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The University of Sheffield
ScHARR School of Health and Related Research
Public Health Collaborating Centre

Prevention of type 2 diabetes: Reviewing mechanisms of successful interventions and translation of major trial evidence to practice.

Prevention of progression to type 2 diabetes in practice.

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About the ScHARR Public Health Collaborating Centre

The School of Health and Related Research (ScHARR), in the Faculty of Medicine, Dentistry and Health, University of Sheffield, is a multidisciplinary research-led academic department with established strengths in health technology assessment, health services research, public health, medical statistics, information science, health economics, operational research and mathematical modelling, and qualitative research methods. It has close links with the NHS locally and nationally and an extensive programme of undergraduate and postgraduate teaching, with Masters courses in public health, health services research, health economics and decision modelling.

ScHARR is one of the two Public Health Collaborating Centres for the Centre for Public Health Excellence (CPHE) in the National Institute for Health and Clinical Excellence (NICE) established in May 2008. The Public Health Collaborating Centres work closely with colleagues in the Centre for Public Health Excellence to produce evidence reviews, economic appraisals, systematic reviews and other evidence based products to support the development of guidance by the public health advisory committees of NICE (the Public Health Interventions Advisory Committee (PHIAC) and Programme Development Groups).

Contribution of Authors

Maxine Johnson was the systematic review lead. Crystal Freemen and Roy Jones were reviewers on the project. Helen Buckley Woods developed and undertook literature searches. Mike Gillett identified additional literature and contributed to topic discussions. Vishal Ram and Annabel Sidwell assisted reviewers as part of their student placement at ScHARR. Nick Payne and Jim Chilcott were the senior leads. Elizabeth Goyder was the topic expert.

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Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

1. LIST OF ABBREVIATIONS

BME	Black and Minority Ethnic (groups)
BMI	Body Mass Index
CHD	Coronary Heart Disease
CI	Confidence Interval
CPHE	Centre for Public Health Excellence
DH	Department of Health
DPP	Diabetes Prevention Programme (US)
DPS	Diabetes Prevention Study (Finland)
GP	General Practitioner
IDDP	Indian Diabetes Prevention Programme
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
ITT	Intention to Treat
JDPP	Japanese Diabetes Prevention Programme
n-RCT	Non-Randomised Trial with control arm(s)
NGT	Normal Glucose Tolerance
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NNT	Number Needed to Treat
NA	Not Applicable
NR	Not reported
OR	Odds Ratio
QUOROM	Quality Of Reporting Of Meta-analyses
RCT	Randomised Controlled Trial
RR (R)	Relative Risk (Reduction)
SES	Socio-economic status
SR	Systematic review

2. EXECUTIVE SUMMARY

2.1 Background

Type 2 diabetes is associated with significant clinical and social consequences. The National Institute for Health and Clinical Excellence has been asked by the Department of Health to develop public health guidance on the prevention of type 2 diabetes among high-risk groups. The referral is divided into 2 separate pieces of guidance. The first addressed the prevention of pre-diabetes (raised and impaired glucose levels) in populations and communities of high risk adults aged 18-74 using determinants of health such as creating an environment supportive of behaviour change.

This second piece of guidance addresses how to prevent the progression of pre-diabetes to type 2 diabetes at the individual level.

It is recognised that the term 'pre-diabetes' is not ideal, as not everyone with raised or impaired blood glucose levels will go on to develop type 2 diabetes. However, the term 'pre-diabetes' has been chosen because of its widespread use and recognition by a broad range of stakeholder groups, and because of the lack of consensus on a suitable alternative.

Within this second piece of guidance, four reviews of world-wide evidence were carried out that address the prevention of progression to type 2 diabetes. This document reports on the third of such reviews. It focuses on how lifestyle interventions work best by assessing review level evidence of, for example, evaluations of interventions in practice, and the successful components of interventions. Included reviews will have synthesised evidence across individual studies that used a range of methods, and therefore provide information and analysis in respect of successful components of interventions that is not available from individual study findings. This review does not aim to assess or measure the overall effectiveness of such interventions, since this is covered in our second review "Systematic review and meta-analysis of lifestyle, pharmacological and surgical interventions". Rather, this review will complement the findings from RCTs included in Review 2 by focusing on a range of studies (not all RCTs) and, within these studies, what components of lifestyle and related interventions work best in practice, and what their key features are.

2.2 Aims and Objectives

The aims of this, the third of four reviews, were firstly to undertake an assessment of review level evidence that synthesises findings relating to identifying and characterising successful components and elements of lifestyle interventions to prevention progression to diabetes in

diagnosed populations with pre-diabetes. Secondly, to assess and synthesise findings from individual studies / trials that use trial evidence and evaluations of interventions carried out in everyday settings.

The objectives for this review are:

To retrieve relevant review level evidence that identifies components of lifestyle interventions and translational studies of large trials of lifestyle interventions for the prevention of type 2 diabetes.

To retrieve review level papers to identify evidence on the effectiveness and context of translational studies and to identify primary studies that fill gaps in the knowledge base.

To use primary level evidence where detailed information on specific interventions is not available in review level evidence.

To analyse and synthesise the findings from both sets of evidence.

Review Questions:

What is the review level evidence for specific components (or combinations of components) of intervention programme / strategies which are most effective in preventing or delaying progression to type 2 diabetes in adults with pre-diabetes?

What is the review and primary level evidence for the most effective methods of preventing or delaying progression to type 2 diabetes in adults with pre-diabetes when intensive interventions assessed in RCTs are adapted to real world settings?

Evidence from assessed reviews is reported for each of the two questions in terms of content, mode of delivery, setting, intensity and duration. It is also reported by sub-groups including sex, age and ethnicity.

2.3 Methods

An iterative searching process was carried out to identify review level evidence that addressed the first question. This comprised an overarching topic search followed by a focussed search using a filter for review level material. Reviews were considered that included any type of study with the aim of prevention of type 2 diabetes, and that assessed the components of interventions.

A focussed search for primary level evidence covering a range of research methods to address the second question was subsequently undertaken. Studies were considered if they assessed the translation of any of the major diabetes prevention trials into 'real world' settings, that is, primary care or other settings within the community.

2.4 Results

Part One: Review of Reviews of intervention components

Initial (overarching) searches (not restricted to any study design) identified 1404 potential papers (following de-duplication) potentially relevant to this guidance. Of these, 1382 were rejected at title / abstract level. An additional focused search (for review 3, filtered for review level evidence) of a range of database sources identified 1623 papers following de-duplication that were potentially relevant to this review. Of these, a total of 1584 were rejected at title / abstract level. From the resulting 61 papers (from initial and focussed searches), a total of 52 papers were rejected at full text level. Four further papers were identified from reference lists. Thus, a total of 13 papers were identified that were relevant to Part 1.

Overall, the quality of review level papers was good; only two papers (reviews) were rated as poor. Quality assessment issues were mainly around type of study. For example, a number of review authors did not aim to write a systematic review; therefore quality assessment scores in these cases might be lower using review assessment criteria. Generally, the RCTs included in the assessed reviews were reported as having a high risk of bias by authors that carried out quality assessment. This was mainly due to a lack of reporting of randomisation and allocation methods.

Included reviews provided no comparisons between different settings in which studies that had reported effective outcomes such as a reduction in diabetes incidence and weight change had been carried out. There was evidence however for such individual trials having been carried out in a range of settings, mainly outpatient clinics and primary care.

Whilst there was no formal statistical comparison made between characteristics of intervention providers, three of the included reviews identified a high level of skill, and preferably high level qualifications such as a Master's degree as common requirements in those trials that had demonstrated reduction in diabetes incidence and / or weight loss. Staff awareness of the clinical significance of prevention was reported as an important factor, as were skills in assessing individuals for risk, as well as delivering counselling or referring to experts.

One review assessed the differences between intervention and control arms in seven RCTs that had demonstrated effective reduction in diabetes incidence and weight, concluding that most interventions were delivered on an individual basis, with two utilising small groups.

Four reviews reported on frequency of contact within the interventions. Whilst frequency of contact was not formally compared in the trials, and there is no consensus regarding the optimal number of contacts, one review concluded that frequency was significantly associated with weight loss in three out of nine included trials. Frequency of contact may have an impact on outcomes since one review reported that regular contact can encourage sustained participation.

A range of dietary interventions were reported across three reviews, with no formal comparison found between different diets. However, common components of trials were a reduction in total fat, saturated fat and total calorie intake as well as an increase in dietary fibre, fruit, vegetables and nuts. Adherence to a Mediterranean diet was reported to be associated with weight loss in one review of observational studies.

These dietary changes, either alone or combined with at least 150 minutes of moderate level physical activity per week were shown to be effective in reducing weight, and / or reducing diabetes incidence. Resistance training was advised in two trials. The rate of increase in physical activity was reported to impact on reduction of diabetes incidence in one review with those exercising most having a reduced risk.

Three reviews assessed behaviour change components. One review compared intervention and control arms of 7 RCTs and concluded that theoretically based interventions are more likely to bring about desired effects than advice and information alone. Though the trials did not necessarily describe the theories underpinning lifestyle interventions, those that achieved diabetes risk reduction and weight reduction focussed on behavioural intent. For example, staging information and tailoring interventions to individual needs as well as regular re-inforcement of goal-setting by use of self-monitoring dietary, physical activity and weight changes were used in a number of trials.

Five reviews reported on intervention recipient factors. Awareness of risk and stage of readiness to change were reported as important motivators. Participants that made the most changes to dietary and physical activity behaviours were more likely to reduce their risk for diabetes.

Three reviews reported on potential strategies to increase attendance and adherence. These included provision of feedback to participants, free supervised physical activity sessions and the involvement of family in the intervention. There was evidence that motivation to adhere

may be reduced by encouraging high intensity or prolonged physical activity due to a perceived risk of injury, and lack of time respectively.

Part two: Review of primary translational studies

Searches were carried out in three databases to identify primary level papers focussing on translational studies resulting in a total of 789 references following de-duplication. Of these, 723 were rejected at title / abstract level and 66 were considered at full text. Fifty three papers were rejected at full text level. Thus, a total of thirteen primary level papers were included in this review.

The quality of retrieved papers was good, with one primary level paper rated ++. The remaining eight papers were rated +.

Studies reported in the primary papers were based on either the US based Diabetes Prevention Program (DPP) or the Finnish based Diabetes Prevention Study DPS protocols. No papers were retrieved that were based on the Chinese Da Qing Diabetes Prevention trial, the Indian based Diabetes Prevention programme (IDPP) or any other major trial. Ten US studies (reported in nine papers) were based on the DPP and three (from Finland and Australia) on the DPS. All but one were carried out in health care settings (one utilised a church setting), with one US study also utilising YMCA facilities, one US study utilising internet technology to access the target population and one Australian study delivering an intervention arm via telehealth (video conferencing) technology.

Follow up times ranged from 16 weeks in one US based tele-health study to 3 years in one Finnish study. Only four out of the fourteen studies included a comparator, two of which were randomised trials. The populations in all studies were assessed to be at risk from type 2 diabetes either by having a raised BMI or a high FINDRISC score. Interventions included dietary and physical activity sessions as well as behavioural strategies, as developed in the two major trials.

The main modifications in the translational studies were shorter follow up which ranged from 16 weeks to 12 months, as well as a range of intensity in terms of number of sessions. All the sessions carried out in the translational studies were group-based rather than individual. All interventions were delivered by trained personnel and based on similar behavioural strategies as the DPP or the DPS in terms of goal-setting and self-monitoring.

The primary outcome of all thirteen studies was weight change, rather than diabetes incidence. All but one study reported weight loss following intervention, and all studies that included a comparator reported better outcomes in the intervention group compared to controls. There was mixed evidence from six studies reporting mean changes in blood

glucose levels following both the DPP and DPS based interventions, with four studies out of the six reporting reductions.

Four studies reported reductions in BMI, and three reported waist circumference reduction at 6 or 12 months, though this was not sustained in one study at 3 years. The remaining studies did not assess these outcomes.

Attendance rates were reported as good, though methods of reporting varied. Attendance was least successful for telephone contacts due to difficulties arranging appropriate times. Reasons for lack of attendance in one DPS based study included lack of time and fuel costs as well as health conditions. Internet delivery of a lifestyle intervention was well attended in the initial stages but slowed down over the following few weeks. Intervention adherence was reported in two studies, with increased adherence observed in men and older participants.

From this small selection of studies it appears that positive results can be achieved in real world settings, though there needs to be caution in interpretation, as only four of the studies included a comparator, and two used randomisation. In addition, sample sizes were often small, and follow up times short.

Comparison of findings from the review of reviews and the review of translational studies.

Though no specific components of major diabetes prevention trials have been compared statistically, some trends can be observed from the reviews of these trials as well as the evaluations of translational programmes. Major trials were designed to incorporate behavioural strategies, and aspects such as the encouragement of self-monitoring appear from reviews of the trials to increase adherence to the programme with subsequent improvement in outcomes. Whilst translational papers did not particularly describe behavioural strategies, there appeared to be fidelity to the original DPP or DPS protocols when translating the programmes to primary care. In one study fidelity was less pronounced and the authors state that this may be one contributor to a lack of desired outcome.

Translational studies highlighted an association between improved outcomes and number of contacts between participants and those delivering the intervention and / or providing support. This supports the finding in one review of dietary support interventions that access to such support needs to be made available at least every 3- 6 months.

Conclusion

A potential tension exists between achieving optimal outcomes and adapting diabetes prevention programmes into the 'real world'. In primary care and community settings the populations are diverse and resources are limited, which restricts the extent to which interventions can be tailored to meet individual preferences and be culturally sensitive. In addition, tailoring may limit the extent to which protocol fidelity can be maintained. This has an impact on the evaluation and comparisons of outcomes in translational studies.

However, reviews of major trials and the review of translational studies both show that diabetes prevention and weight loss are achievable in intense research settings and that significant weight loss can be achieved at least in up to twelve months of follow up in 'real world' settings. Outcomes from longer follow up of translational studies are needed to evaluate whether these results can be sustained.

2.5 Evidence statements

Whilst the evidence statements relating to part one of this review show the number of review level studies reporting important findings, it must be acknowledged that a number of major studies have been repeatedly reviewed. These statements therefore show the synthesis of main findings across reviews, but do not place more emphasis on those reported in more than one review.

Evidence statement 1:

Intervention Settings

Evidence was found from two systematic reviews of randomised controlled trials (Baker *et al* (2011 ++; Norris *et al* 2009 ++) of diabetes prevention programmes that effective programmes can be delivered in a range of clinical (in-patient and outpatient) and community settings.

However, there is a lack of evidence that directly compares intervention effectiveness between different settings, therefore it was not possible to determine whether any particular setting is better than another in terms of outcomes, or the potential scale of the impact this might have.

Baker *et al* (2011 ++) reported that four major trials delivered successful interventions (which we have defined here as delivering significant reduction in diabetes incidence or significant weight loss at a minimum of 12 months follow up compared to controls) in clinical outpatient settings. The trials were conducted in Japan, India, Italy and China. The quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from Norris *et al* (2009 ++) provides examples of three trials that were effective in reducing the incidence of type 2 diabetes in clinical and community settings (no further details given), as well a combination of the two. These trials were carried out in the US, Finland and China. Quality rating was not detailed, though it was noted that randomisation procedures were only described in one of the three trials. All three trials were described as adequately powered.

Applicability rating: Evidence statement 1:

Trials were carried out in a range of settings in different countries, but mainly in outpatient clinics so there is partial applicability to UK settings. The populations that were included in the trials are at risk of type 2 diabetes and so individual effects may be transferable to the UK at risk population.

Evidence statement 2:

Characteristics of those delivering interventions

Evidence was extracted from two systematic reviews of RCTs (Baker *et al* 2011++; Nield *et al* 2008 ++) and weak evidence from one non-systematic review (Roumen *et al* 2009 -) for an observational association of high levels of skill and / or a relevant professional qualification with intervention effectiveness for diabetes prevention.

However, there is a lack of evidence that directly compares or that statistically examines difference in intervention effectiveness between providers with different characteristics. Hence, it is not currently possible to determine the optimal characteristics of intervention providers or the scale of the impact this might have.

The two systematic reviews present the observation that high levels of skill and relevant professional qualifications were characteristics of successful interventions in a total of 7 trials that resulted in a reduction of diabetes incidence. The trials were conducted in the US, Finland, China, India, Japan, Italy and Sweden.

In a non-systematic review of a range of study types (Roumen *et al* 2009 -) the authors suggest, based on a qualitative study of general practitioner knowledge that was carried out in the UK, that awareness of the importance of reducing the incidence of type 2 diabetes as well as being able to effectively assess and counsel recipients about diet and physical activity may be important contributors to sustainable changes in diet and / or physical activity.

Applicability rating: Evidence statement 2:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the characteristics of those delivering interventions cannot be transferable to interventions carried out in the UK.

Evidence statement 3:

Mode of intervention delivery

There is evidence from one systematic review of RCTs (Baker *et al* 2011++) relating to the mode of intervention delivery.

However, there is a lack of evidence that directly compares intervention effectiveness between individual or group delivery, therefore it was not possible to determine whether individual delivery is better than group delivery in terms of outcomes, or the potential scale of the impact this might have.

One systematic review of RCTs (Baker *et al* 2011++) reported that 7 trials achieving a reduction in the incidence of type 2 diabetes and with a follow up of at least 12 months delivered an initial individual assessment followed by either individual or group counselling. In five out of seven of these trials, counselling was delivered mainly on an individual basis. These trials were based in the US, Finland, Japan, India and Sweden. Two trials delivered counselling in small groups following the initial individual assessment. These trials were carried out in China and Italy. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Applicability rating: Evidence statement 3:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the mode of delivery of interventions (i.e. group or individual) is not transferable to interventions carried out in the UK.

Evidence statement 4:

Frequency of contacts

Evidence was extracted from four systematic reviews of randomised controlled trials (Baker *et al* 2011 ++; Nield *et al* 2008 ++; Norris *et al* 2007 ++; Yuen *et al* 2010 ++) and one non-systematic review of lifestyle and medication studies (Davies *et al* 2004 +). Contact is defined here as individual face-to-face counselling, assessments or telephone contact between intervention participants and those facilitating the intervention or assessing outcomes.

There is a lack of evidence that directly compares intervention effectiveness between the frequencies of contact, therefore it was not possible to determine the potential scale of the impact that different frequencies might have.

Baker *et al* (2011 ++ UK) reported that of seven included trials that achieved successful reduction in diabetes incidence, the frequency of contacts during the first 12 months of implementation ranged from 6 in one Japanese trial and one Italian trial to more than 22 in one Swedish trial and one US based trial. When supervised physical activity sessions were included in one Finnish trial, this number extended to 165.

Nield *et al* (2008 ++) recommended access to dietary support and guidance at least 3- 6 monthly based on their review of 2 RCTs. One trial was carried out in the Netherlands and assessed weight reduction as the primary outcome. One trial was based in China (the same trial as in Baker *et al* 2011). The authors assessed the quality of these trials as quite poor based on the Jadad score.

Norris *et al* (2007 ++) reported total contact frequencies ranging from four over one year in one trial based in the UK and France that demonstrated a small weight loss (< 0.5kg) compared to the control group, to 78 over 2 years in one US trial that demonstrated > 2kg weight loss compared to controls. One included Finnish trial achieved a 58% reduction in relative risk for diabetes incidence with 15 contacts over 3.2 years ($p<0.001$). One Swedish based trial assessed the effects of a 28-day residential course. The authors report that the number of dietary and physical activity intervention contacts in three well powered studies (carried out in the US, Finland and China) that achieved reduction in diabetes incidence also significantly correlated

with weight loss (p=0.015). Quality rating was not detailed, though it was noted that randomisation procedures were only described in one of the three trials.

Yuen *et al* (2010 ++) speculated from a review of three trials carried out in the US, India, China and internationally that lifestyle advice re-reinforced regularly might be more effective because it encourages sustained participation. Studies were assessed for risk of bias, with all four trials having at least 2 elements out of six that were rated as high risk. The DPP (US) was rated lowest risk of bias. This trial also reported similar diabetes incidence rates at two different time points.

One non-systematic review (Davies *et al* 2004 +) that assessed six trials comparing lifestyle interventions or lifestyle and medication reported that successful interventions included individual counselling on at least 7 sessions during the first year followed by individual or group sessions every 3 months for the remainder of the study. The trials were carried out in China, US, Finland, Brazil and internationally. One trial was carried out with women who had a history of gestational diabetes. There was no quality rating reported for the studies.

Applicability rating: Evidence statement 4:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the effect of frequency of contacts is not transferable to interventions carried out in the UK.

Evidence statement 5:

Dietary interventions

There was evidence from four systematic reviews of randomised controlled trials (Baker *et al* 2011++; Burnet *et al* 2006 +; Waugh *et al* 2010 ++; Paulweber *et al* 2010 ++) and two non-systematic reviews of a range of study types (Davies *et al* 2004 +; Roumen *et al* 2009 -) for dietary components of lifestyle interventions for the prevention of type 2 diabetes.

Baker *et al* (2011++) assessed seven RCTs in which all participants were advised

individually to modify their diet. All the interventions advised a reduction in fat (with four studies carried out in the US, Finland, China and Sweden) specifying a reduction to <20-30% of total energy intake, and six studies advised adjustment of portion control. Four studies (carried out in the US, India, Italy and Sweden) recommended an increase in fibre intake, and all seven studies advised increased fibre intake in the form of fruit and vegetables. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from three systematic reviews of RCTs (Burnet *et al* 2006 +; Waugh *et al*. 2010 ++; Paulweber *et al* 2010 ++) and one non-systematic review (Roumen 2009 -) report similar detail from between five and nine diabetes prevention trials carried out in the US, Finland, China, Japan, Sweden, Australia, India, Netherlands and the UK regarding dietary aims to sustain a weight reduction of 5-7% when combined with physical activity goals. They include the consumption of 55% total energy intake as carbohydrates; fat 30% - 35% of total energy with saturated fat ≤ 10%; protein 10-15 % of total energy intake and fibre ≥ 15g per 1000kcal. Quality ratings are not available within the reviews.

There was also evidence from epidemiological studies included in two reviews of a range of study types (Burnet *et al* 2006 +; Walker *et al* 2010 +) that a diet of fruits, vegetables, legumes, fish and whole grains was associated with a lower diabetes risk. Walker *et al* (2010 +) describe the 'Mediterranean' diet, as rich in fat, but mainly in the form of olive oil, and includes a wide range of vegetables and legumes, fruit and nuts. They provide evidence from a range of cohort studies, two of which were carried out in Spain and US that adherence to the diet was associated with up to 15% reduced diabetes risk, weight maintenance or weight loss. One Spanish arm of an international cohort study reported a decreased risk for obesity at 3 years in those that adhered well to the Mediterranean diet (OR 0.68, 95% CI 0.53-89 in men, OR 0.69, 95% CI 0.54-0.89 in women). These reviews did not report quality ratings for the epidemiological studies.

Epidemiological evidence from one non-systematic review of a range of study types (Davies *et al* 2004+) suggests that the frequency of fruit and vegetable intake was inversely associated with HbA1c levels in the UK based EPIC study and that in the US, an increased intake of whole grains was associated with decreased diabetes risk, though there was no clinical significance reported. Quality ratings were not reported for these studies.

Findings from reviews of epidemiological studies need to be viewed with caution due to the risk of bias.

There is a lack of quality evidence that assesses the effect of diet and physical activity alone in trials that have demonstrated reduction in the incidence of type 2 diabetes and / or weight reduction. Therefore, it is difficult to make inferences about the impact that any particular dietary intervention may have on outcomes.

Applicability rating: Evidence statement 5:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the dietary advice provided is not transferable to interventions carried out in the UK.

Evidence statement 6:

Physical activity interventions

Evidence was obtained from two systematic reviews of randomised controlled trials (Baker *et al* 2011++; Paulweber *et al* 2010++) and one review of randomised and non-randomised controlled trials (Yates *et al* 2007 +).

Baker *et al* (2011++) and Paulweber *et al* (2010 ++) provided evidence from five and seven RCTs respectively in which participants had been advised to increase their level of physical activity. All trials reviewed reported a reduction in incidence of type 2 diabetes. The advice was to increase physical activity to a level of at least 150 minutes per week at moderate intensity in trials carried out in US, Italy, and Sweden. Baker *et al* (2011 ++) also report that up to 30-40 minutes of moderate activity (e.g. brisk walking) per day was advised in one trial carried out in Japan. The US based and Chinese trial allowed participants to reduce the volume of activity if it was carried out more vigorously. Resistance training was included in some US and Finnish based clinics. A Swedish trial included counselling on the importance of muscular strengthening twice a week. Supervised physical activity was included free of charge 2 days per week in the US and Finnish trials. The Swedish trial included a residential component of 2.5 hours per day for one month. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met

threshold criteria were included in the review.

Evidence from one systematic review of randomised and non-randomised controlled trials (Yates *et al* 2007 +) suggests that, from four included RCTs that assessed the reduction of type 2 diabetes incidence (carried out in US, China, Finland and Sweden), risk of diabetes was reduced by 42-63% compared to the control groups. Quality assessment was not reported on the studies. Issues that may have impacted on the findings include self-reporting of physical activity and use of physical activity questionnaires that lack validity.

There is a lack of good quality evidence that assesses the effect of diet and physical activity alone in trials that have demonstrated reduction in type 2 diabetes incidence and / or weight reduction. Therefore, it is difficult to make inferences about the impact that any particular form, volume or intensity of physical activity may have on outcomes.

Applicability rating: Evidence statement 6:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the physical activity advice provided is not transferable to interventions carried out in the UK.

Evidence statement 7:

Intensity / duration of physical activity

Evidence exists from one systematic review of randomised controlled trials (Waugh *et al* 2010 ++).

There is a lack of evidence that directly compares intervention effectiveness between different intensities and duration of physical activity, therefore it was not possible to determine the potential scale of the impact that different intensities may have.

Waugh *et al* (2010 ++) report that at least 150 minutes of moderate activity a week is required to have an effect on diabetes risk. However, even 10 minutes activity in sedentary individuals can show improvement in risk profile. There was evidence of a dose response one Finnish trial. Those who increased their physical activity were 60% less likely to develop diabetes, though this decreased to 51% after adjusting for weight loss. Those that increased their physical activity the most were 59% less likely to develop diabetes than those with least change in exercise patterns. There was no quality assessment grading available for included studies.

Applicability rating: Evidence statement 7:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the effect of frequency or duration of physical activity carried out is not transferable to interventions carried out in the UK.

Evidence statement 8:

Behavioural components

There was evidence from four systematic reviews of randomised controlled trials (Baker *et al* 2011++; Burnet *et al* 2006 +; Norris *et al* 2007 ++; Yuen *et al* 2010 ++), for the use of behavioural strategies to enhance effectiveness of interventions.

There is a lack of evidence that directly compares different intervention effectiveness between behavioural components, therefore it was not possible to determine the potential scale of the impact that different components may have.

