, stakeholder interviews, and ongoing prevention programmes (38). Development benefited from a systematic process (26, 27), with sound theoretical underpinnings informing the content and style of the approach, combined with qualitative interviews and multi-disciplinary expertise.

The service users that we interviewed appeared to enjoy the sessions and said they changed their behaviour. One of the most important findings from the developmental and pilot phases of our study related to how people with ID learned differently. We purposely aligned with the current literature and health professionals' views by favouring concrete kinaesthetic methods of learning (33), visual aids (41) and avoiding abstract concepts (42), but service users sometimes misinterpreted the pictures that we had originally developed to facilitate learning. Our findings highlight the importance of service user involvement, which was actively supported during the research programme (43), to gain as many different perspectives as possible.

Service users also reported enjoying the interactive activities and valued the opportunity to take short breaks during the sessions. Most of the participants were supported by carers who played a crucial role in encouraging, motivating and enabling participants to make lifestyle changes. Participants did not always have control over their activities, such as going shopping or cooking their own food, so engagement from carers was seen as a vital component to educators. That carers provide emotional and practical support is supported in previous research (44), particularly in relation to behaviour change (45, 46).

## **What is already known on this topic**

- Lifestyle behaviour change interventions that target both diet and physical activity can prevent or delay onset of T2DM in the general population (5-7).
- There are few studies that assess the effectiveness of multi-component lifestyle behaviour change interventions in the ID population; these have shown inconclusive results (33, 47-50).

## **What this study adds**

- The STOP Diabetes education programme has employed a theoretical framework, using sound learning and behavioural principles and concrete kinaesthetic methods, to provide the grounding for the development of innovative games and activities to promote health behaviour change in adults with ID.
- Interviews with stakeholders suggest that the education programme was acceptable to participants and carers, and support further feasibility work to determine whether a definitive RCT to evaluate the effectiveness of the STOP Diabetes education programme is possible.

## **Limitations of this study**

This study was designed to develop and initially test the lifestyle behaviour change programme and did not involve a full validation of the programme. Similarly, whilst the interview schedules were developed by the core multidisciplinary team, which included ID specialists, the interviewer observed that the service users sometimes seemed 'eager to please', and she could not always prompt further to explore their responses in more depth. This concern has been raised in previous research (51) and may have over-inflated the positive responses that we encountered. It was also noted that the carers could sometimes interrupt or 'speak for' the service user, particularly where the service user was struggling to voice their opinion. Although this was a supportive gesture, it was sometimes difficult to distinguish whose views were being obtained. Similarly, the paid carers only attended the interviews intermittently, and their views were not always explored fully.

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## **Ethical approval**

NHS ethical approval for this study and the STOP Diabetes programme of work was obtained from the East of England – Cambridge Central Research Ethics Committee (reference: 12/EE/0340).

## **Conflicts of interest**

Alison Dunkley – none declared.

Freya Tyrer – none declared.

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Dr Thomas Yates is a member of the National Institute for Health and Clinical Excellence public health guidance on preventing type 2 diabetes.

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Professor Kamlesh Khunti is Chair of the National Institute for Health and Clinical Excellence public health guidance on preventing type 2 diabetes and adviser to the UK Department of Health for the NHS Health Checks Programme. He has acted as a consultant, served on advisory boards for and speaker for Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Janssen, Boehringer Ingelheim and Merck Sharp & Dohme. He has received grants in support of investigator and investigator-initiated trials from Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Roche, Boehringer Ingelheim and Merck Sharp & Dohme. He has also received grants and support from the NIHR during the conduct of this study.