Baker *et al* (2011++) carried out an analysis of intervention versus control data in a systematic review of RCTs. Whilst they state that the trials included in their review use few behavioural strategies relating to the Theory of Planned Behaviour, there was a focus on behavioural intention and evidence of strategies that were common to more than one theoretical model. They suggest that information and advice alone is insufficient to bring about lifestyle change compared to theoretically-based detailed lifestyle interventions such as those used in the major diabetes prevention trials. These include: staging of information provision and tailoring programmes to individual needs; using multiple sessions to reinforce information; delivery to small groups or individuals; delivering written information as well as verbal advice; encouraging self-monitoring; and logging of physical activity, diet and weight change.

For dietary behaviour change, taking small steps and providing both observational and vicarious leaning opportunities as well as encouraging the identification of barriers and problem solving were reported as strategies used in prevention programmes that had achieved reduction in diabetes incidence. For physical activity, a prescriptive approach that gradually increased the frequency and volume of activity over time as well as providing observational and vicarious leaning opportunities and encouraging self-monitoring were suggested. Three of the successful trials also included direct supervision of physical activity.

Norris *et al* 2007 ++ and Yuen *et al* 2010 ++ also assessed RCTs for prevention of diabetes (carried out in the US, UK, India, France, Finland, the Netherlands and Japan) and reported on the importance of gradually increasing volume and frequency of physical activity levels and of the importance of encouragement through direct supervision. Regular reinforcement of set goals was reported as an important

strategy in the early stages of an intervention.

Burnett *et al* (2006 +) reported from three trials carried out in the US, Finland and Sweden that self-monitoring through the use of regular weighing, and recorded measurement of dietary input and physical activity increased self-efficacy and empowerment. Family was a key social support in prevention efforts. Trials carried out in the US, Finland, China and Sweden encouraged spouses, where appropriate, to co-participate in counselling sessions.

Trials in the Norris and Yuen reviews were quality assessed and rated as generally having high risk for bias.

Applicability rating: Evidence statement 8:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the behavioural components of interventions are not transferable to interventions carried out in the UK.

Evidence statement 9:

Characteristics of intervention recipients

There was evidence from two systematic review of RCTs (Waugh *et al* 2010 ++; Yuen *et al* 2010 ++) and three non-systematic reviews (Davies *et al* 2004 +; Walker *et al* 2010 +; Roumen *et al* 2009 -). No quality assessment ratings are available for the included studies within these reviews.

There is a lack of evidence that directly compares the characteristics of intervention recipients in relation to intervention effectiveness, therefore it was not possible to determine the potential scale of the impact that different characteristics may have.

Waugh *et al* (2010 ++) reported that greater readiness to change physical activity levels correlated with higher levels of baseline physical activity ($p<0.0001$) at baseline, 1 year and the end of one US based trial. Yuen *et al* (2010 ++) also reported, from the same US trial, that the sample were more physically active at baseline and at a later stage of readiness to change than a representative IGT population.

Cross-sectional evidence from one non-systematic review of a range of study types (Roumen *et al* 2009 -) suggests that recipients that are aware of the potential impact of the lifestyle choices they make are more likely make sustained changes.

Davies *et al* (2004 +) report from one Finnish trial that lifestyle interventions were more effective in participants who achieved more of their dietary and physical activity goals. However, these changes needed to be sustained. Overall diabetes reduction in the intensive intervention group was 58%, with no new cases of diabetes reported in those that achieved at least four of their goals.

Waugh *et al* 2010++ provided evidence from one Finnish trial of under-reporting food consumption in overweight and obese participants. Walker *et al* (2010 +) report findings from one epidemiological study of a risk of ‘rebound’ weight gain in this group if there is a reversion to pre-intervention energy intake.

Applicability rating: Evidence statement 9:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the potential effect of the characteristics of participants is not transferable to the UK.

Evidence statement 10:

Strategies to encourage attendance / adherence

There was evidence from two systematic reviews of randomised controlled trials (Baker *et al* 2011++; Waugh *et al* 2010 ++), one review of RCTs and other study types (Burnet *et al* 2006 +).

Baker *et al* (2011++) reported that three RCTs (carried out in the US, Finland and Sweden) that obtained success in reducing the incidence of diabetes, used logging of physical activity, calorie intake and fat intake to provide feedback to participants and maintain motivation. The provision of free supervised physical activity sessions for the duration of the programme was implemented to encourage take up of structured physical activity in two trials carried out in the US, and Finland. No data are available on the rate of attendance at these sessions. Whilst no formal quality assessment is available, included studies were required to meet minimum criteria for inclusion.

Waugh *et al* (2010 ++) assessed adherence strategies in three US based RCTs of physical activity. They report that adherence to physical activities in one RCT of 2 year duration was more likely in programmes delivered over 3-4 days rather than 5-7 days per week. They also report from another RCT that lower intensity activities at 6 month follow up were related to better adherence compared to higher intensity activity, possibly due to perceived risk of injury with high intensity activities. Findings from a third RCT of 3 years duration with 10 year follow up suggest that incorporating activity into daily life, such as walking regularly might be easier to achieve than high intensity sport. There was no quality assessment available for these studies.

There was evidence from one review of RCTs and other study types (Burnet *et al* 2006 +) with no quality assessment ratings reported, that family was a key social support in prevention efforts. Three of the 4 included trials carried out in the US, Finland, China and Sweden encouraged spouses, where appropriate, to co-participate in counselling sessions. Whilst this approach has a much wider value than encouraging adherence and attendance, evidence from one included review of factors linking family with clinical outcomes reports that family can affect willingness to make use of health care services. The three included trials also incorporated follow up efforts such as active encouragement from staff, computer monitoring and development of a personal ‘toolbox’ of problem solving strategies for each participant.

Applicability rating: Evidence statement 10:

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that strategies carried out with the aim of encouraging attendance or adherence to interventions is not transferable to interventions carried out in the UK.

Part Two: Primary level Translational Studies

Evidence for this section is based on primary level translational studies, that is, studies based on the DPP or the DPS protocols.

Evidence statement 11:

Translational studies based on the DPP

Modifications to the DPP interventions

There was strong evidence [++; +; -] for successful modifications of the DPP protocol.

One randomised controlled trial (Kulzer *et al* 2009 + Germany), two pilot cluster randomised controlled trials (Ackermann *et al* 2008 + US; Whittemore *et al* 2009 ++ US), two matched pair and one controlled cohort study (Almeida *et al* 2010 ++, US; Faridi *et al* 2009 - US; McTigue *et al* 2009a + US), four pre-test / post test single group studies (Amundsen *et al* 2009 +, US; Davis-Smith 2007 + US; Kramer 2009 + US; McTigue *et al* 2009b + US; Seidal *et al* 2008 + US), and one non-randomised controlled feasibility trial (Vadheim *et al* 2010 + US) all adapted the DPP in a range of settings including primary care, YMCA facilities, and churches. Two studies (McTigue *et al* 2009b + US; Vadheim 2010 + US) used technology such as the internet and video-conferencing to access the target audience.

Eight DPP based studies selected populations with a raised BMI (≥25 kg/ m^2). Two DPP based studies (Ackermann *et al* 2008 + US; Davis-Smith 2007 + US) and all three studies DPS based studies selected populations using a risk score.

All but one DPP based (Amundsen *et al* 2009 + US) intervention were delivered using group sessions rather than individual sessions. One study (Whittemore *et al* 2009 ++ US) also provided phone-in sessions.

Three pre-test / post test single group studies (Kramer *et al* 2009 +, US; McTigue *et al* 2009a + US; Seidal *et al* 2008 + US) modified the DPP from 16 sessions to between 12-15. A further three studies delivered six or fewer sessions (Almeida 2010 ++ US; Davis-Smith 2007 + US; Whittemore *et al* 2009 ++ US).

DPP based sessions included both a dietary and physical activity component and all aimed to reduce body weight by 5-7% and increase physical activity to a moderate

level (e.g. brisk walking) for 150 minutes per week as specified in the DPP protocol. Modifications included the introduction of pedometers early in the programme than in the DPP (Kramer *et al* 2009 + US; Seidal *et al* 2008 + US). Follow up in the DPP based studies ranged from 4-12 months.

Applicability rating: Evidence statement 11:

The evidence is partially applicable since most studies were carried out in the US where health service delivery differs from that in the UK. Settings such as churches and the YMCA may be utilised for delivery of interventions within the UK, though the YMCA network appears to be stronger in the US. There is no reason to assume that the adaptation of trial protocols in terms of mode of delivery (e.g. group rather than individual) and number of sessions could not be transferred to the UK.

Evidence statement 12:

Translational studies based on the DPP

Incidence of type 2 diabetes

There was no available evidence from the DPP based studies for the impact on incidence of type 2 diabetes.

Evidence statement 13:

Translational studies based on the DPP

Changes in blood glucose levels

There was mixed evidence [++;+] from one randomised controlled trial, two pilot cluster randomised controlled trials and two pre-test / post test single group studies for reductions in blood glucose following interventions translated into community settings.

Fasting blood glucose was reported to decrease by 4.3 mg/dl (SD 11.3) over the 12 month intervention period from 105.7 mg/dl (SD 12.4) to 101.4 mg/dl (SD 11.3) in the intervention group compared to a reduction of 1.8 mg/dl (SD 13.1) in the control

group (p=0.001) in one primary care based randomised controlled trial (Kulzer *et al* 2009 + Germany). There was no change in HbA1c in the intervention group and a rise of 0.1% in the control group (p=0.165).

Fasting blood glucose was reported to decreased by 9mg / dl in one church based single group study (Davis-Smith 2007 + US) and by 1.5 mg / dl (p=0.52) in a primary care based study at 12 months.

A reduction in mean HbA1c of 0.1% compared to no change in the controls (p=0.28) was reported at 12 months follow up in a pilot cluster randomised controlled trial carried out using YMCA facilities (Ackermann *et al* 2008 + US).

Rises in monthly OGTT measurements were reported to be lower in the intervention group (0.28 mg/dl) than in the control group (1.50 mg/dl) over 6 months in one pilot cluster randomised controlled trial (Whittemore *et al* 2009 ++ US), though this finding was not statistically significant between groups (p=0.30).

There was however evidence from one pre-test / post test single group study carried out in a low socioeconomic population (Seidal *et al* 2008 + US) for an increase in those with a fasting blood glucose of reading ≥ 100 mg/dl in more than half of the sample at 3 months (51.0%) and 6 months (61.2%; p=0.06).

Applicability rating: Evidence statement 13:

The evidence is only partially applicable to UK settings since most studies were carried out in the US where health service delivery differs from that in the UK. Settings such as churches and the YMCA may be utilised for delivery of interventions within the UK, though the YMCA network appears to be stronger in the US. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK. Findings relating to blood glucose levels were modest; this may be part due to short follow up and part to the lower intensity of interventions as well as the range of study designs.

Evidence statement 14:

Translational studies based on the DPP

Weight change

There was strong evidence [++; +] from 11 studies based on the DPP protocol for achievement of weight loss and weak evidence [-] from one non-randomised study of

a small weight gain at 12 months.

A randomised controlled trial (Kulzer *et al* 2009 + Germany) achieved a weight loss of 3.8kg (SD 5.2) in the intervention arm at 12 months, compared to 1.4kg in the control. One pilot cluster randomised trial (Ackermann *et al* 2008 +US) achieved significant weight loss (6%) in the intervention arm at 4-6 months, which was sustained at 12 months. Mean weight loss was 5.7kg at both measurement points (p=0.008).

A matched pair cohort study with a large sample size (n=1520) (Almeida *et al* 2010 ++US) found that an intervention group were 1.5 times more likely to lose >5% body weight than matched controls after 12 months. Mean body weight loss was 1.4kg in the intervention group and 0.6 kg in controls (p< 0.001). A pilot randomised trial (Whittemore *et al* 2009 ++ US) delivered by nurse practitioners achieved ≥ 5% weight loss in 25% of the intervention group compared to 11% of the control group at 6 months.

One controlled cohort study (McTigue *et al* 2009a +US) achieved a mean weight loss of 5.19kg in the intervention arm compared to a mean weight gain of 0.21 kg in the control group at 12 months (p<0.001). The intervention population were obese at baseline and the control group comprised non-enrollees onto the programme.

One non-randomised controlled feasibility trial (Vadheim *et al* 2010 +US) compared telehealth (video conferencing) with an on-site intervention, and found similar weight loss for the two groups at 16 weeks (48% vs 50%; p=0.84). However, in this study both groups received a lifestyle intervention.

Faridi *et al* (2009 - US) reported no reduction in weight at 12 months following a church-based intervention for an African American population. Intervention and control sites gained less than 0.5kg, with the intervention group gaining least (0.14kg versus 0.37kg).

Mean weight loss in two pre-test / post test single group studies was greater than 4.5kg at 12 months (Kramer *et al* 2009 + US; Amundsen *et al* 2009 +US). However, these studies had no comparator groups. Other single group studies included one church based single group intervention of six week duration (Davis-Smith 2007 + US), which achieved mean weight loss of 4.8kg at 12 months follow up. Another (McTigue *et al* 2009b + US) that utilised the internet to deliver the intervention achieved a mean weight loss of 4.79kg, with over 30% of those completing the intervention achieving at least 5% weight loss. One study that targeted underserved

populations also achieved and sustained 5-7% weight loss in over 65% of the sample at 6 months (Seidal *et al* 2008 +US).

Applicability rating: Evidence statement 14:

The evidence is only partially applicable to UK settings since most studies were carried out in the US where health service delivery differs from the NHS. Settings such as churches and the YMCA may be utilised for delivery of interventions within the UK, though the YMCA network appears to be stronger in the US. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK or that the protocol could not be delivered using available technologies. Longer follow ups would be required to assess the sustainability of weight management achieved using DPP adaptations in the UK.

Evidence statement 15:

Translational studies based on the DPP

Changes to BMI

There was strong evidence [++; +] from six studies based on the DPP for reduction in BMI following intervention and mixed evidence [-] from one non-randomised study.

One randomised controlled trial (Kulzer *et al* 2009 Germany) reported a reduction in BMI of 1.3 kg/m^2 in the intervention group compared to 0.5 kg/m^2 in the control (P<0.002).One pilot cluster randomised trial (Ackermann *et al* 2008 ++US) carried out in YMCA settings reported a mean reduction of 6.7 kg/m^2 in the intervention group compared with 1.4 kg/m^2 at 12 months (p=0.002). One non-randomised controlled feasibility trial (Vadheim *et al* 2010 + US) reported a reduction of 2.7 kg/m^2 in the telehealth group compared to 2.5 kg/m^2 in the on-site group. Both of these groups received a lifestyle intervention. One non-randomised church based study (Faridi *et al* 2009 - US) achieved reduction in BMI of 0.63 kg/m^2 in the intervention arm compared to a gain of 0.13 kg/m^2 in the control arm at 12 months.

Three pre-test / post test single group studies also found reduction in BMI. Kramer *et al* (2009 +US) found a significant reduction in BMI of 1.6 kg/m^2 (p< 0.001) at 12 months. A church based intervention (Davis-Smith 2007 +US) achieved a reduction of 1.9kg / m^2 at 12 months (p<0.05), and Amundsen *et al* (2009 +US) achieved a

significant reduction in BMI of 2.4 kg / m^2 after 16 weeks ($p<0.001$).

Applicability rating: Evidence statement 15:

The evidence is only partially applicable to UK settings since most studies were carried out in the US where health service delivery differs from the NHS. Settings such as churches and the YMCA may be utilised for delivery of interventions within the UK, though the YMCA network appears to be stronger in the US. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK or that the protocol could not be delivered using available technologies. Longer follow ups would be required to assess the sustainability of BMI management achieved using DPP adaptations in the UK.

Evidence statement 16:

Translational studies based on the DPP

Changes in waist circumference

Moderate evidence [+] exists from 3 studies for reduction in waist circumference following intervention.

One randomised controlled trial (Kulzer *et al* 2009 + Germany) reported a reduction of 4.1 cm (SD 11.3) in the intervention arm compared to 0.4cm in the control group. One pre-test / post test single group study (Kramer *et al* 2009 +US) reported significant changes in waist circumference (around - 4.3 cm; $p< 0.001$) after 12 months. One pre-test / post test single group study (Seidal *et al* 2008 + US) found evidence of a reduction in abdominal obesity from 90% at baseline to 68% in their sample at 6 months ($p=0.006$).

Applicability rating: Evidence statement 16:

The evidence is only partially applicable to UK settings since most studies were carried out in the US and one in Germany, where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPP protocol could not be transferred to the

UK. Longer follow ups would be required to assess the sustainability of waist circumference reduction achieved using DPP adaptations in the UK.

Evidence statement 17:

Translational studies based on the DPP

Changes in achievement in goals

There was strong evidence available [++; +] from five studies (Amundsen *et al* 2009 + US; Faridi *et al* 2009 - US; Kulzer *et al* 2009 + Germany; Vadheim *et al* 2010 + US; Whittemore *et al* 2009 ++ US) for changes in achievement in goals following intervention.

One randomised controlled trial (Kulzer *et al* + 2009) reported a mean increase of 46.6 (SD 95.5) minutes per week physical activity in the intervention group compared to 17.9 (SD 63.8) minutes in the control group. Amundsen *et al* (2009 + US) reported an increase in physical activity by a mean of 80 minutes from week 6 to week 16.

Vadheim *et al* (2010 + US) reported a greater mean weekly increase in physical activity with their on-site group (mean increase 243 minutes; SD 146) than in the telehealth group (mean197 minutes; SD 103) (p=0.37). There was evidence of reduced fat intake after both intervention arms, with a greater proportion of those in the on-site group achieving the goal of fat reduction compared with the telehealth group (54% vs 38%) (p=0.49). A church based intervention targeted at an African American sample (Faridi *et al* 2009 - US) showed greater achievements in all eight dietary goals compared to controls.

Whittemore *et al* (2009 ++ US) reported a monthly increase in physical activity in both groups (p=0.001) with a tendency toward greater improvement in the intervention group (0.10 minutes vs 0.05 minutes) (p=0.8). The physical activity goal was achieved by 29% of the intervention group at baseline, rising to 46% at 6 months. This compares to almost no change in the proportion achieving physical activity goals in the control arm (39% to 40%). In addition, both groups improved their dietary intake (p=0.001).

In terms of dietary goals, one feasibility study (Vadheim *et al* 2010 + US) reported reduced fat intake following both telehealth and on-site interventions, with a greater proportion of those in the on-site group achieving the goal of fat reduction compared with the telehealth group (54% vs 38%) (p=0.49). One pilot randomised controlled trial (Whittemore *et al* 2009 ++ US) reported that both intervention and control groups improved their dietary intake (p=0.001). A church based intervention (Faridi *et al* 2009 -) showed greater achievements in all eight dietary goals compared to the control group.

Applicability rating: Evidence statement 17:

The evidence is only partially applicable to UK settings since most studies were carried out in the US where health service delivery differs from the NHS. Settings such as churches or the utilisation of available technologies may be adapted for delivery of interventions within the UK. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK. Longer follow ups would be required to assess the sustainability of goals achieved using DPP adaptations in the UK.

Evidence statement 18:

Translational studies based on the DPP

Participation / Attendance / Adherence

Moderate evidence [+] was found from two pre-test / post-test single group studies regarding adherence to intervention aims.

One study (Amundsen *et al* 2009 +US) reported a mean of 10.1 (SD 4.0) weeks completion of dietary self-monitoring (range 0-14). Men were significantly more likely to complete (mean 11.6 weeks; SD 3.2) compared to women (9.7 weeks SD 4.1; p=0.001). Older participants (≥ 60 years) were more likely to complete their records than younger participants (10.3 weeks SD 4.7; p=0.02). There was an eight-fold likelihood that those completing self-monitoring during all 16 weeks of the programme would achieve their weight loss goal (OR, 7.60; 95% CI 2.75-21.01).

McTigue *et al* (2009b + US) reported a mean completion of 12.8 (SD 7.29) internet-based lessons, with self-monitoring recorded on an average of 27.32 weeks over 12

months. 40% reported weight on-line for at least 40 weeks.

Applicability rating: Evidence statement 18:

The evidence is only partially applicable to UK settings since most studies were carried out in the US where health service delivery differs from the NHS. Participation in prevention studies and adherence to intervention aims would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

Evidence statement 19:

Translational studies based on the DPP

Sustainability

There was moderate evidence [+] from one pre-test / post test single group study (Seidal *et al* 2008 + US) that the achievement of a 5% - 7% weight reduction by 46.4% of the sample following the lifestyle intervention was sustained at 6 months follow up (66.7% achieved 5% weight reduction and 87.5% achieved 7% reduction).

Applicability rating: Evidence statement 19:

The evidence is only partially applicable to UK settings since this study was carried out in the US where health service delivery differs from the NHS. Sustainability of intervention achievements would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

Evidence statement 20:

Translational studies based on the DPS

Modifications to the DPS interventions

There was moderate evidence [+] for successful modifications of the DPS protocol.

Three pre-test post-test studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland) based on the DPS protocol were all set in

primary care, selecting populations using a risk score.

One study (Saaristo *et al* 2010 + Finland) delivered a mix of individual and group sessions, while two (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia) delivered group sessions. They all delivered an average of 6 sessions over 2 months compared to the 7 session DPS protocol. Most sessions were of an average of 60 minute duration.

Sessions were based on either the DPS lifestyle objectives (Absetz *et al* 2009 + Finland; Saaristo *et al* 2007 + Finland) or in one study, Australian Dietary Guidelines (Laatikainen *et al* 2007 + Australia).

Follow up ranged from 12 months (Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland) to three years (Absetz *et al* 2009 + Finland).

Applicability rating: Evidence statement 20:

The evidence is only partially applicable to UK settings since studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that the adaptation of the DPS protocol in terms of mode of delivery (e.g. group rather than individual) and number of sessions could not be transferred to the UK.

Evidence statement 21:

Translational studies based on the DPS

Incidence of type 2 diabetes

There was no evidence for impact upon diabetes incidence in the DPS based studies.

Evidence statement 22:

Translational studies based on the DPS

Changes in blood glucose levels

There was moderate evidence [+] from two pre-test / post-test studies for positive changes in blood glucose levels following intervention.

In one pre-test / post-test study (Absetz *et al* 2009 + Finland) mean change in fasting plasma glucose at 12 months was +0.1 mmol/l (SD 0.6; p<0.001) and at 3 years 0.0 1 mmol/l (SD 0.8; not significant). Mean change in OGTT at 12 months was +0.1 mmol/l (SD 1.7; not significant), and at 3 years +0.1 (SD 1.9; not significant). 55% had normal glucose tolerance at baseline. By year three, 10.9% of these had developed IGT. Of the 65 participants (18%) that had IGT at baseline, 12% had developed type 2 diabetes and 43% had reverted to normal glucose tolerance at year three.

Laatikainen *et al* (2007 + Australia) reported a mean change in fasting plasma glucose of -0.14 mmol/l (95% CI -0.20 to -0.07), at 12 months, representing a -2.5% change. Mean change in OGTT was -0.58 (95% CI -0.79 to -0.36), representing a change of -8.6%. At baseline, 66% of participants had normal baseline glucose levels and 34% had impaired levels. At 12 months, 78% had normal glucose values and 19.8% impaired values. Of the 79 who had impaired values at baseline, 42 (18%) reverted back to normal levels.

Saaristo *et al* (2010 + Finland) did not report changes in blood glucose levels in their pre-test / post-test study. 1.6% of those with normal glucose levels at baseline developed impaired glucose tolerance at 14 months. Of those with IFG at baseline, type 2 diabetes developed in 10.5%. In those with IGT at baseline, type 2 diabetes developed in 14%. The authors conclude that the study identified individuals with a very high early conversion rate from IGT to type 2 diabetes.

Applicability rating: Evidence statement 22:

The evidence is only partially applicable to UK settings since studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK.

Findings relating to blood glucose levels were modest; this may be part due to short follow up and part to the lower intensity of interventions as well as the range of study designs.

Evidence statement 23:

Translational studies based on the DPS

Weight change

There was moderate evidence [+] from 3 pre-test / post-test studies based on the DPS protocol for weight loss following translational interventions. However, none of these studies included a comparator.

Mean weight was reduced in three studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* + 2007 Finland) at 12 months follow up. Two studies (Laatikainen *et al* 2007 + Australia; Saaristo *et al* + 2007 Finland) achieved a mean weight loss of 2.5 kg (95% CI, 1.85 to 3.19) and 1.2 kg ($p<0.0001$) respectively. In one study (Absetz *et al* 2009 + Finland) mean weight reduction of 0.8 kg at 12 months ($p=0.002$) was maintained at 3 years (1.0 kg; $p=0.003$).

Applicability rating: Evidence statement 23:

The evidence is only partially applicable to UK settings since studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK. Longer follow ups would be required to assess the sustainability of weight management achieved using DPS adaptations in the UK.

Evidence statement 24:

Translational studies based on the DPS

Changes to BMI

Moderate evidence [+] exists from 3 pre-test / post-test studies based on the DPS protocol for reduction in BMI at 12 months following intervention.

Mean BMI was reduced from baseline to 12 months follow up in three studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland), with reductions ranging from 0.3 kg/m^2 to 0.93 kg/m^2. At three years, a further reduction of 0.2 kg/m^2 was observed in one study (Absetz *et al* 2009 + Finland).

Applicability rating: Evidence statement 24:

The evidence is only partially applicable to UK settings since studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK. Longer follow ups would be required to assess the sustainability of BMI management achieved using DPS adaptations in the UK.

Evidence statement 25:

Translational studies based on the DPS

Changes in waist circumference

Moderate evidence [+] exists from three studies for reduction in waist circumference following intervention.

Waist circumference was reported to decrease in all three DPS based pre-test / post-test studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland), ranging from -1.6cm to -4.2cm at 12 months. However, the reduction at 12 months was not sustained at three years in one study (Absetz *et al* 2009 + Finland).

Applicability rating: Evidence statement 25:

The evidence is only partially applicable to UK settings since studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK. Longer follow ups would be required to assess the sustainability of waist circumference reduction achieved using DPS adaptations in the UK.

Evidence statement 26:

Translational studies based on the DPS

Changes in achievement in goals

There was no evidence available from three studies for changes in achievement in goals following intervention.

Evidence statement 27:

Translational studies based on the DPS

Participation / Attendance

There was moderate evidence [+] from 3 pre-test / post test single group studies based on the DPS of reasonable to good attendance rates.

One study (Absetz *et al* 2009 + Finland) reported that 57% of the participants attended all six sessions with the final session being least well attended (81% compared to 90%). Laatikainen *et al* (2007 + Australia) reported that 43% of participants attended all six sessions with reasons for non-attendance given as lack of transport, fuel costs, time constraints, low literacy and health conditions. Saaristo *et al* (2010 + Finland) reported 29.1% of participants achieving at least 3 visits. In this study, weight loss was associated with more intervention visits ($p<0.001$).

Applicability rating: Evidence statement 27:

The evidence is only partially applicable to UK settings since these studies were carried out in Europe and Australia where health service delivery differs from the NHS. Participation in prevention programmes and adherence to intervention aims would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

Evidence statement 28:

Translational studies based on the DPS

Sustainability

There is moderate evidence [+] from one DPS based study relating to sustainability of outcomes beyond the 12 month follow-up.

Only one pre-test / post test single group study (Absetz *et al* 2009 + Finland) had a follow up longer than 12 months. Whilst weight loss (0.8 kg) and BMI reduction (0.3 kg/m^2) at 12 months was maintained at 3 years (1.0 kg and 0.5 kg/m^2), waist circumference reduction at 12 months (1.6 cm) was not sustained (0.1 cm).

Applicability rating: Evidence statement 28:

The evidence is only partially applicable to UK settings since this study was carried out in Finland where health service delivery differs from the NHS. Sustainability of intervention achievements would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

Evidence statement 29:

Weight loss achievement in translational studies compared with the DPP and DPS.

There was strong evidence [+; ++] for similar trends in weight loss achievements in randomised controlled translational studies to those achieved in the DPP and DPS at 12 months, though effects were generally weaker.

None of the translational studies achieved the 7kg weight loss of the DPP at one year follow-up, though one pilot randomised controlled trial utilising YMCA facilities (Ackermann *et al* 2008 + US) reported a loss of 6.0kg in the intervention arm. One

RCT based on both the DPP and DPS (Kulzer *et al* 2009 + Germany) achieved 3.8kg weight loss in the intervention arm.

There was strong mixed evidence [+; ++] from non-randomised translational studies for weight losses ranging from 1.4kg in a primary care based intervention compared to 0.6kg in the control group (Almeida *et al* 2010 ++ US) to 5.19kg compared to a weight increase of 0.21 kg in controls (McTigue *et al* 2009a + US) at 12 months. One church based intervention that targeted African American communities (Faridi *et al* 2009 - US) did not report weight loss in either intervention or control groups, though the increase was less than 0.5kg in both groups and was greater in the control group.

There was moderate evidence from three translational studies based on the DPS [+] for a trend in weight loss at 12 months, though the effect was weaker than in the DPS.

The three studies based on the DPS (Absetz *et al* 2009 Finland +; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2010 + Finland) did not include controls or comparators. None achieved the 4.2 kg (SD 5.1) weight loss at 12 months reported from the DPS. Weight change ranged from -0.8kg to -2.36kg across the three studies. At three years, one study (Absetz *et al* 2009 + Finland) reported a sustained change from -0.8kg to -1.0kg.

2.6 Discussion

Part one: Review of reviews of intervention components

For question one of this review, thirteen reviews, of generally good quality, were identified that described successful components of lifestyle interventions for the prevention of type 2 diabetes in populations at high risk.

There was generally a lack of evidence that compared intervention components used in diabetes prevention studies that achieved a reduction in diabetes incidence or weight, in order adequately to identify those components that may have the most impact on outcomes.

Rather, included reviews identified effective trials or studies and described the components that were used. This review can therefore only synthesise that information. The few comparisons that were reported identified that theoretically based interventions were associated with greater positive outcomes than controls (advice and information only).

Increased physical activity was incrementally associated with reduced diabetes risk in one review.

A recently published review of reviews (Greaves *et al* 2011) examined evidence relating the content of interventions for promoting dietary and /or physical activity change to their effectiveness in producing weight and behaviour change. The review focused on evidence relating to individuals with a wider group of clinical risk factors and therefore had a broader scope than that specified by NICE for this review. However the work is a very important contribution to this field. There was mixed evidence from thirty included studies for the benefit of interventions having a theoretical underpinning, with stronger evidence for the use of self-regulatory techniques such as goal planning, self-monitoring, and provision of feedback.

Greaves *et al.* (2011) concluded that interventions should include both diet and physical activity components using well established behaviour techniques delivered by trained personnel. Social support from friends and family is an important aspect in engaging participants. The evidence supported group or individual modes of delivery in a wide range of settings with maximum frequency of contact.

The main findings in our review are, therefore, supported when evidence from a broader range of studies that include those from high risk populations, but without necessarily having pre-diabetes, are considered.

Part two: Review of primary translational studies

The second part of this review assessed primary studies that report on interventions that have been translated from use in major trials to those in the 'real world'. Thirteen primary level studies were included. Although the papers were of good quality, the studies generally lacked a control and varied widely in sample size. All of the study samples included more females, in some cases many more, than males. The translational studies were carried out in health care settings or community settings such as the YMCA and a church.

Diabetes incidence was not measured as a primary outcome though one DPS based study reported an inverse association between weight loss and diabetes incidence. There were also reports of reversion from IGT to normoglycaemia. It cannot be concluded whether this was a result of the interventions due to the lack of comparators.

The studies reported positive results in respect to weight loss, BMI and waist circumference at up to 12 months. All samples had a mean baseline BMI of 29 kg/m^2 or more. Weight loss was sustained at 3 years in one DPS based study, but waist circumference was not. One

study found a step-wise inverse association between weight loss and diabetes incidence. One study reported an association between number of intervention attendances and weight loss. This would suggest a potential indirect association between frequency of attendance and diabetes incidence.

It can be concluded that translational studies have a potential to be effective in real world settings, since the results from this set of studies are positive. However, there is a lack of comparative evidence to make assertions about the effectiveness of particular aspects of the interventions, frequency of contacts, settings, or mode of delivery.

3. INTRODUCTION

3.1 Aims and Objectives

The aims of this, the third of four reviews, were firstly to undertake an assessment of review level evidence that synthesises findings relating to identifying and characterising successful components and elements of lifestyle interventions to prevention progression to diabetes in diagnosed populations with pre-diabetes. Secondly, to assess and synthesise findings from individual studies / trials that use trial evidence and evaluations of interventions carried out in everyday settings.

The objectives for this review are:

To retrieve relevant review level evidence that identifies components of lifestyle interventions and translational studies of large trials of lifestyle interventions for the prevention of type 2 diabetes.

To retrieve review level papers to identify evidence on the effectiveness and context of translational studies and to identify primary studies that fill gaps in the knowledge base.

To use primary level evidence where detailed information on specific interventions is not available in review level evidence.

To analyse and synthesise the findings from both sets of evidence.

3.2 Rational for review focus

Type 2 diabetes is associated with significant clinical and social consequences. The National Institute for Health and Clinical Excellence has been asked by the Department of Health to develop public health guidance on the prevention of type 2 diabetes among high-risk groups. The referral is divided into 2 separate pieces of guidance. The first addressed the prevention of pre-diabetes (raised and impaired glucose levels) in populations and communities of high risk adults aged 18-74 using determinants of health such as creating an environment supportive of behaviour change.

This second piece of guidance addresses how to prevent the progression of pre-diabetes to type 2 diabetes at the individual level.

It is recognised that the term ‘pre-diabetes’ is not ideal, as not everyone with raised or impaired blood glucose levels will go on to develop type 2 diabetes. However, the term ‘pre-diabetes’ has been chosen because of its widespread use and recognition by a broad range of stakeholder groups, and because of the lack of consensus on a suitable alternative.

Within this second piece of guidance, four reviews of world-wide evidence were carried out that address the prevention of progression to type 2 diabetes. This document reports on the third of such reviews. It focuses on how lifestyle interventions work best by assessing review level evidence of, for example, evaluations of interventions in practice, and the successful components of interventions. Included reviews will have synthesised evidence across individual studies that used a range of methods, and therefore provide information and analysis in respect of successful components of interventions that is not available from individual study findings. This review does not aim to assess or measure the overall effectiveness of such interventions, since this is covered in our second review “*Systematic review and meta-analysis of lifestyle, pharmacological and surgical interventions*”. Rather, this review will complement the findings from RCTs included in Review 2 by focusing on a range of studies (not all RCTs) and, within these studies, what components of lifestyle and related interventions work best in practice, and what their key features are.

Review Questions:

What is the review level evidence for specific components (or combinations of components) of intervention programme / strategies which are most effective in preventing or delaying progression to type 2 diabetes in adults with pre-diabetes?

What is the review and primary level evidence for the most effective methods of preventing or delaying progression to type 2 diabetes in adults with pre-diabetes when intensive interventions assessed in RCTs are adapted to real world settings?

Evidence from assessed reviews is reported for each of the two questions in terms of content, mode of delivery, setting, intensity and duration. It is also reported by sub-groups including sex, age and ethnicity.

4. BACKGROUND

4.1 Description of the health problem

The NICE scope (2009b), which sets out what the guidance will and will not cover, highlights that every year, 100,000 people in the UK are diagnosed with type 2 diabetes and many more may have the condition (Diabetes UK 2006). It can lead to long-term complications including micro- and macrovascular diseases such as eye problems, kidney disease, foot ulcers and cardiovascular pathologies. Between 33% and 66% of people with pre-diabetes – raised or impaired blood glucose levels – will go on to develop type 2 diabetes over a period of 3–6 years (Diabetes Prevention Programme Research Group 2002; Lindstrom *et al* 2003; Pan *et al* 1997; Ramachandran *et al* 2006). During that time they will also be at increased risk of cardiovascular disease (Waugh 2007).

In addition to the personal cost to individuals, families and communities, diabetes is estimated to account for at least 5% of UK healthcare expenditure. Up to 10% of hospital budgets are used for the care of people with the condition – drug costs alone for people with type 2 diabetes have been estimated to account for about 7% of the total NHS drugs budget (Waugh *et al* 2007). Preventing pre-diabetes among groups at high risk of developing type 2 diabetes could help save some of these NHS resources.

In 2007, 60% of primary care trusts (PCTs) had programmes in place to raise public awareness of the risk factors for diabetes and 37% were raising awareness of its signs and symptoms. Only 42% had specifically assessed the needs of their population in relation to diabetes and less than 40% had developed a diabetes strategy (Innove 2008).

An individual's risk factors for pre-diabetes include: obesity (a body mass index [BMI] of more than 30 kg/m^2); a high waist circumference measurement (more than 80 cm in women and 94 cm in men); a sedentary lifestyle; a close family history of type 2 diabetes; a history of gestational diabetes in women; and being older than 40 (or older than 25 for some black and minority ethnic groups). In addition, certain groups of people are at greater overall risk of developing pre-diabetes, for example people of south Asian, African–Caribbean and black African descent. With rates of obesity on the increase and the population becoming more sedentary (The Health and Social Care Information Centre 2009) type 2 diabetes (and pre-diabetes) is becoming more prevalent.

For many people, both pre-diabetes and type 2 diabetes can be prevented by being supported in changing lifestyle behaviours such as improving diet and increasing physical activity levels (Tuomilehto 2001).

Part one of this review focuses on the particular aspects of lifestyle intervention that might be more successful in preventing individuals with pre-diabetes from progressing to type 2 diabetes. This has been done by reviewing synthesised evidence from review level articles that have assessed lifestyle intervention diabetes prevention studies.

Part two of this review focuses on the adaptation of major lifestyle diabetes trial protocols to smaller studies carried out in a range of community settings. This part of the review assesses the modifications made to the protocols and the impact that the interventions had on outcomes such as diabetes incidence, blood glucose levels, weight loss, BMI and waist circumference.

5. METHODS

5.1 Methods for identification of evidence

A systematic review of review level evidence to identify successful intervention components to prevent the progression of pre-diabetes to type 2 diabetes was undertaken. In addition, a systematic review of primary level evidence was undertaken to identify studies that modify the protocols of major trials for utilisation in community settings. Both reviews were carried out according to the general principles recommended in the methods guide for development of NICE public health guidance (2009). Methods followed the development of a review protocol and search protocol and are detailed below.

5.2 Remit of the assessment

Part One: Review of review level evidence of intervention components

Initial searches showed the breadth of evidence relating to the first research question to be very extensive. The methods guide for the development of NICE public health methods guidance (2009) states that "if the evidence base for the specific topic is so large that resource limitations make it impossible to cover all available primary studies" then this constitutes an exceptional circumstance in which review level literature can be assessed. In addition, the type of information being sought to address the two questions was a synthesis of comparative details across studies in order to assess the success of translational research and components of interventions. This type of synthesised information was not likely to be extracted from individual studies, but was more likely to emerge and be discussed in reviews that were focussing on successful components of interventions. As mechanisms of interventions can be seen as theories (Astbury & Leeuw 2010), then this type of literature is related to the rationale in the NICE public health methods guidance (2009) for using review level material:

"if the topic referral draws heavily on published theories (for example, on how to support attitude and behaviour change)". (NICE 2009 p.53)

It was therefore agreed that an iterative and emergent approach to identifying relevant review level material would be taken, with any gaps in available evidence being noted and searched for using specific searching strategies for additional material. These searches would not be filtered by study design. It was acknowledged that gaps in knowledge could also be due to lack of published evidence, in which case it would be reported that no evidence could be found.

Part Two: Review of primary level translational studies

To address the identification of translational studies that are based on major trial protocols, review level evidence was sought first. Two reviews were identified that assessed translational studies, though they also included studies that were not based on diabetes prevention trials. Therefore those primary studies that were translational have been assessed independently along with primary studies not included in the reviews.

5.2.1 Individuals / groups that will be covered

Adults aged 18 years and over with a diagnosis of pre-diabetes using current World Health Organization criteria (World Health Organization 2006), that is either or both:

Impaired fasting glucose (IFG) – a fasting plasma glucose (FPG) between 6.1 and 6.9 mmol/litre.

Impaired glucose tolerance (IGT) – FPG less than 7.0 mmol/litre and a plasma glucose (2 hours after ingestion of a 75 g oral glucose load, the oral glucose tolerance test) between 7.8 and 11.0 mmol/litre.

Since the scope for this piece of guidance was published, the diagnostic criteria for type 2 diabetes has been revised by the World Health Organization to include HbA1c at 6.5%. However WHO did not identify sufficient evidence on which to base changes in the diagnostic criteria for IFG and IGT (WHO 2011).

5.2.2 Groups that will not be covered

People with a diagnosis of type 2 diabetes or other forms of diabetes.

Children and young people aged under 18 years.

Pregnant women.

5.2.3 Interventions /Activities that will be covered.

Interventions delivered at individual, family, community and population levels in primary, secondary and tertiary care, the community, residential care sector, and prisons including:

Lifestyle interventions involving any or all of the following:

Weight-loss strategies (for example, education, motivational support, slimming clubs);

Diet (for example, low glycaemic index, reduced fat, controlled carbohydrate, low calorie diets);

Physical activity (for example, cardiorespiratory training, organised programmes, individual programmes).

5.2.4 Interventions /Activities that will not be covered.

The treatment and management of type 2 diabetes, gestational diabetes or any other form of diabetes. (Type 1 diabetes, type 2 diabetes and diabetes in pregnancy are the subjects of previously published NICE guidance).

5.3 Search Strategy

The standard NICE Methods, as outlined in the Methods for the Development of NICE Public Health Guidance (2009) were used to guide the development of the search methods. The aim of the search strategy for Review 3 was to retrieve the best available evidence to inform this review of reviews.

An initial overarching search had been undertaken at the outset of all reviews for this programme guidance. This search was generated by identifying concepts from the programme scope and from studies identified from key known literature as being relevant to the review questions. Free text and MeSH terms were then devised.

Following from this, a specific search was designed and implemented for Review 3 in order to identify appropriate review level evidence. This search comprised prevention or limiting terms combined with population terms; this set was then combined with the Scottish Intercollegiate Guidelines Network (SIGN) Systematic Review filter. The search strategies were developed in conjunction with NICE Information Specialists.

It was agreed with the CPHE project team that review level material would be identified at least initially to address the review question, with any gaps in available evidence being noted for potential additional searching. It was acknowledged that gaps in knowledge could also be due to lack of published evidence, in which case following additional searching it would be reported that no evidence could be found.

Additional searching was carried out in key databases to identify primary studies that report translation of the major trial methods to the ‘real world’. It was agreed that further searching might comprise citation searching from the reviews included in review three. All searches were limited to English Language, 1990-current and human studies where data sources allowed.

A thorough audit trail of the search process was maintained; this includes all searches, number of results and number of relevant references identified. This process ensures that the search process is transparent, systematic and replicable.

An overview of evidence sources are listed below, with detailed information including location of websites and sample search strategies presented in Appendix 1.

List of Databases Searched for Review Three

Medline and Medline in Process via OVID SP

Embase via OVID SP

CINAHL via EBSCO

British Nursing Index and Archive via OVID SP

The Cochrane Library via Wiley

Science Citation Index via Thomson ISI

Social Science Citation Index via Thomson ISI

PsycINFO via OVID SP

Selected EPPI Centre Databases

5.4 Study selection

All of the retrieved literature was screened by one reviewer (MJ) and double-checked by one other reviewer (CF or RJ) at title and abstract level for relevance, using the screening tool for review evidence found in the Methods for the Development of NICE Public Health Guidance (2009). Those papers meeting the screening criteria and being relevant to either of the two research questions were taken through to full paper appraisal (see section 5.4 for full process details). Figures 1 and 2 show numbers of studies that were retrieved from initial searches and from more focussed searching for both parts of this review.

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

Figure 1: Flow chart of paper selection: Part One

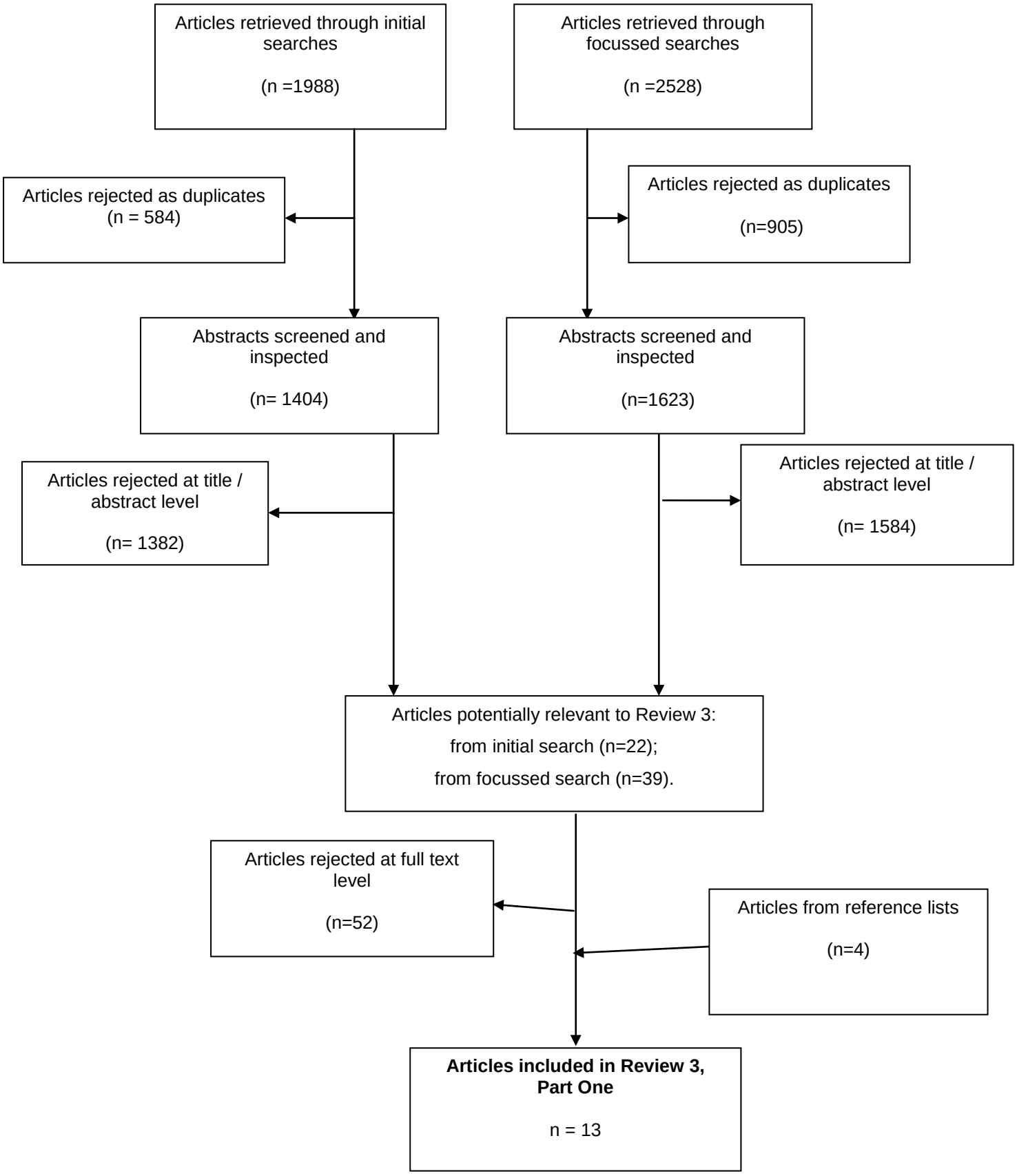
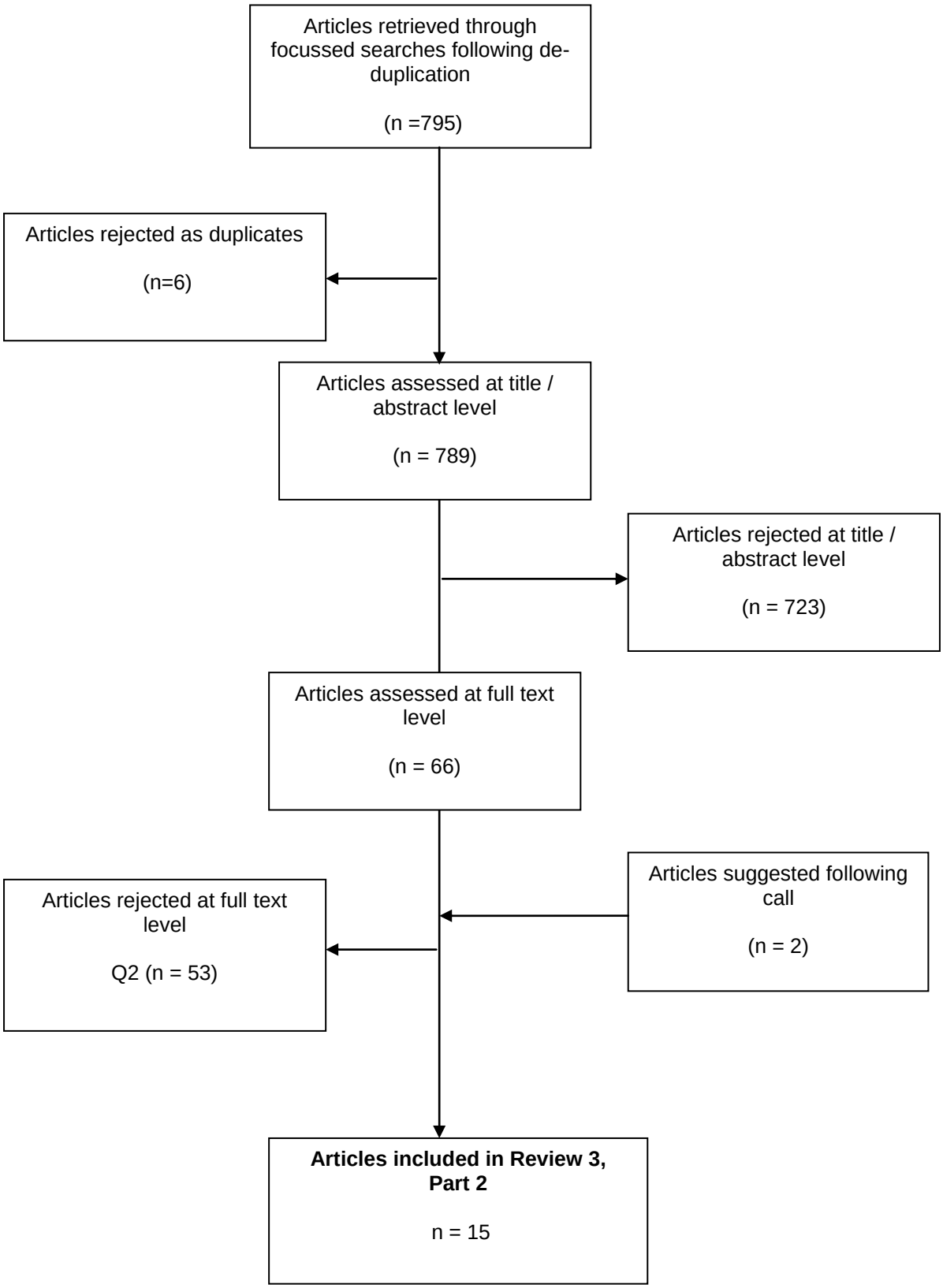


Figure 2: Flow chart of paper selection: Part Two



5.5 Data Extraction

As highlighted in the Cochrane Collaboration guidelines for systematic reviews of health promotion and public health interventions, extraction forms should be developed for each review in order to make them relevant to the information that is required. The standardised form for extracting data from review level evidence as presented within the NICE public health methods guidance (2009) includes the following items:

1) Characteristics of those delivering the intervention;

2) Characteristics of the recipients;

3) Setting (*e.g.*, worksite, time, and place of intervention);

4) Mode of delivery (*e.g.*, face-to-face);

5) Intensity (*e.g.*, contact time);

6) Duration (*e.g.*, number of sessions and their spacing over a given period);

7) Adherence/fidelity to delivery protocols;

8) Detailed description of the intervention content provided for each study group.

Data extraction forms were piloted on two randomly selected articles in order to confirm appropriateness for use. Data were extracted with no blinding to authors by one reviewer (MJ), with a 20% sample double checked by another reviewer (CF, RJ). Any studies giving rise to uncertainty were reviewed independently by a third reviewer, and discrepancies, for example where studies were not clearly reported, were resolved by discussion.

5.6 Quality assessment

The quality of included studies was assessed by five reviewers (MJ, AS, VR, CF, RJ) using quality assessment tools for specific study types recommended in the methods guide for development of NICE public health guidance (2009) (see Appendix 4). Quality assessment was double checked by a reviewer not involved in the initial assessment.

The purpose of quality assessment is to provide a narrative account of study quality for the reader, in order to inform judgements on the strength of the evidence presented. Within the NICE methods guide (2009), it is recommended that studies are categorised according to study type and methodological rigour and quality (categories ++, + or -) in order to provide a clear representation of type of evidence (See Table 1).

Table 1: Study quality

Grade	Criteria
++	All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions are thought very unlikely to alter.
+	Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or adequately described are thought unlikely to alter the conclusions.
-	Few or no criteria have been fulfilled. The conclusions of the study are thought likely or very likely to alter.

5.7 Data analysis and synthesis

Data relevant to the particular research question were extracted for each paper (see Appendix 5). Characteristics and findings from studies were also tabulated to aid analysis. For Question one, synthesised data from review level evidence was tabulated so that the components that were found to contribute to the success of interventions (where possible) could be presented. The type of information required for Question one included specific data on successful content, mode of delivery, duration and number of sessions. Data relating to each of these items were synthesised.