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## Tables

**Table I: Needs identified and actions incorporated into the STOP Diabetes programme**

| Identified need   | Actions  |
|---|--|
| ♦ Concrete kinaesthetic learning style  | <ul style="list-style-type: none"> <li>♦ Session material used to create concrete examples</li> <li>♦ Use of activities, games and social stories</li> <li>♦ Activities developed to create movement and participation</li> <li>♦ Use of visual aids</li> <li>♦ Short walks</li> </ul>   |
| ♦ Tailor to meet individual needs (learning styles and level of ID)   | <ul style="list-style-type: none"> <li>♦ Employment of multiple learning methods and multiple modalities with support from experienced ID healthcare assistant</li> <li>♦ Regular breaks</li> <li>♦ Recall and repetition to support learning</li> </ul>   |
| ♦ Involvement of carers to engage and promote interest  | <ul style="list-style-type: none"> <li>♦ Carer session held prior to education session</li> <li>♦ Homework</li> <li>♦ Involve carers in sessions</li> </ul>  |
| ♦ Preparation prior to attendance and at start of each session  | <ul style="list-style-type: none"> <li>♦ Educators should meet all service users before commencing the programme to describe the programme, assess needs and determine willingness to attend</li> <li>♦ Educators to meet and greet participants and carers before start of each session.</li> <li>♦ Establish set of mutually agreed group guidelines.</li> </ul> |
| ♦ Reflection on personal levels of risk   | ♦ Activities   |
| ♦ Self-monitoring   | ♦ Provision of optional food diaries and pedometers  |
| ♦ Individualised goal setting and action planning (more generalised behavioural goals rather than prescriptive targets) | <ul style="list-style-type: none"> <li>♦ Create goal setting opportunities around activity, food and other behaviour goals</li> <li>♦ Personalised resources developed by participants, such as posters, cues/prompt cards, postcards</li> <li>♦ Exploration of barriers and individualised solutions</li> </ul>   |

ID intellectual disability

**Table II: Key behaviour change goals**

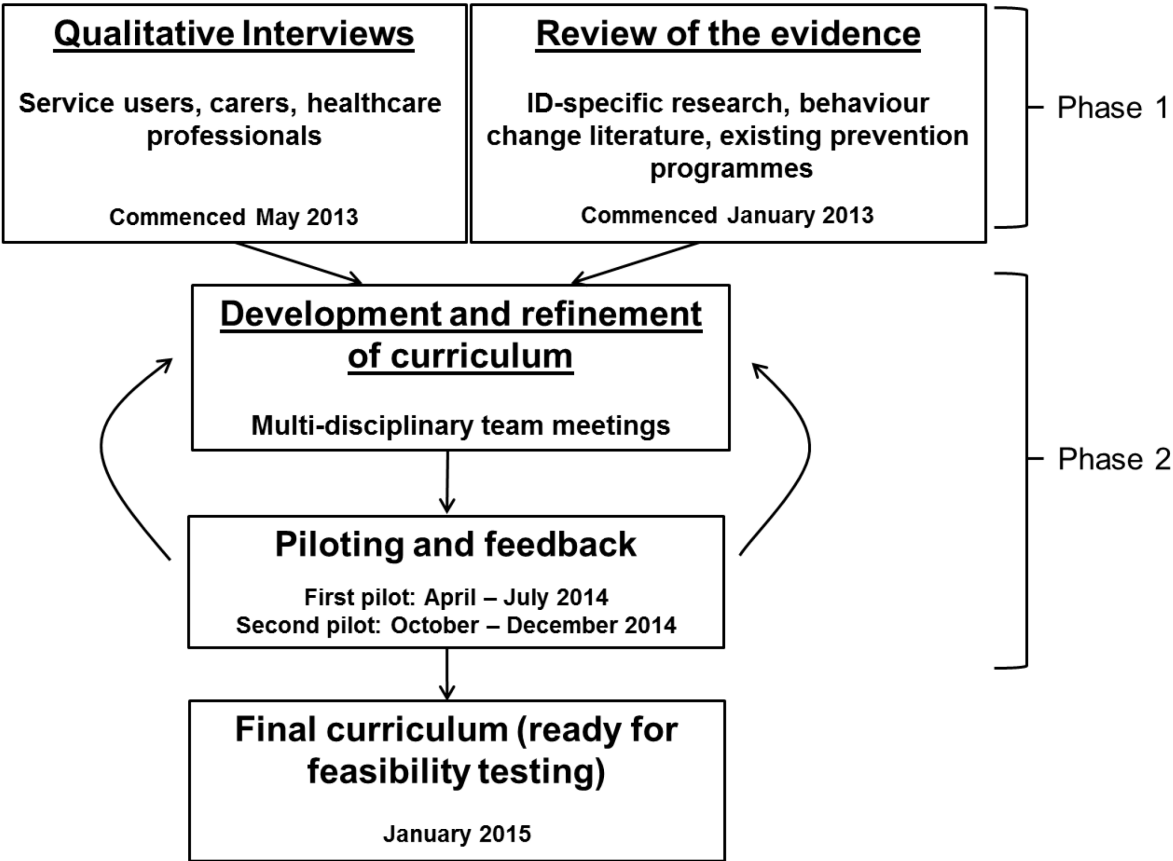
| <b>Specific nutritional and physical activity goals</b>   | <b>STOP Diabetes key behavioural goals</b>  |
|---|---|
| <ul style="list-style-type: none"> <li>◆ Weight reduction</li> <li>◆ Sustained weight reduction of &gt; 5 % body weight</li> </ul>  | <ul style="list-style-type: none"> <li>◆ Choose smaller portions</li> <li>◆ Reduce fat intake from all sources</li> <li>◆ Reduce sugary drinks and foods</li> <li>◆ Choose healthier cooking methods</li> <li>◆ Choose healthier snacks and treats</li> <li>◆ Increase physical activity/ reducing sedentary</li> </ul> |
| <ul style="list-style-type: none"> <li>◆ Reduce total fat consumption</li> <li>◆ Moderate reduction in total fat to &lt; 30% energy intake</li> </ul>   | <ul style="list-style-type: none"> <li>◆ Reduce fat from all sources</li> <li>◆ Choose lower fat options</li> <li>◆ Reduce processed foods and ready meals</li> <li>◆ Choose healthier snacks and treats</li> </ul>   |
| <ul style="list-style-type: none"> <li>◆ Low saturated fat intake</li> <li>◆ Reduce saturated fat intake to &lt; 10% energy intake</li> </ul>   | <ul style="list-style-type: none"> <li>◆ Reduce fat from all sources</li> <li>◆ Reduce processed and ready meals</li> <li>◆ Choosing healthier snacks and treats</li> </ul>   |
| <ul style="list-style-type: none"> <li>◆ Higher fibre intake</li> <li>◆ Increase fibre intake to &gt;15g per 1000 calories</li> </ul>   | <ul style="list-style-type: none"> <li>◆ Increase fruit and vegetable intake to 5 a day minimum</li> <li>◆ Choose healthier snacks and treats</li> </ul>  |
| <ul style="list-style-type: none"> <li>◆ Increase physical activity / reduce sedentary behaviour</li> <li>◆ A minimum recommendation of 30 minutes of moderate intensity physical activity per day</li> </ul> | <ul style="list-style-type: none"> <li>◆ Increase moderate intensity activity by increasing steps or adding extra physical activity</li> <li>◆ Reduce sitting time</li> </ul>   |