For Question two, the characteristics, intervention components and findings of translational studies were tabulated from included primary studies. The data were then analysed in terms of intervention modifications from the original DPP or DPS trials, as well as differences between, for example, settings, populations, sample sizes. Attention was also given to sub-groups where reported within each study.

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6. RESULTS

PART ONE

What is the review level evidence for which specific components (or combinations of components) of intervention programme / strategies are most effective in preventing or delaying progression to type 2 diabetes in adults with pre-diabetes?

6.1 Quantity of the evidence available

Initial searches within Medline identified 1404 potential reviews following de-duplication potentially relevant to this guidance. Of these, 1382 were rejected at title / abstract level. An additional focused search of a range of database sources identified 1623 papers (following de-duplication) that were potentially relevant to this review. Of these, 1587 were rejected at title / abstract level. A total of 49 papers were rejected at full text level following assessment using the screening tool for review level evidence (NICE methods 2009) as well as for relevance to the review question. Four further papers were identified from reference lists.

A total of 13 papers were identified that were relevant to this review of reviews.

6.2 Quality of the evidence available

Review Question 1: Of the 13 review level papers included that addressed question one, 6 were of very good quality (++), 5 were good quality (+) and two were assessed as poor quality (-).

The main quality assessment issues were around the lack of fit between reported methods and quality assessment criteria. For example, review level evidence varied in terms of how many stages of systematic review methods were reported. Many did not report quality assessment of included studies and some did not include methods for searching.

Where quality assessment was carried out on included studies within reviews, most were found to have a high rate of bias.

6.3 Characteristics of included Reviews:

Review Question 1. Reviews focusing on the most effective components of lifestyle interventions

The first part of this review focuses on review level evidence to identify the most effective components of lifestyle interventions for the prevention of type 2 diabetes.

Included reviews assessed studies of any type that describe interventions that aim to prevent type 2 diabetes. Populations were mainly diagnosed with IGT or pre-diabetes. Some reviews included studies that assessed a number of normoglycaemic participants.

Of the 13 included reviews that assessed lifestyle interventions, 11 addressed combinations of physical activity and dietary / dietary interventions. One assessed dietary interventions only, and one physical activity related interventions only.

Evidence relating to components that were shown to have an effect on intervention success is listed for each included review in the evidence tables (Appendix 6).

Related work

Effectiveness findings from the major diabetes prevention programmes are addressed in detail in our second review "*Systematic review and meta-analysis of lifestyle, pharmacological and surgical interventions*" so will not be repeated in this review.

The use of pharmacological interventions following unsuccessful attempts at lifestyle interventions is addressed in "Non-pharmacological interventions to reduce the risk of diabetes in people with impaired glucose regulation: systematic review and economic evaluation" (Waugh / Gillett *et al* 2010 in progress). Consent has been received to use this review in the context of economic modelling, and therefore it will not be reviewed here, particularly as this review focuses on successful components of interventions. However the report in progress by Waugh *et al* (2010) includes a review of lifestyle interventions, and data from that section of the report will be included.

A review of reviews has recently been published that assesses lifestyle interventions across a broader range of populations. "Systematic review of reviews of intervention components associated with increased effectiveness in dietary and physical activity interventions" (Greaves *et al* 2011) included 30 review level studies that assessed interventions promoting physical activity and/or dietary change at the individual-level in adults at risk of developing type 2 diabetes, because they were "*obese, overweight, sedentary, had hypertension, impaired fasting glucose, impaired glucose tolerance, hyperlipidaemia, metabolic syndrome,*

polycystic ovarian syndrome, gestational diabetes, a family history of type 2 diabetes or cardiovascular disease, or had been identified as having a high cardiovascular disease risk score (e.g. using a validated risk score such as Q-RISK or Framingham)" (Greaves *et al* 2011 p.5). Our review was limited (by the pre-agreed NICE Scope; see http://guidance.nice.org.uk/PHG/Wave19/62/Scope/pdf/English) to interventions aimed at populations with pre-diabetes, and specifically excluded those with gestational diabetes. Therefore most of the studies within the review by Greaves *et al* fell outside our inclusion criteria. However, as the Greaves review was focussed specifically on lifestyle change intervention components that were associated with effectiveness in populations that might be at risk of type 2 diabetes, this work is regarded as an important contribution to the topic area. The findings from the review will therefore be discussed with the caveat that the inclusion criteria differed from that outlined in section 3.2.1 of this report.

Similarly, NICE has previously published guidance related to this review topic that is clearly relevant and of interest: "Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children" (NICE Clinical Guideline 43: 2006), and "Behaviour change at population, community and individual levels" (NICE Public Health Guidance 6: 2007).

6.3.1 Characteristics of included review level evidence

Characteristics of reviews that were included as relevant to Review Question One are summarised in table 2. A range of methods for assessing the effects of lifestyle change for the prevention of type 2 diabetes is used in the 13 included reviews addressing Question One. Major trials such as the Da Qing, the DPP and DPS are reported repeatedly across reviews, though the emphasis and focus of the findings differ across reviews. Included papers are summarised by review in Table 2 with those papers that have been included by more than one review being highlighted in bold.

Table 2. Characteristics of reviews focusing on the most effective components of lifestyle interventions

Review	Focus of Review	Number and type of studies	Interventions	Included studies	
				Programmes	Primary study papers
Baker *et al* 2011 ++ Systematic review.	Behavioural strategies in diabetes prevention programs.	7 RCTs	Exercise training / physical activity / dietary intervention	**DPP** (US); **DPS** (Finland); **Da Qing** (China); **IDPP** (India); **JDPP** (Japan); ADPP (Italy); VIP (Sweden).	**Total of 95**; 41 from DPP, 39 from DPS, 5 from IDPP, 4 from Da Qing, 2 from JDPP, 3 from VIP, and 1 from ADPP.
Burnet *et al* 2005 + Review	To review available evidence on lifestyle interventions from the perspective of practising clinicians.	4 major diabetes prevention trials.	Lifestyle	**DPP; DPS; Da Qing; Malmo (Sweden).**	Eriksson 1999; Tuomilehto 2001; DPP 2002; Lindegarde 1982; Pan 1997.
Davies *et al* 2004 + Review	Prevention of type 2 diabetes mellitus in a UK setting.	8 lifestyle intervention studies and 6 lifestyle / pharmacological studies.	For this review, focus on lifestyle interventions only (7).	**Malmo**; **Da Qing**; **DPS**; Malmohus (Sweden); FHS; **DPP** (US); Whitehall; **STOP-NIDDM**; EDIT.	Eriksson 1991; Eriksson 1998; Pan 1997; Tuomilehto 2001; DPP 2002; Swinburn 2001; Sartor 1980; Dyson 1997.
Davis *et al* 2009 - Review	Role of obesity and lifestyle interventions in the prevention and management of type 2 diabetes.	3 studies	Lifestyle	**Da Qing**; **DPS**; **DPP**;	
Madden *et al* 2008 + Literature review	Review of lifestyle interventions for the prevention of type II diabetes mellitus.	12 studies	Lifestyle	DPPRG; **DPS; SLIM; Da Qing;**	Hu 1999; Smith 2005; **Swinburn 2001**; Tate 2003; Watanabe 2003; **Wein 1999**; Wing 1998.
Nield *et al* 2008 ++ Cochrane Systematic Review	Dietary advice for the prevention of type 2 diabetes mellitus in adults.	5 papers reporting on 2 RCT studies (Da Qing; ODES)	Dietary advice	**Da Qing**; ODES.	Da Qing reported in Pan 1993; **Pan 1997;** ODES reported in Anderssen 1995; Holme 1993; Torjesen 1997.

Norris *et al* 2007 ++ Cochrane Systematic Review	Long-term non-pharmacological weight loss interventions for adults with pre-diabetes.	9 RCTs	Dietary, physical activity, Behavioural	**DPP; DPS; Da Qing**; **SLIM**	DPP 2002; Dyson 1997; Jarrett 1979; **Liao 2002; Lindahl 1999**; Mensink 2003; Page 1992; Pan 1997; Tuomilehto 2001.
Paulweber *et al* (IMAGE) 2010 + Review	Prevention of Type 2 Diabetes and its co-morbidities by lifestyle modification.	5 RCTs	Lifestyle modification	**Da Qing**; **DPS; DPP; IDPP; JDPP.**	See Review of Reviews
Roumen *et al* 2009 - Review	Lifestyle intervention for prevention of diabetes.	16 studies, any study type included.	Lifestyle interventions	**DPS; Malmo; Da Qing; SLIM; DPP; JDDP; IDPP-1.**	4 from DPS; 2 from DPP; 2 from Da Qing; 1 from Malmo; 1 from SLIM, 1 from IDPP. Also: Swinburn 2001 (NZ); Carr 2005 (US); Oldroyd 2006 (UK); Lindahl 1999 (Sweden); Kosaka 2005 (Japan).
Walker *et al* 2010 + Review	Diet and exercise in the prevention of diabetes.	4 major programmes and 3 follow up studies. 4 systematic reviews.	Lifestyle	**Da Qing; DPS; DPP;** DPPOS**; IDPP.**	**Li 2008.**
Waugh / Gillett *et al* 2010 ++ Systematic review (in progress).	Non-pharmacological interventions to reduce the risk of diabetes in people with impaired glucose regulation.	9 RCTs; 5 SRs	Lifestyle (weight loss, physical activity, diet; alone or combinations)	**DPP; DPS; Da Qing; IDDP**.	**Kosaka 2005**; **Liao 2002; Mensink 2003; Oldroyd 2006; Wein 1999.**
Yates *et al* 2007 + Systematic review.	The role of physical activity in the management of impaired glucose tolerance.	7 RCTs, 1 nRCT	Physical activity programmes (actively promoted / supported physical activity or structured exercise training).	**DPS; DPP; Da Qing; Malmo**.	**Oldroyd 2006; Mensink 2003; Lindahl 1999**; **Carr 2005.**

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Yuen *et al* 2010 ++ Systematic review of randomised controlled trials.	Lifestyle and medication interventions for the prevention or delay of type 2 diabetes mellitus in pre-diabetes.	3 RCTs	Lifestyle vs medication	**DPP**; **STOP-NIDMM**; **IDPP.**	

6.3.2 Synthesis of findings of included review level evidence

Review level evidence provided synthesis of findings across key primary studies as well as discussion of intervention components related to effective trials. Due to the major diabetes prevention trials featuring so prominently in the review level evidence (see Table 2), components of interventions from those trials have been presented in tabular form (see Table 3) for reference. Components that were described as successful in the included reviews are presented in table 4.

Synthesis of the findings from included reviews is presented in both in tabular and narrative form. This provides details of components that were identified in included reviews as being associated with studies that had achieved their aim. Components of interest include the intervention setting, mode of delivery, contact information, and characteristics of those providing and using the intervention. In addition, intervention content in terms of lifestyle advice and provision of services is also discussed.

Table 3. Components of the main diabetes prevention trials represented in included reviews

Study	Physical activity goal	Dietary goal	Group Counselling	Individual counselling	Contacts		Delivery	Behaviour change
					First year	Total		
DPP (US) n = 3234	≥700kcal expenditure per week (≥150 minutes moderate physical activity (e.g. brisk walking). Twice weekly supervised physical activity offered.	Reduction of 500-1000 kcals / day from calculated estimated calorific requirements gave a goal of 1-2 lbs weight loss per week. Fat reduction based on 25% of calories derived from fat.	Face to face (group or individual) every 2 months after 6 months	16 initial sessions in first 24 weeks. Phone contact between sessions.	22	126	Registered dieticians Masters degree in exercise physiology or psychology	Self-monitoring emphasised as the most important strategy in behaviour change. Positive behaviour changes were reinforced. Motivational campaigns to assist with maintenance. Rewards such as t-shirts, newsletters, or other small incentives.

Study	Physical activity goal	Dietary goal	Group Counselling	Individual counselling	Contacts		Delivery	Behaviour change
					First year	Total		
DPS (Finland) n = 522	Differ between study centres according to local situation and facilities. Endurance exercise (walking, jogging, swimming, aerobic ball games, skiing) Moderate intensity / medium- to high-volume programmes designed to improve functional capacity and strength of large muscle groups. Circuit, resistance training offered free of charge	>50% of daily calories from carbohydrates; <10% from saturated fat and 20% from mono- and poly-unsaturated fat, or up to 25% if surplus is from mono-unsaturated fat. Cholesterol <300 mg/ day; ~ 1.0 g protein per kg ideal body weight per day. Intake of dietary fibre to 15 g per 1000 kcal / day.	None	7 initial sessions in first year then 1 every 3 months.	9	165	Dieticians	NR
VIP (Sweden) n = 168	140 hours of scheduled activities. Aerobic physical activity of moderate intensity daily for 2.5 hours, e.g. brisk walks, gymnastics, cycling and swimming.	~20% of energy in the form of fat and high fibre content. No alcohol consumption.	140 hours activity in first month.	Initial session. Phone contact once after 6 months.	32 (first month)	32	Residential inpatient: physicians, dieticians, nurse, physical fitness therapist, psychologist, physiotherapists.	Goalsetting, self-monitoring and problem-solving techniques. Stress management and relapse prevention.
ADPP (Italy) n = 375	Individualised physical activity and weight loss goals. No supervised activity.	50-60% of energy as carbohydrates, < 30% as fat, < 10% as saturated fat, 15-20% as protein, and 20-30g fibre per day.	4 x 60 minute sessions.	Physician counselling and nutritionist session at baseline.	7	7	Health care clinic: physicians, nutritionists, dieticians.	NR

Study	Physical activity goal	Dietary goal	Group Counselling	Individual counselling	Contacts		Delivery	Behaviour change
					First year	Total		
Da Qing (China) n = 577	Increase in leisure-time activity by at least 1-2 units per day. One unit = 30 minutes walking, 20 minutes cycling, 10 minutes slow running or 5 minutes swimming. No supervised activity.	Carbohydrate 55-65% of energy intake, fat 25-30% with an aim of reducing weight to < 24 kg/m^2. Vegetable consumption was encouraged whilst simple carbohydrates and alcohol were reduced.	All 3 arms: weekly for 1 month; monthly for 3 months, then once every 3 months.	Initial session for each of 3 arms.	14	14	Health care clinic: physicians, nurses, technicians.	NR
JDPP (Japan) n= 458 men	Increase to 30-40 minutes of walking per day. No supervised activity.	Large amount of vegetables and reducing other food intake by10%. Intake of fat limited to < 5g per day.	None	Every 3-4 months	≤6	≤6	Clinical outpatients; physicians, nurses.	NR
IDDP (India) n = 531	30 minutes brisk walking per day. No supervised activity.	Reduction in total calories, simple carbohydrates and fats. Fibre rich foods encouraged.	None	Baseline and every 6 months	16	16	Clinical team; physicians, lab technicians, social worker, dietician.	NR

Table 4: Effective components of studies reported in reviews focusing on lifestyle interventions

Study	Successful components	
Baker *et al* 2011 ++ **Type**: Systematic review (RCTs) **Focus**: Behavioural strategies in diabetes prevention programs	Characteristics of those delivering the intervention	Highly skilled personnel
	Behavioural strategies	Staging of information provision Individual tailoring of programme components Multiple sessions, reinforcement, specified small group size; individual or group programmes. Written materials to reinforce verbal advice Nutritional change: Small steps Vicarious and observational learning Identification of barriers to change and problem solving Learning to deal with relapse Increasing confidence to change

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

Study	Successful components	
		Physical activity change: Prescriptive approach with progressive increase in volume and frequency Self-monitoring Building problem solving and decisional balance into increasing motivation for activity Direct supervision (3 studies)
	Characteristics of recipients	NR
	Setting	Four major trials delivered interventions in a clinical outpatient setting utilising a team that included physicians and nurses.
	Intensity / Duration	Resource intensive during induction Moderate to very large number of face-to-face contacts over first 12 months.
	Adherence/ loss to follow up	Strategies to increase attendance: Contacts in person / by phone at regular intervals for duration of programme. 2 studies with obese cohorts (DPS; DPP) provided free exercise classes for the duration of the trial.
	Intervention content	Self-management and monitoring through log books on physical activity and diet Physical activity change: Structured programmes (observational learning and modelling of behaviour)
	Outcomes / Recommendations	Achievable, modest changes across multiple lifestyle goals

Study	Successful components	
Davies *et al* 2004. + **Type:** Review **Focus**: Prevention of type 2 diabetes mellitus in a UK setting.	Characteristics of those delivering the intervention	NR
	Mode of delivery	One-to-one dietary and physical activity sessions.
	Characteristics of recipients	NR
	Setting	NR
	Intensity / Duration	Target: 30 minutes physical activity each day or 150 minutes / week. Need for sustained input in dietary intervention (Swinburn) to maintain weight loss. At least 7 dietary / physical activity sessions over first year then individual or group sessions every 3 months over the remainder of the study.
	Adherence/ loss to follow up	NR
	Intervention content	Physical activity seems to be major contributing factor to non-progression from IGT to T2DM. (Da Qing).
	Outcomes / Recommendations	Weight loss surrogate marker for dietary or physical activity change (difficult to tease one from the other). Weight loss / weight stabilisation is essential. Benefits most pronounced in those who made most lifestyle changes (DPS).
Davis *et al* 2009. - **Type:** Review **Focus:** Role of obesity and lifestyle interventions in the prevention and management of type 2 diabetes.	Characteristics of those delivering the intervention	NR
	Mode of delivery	NR
	Characteristics of recipients	NR
	Setting	NR
	Intensity / Duration	NR

Study	Successful components	
	Adherence/ loss to follow up	NR
	Intervention content	NR
	Outcomes / Recommendations	Weight loss surrogate marker for dietary or physical activity change.
Madden *et al* 2008 + **Type:** Literature review **Focus:** Review of lifestyle interventions for the prevention of type II diabetes mellitus.	Characteristics of those delivering the intervention	NR
	Mode of delivery	NR
	Characteristics of recipients	Only males were involved in the trial that , in this review, resulted in the lowest incidence of T2DM (Kosaka 2005)
	Setting	NR
	Intensity / Duration	Benefits from sustained intervention
	Adherence/ loss to follow up	NR
	Intervention content	Low fat and low calorie diet had greatest results with mean weight loss 5.6kg (Wing). Balanced diet demonstrated lowest T2DM incidence in IGT participants over 4 years (Wein). Highest mean weight loss found in physical activity intervention that involved behavioural counselling via e-mail (Tate), though no follow up after 1 year. The greatest weight change overall followed a strict caloric intake of 800 – 1200 kcal / day and physical activity of 1-2 50-60 min supervised walks per week gradually increasing to 1500 kcal / week (Wing). Lowest T2DM incidence in diet plus physical activity intervention of healthy diet and moderate physical activity 30-40 minutes / day (Kosaka).
	Outcomes / Recommendations	Sustaining the interventions appears to be difficult for individuals. Programme selection should be a joint decision by patient and clinician.
Nield *et al* 2008 ++ **Type:**Cochrane Systematic Review	Characteristics of those delivering the intervention	Dietary advisors.
	Mode of delivery	NR

Study	Successful components	
Focus:Dietary advice for the prevention of type 2 diabetes mellitus in adults	Characteristics of recipients	High-risk
	Setting	NR
	Intensity / Duration	Support and guidance provided at least 3-6 monthly
	Adherence / loss to follow up	NR
	Intervention content	Energy-controlled diet with increase in fresh fruit and vegetables, and a decrease in simple sugars.
	Outcomes / Recommendations	Benefits in following diet as above. Over-riding factor was the frequency of support and guidance.
Norris *et al* 2007 ++ **Type:** Cochrane Systematic Review **Focus**: Long-term non-pharmacological weight loss interventions for adults with pre-diabetes.	Characteristics of those delivering the intervention	NR
	Mode of delivery	One residential treatment programme with close supervision and 2.5 hours physical activity per day was very successful
	Characteristics of recipients	High risk overweight and obese
	Setting	3 studies that were effective in reducing diabetes incidence demonstrated that prevention can be achieved in a variety of settings
	Intensity / Duration	Number of contacts significantly correlated with weight loss.
	Adherence/ loss to follow up	NR
	Description of the intervention content	Diet, physical activity or combination
	Outcomes / Recommendations	Sustained, long-term, intensive, multi-component interventions required to decrease incidence of T2DM.
Paulweber *et al* 2010 ++	Characteristics of those delivering	NR

Study	Successful components	
Type: Systematic review **Focus**: Review of lifestyle modification interventions for the prevention of type 2 diabetes	the intervention	
	Mode of delivery	Monitor co-morbidities and taken into account when planning diet.
	Characteristics of recipients	NR
	Setting	NR
	Intensity / Duration	Increase in physical activity at 30 minutes per day moderate exercise.
	Adherence/ loss to follow up	NR
	Description of the intervention content	Encourage to change diet and increase physical activity. Sustained weight reduction by 5-7%. Diet high in fibre (≥ 15g per 1000kcal), moderate fat (≤ 35% total energy), reduced saturated and trans fat (≤10% total energy).
	Outcomes / Recommendations	Weight reduction essential element.
Roumen *et al* 2009 - **Type:** Review **Focus**: Lifestyle intervention for prevention of diabetes.	Characteristics of those delivering the intervention	Need to know the behavioural stage of the recipient. Need to be aware of the clinical significance of IGT and reducing risk by targeting interventions. Practitioners skilled in assessment of dietary history and physical activity counselling or the willingness to refer.
	Mode of delivery	As there is high heterogeneity among high risk individuals in terms of co-morbidities and muscle strength, physical activity needs to be individually tailored to increase therapeutic value. Motivational interviewing may be beneficial to assist in positive attitude towards diet and physical activity.
	Characteristics of recipients	Need to be aware of increased risk for diabetes and own lifestyle. This can be achieved in general practice by asking questions of at risk individuals.
	Setting	NR
	Intensity / Duration	NR
	Adherence/ loss to follow up	Those with lower BMI seem more able to achieve activity goals. However, even small but sustained increases in activity are beneficial in the long term. Increasing motivation, self-efficacy and social activities, decreasing stress, emphasising the importance of

Study	Successful components	
		prevention and tailoring advice may increase adherence.
	Intervention content	There are indicators that moderate to vigorous physical activity helps prevent T2DM. Combined aerobic and resistance training showed greatest improvement on HbA1c. A high fibre, low fat diet predicts weight loss and prevention of T2DM.
	Outcomes / Recommendations	Weight reduction the dominant predictor of reduced diabetes risk. Physical activity contributes to improvement in glucose metabolism independent of weight loss, so seems to have an additive effect on prevention.
Walker *et al* 2010 + **Type: Review** **Focus:** Diet and exercise in the prevention of diabetes.	Characteristics of those delivering the intervention	NR
	Mode of delivery	NR
	Characteristics of recipients	Mediterranean diet is particularly effective in women compared to a low fat diet.
	Setting	NR
	Intensity / Duration	NR
	Adherence/ loss to follow up	NR
	Intervention content	Mediterranean diet
	Outcomes / Recommendations	Effects of lifestyle intervention increase in those severely overweight (One unit increase in baseline BMI leads to a decrease in HR of 7.3%. Mediterranean diet seems to have a long term impact on weight loss.
Waugh / Gillett *et al* 2010 ++ **Type:** Systematic review and economic evaluation (in progress). **Focus:** Non-pharmacological interventions to reduce the risk of diabetes in people with impaired glucose	Characteristics of those delivering the intervention	NR
	Mode of delivery	NR
	Characteristics of recipients	Goals more likely to be achieved by those at least risk. Older age groups (>60 years compared with 25-4 years) had greater physical activity increase at 1 and 2 years (DPP),greater percent weight loss and greater risk reductions for developing diabetes. Males had lower baseline, 1 and 2 year BMI, stress, anxiety and depression measures than women. They had higher physical activity levels than women at all three time

Study	Successful components	
regulation.		points. Greater readiness to change was associated with higher levels of baseline physical activity.
	Setting	NR
	Intensity / Duration	At least 150 minutes of moderate activity a week are required to have an effect on diabetes risk. However, even 10 minutes activity in sedentary individuals can show improvement in risk profile. Evidence suggests that physical activity needs to be taken regularly to have a preventative effect as effect of physical activity on insulin sensitivity lasts 24 – 72 hours (ADA recommend no more than 2 days without aerobic exercise). Dose response for physical activity (in Japanese - American men, not clear in women); lower risk of diabetes associated with taking more exercise. Risk of diabetes found to decrease incrementally with amount of energy expenditure (6% for every 500 kcal) and level of activity (none through to vigorous) although some evidence suggests exceeding moderate levels confers no extra benefit. Higher frequency of physical activity resulted in a greater amount of exercise.
	Adherence/ loss to follow up	Elderly people, females, self-referred participants and those participating with a spouse are more likely to adhere to intervention programmes. Adherence is more likely in programmes of physical activity over 3-4 days than 5-7 days per week, although one study found no difference in adherence between these programmes. Better adherence found in lower intensity activities than high intensity; this may be due to perceived higher risk of injury from high intensity activities. Maintenance of physical activity can be improved by incorporating physical activity into one's life (e.g. walking regularly). More convenient to attend fewer longer sessions than more frequent sessions. However, recommendations that > 30 minutes exercise per day. Multiple small, say 10 minute, sessions also improve adherence. May be useful to distinguish between physical activity as it relates to (and can be fitted into) everyday life, from exercise that requires the use of facilities.
	Intervention content	In the Netherlands, diabetes risk, weight and BMI were significantly reduced by encouraging carbohydrate ≥ 55%, fat 30-35%, sat fats < 10%, cholesterol < 33mg / 239 kcal, protein 10 -15 and fibre 3g / 239 kcal total energy intake as well as ≥ 30 minutes moderate physical activity ≥ 5 days per week (SLIM). Differences were maintained at 2 years.

Study	Successful components	
		In the UK a similar dietary intervention (more fruit and vegetables, fibre, less fat (particularly saturated fat), sugar, as well as 20 – 30 minutes aerobic activity > once per week did not reduce diabetes incidence but did increase reversion from IGT to NGT as well as weight loss compared to controls. Increased consumption of vegetables, reduction in fat and alcohol intake and 30-40 minutes moderate exercise daily reduced risk of diabetes compared to standard intervention (3% vs 9.3%) in Japanese males. Most common form of leisure time physical activity is walking, second most common is cycling. Gardening and shovelling snow were common non-leisure activities (DPS). All forms of physical activity shown to be beneficial (aerobic, resistance, combined) to HbA1c levels, with combined training generally more effective.
	Outcomes / Recommendations	Greater reduction in energy intake after one year in lifestyle intervention group compared to metformin or placebo groups. Much of the diabetes incidence reduction was related to weight loss, though there was also 50% reduction in those that met physical activity goals.
Yates *et al* 2007 + **Type:** Systematic review. **Focus**: The role of physical activity in the management of impaired glucose tolerance.	Characteristics of those delivering the intervention	NR
	Mode of delivery	NR
	Characteristics of recipients	NR
	Setting	NR
	Intensity / Duration	Inconclusive
	Adherence/ loss to follow up	NR
	Intervention content	Greater reduction in incidence of T2DM in physical activity group than either diet or physical activity alone, or in combination. Physical activity alone not associated with greater weight loss. Aerobic training at 3hr / week did not lower blood glucose but did improve insulin sensitivity at 6 and 24 months.
	Outcomes / Recommendations	150 min/week of moderate to vigorous intensity exercise unlikely to be sufficient to

Study	Successful components	
		reduce risk of T2DM in those with IGT independently of other lifestyle changes.
Yuen *et al* 2010 ++ **Type:** Systematic review **Focus:** Lifestyle and medication interventions for the prevention or delay of type 2 diabetes mellitus in pre-diabetes.	Characteristics of those delivering the intervention	Unclear how capable health care systems are around the word to provide adequate lifestyle interventions.
	Mode of delivery	NR
	Characteristics of recipients	None of participants in the DPP were in the pre-contemplative phase.
	Setting	NR
	Intensity / Duration	Lifestyle advice needs to be re-reinforced regularly. DPP found that initial attainment of physical exercise and weight loss goals predicted future success; may be beneficial to employ an initial period of regular contact.
	Adherence/ loss to follow up	NR
	Description of the intervention content	Not possible to draw conclusions on which interventions were most effective in delaying T2DM
	Outcomes / Recommendations	May need more time to deliver interventions in the real world

'NR' = Not Reported

6.4 Synthesis of findings

The following is a synthesis of findings from the included reviews, in respect of the aspects of interventions under scrutiny. Whilst a number of reviews reported similar findings, it needs to be acknowledged that some of the findings are taken from the same prevention programmes.

Intervention settings

There was a lack of evidence that compares intervention effectiveness directly between settings, therefore it is not possible to determine whether a particular setting is better than any other in terms of outcomes. However, two reviews (Baker *et al* 2011; Norris *et al* 2009) report that diabetes prevention trials that were successful in reducing the incidence of type 2 diabetes were carried out in a range of settings, mainly clinical outpatients.

Evidence statement 1:

Intervention Settings

Evidence was found from two systematic reviews of randomised controlled trials (Baker *et al* (2011 ++; Norris *et al* 2009 ++) of diabetes prevention programmes that effective programmes can be delivered in a range of clinical (in-patient and outpatient) and community settings.

However, there is a lack of evidence that directly compares intervention effectiveness between different settings, therefore it was not possible to determine whether any particular setting is better than another in terms of outcomes, or the potential scale of the impact this might have.

Baker *et al* (2011 ++) reported that four major trials delivered successful interventions (which we have defined here as delivering significant reduction in diabetes incidence or significant weight loss at a minimum of 12 months follow up compared to controls) in clinical outpatient settings. The trials were conducted in Japan, India, Italy and China. The quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from Norris *et al* (2009 ++) provides examples of three trials that were effective in reducing the incidence of type 2 diabetes in clinical and community

settings (no further details given), as well a combination of the two. These trials were carried out in the US, Finland and China. Quality rating was not detailed, though it was noted that randomisation procedures were only described in one of the three trials. All three trials were described as adequately powered.

Characteristics of those delivering the intervention

Three of the included reviews (Baker *et al* 2011; Nield *et al* 2008; Roumen *et al* 2009) described characteristics of those delivering interventions that might contribute to success. However there was a lack of evidence that directly compares these characteristics.

Highly skilled personnel such as physicians, nurses, dieticians, psychologists were described in reviews of the major trials. The DPP required exercise and behaviour specialists to be educated to at least Master Degree level to presume the role of "case manager", and the JDPP. IDPP, Da Qing and ADPP utilised a team that included physicians and nurses (Baker 2011; Nield 2008).

Staff that are aware of the clinical significance of impaired glucose as well as the need to reduce incidence of type 2 diabetes by targeting interventions to those at risk were highlighted as important contributors. In addition, having skills that include assessment of a patient's dietary history and physical activity counselling or the willingness to refer to professionals who have those skills was reported as an asset (Roumen 2009).

Evidence statement 2:

Characteristics of those delivering interventions

Evidence was extracted from two systematic reviews of RCTs (Baker *et al* 2011++; Nield *et al* 2008 ++) and weak evidence from one non-systematic review (Roumen *et al* 2009 -) for an observational association of high levels of skill and / or a relevant professional qualification with intervention effectiveness for diabetes prevention.

However, there is a lack of evidence that directly compares or that statistically examines difference in intervention effectiveness between providers with different characteristics. Hence, it is not currently possible to determine the optimal characteristics of intervention providers or the scale of the impact this might have.

The two systematic reviews present the observation that high levels of skill and relevant professional qualifications were characteristics of successful interventions in a total of 7 trials that resulted in a reduction of diabetes incidence. The trials were

conducted in the US, Finland, China, India, Japan, Italy and Sweden.

In a non-systematic review of a range of study types (Roumen *et al* 2009 -) the authors suggest, based on a qualitative study of general practitioner knowledge that was carried out in the UK, that awareness of the importance of reducing the incidence of type 2 diabetes as well as being able to effectively assess and counsel recipients about diet and physical activity may be important contributors to sustainable changes in diet and / or physical activity.

Mode of intervention delivery

Whilst there is a lack of evidence directly comparing mode of delivery between trials that were successful in reducing the incidence of type 2 diabetes, one review of RCTs (Baker *et al* 2011) reported that seven such trials delivered an initial individual assessment followed by group or individual counselling. Five of the trials (DPP, DPS, JDPP, IDPP and VIP) delivered counselling mainly on an individual basis, whilst two (Da Qing, ADDP) delivered sessions in small groups following the initial assessment.

Evidence statement 3:

Mode of intervention delivery

There is evidence from one systematic review of RCTs (Baker *et al* 2011++) relating to the mode of intervention delivery.

However, there is a lack of evidence that directly compares intervention effectiveness between individual or group delivery, therefore it was not possible to determine whether individual delivery is better than group delivery in terms of outcomes, or the potential scale of the impact this might have.

One systematic review of RCTs (Baker *et al* 2011++) reported that 7 trials achieving a reduction in the incidence of type 2 diabetes and with a follow up of at least 12 months delivered an initial individual assessment followed by either individual or group counselling. In five out of seven of these trials, counselling was delivered mainly on an individual basis. These trials were based in the US, Finland, Japan, India and Sweden. Two trials delivered counselling in small groups following the initial individual assessment. These trials were carried out in China and Italy. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Frequency of contacts

Contact is defined as face-to-face counselling or assessment as well as telephone contact between intervention participants and those facilitating the intervention or assessing outcomes. Frequency of such contacts over a given time was assessed in five reviews (Baker *et al* 2011; Davies *et al* 2004; Nield *et al* 2008; Norris *et al* 2007; Yuen *et al* 2010).

Whilst there is as lack of evidence that directly compares frequency of contact between trials that were successful in reducing the incidence of type 2 diabetes, these reviews reported on the association between number of contacts, particularly over the first 12 months, with weight loss.

Number of contacts between delivering personnel and recipients during the first 12 months of intervention implementation in trials that had ranged from 6 in the JDPP and ADPP to 22 in the VIP (when supervised physical activity sessions are also included, there was up to a maximum of 126 contacts in the DPS and a maximum of165 contacts in the DPP). Similar results were achieved with 9 non-supervisory contacts in the DPS compared to 22 in the DPP (Baker 2011).

Norris *et al* (2007) found that the number of intervention contacts was significantly correlated with weight loss; the number of contacts in the trials that they assessed ranged between 4 and 78. The UK/France trial that delivered four contacts achieved <0.5kg weight loss compared to the control group. One US trial achieved more than 2kg weight loss over two years compared to controls. The DPS achieved a 58% reduction in relative risk for diabetes incidence with 15 contacts over 3.2 years ($p<0.001$).

Yuen *et al* (2010) observed that the provision of regular lifestyle advice might lead to effectiveness because it encourages participants to sustain participation. Nield *et al* (2008) recommended access to support and guidance at least 3- 6 monthly.

Davies *et al* (2004) reported that successful studies had included at least seven counselling sessions during the first year followed by individual or group counselling.

Evidence statement 4:

Frequency of contacts

Evidence was extracted from four systematic reviews of randomised controlled trials (Baker *et al* 2011 ++; Nield *et al* 2008 ++; Norris *et al* 2007 ++; Yuen *et al* 2010 ++) and one non-systematic review of lifestyle and medication studies (Davies *et al* 2004 +). Contact is defined here as individual face-to-face counselling, assessments or telephone contact between intervention participants and those facilitating the intervention or assessing outcomes.

There is a lack of evidence that directly compares intervention effectiveness between the frequencies of contact, therefore it was not possible to determine the potential scale of the impact that different frequencies might have.

Baker *et al* (2011 ++ UK) reported that of seven included trials that achieved successful reduction in diabetes incidence, the frequency of contacts during the first 12 months of implementation ranged from 6 in one Japanese trial and one Italian trial to more than 22 in one Swedish trial and one US based trial. When supervised physical activity sessions were included in one Finnish trial, this number extended to 165.

Nield *et al* (2008 ++) recommended access to dietary support and guidance at least 3- 6 monthly based on their review of 2 RCTs. One trial was carried out in the Netherlands and assessed weight reduction as the primary outcome. One trial was based in China (the same trial as in Baker *et al* 2011). The authors assessed the quality of these trials as quite poor based on the Jadad score.

Norris *et al* (2007 ++) reported total contact frequencies ranging from four over one year in one trial based in the UK and France that demonstrated a small weight loss (< 0.5kg) compared to the control group, to 78 over 2 years in one US trial that demonstrated > 2kg weight loss compared to controls. One included Finnish trial achieved a 58% reduction in relative risk for diabetes incidence with 15 contacts over 3.2 years ($p<0.001$). One Swedish based trial assessed the effects of a 28-day residential course. The authors report that the number of dietary and physical activity intervention contacts in three well powered studies (carried out in the US, Finland

and China) that achieved reduction in diabetes incidence also significantly correlated with weight loss (p=0.015). Quality rating was not detailed, though it was noted that randomisation procedures were only described in one of the three trials.

Yuen *et al* (2010 ++) speculated from a review of four trials carried out in the US, India, China and internationally that lifestyle advice re-reinforced regularly might be more effective because it encourages sustained participation. Studies were assessed for risk of bias, with all four trials having at least 2 elements out of six that were rated as high risk. The DPP (US) was rated lowest risk of bias. This trial also reported similar diabetes incidence rates at two different time points.

One non-systematic review (Davies *et al* 2004 +) that assessed six trials comparing lifestyle interventions or lifestyle and medication reported that successful interventions included individual counselling on at least 7 sessions during the first year followed by individual or group sessions every 3 months for the remainder of the study. The trials were carried out in China, US, Finland, Brazil and internationally. One trial was carried out with women who had a history of gestational diabetes. There was no quality rating reported for the studies.

Content of dietary interventions

There was a lack of evidence that directly compares dietary components that might lead to the reduction of diabetes incidence, since many of the interventions also included a physical activity component.

Six included systematic reviews of RCTs (Baker *et al* 2011; Burnet *et al* 2006; Nield *et al* 2008; Norris *et al* 2007; Waugh *et al* 2010; Paulweber *et al* 2010) and two reviews of a range of study types (Roumen *et al* 2009; Walker *et al* 2010) assessed dietary components included in studies that had been successful in reducing diabetes incidence or weight.

Baker *et al* (2011) assessed seven such RCTs; all the dietary interventions advised reduced fat intake (the DPP, DPS, Da Qing and VIP specified a reduction to 20-30% total energy) and six advised portion control. Four (DPP, IDPP, ADPP and VIP) advised an increase in fibre intake and all seven advised the increased consumption of fruit and vegetables.

Three reviews (Burnet *et al* 2006; Paulweber *et al* 2010; Waugh *et al* 2010) reported that a diet high in fibre (≥ 15g per 1000kcal), moderate fat (≤ 35% total energy), reduced saturated and trans fats (≤10% total energy) combined with physical activity could achieve 5-7% weight reduction. In one study, diabetes risk, weight and BMI were significantly reduced by encouraging carbohydrate ≥ 55%, fat 30-35%, of which saturated fats < 10%, cholesterol <

33mg / 239 kcal, protein 10% - 15% and fibre 3g / 239 kcal total energy intake as well as ≥ 30 minutes moderate physical activity ≥ 5 days per week (SLIM). Differences were maintained at 2 years. Common features of lifestyle interventions reviewed by Roumen (2009) include the following dietary advice for proportion of energy consumption: Carbohydrates approximately 55% of total energy; total fat <30% of total energy; Saturated fat ≤ 10%; Cholesterol <33g/mj day; Protein 10-15 % of total energy; Fibre 3g / mj day. The most frequently recommended physical activity was 30 minutes moderate activity at least 5 days per week.

In the UK, a similar dietary intervention for an overweight or obese sample (n = 39) encouraged regular meals that included more fruit, vegetables and fibre, less fat (particularly saturated fat) and sugar. The specific dietary requirements were fat intake ≤ 30% of total energy intake, polyunsaturated fat to saturated fat ratio ≥ 1.0, 50% of energy from carbohydrates, and fibre intake of ≥ 20g per 239 kcal. In addition, the intervention encouraged 20 – 30 minutes of aerobic activity at least once a week. However, this intervention did not reduce diabetes incidence, but did increase reversion from IGT to NGT as well as weight loss compared to controls (Waugh *et al* 2010).

Walker *et al* (2010) reviewed epidemiological and cohort studies, assessing the effect of consuming a Mediterranean diet on weight loss. The diet is rich in fat, but mainly in the form of mono-saturated fat which has beneficial properties. In addition, fish and dairy foods are consumed more often than is red meat, and a wide range of vegetables and legumes, fruit and nuts are also typical fare. Walker *et al* (2010) reported that the Mediterranean diet was associated with either weight maintenance or weight loss in cohort studies. Two studies carried out in Spain and the US reported that adherence to the Mediterranean diet was associated with up to 15% reduced diabetes risk, weight maintenance or weight loss. There was a decreased risk for obesity in one Spanish arm of an international study at 3 years (OR 0.68, 95% CI 0.53-89 in men, OR 0.69, 95% CI 0.54-0.89 in women).

Davies *et al* (2004) reviewed a range of study types and suggested that HbA1c levels were inversely associated with the frequency of consumption of fruit and vegetables in the UK based EPIC study.

Evidence statement 5:

Dietary interventions

There was evidence from four systematic reviews of randomised controlled trials (Baker *et al* 2011++; Burnet *et al* 2006 +; Waugh *et al* 2010 ++; Paulweber *et al* 2010 ++) and two non-systematic reviews of a range of study types (Davies *et al* 2004 +; Roumen *et al* 2009 -) for dietary components of lifestyle interventions for the prevention of type 2 diabetes.

Baker *et al* (2011++) assessed seven RCTs in which all participants were advised individually to modify their diet. All the interventions advised a reduction in fat (with four studies (carried out in the US, Finland, China and Sweden) specifying a reduction to <20-30% of total energy intake, and six studies advised adjustment of portion control. Four studies (carried out in the US, India, Italy and Sweden) recommended an increase in fibre intake and all seven studies advised increased fibre intake in the form of fruit and vegetables. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from three systematic reviews of RCTs (Burnet *et al* 2006 +; Waugh *et al*. 2010 ++; Paulweber *et al* 2010 ++) and one non-systematic review (Roumen 2009 -) report similar detail from between five and nine diabetes prevention trials carried out in the US, Finland, China, Japan, Sweden, Australia, India, Netherlands and the UK regarding dietary aims to sustain a weight reduction of 5-7% when combined with physical activity goals. They include the consumption of 55% total energy intake as carbohydrates; fat 30% - 35% of total energy with saturated fat ≤ 10%; cholesterol <33g per mj per day; protein 10-15 % of total energy intake and fibre ≥ 15g per 1000kcal. Quality ratings are not available within the reviews.

There was also evidence from epidemiological studies included in two reviews of a range of study types (Burnet *et al* 2006 +; Walker *et al* 2010 +) that a diet of fruits, vegetables, legumes, fish and whole grains was associated with a lower diabetes risk. Walker *et al* (2010 +) describe the 'Mediterranean' diet, as rich in fat, but mainly in the form of olive oil, and includes a wide range of vegetables and legumes, fruit and nuts. They provide evidence from a range of cohort studies, two of which were carried out in Spain and US that adherence to the diet was associated with up to 15% reduced diabetes risk, weight maintenance or weight loss. One Spanish arm of

an international cohort study reported a decreased risk for obesity at 3 years in those that adhered well to the Mediterranean diet (OR 0.68, 95% CI 0.53-89 in men, OR 0.69, 95% CI 0.54-0.89 in women). These reviews did not report quality ratings for the epidemiological studies.

Epidemiological evidence from one non-systematic review of a range of study types (Davies *et al* 2004+) suggests that the frequency of fruit and vegetable intake was inversely associated with HbA1c levels in the UK based EPIC study and that in the US, an increased intake of whole grains was associated with decreased diabetes risk, though there was no clinical significance reported. Quality ratings were not reported for these studies.

Findings from reviews of epidemiological studies need to be viewed with caution due to the risk of bias.

There is a lack of quality evidence that assesses the effect of diet and physical activity alone in trials that have demonstrated reduction in the incidence of type 2 diabetes and / or weight reduction. Therefore, it is difficult to make inferences about the impact that any particular dietary intervention may have on outcomes.

Physical activity intervention components

Three reviews (Baker *et al* 2011; Paulweber *et al* 2010; Yates *et al* 2007) assessed physical activity intervention components. There was a lack of evidence of the effectiveness of particular physical activity components compared with others, though there was some consensus regarding the type and intensity of activity utilised in studies that had achieved a reduction in diabetes incidence and / or weight loss.

There was evidence from a total of seven RCTs assessed in two reviews (Baker *et al* 2011; Paulweber *et al* 2010) that had demonstrated reduction in diabetes incidence that participants were advised to increase physical activity to at least 150 minutes per week at moderate intensity. In the Japanese prevention trial, 30-40 minutes per day was advised. In the DPP and Da Qing, participants could reduce the activity volume if they carried the activity out more vigorously. Resistance training was included in some DPP and DPS clinics, and supervised physical activity sessions were provided free of charge twice a week. In the VIP there was an emphasis on muscle strengthening twice per week.

Yates *et al* (2007) reported from a review of four RCTs, that the risk of diabetes was reduced by 42-63% compared to controls. In one study the effect of physical activity alone was assessed and found to be greater than that of di*et al* one (46% compared to 42%

combination of diet and physical activity, and 13% for dietary intervention alone), though the result was not statistically significant.

Evidence statement 6:

Physical activity interventions

Evidence was obtained from two systematic reviews of randomised controlled trials (Baker *et al* 2011++; Paulweber *et al* 2010++) and one review of randomised and non-randomised controlled trials (Yates *et al* 2007 +).

Baker *et al* (2011++) and Paulweber *et al* (2010 ++) provided evidence from five and seven RCTs respectively that had demonstrated reduction in incidence of type 2 diabetes, that participants had been advised to increase their level of physical activity. This was to a level of at least 150 minutes per week at moderate intensity in trials carried out in US, Italy, and Sweden. Baker *et al* (2011 ++) also report that up to 30-40 minutes of moderate activity (e.g. brisk walking) per day was advised in one trial carried out in Japan. The US based and Chinese trial allowed participants to reduce the volume of activity if it was carried out more vigorously. Resistance training was included in some US and Finnish based clinics. A Swedish trial included counselling on the importance of muscular strengthening twice a week. Supervised physical activity was included free of charge 2 days per week in the US and Finnish trials. The Swedish trial included a residential component of 2.5 hours per day for one month. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from one systematic review of randomised and non-randomised controlled trials (Yates *et al* 2007 +) suggests that, from four included RCTs that assessed the reduction of type 2 diabetes incidence (carried out in US, China, Finland and Sweden), risk of diabetes was reduced by 42-63% compared to the control groups. One of these studies assessed the effect of diet and physical activity in combination and separately and found a greater effect in physical activity alone (46% diabetes reduction compared to 42% in combination with dietary intervention or 13% reduction for di*et al* one). However, this result is not statistically significant. Quality assessment was not reported on the studies. Issues that may have impacted on the findings include self-reporting of physical activity and use of physical activity questionnaires that lack validity.

There is a lack of quality evidence that assesses the effect of diet and physical activity alone in trials that have demonstrated reduction in type 2 diabetes incidence and / or weight reduction. Therefore, it is difficult to make inferences about the impact that any particular form, volume or intensity of physical activity may have on outcomes.

Combined Dietary and physical activity interventions

Three systematic reviews (Paulweber *et al* 2010; Norris *et al* 2007; Waugh *et al* 2010) and one non-systematic review of any study type (Madden *et al* 2008) assessed the role of multi-component interventions. There was a lack of evidence that directly compared different combinations of different components therefore it is not possible to report that any combination is better than another or make statements about the impact that any combination might have on outcomes.

Waugh *et al* (2010) reported a 3% cumulative incidence of type 2 diabetes in the intervention group compared 9.3% in the control group in a trial of Japanese males with 4 year follow up ($p<0.043$). This equated to a reduction of 67.4% in the intensive lifestyle group. The intervention stressed a healthy diet including increased fresh fruit and vegetables, provision of education about portion control, and encouragement of moderate levels of physical activity for approximately 30-40 minutes per day.

Norris *et al* (2007) assessed nine RCTs and reported that sustained, long term, intensive multi-component interventions were the most successful determinant of decreasing incidence of diabetes. One review of five RCTs (Paulweber *et al* 2010) recommended both a change in diet and an increase physical activity to sustain a weight reduction by 5-7%.

Evidence from one non-systematic review of a range of study types (Madden *et al* 2008 +) reported from seven studies carried out in China, Finland, US, Netherlands, and Japan that a low fat and low calorie diet combined with a 50-60 minute supervised walk each week increased mean weight loss as did one year of physical activity behavioural counselling by e-mail.

Sustained, long term, intensive multi-component interventions were reported as being the most successful determinant of decreasing incidence of diabetes in one review (Norris 2007), whilst another stated that improved dietary or physical activity behaviours alone or in combination were sufficient to prevent diabetes (Yuen 2010). Combined interventions were generally reported to be more effective. Recipients that made the most behaviour changes

were found to benefit most from lifestyle change (Davies 2004). However, as previously described, those that were most at risk were least likely to achieve lifestyle goals.

Evidence statement 6:

Combined diet and physical activity

Evidence exists from three systematic reviews of randomised controlled trials (Paulweber *et al* 2010++; Norris *et al* 2007 ++; Waugh *et al* 2010 ++) and one non-systematic review (Madden *et al* 2008 +) for combinations of dietary and physical activity intervention.

There is a lack of quality evidence that assesses the effect of diet and physical activity combined compared with dietary or physical activity interventions alone in trials that have demonstrated reduction in type 2 diabetes incidence and / or weight reduction. Therefore, it is difficult to make inferences about the impact that any particular combination of dietary or physical activity intervention may have on outcomes

Waugh *et al* (2010 ++) reported that in one Japanese trial of males with a 4 year follow up a combined dietary and physical activity intervention resulted in cumulative incidence of type 2 diabetes of 3% in the intervention group compared 9.3% in the control group ($p<0.043$). This equated to a reduction of 67.4% in the intensive lifestyle group. The intervention stressed a healthy diet including increased fresh fruit and vegetables, provision of education about portion control, and encouragement of moderate levels of physical activity for approximately 30-40 minutes per day. Quality assessment was not available from this review.

Norris *et al* (2007 ++) assessed nine RCTs carried out in US, France, UK, Finland, Japan, and the Netherlands reported that sustained, long term, intensive multi-component interventions were the most successful determinant of decreasing incidence of diabetes (Norris *et al* 2007 ++). Trials were quality assessed and rated as generally having high risk for bias.

One review of five RCTs (Paulweber *et al* 2010 ++) carried out in US, Finland, China, Japan, Sweden and India, recommended both a change in diet and an increase physical activity to sustain a weight reduction by 5-7%.

Evidence from one non-systematic review of a range of study types (Madden *et al*

2008 +) reported from seven studies carried out in China, Finland, US, Netherlands, and Japan that a low fat and low calorie diet combined with a 50-60 minute supervised walk each week increased mean weight loss as did one year of physical activity behavioural counselling by e-mail. This review did not report quality assessment of included studies.

Intensity / duration of physical activity

Though there was a lack of evidence directly comparing different intensities and duration of physical activity, one systematic review of RCTs (Waugh *et al* 2010) reported a dose response in the DPS where participants that increased their level of physical activity were 60% less likely to develop type 2 diabetes. After adjusting for weight loss, this figure was reduced to 51%. The more physical activity was increased, the less the risk for diabetes with those exercising the most having a 59% less risk than those exercising the least.

Evidence statement 7:

Intensity / duration of physical activity

Evidence exists from one systematic review of randomised controlled trials (Waugh *et al* 2010 ++).

There is a lack of evidence that directly compares intervention effectiveness between different intensities and duration of physical activity, therefore it was not possible to determine the potential scale of the impact that different intensities may have.

Waugh *et al* (2010 ++) report that at least 150 minutes of moderate activity a week is required to have an effect on diabetes risk. However, even 10 minutes activity in sedentary individuals can show improvement in risk profile. There was evidence of a dose response one Finnish trial. Those who increased their physical activity were 60% less likely to develop diabetes, though this decreased to 51% after adjusting for weight loss. Those that increased their physical activity the most were 59% less likely to develop diabetes than those with least change in exercise patterns. There was no quality assessment grading available for included studies.

Behavioural components

Three reviews (Baker 2011; Norris 2007; Yuen 2010) reported on behavioural components of interventions that had achieved success in reducing the risk of diabetes and / or reduced weight loss. There was a lack of evidence comparing the effect of particular behavioural components therefore we cannot state that any one is a better than another. In addition, Baker *et al* (2011) state that the seven diabetes prevention trials that they assessed did not specifically report using strategies relating to the Theory of Planned Behaviour, there was an emphasis in the intervention on behavioural intent.

All the trials (DPP, DPS, Da Qing, JDPP, IDPP) assessed the incorporation of goal setting early in the intervention. According to Baker *et al* (2011), goal setting has two effects on behaviour change. The first is to influence the participant's intention directly by setting out what is intended, and secondly by allowing the participant to feel in control of the situation. For dietary interventions it was important for recipients to be encouraged to take small steps, using learning techniques that include observation and problem solving. Confidence is important, particularly with regard to changing behaviours and dealing with set-backs (Baker *et al* 2011).

Yuen *et al* (2010) reported that regular reinforcement of set goals was found to be beneficial, particularly in the early stages of an intervention. Burnet *et al* (2006) also emphasised the importance of individualised goal-setting by recipients, which built upon initial dietary and weight management goals specified within the intervention protocol. These individual goals were documented by recipients and could be modified progressively. Problem solving, decisional balance (this term was not explained within the review but Janis & Mann wrote in 1977 that decisional balance can be conceptualised as a balance sheet of comparative gains and losses) and self-monitoring were also highlighted as elements of successful achievements (Baker *et al* 2011; Burnett *et al* 2005). According to Burnett *et al* (2005), self-monitoring through the use of regular weighing, and recorded measurement of dietary input and physical activity increased self-efficacy and empowerment.