**Table III: Modifications to STOP diabetes programme in response to feedback from the first and second pilot cycles**

| Feedback  | Modification  |
|---|---|
| <b>First pilot cycle</b>                        |   |
| ♦ Too many resources and messages               | <ul style="list-style-type: none"> <li>♦ Reduce information provided in carer session</li> <li>♦ Reduce number of worksheets and only provide them when required in the programme</li> <li>♦ Reduce/simplify content of some sessions</li> <li>♦ Simplify physical activity diary to a single page of A4</li> </ul>   |
| ♦ Confusing images and pictures                 | <ul style="list-style-type: none"> <li>♦ Increase size of image cards used to support learning, recognition, recall and summaries</li> <li>♦ Change symbols to illustrate healthy and less healthy foods and ensure educators explain and check understanding when symbols are used</li> </ul>  |
| ♦ Overly conceptualised messages and activities | <ul style="list-style-type: none"> <li>♦ Use realistic images and/or photographs (sourced and approved by service user groups).</li> </ul>  |
| ♦ Maintaining and maximising engagement         | <ul style="list-style-type: none"> <li>♦ Use communication aids to manage discussions in the group</li> <li>♦ Walking activities for engagement, highlighting step counts</li> </ul>  |
| <b>Second pilot cycle</b>                       |   |
| ♦ Maintaining and maximising engagement         | <ul style="list-style-type: none"> <li>♦ Allow educator flexibility to adjust the timetable and breaks</li> <li>♦ Arrange seating and positioning of participants to support engagement and one-to-one support (if required)</li> <li>♦ Include more interactive games/activities</li> <li>♦ Add photos of participants to their “health checklist” to personalise documents</li> <li>♦ Provide options for prompts and motivation towards goals</li> </ul> |

Figures

Figure I: Phases of development for the STOP diabetes programme



**Figure II: Theoretical framework for the STOP diabetes programme**