For physical activity interventions, a prescriptive approach was recommended which emphasised increased activity in terms of volume and frequency. Increasing motivation was highlighted as an important aspect which can be achieved by observational and vicarious learning Direct supervision in the form of a residential programme was a component of the VIP trial in Sweden (Norris 2007) that included 2.5 hours per day of supervision.

Burnet *et al* (2005) also found that family and social context were important supporting factors. In the DPP, DPS, and Malmo studies, spouses were encouraged to participate in counselling sessions with the participant. This can provide a key source of social support.

Evidence statement 8:

Behavioural components

There was evidence from four systematic reviews of randomised controlled trials (Baker *et al* 2011++; Burnet *et al* 2006 +; Norris *et al* 2007 ++; Yuen *et al* 2010 ++), for the use of behavioural strategies to enhance effectiveness of interventions.

There is a lack of evidence that directly compares different intervention effectiveness between behavioural components, therefore it was not possible to determine the potential scale of the impact that different components may have.

Baker *et al* 2011++ carried out an analysis of intervention versus control data in a systematic review of RCTs. Whilst they state that the trials included in their review use few behavioural strategies relating to the Theory of Planned Behaviour, there was a focus on behavioural intention and evidence of strategies that were common to more than one theoretical model. They suggest that information and advice alone is insufficient to bring about lifestyle change and associated effects compared to theoretically-based detailed lifestyle interventions such as those used in the major diabetes prevention trials. These include staging of information provision and tailoring programmes to individual needs, using multiple sessions to reinforce information, delivered to small groups or individuals, delivering written information as well as verbal advice, encouraging self-monitoring and logging of physical activity, diet and weight change.

For dietary behaviour change, taking small steps and providing both observational and vicarious leaning opportunities as well as encouraging the identification of barriers and problem solving were reported as strategies used in prevention programmes that had achieved reduction in diabetes incidence. For physical activity, a prescriptive approach that gradually increased the frequency and volume of activity over time as well as providing observational and vicarious leaning opportunities and encouraging self-monitoring were suggested. Three of the successful trials also included direct supervision of physical activity.

Norris *et al* 2007 ++ and Yuen *et al* 2010 ++ also assessed RCTs for prevention of diabetes (carried out in the US, UK, India, France, Finland, the Netherlands and Japan) and reported on the importance of gradually increasing volume and frequency of physical activity levels and of the importance of encouragement through direct supervision. Regular reinforcement of set goals was reported as an important

strategy in the early stages of an intervention.

Burnett *et al* (2006 +) reported from three trials carried out in the US, Finland and Sweden that self-monitoring through the use of regular weighing, and recorded measurement of dietary input and physical activity increased self-efficacy and empowerment. Family was a key social support in prevention efforts. Trials carried out in the US, Finland, China and Sweden encouraged spouses, where appropriate, to co-participate in counselling sessions.

Trials in the Norris and Yuen reviews were quality assessed and rated as generally having high risk for bias.

Characteristics of intervention recipients

Two systematic reviews of RCTs (Waugh *et al;* Yuen *et al* 2010) and three non-systematic reviews (Davies *et al* 2004; Roumen *et al* 2009; Walker *et al* 2010) reported on characteristics of recipients of interventions. There was generally a lack of evidence comparing the characteristics of recipients so that it is not possible to make statements about the impact that this may have on outcomes.

Waugh *et al* (2010) reported that a higher stage of readiness for change in physical activity was associated with a higher level of baseline activity ($p<0.0001$) and at 12 months and the end of one US trial. From the same trial, Yuen *et al* (2010) suggested that this sample demonstrated a greater readiness to change than the representative IGT population.

Roumen *et al* (2009) reported from cross-sectional evidence that recipients that are aware of the potential impact that lifestyle changes might make are more likely to sustain those changes.

Davies *et al* (2004) suggest that intervention sin the DPS were more effective in those participants who made the most change in their dietary and physical activity behaviours providing that the changes were sustained over time. In the trial the overall reduction in diabetes incidence was 58% with no new cases detected in participants that achieved at least four of their set goals.

Waugh *et al* (2010) highlighted under-reporting of food consumption in the DPS by overweight and obese participants. In one non-systematic review, epidemiological data provided evidence of ‘rebound’ weight gain in overweight and obese participants if they returned to the pre-study dietary intake.

Evidence statement 9:

Characteristics of intervention recipients

There was evidence from two systematic review of RCTs (Waugh *et al* 2010 ++; Yuen *et al* 2010 ++) and three non-systematic reviews (Davies *et al* 2004 +; Walker *et al* 2010 +; Roumen *et al* 2009 -). No quality assessment ratings are available for the included studies within these reviews.

There is a lack of evidence that directly compares the characteristics of intervention recipients in relation to intervention effectiveness, therefore it was not possible to determine the potential scale of the impact that different characteristics may have.

Waugh *et al* (2010 ++) reported that greater readiness to change physical activity levels correlated with higher levels of baseline physical activity ($p<0.0001$) at baseline, 1 year and the end of one US based trial. Yuen *et al* (2010 ++) also reported, from the same US trial, that the sample were more physically active at baseline and at a later stage of readiness to change than a representative IGT population.

Cross-sectional evidence from one non-systematic review of a range of study types (Roumen *et al* 2009 -) suggests that recipients that are aware of the potential impact of the lifestyle choices they make are more likely make sustained changes.

Davies *et al* (2004 +) report from one Finnish trial that lifestyle interventions were more effective in participants who achieved more of their dietary and physical activity goals. However, these changes needed to be sustained. Overall diabetes reduction in the intensive intervention group was 58%, with no new cases of diabetes reported in those that achieved at least four of their goals.

Waugh *et al* 2010++ provided evidence from one Finnish trial of under-reporting food consumption in overweight and obese participants. Walker *et al* (2010 +) report findings from one epidemiological study of a risk of ‘rebound’ weight gain in this group if there is a reversion to pre-intervention energy intake.

Strategies to encourage attendance / adherence

Two systematic reviews of RCTs (Baker *et al* 2011 ++; Waugh *et al* 2010 ++) and one review of RCTs and other study types reported on strategies that might be used to encourage attendance and / or adherence to interventions.

Baker *et al* (2011) found evidence from three RCTs (DPP, DPS and VIP) that self-monitoring of physical activity, dietary intake and weight change was encouraged to provide feedback and motivation in participants. There was also provision of free supervised physical activity in the DPP and DPS to encourage take up of activities whilst removing the barriers of cost.

Waugh *et al* (2010++) assessed strategies in three US trials of physical activity. The duration of the advised activity was associated with motivation in that adherence was more likely in interventions delivered over 3-4 days that 5-7 days per week. Lower intensity activities were also more likely to promote adherence at 6 months than those of high intensity. The authors suggest that this may be due to fear of injury. A third 3-year study revealed that incorporating physical activity into daily life could be more achievable than high intensity sport.

Evidence statement 10:

Strategies to encourage attendance / adherence

There was evidence from two systematic reviews of randomised controlled trials (Baker *et al* 2011++; Waugh *et al* 2010 ++), one review of RCTs and other study types (Burnet *et al* 2006 +).

Baker *et al* (2011++) reported that three RCTs (carried out in the US, Finland and Sweden) that obtained success in reducing the incidence of diabetes, used logging of physical activity, calorie intake and fat intake to provide feedback to participants and maintain motivation. The provision of free supervised physical activity sessions for the duration of the programme was implemented to encourage take up of structured physical activity in two trials carried out in the US, and Finland. No data is available on the rate of attendance at these sessions. Whilst no formal quality assessment is available, included studies were required to meet minimum criteria for inclusion.

Waugh *et al* (2010 ++) assessed adherence strategies in three US based RCTs of physical activity. They report that adherence to physical activities in one RCT of 2 year duration was more likely in programmes delivered over 3-4 days rather than 5-7 days per week. They also report from another RCT that lower intensity activities at 6 month follow up were related to better adherence compared to higher intensity activity, possibly due to perceived risk of injury with high intensity activities. Findings from a third RCT of 3 years duration with 10 tear follow up suggest that incorporating activity into daily life, such as walking regularly might be easier to achieve than high intensity sport. There was no quality assessment available for these studies.

Burnet *et al* (2006 +) reported that three of the four included trials in their review also incorporated follow up efforts such as active encouragement from staff, computer monitoring and development of a personal ‘toolbox’ of problem solving strategies for each participant.

6.5 Discussion

This review of review level evidence has assessed components of trials that aim to reduce incidence of type 2 diabetes and / or reduce weight and BMI. Weight loss was reported as a marker for physical activity or dietary change. However it is difficult to untangle the effects of diet and physical activity in isolation from reports of combined interventions.

Successful interventions (i.e. that can reduce risk of diabetes) were delivered by qualified personnel such as nurses, psychologists and dieticians. Interventions included a diet consisting of at least 55% carbohydrates as energy intake, that are low in saturated fat with increased fibre, containing fresh fruit and vegetables, although this conclusion is based on trials that combine diet and physical activity interventions.

Moderate physical activity levels carried out for at least 30 minutes per day, 5 days a week are also associated with lower risk of diabetes, weight loss and reduction in BMI. The effects of physical activity appear to be dose responsive, at least in men, in terms of duration, frequency and intensity, though there is some evidence to suggest that intensity above moderate levels confers no greater benefit. Whilst 30 minutes per day physical activity is recommended to maintain benefit, any amount or type of activity is beneficial.

There is some evidence to suggest that physical activity has an effect on risk reduction independent of weight loss. However, to reduce the incidence of type 2 diabetes it is generally considered beneficial to achieve weight loss in overweight and obese recipients, followed by stabilisation. In the DPP, a 16% reduction in diabetes risk was found for each kg of weight lost during the 3 year follow up. Physical activity may provide an additional protective mechanism.

Whilst type, frequency and intensity of intervention are important, lifestyle changes require motivation and support. Readiness to change at baseline was found to be a factor in achieving goals, with on-going support from qualified professionals. There was no consensus on an optimum number of counselling sessions, though it was suggested that at least 7 sessions over the first year are needed to sustain change. The larger trials included more frequent sessions and it is difficult to interpret the effect of this input on benefit.

Successful programmes incorporated some behavioural strategies, though they were not always identified as such in reports. Reinforcement of change was encouraged by frequent contacts, and allowing participants to set their own targets using small stages to achieve goals was a factor of successful interventions. Individual goal setting, taking into account the requirements and preferences of participants in relation to diet and physical activity increases empowerment and self-efficacy.

A combination of enhanced empowerment, motivation and a perception that interventions are feasible for the individual are more likely to encourage maintenance of attendance and behaviour change. Feasibility is related to the commitments and abilities of participants, who need to integrate activities into their daily lives as well as feel that goals are achievable within individual capabilities. Perhaps this is one underlying factor behind the finding that those least at risk are achieving goals more readily; those most at risk may have more difficulty adapting to lifestyle change, yet once this change is made, evidence shows that this group benefit more from that change.

A recently published review of reviews (Greaves *et al* 2011) examined evidence relating the content of interventions for promoting dietary and /or physical activity change to their effectiveness in producing weight and behaviour change. The review focused on evidence relating to individuals with a wider group of clinical risk factors and therefore had a broader scope than that specified by NICE for this review. However the work is a very important contribution to this field. There was mixed evidence from thirty included studies for the benefit of interventions having a theoretical underpinning, with stronger evidence for the use of self-regulatory techniques such as goal planning, self-monitoring, and provision of feedback.

Greaves *et al* (2011) concluded that interventions should include both diet and physical activity components using well established behaviour techniques delivered by trained personnel. Social support from friends and family is an important aspect in engaging participants. The evidence supported group or individual modes of delivery in a wide range of settings with maximum frequency of contact.

The main findings in our review are, therefore, supported when evidence from a broader range of studies that include those from high risk populations, but without necessarily having pre-diabetes, are considered.

Whilst this review provides some insight into successful aspects of interventions for diabetes prevention, the trials on which this evidence was based were intensive and well resourced. It is unknown whether such effects can be demonstrated in other, smaller community settings. The next part of this review assesses reviews that report on interventions that have been translated from use in major trials to those in the ‘real world’.

PART TWO

What is the review and primary level evidence for the most effective methods of preventing or delaying progression to type 2 diabetes in adults with pre-diabetes when intensive interventions assessed in RCTs are adapted to real world settings (i.e. outside of a formal study context)?

Evidence from the major diabetes prevention trials was obtained using ideal conditions such as large and highly selected samples and intensive interventions. In recent years there have been attempts to translate these studies into less than ideal situations, or the 'real world' such as primary care. Generally such studies need to be adapted to specific circumstances (Garfield 2003).

The second part of this review assesses primary level studies that assessed translational studies based on major diabetes prevention protocols. All included studies were based on either the DPP or DPS protocol. Typically, translational studies adapt one of the two protocols to the resource and time constraints of general practice or another community setting. The following presents characteristics of these studies followed by the findings, and identifies modifications and components.

Characteristics and results of the two major trials (DPP; DPS)

The US based Diabetes Prevention Programme (DPP) was a double-blinded randomised controlled trial (DPP 2002) having a sample of 3,234 with a diagnosis of IGT or IFG and a BMI of > 24 kg/m^2 (> 22 kg/m^2 in the Asian subsample). The trial was conducted over a three year period (1996-9) using standard lifestyle recommendations for the control arm, metformin in the pharmacological arm, and an intensive lifestyle programme as the intervention arm.

The intensive lifestyle intervention comprised a core nutritional and physical activity based programme of 16 weeks duration with sessions lasting 30-60 minutes. These were delivered to individuals by 'lifestyle coaches' who were well qualified (professionals or Masters Degree equivalent) in their topic area. Group sessions and supervised sessions were also provided. Clearly defined weight loss goals of 7% body weight and physical activity goals of > 700kcal expenditure per week, or 150 minutes moderate physical activity per week, as well as dietary goals of a reduction in 500 to 1000 kcals per day consumption (depending on body weight) were set, with the opportunity to vary the methods used to achieve goals depending on individual abilities and preferences.

Participants were encouraged to self-monitor their weight, physical activity and dietary achievements for the first 24 weeks. Maintenance to the intervention was encouraged by

face-to-face contacts at least every 2 months, as well as telephone contact following the core protocol for the duration of the trial. A 'toolbox' of strategies that was individualised to address potential barriers through problem solving was developed with each participant. The strategies were organised in a hierarchy from the most to the least resource intensive.

The primary outcome was incidence of diabetes as diagnosed using the OGTT every 12 months, or the FPG twice a year. Secondary outcomes included cardiovascular risk and morbidity, changes in blood glucose levels, β cell function and insulin sensitivity, renal function, body composition, changes in physical activity and nutrient intake, as well as health-related quality of life (DPP 1999).

At 3 year follow up, incidence per 100 person years was 11 in the placebo group, 7.8 in the metformin group, and 4.8 in the intensive lifestyle intervention group. Incidence was reduced by 58% in the intervention group compared to controls. Average weight loss was 5.6kg in the intervention group compared to 0.12kg in controls after a mean follow up of 2.8 years. In addition, half of the intervention group achieved their weight loss goal of > 7kg (DPP 2002). However, data from the 10 year follow up shows a gradual weight gain after the first year (DPP 2009).

The Finnish Diabetes Prevention Study (DPS) recruited 522 overweight and middle aged participants with a diagnosis of IGT (as determined by two OGTT tests) to intensive lifestyle intervention or control groups. Participants in the intervention group received face-to-face consultation sessions with a duration of 30-60 minutes with a study nutritionist at baseline, at weeks 1–2, 5–6, and at months 3, 4, 6, and 9. This totalled seven sessions during the first year followed by every 3 months thereafter. The first year sessions had a pre-planned topic (e.g., diabetes risk factors, saturated fat, fibre, physical activity, and problem solving), but the discussions were individualised, focusing on specific individual problems.

Printed material was used to illustrate the message and to serve as a reminder at home. In addition, there were voluntary group sessions, expert lectures, low-fat cooking lessons, visits to local supermarkets, and between-visit phone calls and letters. Participants in the intervention group were individually guided to increase their overall level of physical activity. This was done by the nutritionist during the dietary counselling sessions and highlighted by the study physicians at the annual visits. Endurance exercise was recommended to increase aerobic capacity and cardio respiratory fitness. Supervised, progressive, individually tailored circuit type moderate intensity resistance training sessions to improve the functional capacity and strength of the large muscle groups of the upper and lower body were also offered free of charge. As a means for improving motivation, an "exercise competition" between the five

study centres was organized twice during the study period. Voluntary group walking and hiking were also organized.

The primary outcome of the study was development of type 2 diabetes as determined by an annual OGTT. Secondary outcomes included changes in plasma glucose levels, insulin levels and HbA1c, cardiovascular risk factors such as blood pressure, serum lipids and uric acid levels. The effect of lifestyle changes on primary and secondary outcomes was assessed.

During the first three years of the study, 9% of the participants in the intervention group (n = 22) and 20% in the control group (n = 51) developed diabetes (Lindstrom 2003).

At the end of 12 months, mean weight loss in the lifestyle group was 4.2 kg (SD 5.1) compared to 0.8 kg (SD 3.7) in the control group (P< 0.001). At two years, mean weight loss in the intervention group remained greater than that in the control group (3.5 kg vs 0.8 kg), but was less than the loss in the intervention group at one year.

At three years, the mean weight loss in the intervention group was 4.5kg compared with a mean loss of 3.5kg in the control group. Cumulative diabetes incidence at four years was 11% in the intervention group and 23% in the control group (Tuomehleto 2001).

6.5 Quantity of the evidence available

Focussed searches within Medline identified 789 potential primary papers following de-duplication that were potentially relevant to this guidance. Of these, 723 were rejected at title / abstract level. A total of 66 papers were scrutinised at full text level. Of these, 53 were rejected and a total of 13 studies were identified that were relevant to this review. A number of papers that looked relevant from the title were rejected ultimately because there were no results reported. Eleven papers reported translational interventions based on the DPP, three on the DPS and one was based on a combination of both the DPP and the DPS.

6.6 Quality of the evidence available

Of the 15 included primary translational papers, three were rated [++], 11 were rated [+] and one [-]. See Appendix 5 for details of quality assessment.

The main quality assessment issues were around the lack of fit between reported methods and quality assessment criteria. For example, most of the included primary studies used a pre-test / post-test design and therefore bias could not be reduced in the same way as in an RCT. The study rated [-] mainly reported on training of voluntary staff, so that broader ranging details relevant to this review, such as participant demographics and intervention duration were brief or not available.

6.7 Characteristics of included translational studies:

Studies based on the DPP protocol

Eleven US based studies included interventions based on the DPP protocol. Six were carried out in health care settings including primary care (Almeida *et al* 2010; Amundsen *et al* 2009; Kramer *et al* 2009; McTigue *et al* 2009a; Seidal *et al* 2008; Whittemore *et al* 2009), with one based in nurse practitioner practices (Whittemore *et al* 2009). Two studies (McTigue *et al* 2009b; Vadheim 2010) used internet and video-conferencing technology to deliver the intervention, two further interventions (Davis-Smith 2007; Faridi *et al* 2009) were delivered in a church and another through YMCA facilities (Ackermann *et al* 2008). One German primary care study was based on a combination of the DPP and the DPS protocol (Kulzer *et al* 2009).

Eight studies reported selecting samples from overweight populations (≥ 25 kg/m^2) (Ackermann 2008, Amundsen 2009, Kramer 2009, Kulzer 2009, McTigue 2009a and 2009b; Seidal 2008; Vadheim 2010). Two studies (Ackermann 2008; Davis-Smith 2007) used the ADA risk score at a cut point of 10 to identify at risk individuals. The remaining studies used a range of criteria to identify risk.

Four of the DPP based studies used a pre-test post-test study design (Amundsen *et al* 2009; Davis-Smith 2007; McTigue *et al* 2009b; Seidal *et al* 2008), therefore comparisons were not available. Eight studies used a comparator, though only used randomised intervention and control arms (Ackermann *et al* 2008; Kulzer *et al* 2009; Whittemore *et al* 2009). Kramer *et al* 2009 compared intervention delivery in two phases, one in primary care and the other in a Diabetes Support Centre and additional practices. Almeida *et al* 2010 used non-randomised matched pairs to compare a small group intervention. Faridi *et al* (2010) compared two African American church populations. McTigue *et al* (2009a) compared their intervention outcomes with those of non-enrollers to the programme. Vadheim *et al* (2010) compared telehealth, or video-conferencing delivery with on-site delivery.

All studies but one (Almeida *et al* 2010) reported that interventions were delivered by trained 'lifestyle coaches' or health professionals such as dieticians and nurses, diabetes educators and psychologists or trained community workers. Interventions consisted of a combination of dietary and physical activity protocol. The original DPP goal of a 5-7% body weight reduction and increase in physical activity to 150 minutes of moderate activity per week was explicitly reported in all studies apart from McTigue *et al* (2009b), which reported that the

DPP protocol was replicated. Two studies introduced the use of pedometers in the introductory phase (Kramer *et al* 2009; Seidal *et al* 2008) rather than the maintenance phase. Healthful eating, with an emphasis on reduced fat and calorie intake was encouraged in all the studies, though reporting of dietary goals was typically brief, with two studies merely stating that the DPP protocol had been followed (Ackermann *et al* 2008; Davis-Smith 2007).

In addition, DPP based self-monitoring of nutritional intake and physical activity was reported in seven studies. Behavioural techniques such as goal-setting, problem solving and encouragement of self-efficacy were reported in a further two studies. Davis-Smith (2007) and Seidal *et al* (2008) did not report the use of self-monitoring or behavioural techniques.

Three studies (Ackermann *et al* 2008; Amundsen *et al* 2009; Vadheim 2010) included face-to-face sessions over 16 or more weeks, for 60-90 minutes, in line with the DPP. Four studies (Kramer *et al* 2009; Kulzer *et al* 2009; McTigue *et al* 2009a; Seidal *et al* 2008), delivered the intervention over 12 - 15 sessions. Six or fewer face-to-face sessions were delivered in three studies (Almeida *et al* 2010; Davis-Smith 2007; Whittemore *et al* 2009), though Whittemore *et al* (2009) also included five phone sessions. All the face-to-face delivered sessions were group-based apart from one (Amundsen *et al* 2010), which delivered 16 individual sessions followed by monthly group sessions. One study (Faridi *et al* 2009) did not specify number of sessions or mode of delivery.

One study (McTigue *et al* 2009b) delivered 16 sessions via the internet, and another (Vadheim *et al* 2010) included one arm that delivered 16 sessions using video-conferencing technology. Two studies delivered interventions at a church (Davis-Smith 2007; Faridi *et al* 2009) and one through YMCA facilities (Ackermann *et al* 2008).

Studies based on the DPS protocol

Three studies were based on the DPS protocol. Two studies were based in Finland (Absetz *et al* 2007 / 2009; Saaristo *et al* 2010) and one in Australia (Laatikainen *et al* 2007). All were set in primary care. All three studies were set in primary care with health professionals delivering the programmes at a combination of individual or group sessions (Saaristo *et al* 2010) or group based sessions (Absetz *et al* 2007 / 2009; Laatikainen *et al* 2007).

All three studies recruited participants based on results using the FINDRISC risk score for diabetes. Two studies used the cut point ≥ 12 (Absetz *et al* 2007 / 2009; Laatikainen *et al* 2007) and one study used ≥ 15 (Saaristo *et al* 2010) to identify at risk participants.

All used a pre-test / post-test design to assess lifestyle modification Therefore there is no usual care comparator available in this set of studies.

All three studies delivered an average of 6 sessions of 60-90 minute duration over 2 months (Saaristo *et al* 2010) or 8 months (Absetz 2007 / 2009; Laatikainen 2007).

The intervention content was stated to be based on the DPS protocol in all three studies. Absetz *et al* (2007) described their objectives as a reduction of fat intake to less than 30% total energy intake, less than 10% total energy intake from saturated fat, at least 15g of fibre per 1,000 kcal, at least 4 hours a week of moderate level physical activity, and a weight reduction of at least 5%. Self-monitoring, goal setting and planning were encouraged.

Laatikainen *et al* (2007) did not describe their physical activity goals. Dietary goals were based on the Dietary Guidelines for Australian Adults (no further details given). There was an emphasis on goal setting approach and regular self assessment. Saaristo *et al* (2010) briefly stated that either individual or group counselling sessions were delivered that focussed on weight, meal frequency, fat intake, quality of fat, use of salt, fibre intake, use of alcohol, exercise and smoking. There was a range of frequency of visits between health centres, with no further details given.

Table 5. Characteristics of translational intervention studies based on the DPP and DPS.

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
DPP based							
Ackermann 2008 + Pilot cluster-randomized trial	To evaluate the delivery of a group-based DPP lifestyle intervention in partnership with the YMCA	Two YMCA populations (semi-urban, with similar ethnic and SES characteristics) 7500 randomly selected households within approximately 5 miles of each YMCA facility.	YMCA	Participants received testing, brief counselling, then repeat testing and brief counselling again after 6 and 12 months of enrolment.	YMCA staff completed a structured two-and-one-half day group-instructor training curriculum administered by experienced DPP investigators. The YMCA selected instructor candidates based on their good communication skills and prior experience in group education or programming.	To help participants achieve modest weight loss through gradual lifestyle changes.	Weight change
Almeida 2010 ++ Non-randomised longitudinal matched pairs.	To assess a theory-based, brief, small-group weight loss intervention for diabetes prevention	Members of an integrated health care organization newly diagnosed with pre-diabetes	Colorado, US Closed health care.	4-6 monthly sessions; single 90-minute small-group session with 10 to 20 participants.	Presentation by a dietician or weight loss specialist that included information about pre-diabetes and diabetes, recommendations for a healthful diet and regular physical activity, and information on how diet, physical activity, and weight loss delay the onset of diabetes.	To encourage participants to set weight management goals by engaging in recommended amounts of physical activity and eating a healthful, well-rounded diet. Goal-setting, development of a personal action plan for each participant.	Weight
Amundsen 2009 +	To evaluate the	Adults ≥ 18 years	Montana, US	16 sessions	Led by lifestyle	Based on	Same goals as the

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
Evaluation Study	feasibility of translating the Diabetes Prevention Program (DPP) lifestyle intervention into practice in the general community.	BMI ≥25 kg/m2, 1 or more risk factors for diabetes or cardiovascular disease.	Primary care. 4 sites.	adapted from DPP, followed by monthly group sessions over a 6-month period Group size across sites ranged from 8 to 34 participants. Group sessions ~ 1 hour in length.	coaches. Participatory and interactive. Included guided nutrition and physical activity demonstrations.	adaptation of the DPP curriculum developed by Healthy Native Community Partnership. Physical activity components began in week 5. Monitoring and logging of weekly activity. Opportunity to participate in 2 weekly structured physical activity events.	DPP (7% weight loss and moderately intense physical activity for ≥150 minutes per week). Self monitored fat intake and physical activity.
Davis-Smith 2007 + Evaluation Study	To determine the feasibility of implementing a diabetes prevention programme (DPP) in a rural African-American church.	An African-American church in a rural Georgia town with a population of 8,040 was identified based on a Sunday attendance of approximately 150 adults. The church's roster included 407 members with a 3:1 ratio of women to men.	US: African American Church	Six sessions were presented over a seven-week period following a schedule determined by the participants. Each session was led by volunteer healthcare professionals. A six-session program was designed from the 16-session intensive lifestyle arm of the DPP. Two sessions from each of three DPP categories (nutrition, physical activity and behaviour change) were chosen to	The session leaders attended a 60-minute training session led by the research team on how to present the lifestyle balance curriculum to the church community. A paid research assistant brought snacks and handouts and recorded the participants' weight.	To advise participants with a FSG of <100 of their risk score results and to give information on healthy lifestyle habits.	Weight change BMI Blood glucose

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
				make up the six sessions. The material was modified to be used in a church-based group setting from its original design for individual use with a lifestyle coach. A nurse educator and physician performed the modification, adapting the information to a group setting.			
Faridi 2010 – Non-randomised trial (PREDICT).	To test the impact of a Community Health Advisor led diabetes prevention intervention targeting an African American church congregation compared to no intervention	Two African American church congregations	Connecticut, US 13 African American churches in 2 comparison areas.	Intervention methods were chosen by the Community Health Advisors and were tailored to individual preferences.	Both group (church) and individual (outreach) sessions were delivered.	Diabetes knowledge, awareness of risk factors. Improved physical activity and diet, food labels, portion control, healthful cooking, weight loss programmes, social support and empowerment.	Physical activity and dietary patterns Anthropological measures Social support Diabetes knowledge Nutrition and physical activity self-efficacy.
Kramer 2009 + Nonrandomized prospective one-group design.	To develop a comprehensive model for real-world diabetes prevention intervention for application in multiple settings (Group Lifestyle balance)	25–74 years BMI ≥25 kg/m2	Pittsburg area, US. Rural and urban.	12-session program.1-hour sessions delivered over 12–15 weeks. Group sessions.	Handouts, a fat- and calorie-counting book, self-monitoring books for food intake and physical activity, a pedometer with instructions, a chart for self-monitoring weight.	Updated diabetes prevention curriculum and behavioural lifestyle materials. Primary focus on healthy food choices.	Weight loss Waist circumference BMI Cholesterol levels BP

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
Kulzer 2009 ++ RCT (PREDIAS)	To evaluate the efficacy of a group based diabetes prevention programme.	Primary care patients at risk 20-70 years BMI ≥ 26 kg/m2 IGT / IFG >10 Diabetes Risk Score	Primary care Germany.	12 sessions 90 minutes each. Eight core sessions in first 8 weeks then 4 bimonthly sessions. Delivery by psychologists or diabetes educators.	Small groups (median number 7 individuals). Transparencies in sessions; written information. Table of caloric values and worksheets for each activity.	PREDIAS based on self-management theory.	BMI Weight Waist circumference Fasting glucose A1c Lipids, BP, cholesterol
Mc Tigue 2009a + Controlled cohort study	To translate the Diabetes Prevention Program (DPP) lifestyle intervention into a clinical setting and evaluate its effectiveness.	WiLLoW was made available to overweight or obese patients (BMI ≥ 25 kg / m2) with or without diabetes	Primary Care, US	A 12-session, group-based version of the DPP lifestyle curriculum (versus the original 16 sessions delivered via one-on-one counseling) was implemented.	Sessions are led by the clinic's nurse educator. Each session includes discussion of a specific content area and provides opportunities for participants to share their personal experiences. Relevant demonstrations (eg, healthy portion sizes, food labels) accompany most lessons. Behavioural techniques include goal setting, self-monitoring, and problem solving.	Program goals are consistent with those of the DPP: 7% weight loss and 150 minutes of moderate physical activity per week, with total fat reduction (to 25% of calories from fat) and calorie balance and restriction (with a goal of a 500- to 1000-calorie reduction diet).	Weight change
Mc Tigue 2009b + Cohort study	To translate an evidence-based lifestyle program into the clinical setting by adapting it for delivery via the Internet.	From a single, academic general internal practice.Age 18–80, body mass index (BMI) ≥25 kg/m2, history of at	Internet based, US	The intervention started with an approximately 2-hour in-person orientation session that trained participants in the	Internet based	The DPP lifestyle intervention's goals.	Change in body weight (kg). Change in blood pressure and the frequency of clinically significant

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
		least one physician-diagnosed weight-related cardiovascular risk factor (hypertension, dyslipidemia, diabetes, or impaired fasting glucose), and willingness to participate in the program evaluation. Technical requirements included Internet access via Microsoft Internet Explorer 6.0 (Microsoft, Redmond, WA), speakers or headphones that enable use of online audio files, and the ability to turn off system pop-up blockers (instructions provided).		use of the software, and enabled them to meet each other and the study staff, and described the DPP lifestyle intervention's goals. The staff emphasized the need for participants to communicate regularly with their referring physicians and the practice's diabetes nurse educator to facilitate diabetes or hypertension medication adjustments if necessary. The program comprised five components accessed from a home page. Automated e-mail prompts reminded participants of pending lessons, and other tasks. Each 30–45-minute lesson was audio narrated and included an optional quiz. Sixteen weekly lessons comprised the core curriculum			weight loss.

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
				of the DPP Lifestyle Intervention, slightly modified for online delivery. They were followed by eight monthly lessons, adapted from relevant supplemental DPP materials.			
Seidel 2008 + Non-randomized prospective one-group	To determine if a community-based modified Diabetes Prevention Program Group Lifestyle Balance (GLB) intervention, for individuals with metabolic syndrome, was effective in decreasing risk for type 2 diabetes and cardiovascular disease (CVD) in an urban medically underserved community, and subsequently to determine if improvements in clinical outcomes could be sustained in the short term.	11 urban medically underserved neighbourhoods. Participants with a BMI ≥25 kg/m2, physician consent to exercise, and at least three of the five components of metabolic syndrome as defined by the National Cholesterol Education Program's Adult Treatment Panel III	US: Near Pittsburgh, Pennsylvania.	Phase II: modified GLB intervention Members of the DPP lifestyle team adapted the individual ILI to a group-based program, 12 weekly sessions over 12–14 weeks, group classes, healthy food choices, emphasis on fat intake and calories, and more emphasis on pedometer.	Two trained "preventionists" (one dietician and one exercise specialist) were responsible for delivery of the GLB intervention, which took place in the 11 targeted neighbourhoods and was held weekly for 12 weeks and lasted around 90 minutes. Group size ranged from 5 to 13 participants.	The goals of the GLB intervention were to achieve and maintain a 7% weight loss and to progressively increase physical activity to 150 min/ week of moderately intense physical activity.	There were two primary outcomes of the intervention: 1) 5% or 7% weight loss from baseline to 3- and 6-month follow- up and 2) improvement of at least one metabolic syndrome component from baseline to 3- and 6-month follow up. Improvements in triglycerides, abdominal obesity, hypertension status, HDL cholesterol, and glucose levels.
Vadhelm 2010 + Non-randomised feasibility controlled trial	To assess the feasibility of delivering an adapted group-	Respondents to general practice and newspaper advertisements.	General health care, Montana, US. Telehealth and on-site settings.	Lifestyle coaches taught the 16 weekly core curriculum	Delivered by 2 lifestyle coaches (staff members of their ADA	Adapted version of DPP curriculum developed by the Healthy Native	Goal attainment Weight BMI

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
	based version of the Diabetes Prevention Program's (DPP) lifestyle intervention Through telehealth video conferencing.	Adults ready to make changes in diet and physical activity levels, overweight (BMI ≥25 kg/m2), with1 or more risk factors for diabetes or CVD.		sessions and the 6 monthly after-core sessions. Each session was approximately 1 hour in length. The telehealth group simultaneously participated in the weekly and monthly sessions via telehealth video conferencing. The lifestyle coaches, the telehealth coordinator, and all participants at both sites could see and hear each other through the video conferencing system. 2 to 4 weekly supervised physical activity sessions for the on-site participants.	recognized diabetes self-management education programs); 1 paid support staff at on-site facility. One lifestyle coach registered dietician and certified diabetes educator. The other has training in exercise sciences. Tele-health site coordinated by a health care professional from the local medical facility.	Community Partnership designed for group delivery. Goals same as the DPP (7% weight loss and moderately intense physical activity for ≥150 minutes per week). Supervised activity sessions included aerobics, strength training, yoga, dance classes, Pilates, and water aerobics. Self-monitoring and recording fat intake and weight , physical activity.	Lipids
Whittemore 2009 ++ Pilot randomised controlled trial	To examine the reach, implementation and efficacy of a 6-monthy lifestyle programme.	Age > 21 years. At risk for IGT / metabolic syndrome / T2DM (BMI ≥25 kg/m2; age > 65 years; family history of T2DM; history of GDM or baby≥ 9 lbs; hypertension; ethnic group at higher risk of T2DM; lipid	US: Nurse practitioner practices.	Six in-person 20 minute sessions (total 3 hours) and 5 phone sessions (total 1 hour) over 6 months.	Motivational interviewing. Delivered by Nurse Practitioners.	Behavioural change support; recognition of difficulty in changing lifestyle behaviours. Culturally relevant nutrition, physical activity and T2DM prevention education. Identification of lifestyle goals and	Reach. Attendance. Attrition. Satisfaction. Weight loss. Waist circumference. Insulin resistance. Nutrition and physical activity behavioural outcomes. Depressive

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
		abnormalities).				problem solving. Modifications: Some content provided for completion at home. Some content was abbreviated and nutritional content was revised slightly.	symptoms.
DPS based							
Absetz 2009 + (3 year follow up)	To study the effectiveness of the GOAL Lifestyle Implementation Trial at the 36-month follow-up.	Primary Health Centre patients.	Primary care, Finland	Six sessions over a period of 8 months. No other formal postintervention contact with participants, except follow-up measurements at years 1 and 3.	More modest program than DPS, delivered by existing health care personnel (public health nurses).	Underpinned by the five key lifestyle change objectives in the DPS: 1. Less than 30% of total energy intake from fat; 2. Less than 10% of total energy intake from saturated fat; 3. At least 15 g of fibre/1,000 kcal; 4. At least 4 h/week moderate level physical activity; and 5. More than 5% weight reduction.	Weight loss Blood Glucose BMI Waist circumference Lipids BP Dietary intake Physical activity levels
Laatikainen 2007 + Pre-test post-test design.	To determine whether lifestyle modification programmes are feasible in primary health care.	Patients presenting at local General Practices.	Primary care, Australia.	Six structured 90 minute group sessions over eight months. First 5 sessions within first three months, with two week intervals between sessions. The last	Health Action Process Approach. Facilitated by specially trained study nurses, dieticians and physiotherapists.	Goal setting approach to motivate progress from intention to actual behaviour change. Regular self-assessment to empower participants to take	Weight BMI Waist circumference Blood Glucose measures Lipids BP

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
				at eight months.		responsibility for their own decisions and to make informed choices. Content for diet and physical activity based on Dietary Guidelines for Australian Adults and National Physical Activity Guidelines for Adults. Social support enhanced by group setting and encouraging support from social networks. Intervention targets aiming to reduce weight, total and saturated fat intake and increase fibre intake and physical activity.	SF-36v2
Saaristo 2010 + Pre-test post-test design.	To investigate 1-year outcomes of a national diabetes prevention program.	Primary health care centre and occupational health care outpatient clinic patients with FINDRISC score ≥ 15	Primary care, Finland	Either individual counselling visits or group sessions. Frequency among health centres, depending on local circumstances and resources. Default model is group intervention. Group meetings 4 to 8 times during the course of the programme, either once a week or every other week.	Program, content and methods used are planned together with the members and the manager of the group according to patient empowerment principles.	Counselling based on DPS study and application of different stages of change in behaviour. Focus on weight, meal frequency, fat intake, quality of fat, use of salt, fibre intake, use of alcohol, exercise, or smoking, based individual preference. Group sessions varied	Diabetes incidence Weight loss BMI Waist circumference Lipids BP

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

Study	Aim	Population	Setting	Sessions	Mode of delivery	Curriculum content	Outcomes of interest
				Follow-up session one month after the final intervention session.		from weight maintenance groups to exercise groups and lectures on diabetes & lifestyle.	

6.8 Synthesis of included translational study findings:

Studies based on the DPP protocol

Sample sizes varied from small (Vadheim *et al* 2010 n = 29) to large (Almeida *et al* 2010 n = 1,520) with the remaining studies including samples of between 92 and 355. At baseline, all but two of the study populations were reported to have a high mean BMI (≥ 30 kg/m^2). Of the remaining two, 80% of the sample had a BMI of ≥ 30 kg/m^2 (McTigue *et al* 2009b) and one study sample (Almeida *et al* 2010) had a borderline mean BMI (29.8 kg/m^2).

Four studies included a raised blood glucose measure as criteria for participation. Ackermann *et al* (2008) used random capillary glucose at a cut off 110-199 mg/dl as well as an ADA risk score of ≥ 10. For Almeida *et al* (2010) an IFG diagnosis (100-125 mg/dl) was required. Over 50% of the Amundsen *et al* (2009) sample had either IFG or IGT (no specific cut off values provided), with other risks for diabetes and cardiovascular disease such as raised blood pressure, and family history of diabetes also considered as inclusion criteria. The remaining included studies did not specify pre-diabetes as a necessary condition of participation, though it was sufficient if present (as a risk factor) for enrolment onto the studies.

In the study with the largest sample size (Almeida n = 1,520), there were more females than males, though this difference was not as pronounced (61% female) as in the three smaller studies where the samples comprised of at least 80% females. Ethnicity of the samples was not reported in these studies.

Modifications of the DPP protocol to translational studies

In general, the studies included in this review used protocols that were closely based on the DPP trials.

The pilot trial carried out by Ackermann *et al* (2009) utilised YMCA facilities to reach at risk individuals rather than health care settings. Behavioural interventions were delivered in group sessions of 8-12 people rather than individual sessions. Maintenance activities following the core curriculum were in the form of monthly large group meetings as the study was focussed on feasibility.

Almeida *et al* (2010) utilised existing health care facilities and specialists in nutrition or weight loss to deliver 4-6 monthly small group sessions. The main modifications to the DPP were less sessions; the study delivered between one-third and one-quarter of the number of

sessions. In addition, the intensive intervention was delivered to small groups rather than individuals. Weight was the outcome of interest, rather than incidence of diabetes.

Amundsen *et al* (2009) delivered a protocol that matched the DPP in duration (16 sessions) targeting groups rather than individuals. The goals were similar to those of the DPP in terms of weight loss, fat intake and physical activity. However there was no comparator group in this study.

A church setting was utilised in the Davis-Smith study (2007) rather than health care settings. This followed on from previous health promotion programmes that have screened in African-American churches, such as those that focus on hypertension, smoking cessation and cervical cancer. As well as a modified setting, the curriculum was delivered over 6 sessions rather than 16, with materials being modified to the church based group setting.

Faridi *et al* (2009) also delivered a lifestyle intervention in church settings. Two sites were compared, where one received a curriculum of diabetes prevention, including physical activity and dietary advice, portion control, cooking healthily, weight loss programmes, social support and empowerment in communicating with health care professionals. The sessions (no detail on number) were delivered by volunteers trained by certified diabetes educators.

The Kramer study adapted the protocol to 12 sessions over 12-15 weeks compared to the DPP 24 weeks. Group sessions were held rather than individual sessions and the pedometer was introduced during the core sessions rather than afterwards, as in the DPP. Weight loss goals, delivery by trained personnel and a focus on self-monitoring and problem solving were shared with the DPP.

Kulzer *et al* (2009) delivered 12 group sessions of approximately 90 minutes duration. One session a week was provided for the first eight weeks followed by two per month for two months. The programme was based on self-management theory and was delivered by psychologists or diabetes educators. Participants were provided with a diabetes prevention book that included nutritional information as well as log books and worksheets.

McTigue *et al* (2009a) report on a modification from 16 to 12 weeks for the core curriculum in a medical practice based setting, with group counselling rather than individual sessions. Programme goals were otherwise in line with those of the DPP.

McTigue *et al* (2009b) adapted the DPP programme to an on-line version in order to assess the feasibility of using technology to reach at risk individuals at a lower cost in terms of staff. An initial 2 hour orientation session was delivered in-person prior to the intervention, so that participants had an opportunity to discuss the use of software. Delivery was adapted to the on-line mode; e-mails were sent to alert participants to forthcoming sessions, the sessions

were audio-narrated and an optional quiz was included. Materials were adapted for on-line use, and the 16 sessions were followed by eight monthly lessons. Goal-planning and self-monitoring were reported on-line every week. Plans were created using a diverse on-line menu. The use of computer technology allowed physical activity to be calculated in standardised form (step-equivalent) regardless of the type of activity. It also allowed graphical representations to be made of progress data. Chat room sessions were co-ordinated by a trained coach; this allowed questions to be asked and experiences to be shared. Additional resources such as recipes could be downloaded.

Seidal *et al* (2008) targeted their intervention to an older population (36% African Americans) that had experienced industrial downsizing, with high unemployment and a high rate of chronic illness. The DPP programme was adapted as a group based 12 session (over 24 weeks) intervention with more emphasis on the use of pedometers.

Vadheim *et al* (2010) modified one arm of their non-randomised feasibility trial to include intervention delivery by telehealth conferencing technology. Sixteen group sessions were delivered in both arms by trained personnel. However the samples were very small.

A shorter follow up of 6 months was used in the Whittemore *et al* (2009) intervention delivered by nurse practitioners in primary care. Six sessions were delivered in person (20 minutes) as well as five phone sessions. Contents of some of the DPP materials needed to be adapted for participants to use at home. Some content was abbreviated and there were minor changes to the dietary advice.

Evidence statement 11:

Translational studies based on the DPP

Modifications to the DPP interventions

There was strong evidence [++; +; -] for successful modifications of the DPP protocol.

One randomised controlled trial (Kulzer *et al* 2009 + Germany), two pilot cluster randomised controlled trials (Ackermann *et al* 2008 + US; Whittemore *et al* 2009 ++ US), two matched pair and one controlled cohort study (Almeida *et al* 2010 ++, US; Faridi *et al* 2009 - US; McTigue *et al* 2009a + US), four pre-test / post test single group studies (Amundsen *et al* 2009 +, US; Davis-Smith 2007 + US; Kramer 2009 + US; McTigue *et al* 2009b + US; Seidal *et al* 2008 + US), and one non-randomised

controlled feasibility trial (Vadheim *et al* 2010 + US) all adapted the DPP in a range of settings including primary care, YMCA facilities, and churches. Two studies (McTigue *et al* 2009b + US; Vadheim 2010 + US) used technology such as the internet and video-conferencing to access the target audience.

Eight DPP based studies selected populations with a raised BMI (≥25 kg/ m^2). Two DPP based studies (Ackermann *et al* 2008 + US; Davis-Smith 2007 + US) and all three studies DPS based studies selected populations using a risk score.

All but one DPP based (Amundsen *et al* 2009 + US) intervention were delivered using group sessions rather than individual sessions. One study (Whittemore *et al* 2009 ++ US) also provided phone-in sessions.

Three pre-test / post test single group studies (Kramer *et al* 2009 +, US; McTigue *et al* 2009a + US; Seidal *et al* 2008 + US) modified the DPP from 16 sessions to between 12-15. A further three studies delivered six or fewer sessions (Almeida 2010 ++ US; Davis-Smith 2007 + US; Whittemore *et al* 2009 ++ US).

DPP based sessions included both a dietary and physical activity component and all aimed to reduce body weight by 5-7% and increase physical activity to a moderate level (e.g. brisk walking) for 150 minutes per week as specified in the DPP protocol. Modifications included the introduction of pedometers early in the programme than in the DPP (Kramer *et al* 2009 + US; Seidal *et al* 2008 + US). Follow up in the DPP based studies ranged from 4-12 months.

Evidence statement 12:

Translational studies based on the DPP

Incidence of type 2 diabetes

There was no available evidence from the DPP based studies for the impact on incidence of type 2 diabetes.

Changes in blood glucose levels

In the DPP trial, the lifestyle group achieved a mean reduction in HbA1c levels from 5.9% to 5.8%, compared to an increase from 5.9% to 6.0% in the control group.

Five included translational studies assessed changes in blood glucose levels. Three assessed changes in fasting glucose levels (Davis-Smith *et al* 2007; Kramer *et al* 2009; Seidal *et al* 2008), one assessed changes in HbA1c (Ackermann *et al* 2008) and one assessed changes in the OGTT over time (Whittemore *et al* (2009). Three studies had 12 month follow up and two reported 6 month assessments.

One pilot cluster randomised trial (Ackermann *et al* 2008) reported a change of -0.1% in the mean HbA1c of the intervention arm compared to no change in the control arm (p=0.28). This was a similar result to the original DPP over the same follow up period, though for Ackermann the control group HbA1c remained unchanged at 12 months.

One church-based intervention (Davis-Smith 2007) reported a mean decrease in fasting serum glucose levels of 9mg/dl (no significance levels reported) at 12 month follow up. Mean change in fasting blood glucose levels for Kramer *et al* (2009) at 12 months was -1.5mg/dl (p=0.52).

One study (Seidal *et al* 2008) found that the proportion of participants with a fasting blood glucose level of less than 100 mg/dl had decreased from 42% at baseline to 61.2% at six month follow up (p=0.01). Whittemore *et al* (2009) reported a trend for the rise in monthly OGTT levels in their intervention group to be lower (0.28mg/dl per month) compared to the control group (1.50mg/dl per month) over 6 months. There was no statistical significance however in these trends over time (p=0.30) or between groups over time (p=0.48).

It is difficult to compare changes in blood glucose levels between translational studies or with the original DPP findings due to differences in blood glucose measurements, as well as study design. The findings show an associated slowing down of blood glucose level rise in relation to lifestyle intervention either over time or compared to a control. However, the follow up times are relatively short and therefore caution must be taken when interpreting these findings.

Evidence statement 13:

Translational studies based on the DPP

Changes in blood glucose levels

There was mixed evidence [++;+] from one randomised controlled trial, two pilot cluster randomised controlled trials and two pre-test / post test single group studies for reductions in blood glucose following interventions translated into community

settings.

Fasting blood glucose was reported to decrease by 4.3 mg/dl (SD 11.3) over the 12 month intervention period from 105.7 mg/dl (SD 12.4) to 101.4 mg/dl (SD 11.3) in the intervention group compared to a reduction of 1.8 mg/dl (SD 13.1) in the control group (p=0.001) in one primary care based randomised controlled trial (Kulzer *et al* 2009 + Germany). There was no change in HbA1c in the intervention group and a rise of 0.1% in the control group (p=0.165).

Fasting blood glucose was reported to decreased by 9mg / dl in one church based single group study (Davis-Smith 2007 + US) and by 1.5 mg / dl (p=0.52) in a primary care based study at 12 months.

A reduction in mean HbA1c of 0.1% compared to no change in the controls (p=0.28) was reported at 12 months follow up in a pilot cluster randomised controlled trial carried out using YMCA facilities (Ackermann *et al* 2008 + US).

Rises in monthly OGTT measurements were reported to be lower in the intervention group (0.28 mg/dl) than in the control group (1.50 mg/dl) over 6 months in one pilot cluster randomised controlled trial (Whittemore *et al* 2009 ++ US), though this finding was not statistically significant between groups (p=0.30).

There was however evidence from one pre-test / post test single group study carried out in a low socioeconomic population (Seidal *et al* 2008 + US) for an increase in those with a fasting blood glucose of reading ≥ 100 mg/dl in more than half of the sample at 3 months (51.0%) and 6 months (61.2%; p=0.06).

Changes to weight

In the original DPP trial, mean weight loss for the lifestyle intervention group was 7 kg at 12 months.

All the DPP based studies measured weight change and five studies included controls in their design. Kulzer *et al* (2009) achieved a weight loss of 3.8kg (SD 5.2) at 212 months in the intervention arm, compared to 1.4kg in the control. The intervention group in Ackermann *et al* (2008) achieved weight loss (6%) in the intervention arm at 4-6 months which was sustained at 12 months. Mean weight loss in the intervention arm was 6.0 kg compared to 1.8 kg in the control group after 12 months (p=0.008).

Almeida *et al* (2010) found that their intervention group were 1.5 times more likely to lose >5% body weight than matched controls after 12 months. Mean body weight loss was 1.4kg

in the intervention group and 0.6 kg in controls (p< 0.001). The average BMI at baseline for both the intervention and control groups was 29.8 kg/m^2, (borderline obese), which differs from the general population. However, the sample size was relatively large (760 in each group) and the two groups were matched in terms of baseline characteristics.

Faridi *et al* (2010) reported no reduction in weight at 12 months following a church-based intervention for an African American population. Both arms gained less than 0.5kg, with the intervention group gaining least (0.14kg versus 0.37kg).

McTigue *et al* (2009a) achieved a mean weight loss of 5.19kg in the intervention arm compared to a mean weight gain of 0.21 kg in the control. There was less evidence of significant weight loss in one pilot randomised trial (Whittemore *et al* 2009) delivered by nurse practitioners. In this study 25% in the arm intervention achieved 5% weight loss compared to 11% in the controls. Vadheim *et al* (2010) compared telehealth (video conferencing) with an on-site intervention, and found that a similar proportion in the on-site and telehealth groups had achieved 7% weight loss (48% vs 50%) (p=0.84), although the follow up was only 16 weeks.

Five studies did not include controls in their design. Mean weight loss in two pre-test / post test single group studies was greater than 4.5kg at 12 months (Kramer 2009; Amundsen 2009). The largest reported loss was 8.7kg in males; the corresponding loss for females was 6.2kg (Kramer *et al* 2009). Amundsen *et al* (2009) and Vadheim *et al* (2010) achieved a mean weight loss of greater than 6.4kg after 16 weeks; there is no data on longer follow up times available. Other single group studies included one church based single group intervention of six week duration (Davis-Smith 2007), which achieved a mean weight loss of 4.8kg at 12 months follow up. McTigue *et al* (2009b) utilised the internet to deliver the intervention to its target audience, achieving a mean weight loss of 4.79kg. Over 30% of those completing the intervention achieving at least 5% weight loss in this study and in one study that targeted underserved populations (Seidal *et al* 2008).

Evidence statement 14:

Translational studies based on the DPP

Weight change

There was strong evidence [++; +] from 11 studies based on the DPP protocol for achievement of weight loss and weak evidence [-] from one non-randomised study of a small weight gain at 12 months.

A randomised controlled trial (Kulzer *et al* 2009 + Germany) achieved a weight loss of 3.8kg (SD 5.2) in the intervention arm at 12 months, compared to 1.4kg in the

control. One pilot cluster randomised trial (Ackermann *et al* 2008 +US) achieved significant weight loss (6%) in the intervention arm at 4-6 months, which was sustained at 12 months. Mean weight loss was 5.7kg at both measurement points (p=0.008).

A matched pair cohort study with a large sample size (n=1520) (Almeida *et al* 2010 ++US) found that an intervention group were 1.5 times more likely to lose >5% body weight than matched controls after 12 months. Mean body weight loss was 1.4kg in the intervention group and 0.6 kg in controls (p< 0.001). A pilot randomised trial (Whittemore *et al* 2009 ++ US) delivered by nurse practitioners achieved ≥ 5% weight loss in 25% of the intervention group compared to 11% of the control group at 6 months.

One controlled cohort study (McTigue *et al* 2009a +US) achieved a mean weight loss of 5.19kg in the intervention arm compared to a mean weight gain of 0.21 kg in the control group at 12 months (p<0.001). The intervention population were obese at baseline and the control group comprised non-enrollees onto the programme.

One non-randomised controlled feasibility trial (Vadheim *et al* 2010 +US) compared telehealth (video conferencing) with an on-site intervention, and found similar weight loss for the two groups at 16 weeks (48% vs 50%; p=0.84). However, in this study both groups received a lifestyle intervention.

Faridi *et al* (2009 - US) reported no reduction in weight at 12 months following a church-based intervention for an African American population. Intervention and control sites gained less than 0.5kg, with the intervention group gaining least (0.14kg versus 0.37kg).

Mean weight loss in two pre-test / post test single group studies was greater than 4.5kg at 12 months (Kramer *et al* 2009 + US; Amundsen *et al* 2009 +US). However, these studies had no comparator groups. Other single group studies included one church based single group intervention of six week duration (Davis-Smith 2007 + US), which achieved mean weight loss of 4.8kg at 12 months follow up. Another (McTigue *et al* 2009b + US) that utilised the internet to deliver the intervention achieved a mean weight loss of 4.79kg, with over 30% of those completing the intervention achieving at least 5% weight loss. One study that targeted underserved populations also achieved and sustained 5-7% weight loss in over 65% of the sample at 6 months (Seidal *et al* 2008 +US).

Changes to BMI

The original DPP did not report changes to BMI after baseline recordings. However some of the translational studies did report these measurements.

Seven studies measured changes to BMI. Five of these (Ackermann *et al* 2008; Faridi *et al* 2010; Kramer *et al* 2009; Kulzer *et al* 2009; Davis-Smith 2007) had a follow up of 12 months.

Kulzer *et al* (2009) reported a reduction in BMI of 1.3 kg/m^2 in the intervention group compared to 0.5 kg/m^2 in the control (P<0.002). Ackermann *et al* (2008) reported a reduction of -6.7 kg/m^2 in the intervention arm and -1.4 kg/m^2 in the control arm at 12 months (p=0.002). Kramer *et al* (2009) found significant differences in BMI (-1.6 kg/m2; p< 0.001) in the second phase of their study which had a follow up of 12 months (Phase 1 being a three-month pilot). One church based intervention (Davis-Smith 2007) achieved a reduction of 1.9kg / m2 at 12 months (p<0.05). Another church based controlled intervention (Faridi *et al* 2009) achieved reduction in BMI of 0.63 kg/m^2 in the intervention arm, with a gain of 0.13 kg/m^2 in the control arm.

Amundsen (2009) achieved a significant reduction in BMI of 2.4 kg / m2 after a 16 week group adaptation of the DPP (p<0.001). Vadheim *et al* (2010) achieved a reduction of 2.7 kg / m2 in the telehealth group, and 2.5 kg / m2 in the on-site group, though the differences here were not significant (p=0.62). However, the Vadheim study was comparing two lifestyle interventions which both showed a reduction in BMI, though in very small samples (total n=29).

Evidence statement 15:

Translational studies based on the DPP

Changes to BMI

There was strong evidence [++; +] from six studies based on the DPP for reduction in BMI following intervention and mixed evidence [-] from one non-randomised study.

One randomised controlled trial (Kulzer *et al* 2009 Germany) reported a reduction in BMI of 1.3 kg/m^2 in the intervention group compared to 0.5 kg/m^2 in the control (P<0.002).One pilot cluster randomised trial (Ackermann *et al* 2008 ++US) carried out in YMCA settings reported a mean reduction of 6.7 kg/m^2 in the intervention group compared with 1.4 kg/m^2 at 12 months (p=0.002). One non-randomised controlled feasibility trial (Vadheim *et al* 2010 + US) reported a reduction of 2.7 kg/m^2

in the telehealth group compared to 2.5 kg/m^2 in the on-site group. Both of these groups received a lifestyle intervention. One non-randomised church based study (Faridi *et al* 2009 - US) achieved reduction in BMI of 0.63 kg/m^2 in the intervention arm compared to a gain of 0.13 kg/m^2 in the control arm at 12 months.

Three pre-test / post test single group studies also found reduction in BMI. Kramer *et al* (2009 +US) found a significant reduction in BMI of 1.6 kg/m^2 ($p< 0.001$) at 12 months. A church based intervention (Davis-Smith 2007 +US) achieved a reduction of 1.9kg / m^2 at 12 months ($p<0.05$), and Amundsen *et al* (2009 +US) achieved a significant reduction in BMI of 2.4 kg / m^2 after 16 weeks ($p<0.001$).

Changes in waist circumference

The original DPP did not report changes in waist circumference measurements after baseline recordings. Three translational studies did assess changes in waist circumference, two over 12 months and one over 6 months.

Kulzer *et al* (2009) reported a reduction of 4.1 cm (SD 11.3) in the intervention arm compared to 0.4cm in the control group. Kramer *et al* (2009) found significant changes in waist circumference (around - 4.3 cm; $p< 0.001$) after 12 months. Seidal *et al* (2008) found that the proportion of their sample with abdominal obesity reduced over the 6 month follow up from 90% at baseline to 68% at 6 months ($p=0.006$).

Evidence statement 16:

Translational studies based on the DPP

Changes in waist circumference

Moderate evidence [+] exists from 3 studies for reduction in waist circumference following intervention.

One randomised controlled trial (Kulzer *et al* 2009 + Germany) reported a reduction of 4.1 cm (SD 11.3) in the intervention arm compared to 0.4cm in the control group. One pre-test / post test single group study (Kramer *et al* 2009 +US) reported significant changes in waist circumference (around - 4.3 cm; $p< 0.001$) after 12 months. One pre-test / post test single group study (Seidal *et al* 2008 + US) found evidence of a reduction in abdominal obesity from 90% at baseline to 68% in their sample at 6 months ($p=0.006$).

Changes in achievement of goals

Physical activity:

One randomised controlled trial (Kulzer *et al* 2009) reported a mean increase of 46.6 (SD 95.5) minutes per week physical activity in the intervention group compared to 17.9 (SD 63.8) minutes in the control group. Amundsen *et al* (2009) reported an increase in physical activity by a mean of 80 minutes from week 6 to week 16. Vadheim (2010) found a greater mean weekly increase in physical activity with their on-site group (mean increase 243 minutes; SD 146) than in the telehealth group (mean197 minutes; SD 103) (p=0.37).

Whittemore *et al* (2009) reported a monthly increase in physical activity in both groups (p=0.001) with a tendency toward greater improvement in the intervention group (0.10 minutes vs 0.05 minutes) (p=0.8). The physical activity goal was achieved by 29% of the intervention group at baseline, rising to 46% at 6 months. This compares to almost no change in the proportion achieving physical activity goals in the control arm (39% to 40%). A church based intervention (Faridi *et al* 2010) achieved an increase in physical activity levels in only 20% of intervention participants compared to 25% of controls after 3 months.

Dietary changes:

Vadheim *et al* (2010) reported reduced fat intake after both intervention arms, with a greater proportion of those in the on-site group achieving the goal of fat reduction compared with the telehealth group (54% vs 38%) (p=0.49). Similarly, Whittemore *et al* (2009) reported that both groups improved their dietary intake (p=0.001). A church based intervention (Faridi *et al* 2010) showed greater achievements in all eight dietary goals compared to the control group, though differences were not statistically significant.

Evidence statement 17:

Translational studies based on the DPP

Changes in achievement in goals

There was strong evidence available [++; +] from five studies (Amundsen *et al* 2009 + US; Faridi *et al* 2009 - US; Kulzer *et al* 2009 + Germany; Vadheim *et al* 2010 + US; Whittemore *et al* 2009 ++ US) for changes in achievement in goals following intervention.

One randomised controlled trial (Kulzer *et al* + 2009) reported a mean increase of 46.6 (SD 95.5) minutes per week physical activity in the intervention group compared to 17.9 (SD 63.8) minutes in the control group. Amundsen *et al* (2009 + US) reported an increase in physical activity by a mean of 80 minutes from week 6 to week 16.

Vadheim *et al* (2010 + US) reported a greater mean weekly increase in physical activity with their on-site group (mean increase 243 minutes; SD 146) than in the telehealth group (mean197 minutes; SD 103) (p=0.37). There was evidence of reduced fat intake after both intervention arms, with a greater proportion of those in the on-site group achieving the goal of fat reduction compared with the telehealth group (54% vs 38%) (p=0.49). A church based intervention targeted at an African American sample (Faridi *et al* 2009 - US) showed greater achievements in all eight dietary goals compared to controls.

Whittemore *et al* (2009 ++ US) reported a monthly increase in physical activity in both groups (p=0.001) with a tendency toward greater improvement in the intervention group (0.10 minutes vs 0.05 minutes) (p=0.8). The physical activity goal was achieved by 29% of the intervention group at baseline, rising to 46% at 6 months. This compares to almost no change in the proportion achieving physical activity goals in the control arm (39% to 40%). In addition, both groups improved their dietary intake (p=0.001).

In terms of dietary goals, one feasibility study (Vadheim *et al* 2010 + US) reported reduced fat intake following both telehealth and on-site interventions, with a greater proportion of those in the on-site group achieving the goal of fat reduction compared with the telehealth group (54% vs 38%) (p=0.49). One pilot randomised controlled trial (Whittemore *et al* 2009 ++ US) reported that both intervention and control groups improved their dietary intake (p=0.001). A church based intervention (Faridi *et al* - 2009) showed greater achievements in all eight dietary goals compared to the control group.

Participation, adherence and sustainability

Participation / Attendance

There was no available data on attendance and participation in the two of the ten included studies (Ackermann *et al* 2008; Almeida *et al* 2010). A total of 83% completed the Amundsen study, with 91% of these attending at least 12 of the 16 sessions. Attendance at six sessions or more was 61% and 95% in the two phases of the Kramer study (phase 2 had a follow up of 12 months).There was no discussion of possible reasons for the differences,

though phase one was a short pilot study. In a church-based study (Davis –Smith 2007), all 29 initial participants attended for a fasting blood glucose measurement. Of the eleven eligible participants, attendance rate at the six session programme was 78%. Kulzer *et al* (2009) reported a 9.3% loss to follow up out of the randomised sample (n=182). They reported no significant differences between this group and those remaining in the study.

Kramer *et al* (2009) did report that achievement in weight loss and physical activity goals was associated with more frequent attendance at sessions. Ninety-three percent of the 166 patients referred to the WiLLoW programme (McTigue *et al* 2009a) continued through to follow up. Of the original 50 participants that completed the orientation lesson to an internet based intervention (McTigue *et al* 2009b), 98% logged into the programme and entered data. By day 45, only 8% completed their final login, with half the sample still completing 30 days before the 12 month assessment. Sixty-nine percent of 88 eligible participants attended at least 75% of the Group lifestyle Balance sessions evaluated by Seidal *et al* (2008). Reasons for non-attendance were work and family commitments, a diagnosis of diabetes, or loss of interest.

On-site participation was higher (100%) than the telehealth arm (88%) in the Vadheim study, though this was not statistically significant and both arms achieved their weight loss goal of ≥7%. Whittemore *et al* (2009) reported a 70% response rate which resulted in 58 participants being recruited. 12% of these were lost to 6 months follow up. Attendance for those that stayed in the study was 96% for in-person sessions, though phone communication was less successful (37%) due to difficulty making appointments. Of 131 eligible participants in the Ackermann study (2009), 92 (70%) enrolled. At least one session in the intervention arm was attended by 76% participants; these same individuals completed an average of 75% of the 16 sessions (this equates to a 57% average across all the intervention participants).

Adherence

There was no data available on adherence in four of the ten studies (Davis-Smith 2007; McTigue *et al* 2009a; Vadheim *et al* 2010; Whittemore *et al* 2009).

Ackermann *et al* (2008) reported that 16% of their sample did not complete the sessions, therefore there was no weight loss data for this group. There was no further discussion about adherence to the programme. There was no available evidence on adherence in the study by Almeida *et al* (2010).

Amundsen *et al* (2009) reported a mean of 10.1 (SD 4.0) weeks completion of self-monitoring of dietary fat intake with a range of between 0 and 14 weeks completion. Men were more likely to complete (mean 11.6 weeks SD 3.2) compared with women (9.7 weeks SD 4.1; p=0.001). Older participants (i.e. over 60 years) were also more likely to complete their records (11.5 weeks SD 4.1) than younger participants (10.3 weeks SD 4.7; p=0.02). There was no association between BMI and completed records, however those who self-monitored fat intake every week of the 16 week curriculum were reported to be 8 times more likely to achieve the weight loss goal (OR, 7.60: 95% CI 2.75-21.01).

A mean 280 minutes (SD 152) of physical activity per week was reported for men at week 16, which was significantly more than women (219 minutes SD 118; p=0.005). Those who completed dietary fat records for at least 14 weeks of the 16 were 7 times as likely to meet their physical activity goals compared to those who completed 3-13 weeks, who were 3 times more likely to achieve than those who self-monitored less often. Seventy percent of the participants achieved the physical activity goal of at least 150 minutes per week.

Participants in the internet based intervention (McTigue *et al* 2009b) completed a mean 12.8 (SD 7.29) lessons, with 16% completing at least 20. Self-monitoring of weight was recorded on an average of 27.32 (SD 19.81) weeks over the 12 months, with 40% reporting a weight for at least 40 weeks. In the two-phase study by Kramer *et al* (2009), 23.8% of those completing the programme continued to achieve their weight loss goal of 7% at three months.

Evidence statement 18:

Translational studies based on the DPP

Participation / Attendance / Adherence

Moderate evidence [+] was found from two pre-test / post-test single group studies regarding adherence to intervention aims.

One study (Amundsen *et al* 2009 +US) reported a mean of 10.1 (SD 4.0) weeks completion of dietary self-monitoring (range 0-14). Men were significantly more likely to complete (mean 11.6 weeks; SD 3.2) compared to women (9.7 weeks SD 4.1; p=0.001). Older participants (≥ 60 years) were more likely to complete their records than younger participants (10.3 weeks SD 4.7; p=0.02). There was an eight-fold likelihood that those completing self-monitoring during all 16 weeks of the programme would achieve their weight loss goal (OR, 7.60; 95% CI 2.75-21.01).

McTigue *et al* (2009b + US) reported a mean completion of 12.8 (SD 7.29) internet-

based lessons, with self-monitoring recorded on an average of 27.32 weeks over 12 months. 40% reported weight on-line for at least 40 weeks.

Sustainability

Due to the short follow up of these studies, there was little meaningful data on sustainability of lifestyle change. Seidal *et al* (2008) reported that achievement of 5% and 7% weight change goals by 46.4% of the sample following the intervention was sustained at 6 month follow up (87.5% of this group achieved 7% and 66.7% achieved 5% weight loss).

Evidence statement 19:

Translational studies based on the DPP

Sustainability

There was moderate evidence [+] from one pre-test / post test single group study (Seidal *et al* 2008 + US) that the achievement of a 5% - 7% weight reduction by 46.4% of the sample following the lifestyle intervention was sustained at 6 months follow up (66.7% achieved 5% weight reduction and 87.5% achieved 7% reduction).

Studies based on the DPS protocol

Follow up was longest in the Absetz study, with results available at 12 months and 3 years. The remaining two studies had follow up of 12 months. The Saaristo study had the largest sample (n = 3,880), whilst Absetz and Laatikainen had much smaller samples (n = 352; n = 311). All three studies included more females than males (Absetz 68%; Laatikainen 65%), though the study by Saaristo was more evenly balanced (57% female).

Modifications of the DPS protocol to translational studies

Absetz *et al* (2009) report on a community programme (GOAL) in Finland, based on the DPS but also incorporating a social-cognitive approach to health behaviour. One group session covered dietary advice and counselling and another provided an introduction to local sports facilities. There were five sessions over the first eight weeks and a final session at eight months.

Laaikainen *et al* (2007) reported on a study also based on the DPS and GOAL studies. Set in general practices in Southeast South Australia, the group based intervention provided five sessions over three months and a final session at eight months.

The study reported in Saaristo *et al* (2010) provided either individual or group sessions with frequency of visits varying according to available resources and local circumstances.

Evidence statement 20:

Translational studies based on the DPS

Modifications to the DPS interventions

There was moderate evidence [+] for successful modifications of the DPS protocol.

Three pre-test post-test studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland) based on the DPS protocol were all set in primary care, selecting populations using a risk score.

One study (Saaristo *et al* 2010 + Finland) delivered a mix of individual and group sessions, while two (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia) delivered group sessions. They all delivered an average of 6 sessions over 2 months compared to the 7 session DPS protocol. Most sessions were of an average of 60 minute duration.

Sessions were based on either the DPS lifestyle objectives (Absetz *et al* 2009 + Finland; Saaristo *et al* 2007 + Finland) or in one study, Australian Dietary Guidelines (Laatikainen *et al* 2007 + Australia).

Follow up ranged from 12 months (Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland) to three years (Absetz *et al* 2009 + Finland).

Incidence of type 2 diabetes

This was not a primary outcome for the three studies, though progression to diabetes was reported in 6% of the Absetz sample at 12 months and 12% at 3 years. 2.2% of the Laatikainen sample had progressed to diabetes at 12 months. Saaristo found a progression of ≤ 2% in those with normoglycaemia at baseline and ≤ 13.5% of those with IFG, ≤ 16.1% of those with IGT at baseline, over 12 months. The proportion of those progressing was higher in men than women in all cases. As there are no controls included in these studies, no conclusions can be made with reference to this outcome.

However, Saaristo *et al* (2010) demonstrate a relationship in their sample between weight change and 12 month incidence of type 2 diabetes. A number of participants in the Saaristo study did not lose weight, and some gained weight. These two groups showed the highest incidence for diabetes at follow up.

Evidence statement 21:

Translational studies based on the DPS

Incidence of type 2 diabetes

There was no evidence for impact upon diabetes incidence in the DPS based studies.

Changes in blood glucose levels

In the original DPS, 9% of those with IGT developed type 2 diabetes in the intervention group, 20 % in the control group after 3 years.

In the Absetz study, 193 participants (55%) had normal glucose tolerance at baseline. By year three, 10.9% of these had developed IGT. However, of 65 participants (18%) that had IGT at baseline, 12% had developed type 2 diabetes and 43% had reverted to normal glucose tolerance at year three. Mean change in fasting plasma glucose at 12 months was +0.1 mmol/l (SD 0.6; $p<0.001$) and at 3 years 0.0 1 mmol/l (SD 0.8; not significant). Mean change in OGTT at 12 months was +0.1 mmol/l (SD 1.7; not significant), and at 3 years +0.1 (SD 1.9; not significant)

Laatikainen found that 66% of participants had normal baseline glucose levels and 34% had impaired levels. At 12 months, 78% had normal glucose values and 19.8% impaired values. Of the 79 who had impaired values at baseline, 42 (18%) reverted back to normal levels. At 12 months, mean change in fasting plasma glucose was -0.14 mmol/l (95% CI -0.20 to -0.07), representing a -2.5% change. Mean change in OGTT was -0.58 (95% CI -0.79 to -0.36), representing a change of -8.6%.

In the Saaristo study, 1164 (1.6%) of those with normal glucose levels at baseline developed impaired glucose tolerance at 14 months. Of those with IFG at baseline, type 2 diabetes developed in 10.5%. In those with IGT at baseline, type 2 diabetes developed in 14%. There

was a greater incidence of diabetes at 14 months in those who had the least weight reduction. Mean change in glucose levels was not reported. However, Saaristo *et al* conclude that the study identified individuals with a very high early conversion rate from IGT to type 2 diabetes, and report that this is a comparable finding to the ADDITION trial.

Evidence statement 22:

Translational studies based on the DPS

Changes in blood glucose levels

There was moderate evidence [+] from two pre-test / post-test studies for positive changes in blood glucose levels following intervention.

In one pre-test / post-test study (Absetz *et al* 2009 + Finland) mean change in fasting plasma glucose at 12 months was +0.1 mmol/l (SD 0.6; p<0.001) and at 3 years 0.0 1 mmol/l (SD 0.8; not significant). Mean change in OGTT at 12 months was +0.1 mmol/l (SD 1.7; not significant), and at 3 years +0.1 (SD 1.9; not significant). 55% had normal glucose tolerance at baseline. By year three, 10.9% of these had developed IGT. Of the 65 participants (18%) that had IGT at baseline, 12% had developed type 2 diabetes and 43% had reverted to normal glucose tolerance at year three.

Laatikainen *et al* (2007 + Australia) reported a mean change in fasting plasma glucose of -0.14 mmol/l (95% CI -0.20 to -0.07), at 12 months, representing a -2.5% change. Mean change in OGTT was -0.58 (95% CI -0.79 to -0.36), representing a change of -8.6%. At baseline, 66% of participants had normal baseline glucose levels and 34% had impaired levels. At 12 months, 78% had normal glucose values and 19.8% impaired values. Of the 79 who had impaired values at baseline, 42 (18%) reverted back to normal levels.

Saaristo *et al* (2010 + Finland) did not report changes in blood glucose levels in their pre-test / post-test study. 1.6% of those with normal glucose levels at baseline developed impaired glucose tolerance at 14 months. Of those with IFG at baseline, type 2 diabetes developed in 10.5%. In those with IGT at baseline, type 2 diabetes developed in 14%. The authors conclude that the study identified individuals with a very high early conversion rate from IGT to type 2 diabetes.

Changes to weight

Mean weight was reduced in the Laatikainen and Saaristo studies by 2.5 kg and 1.2 kg respectively. In addition, waist circumference was reduced by 4.2 cm and 1.3cm in these studies. However, for Absetz *et al,* though mean weight reduction of 0.8 kg at 12 months was maintained at 3 years (a reduction of 1.0 kg), mean reduction in waist circumference (1.6 cm) was not maintained.

Changes to BMI

All three samples had a high mean BMI at baseline (BMI ≥ 30 kg/m^2). In the Absetz study, mean BMI was reduced by 0.3 kg/m^2 at 12 months follow up and by 0.5 kg/m^2 at 3 years. In the Laatikainen and Saaristo studies, change in mean BMI from baseline to 12 months was a reduction of 0.93 kg/m^2 and 0.4 kg/m^2 respectively.

Evidence statement 23:

Translational studies based on the DPS

Weight change

There was moderate evidence [+] from 3 pre-test / post-test studies based on the DPS protocol for weight loss following translational interventions. However, none of these studies included a comparator.

Mean weight was reduced in three studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* + 2007 Finland) at 12 months follow up. Two studies (Laatikainen *et al* 2007 + Australia; Saaristo *et al* + 2007 Finland) achieved a mean weight loss of 2.5 kg (95% CI, 1.85 to 3.19) and 1.2 kg ($p<0.0001$) respectively. In one study (Absetz *et al* 2009 + Finland) mean weight reduction of 0.8 kg at 12 months ($p=0.002$) was maintained at 3 years (1.0 kg; $p=0.003$).

Changes in BMI

Mean BMI was reduced from baseline to 12 months follow up in three studies (Absetz *et al* 2009; Laatikainen 2007; Saaristo 2007), with reductions ranging from 0.3 kg/m^2 to 0.93 kg/m^2. At three years, a further reduction of 0.2 kg/m^2 was observed in one study (Absetz *et al* 2009).

Evidence statement 24:

Translational studies based on the DPS

Changes to BMI

Moderate evidence [+] exists from 3 pre-test / post-test studies based on the DPS protocol for reduction in BMI at 12 months following intervention.

Mean BMI was reduced from baseline to 12 months follow up in three studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland), with reductions ranging from 0.3 kg/m^2 to 0.93 kg/m^2. At three years, a further reduction of 0.2 kg/m^2 was observed in one study (Absetz *et al* 2009 + Finland).

Changes in waist circumference

Absetz *et al* (2010) reported a 12 months reduction in waist circumference of 1.6 cm (SD 4.8) (p=0.001). However, this was not sustained at 3 years (+0.1 cm (SD 6.4; not significant).

Laatikainen *et al* (2007) reported a greater reduction after 12 months (-4.17 cm; 95% CI -4.87 to -3.48). This represented a change of -4.0%. 75% of the sample experienced some reduction in waist circumference.

Sarristo *et al* (2010) reported a reduction in waist circumference in men and women at 12 months of 1.3 cm (SD 4.9 for men, SD 5.9 for women) (p<0.0001).

Evidence statement 25:

Translational studies based on the DPS

Changes in waist circumference

Moderate evidence [+] exists from three studies for reduction in waist circumference following intervention.

Waist circumference was reported to decrease in all three DPS based pre-test / post-test studies (Absetz *et al* 2009 + Finland; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2007 + Finland), ranging from -1.6cm to -4.2cm at 12 months. However, the reduction at 12 months was not sustained at three years in one study (Absetz *et al* 2009 + Finland).

Changes in achievement of goals

Changes in dietary and physical activity goal achievement were not reported in the DPS results, nor in the three DPS based translational studies.

Evidence statement 26:

Translational studies based on the DPS

Changes in achievement in goals

There was no evidence available from three studies for changes in achievement in goals following intervention.

Participation, adherence and sustainability

Participation / Attendance

Absetz *et al* (2007) report that at 12 months, 57% of participants attended all six sessions, with the final session being least well attended (81% compared to 90% in the first five sessions). There was no statistically significant difference between those that completed the sessions and those that dropped out, though the latter were less likely to be married or co-habiting ($p<0.05$). By 3 years, 81/271 participants had been lost to follow up. The group that dropped out were less likely to be retired (39.5% vs 50% P=0.040), more likely to be unemployed (22.4% vs11.5%) and more likely to have higher BMI and waist circumference measurements at baseline (mean 33.7 kg/m^2 vs 32.3 kg/m^2; p=0.040) (mean 107.9 cm vs 104.6 cm; p=0.036). No reasons were reported for non-attendance or drop-out.

Laatkainen *et al* (2007) considered attendance at baseline and 12 month clinical assessment as well as at least one group session to define completion. 237/311 participants achieved this. Attendance at all six sessions was achieved by 43% of the participants, with 9.7% attending three or less sessions. Reasons given for non-attendance were lack of transport, fuel costs, time constraints, low literacy levels and health conditions. Those that did not complete the programme had significantly higher waist circumference (109.6 SD 14.9 vs 104.9 SD 13.0; p=0.009), lower levels of education (10.7 years SD 3.1 vs 12.1 years SD 3.4; p=0.002), and higher measures of psychological distress (Kessler 10: 19.0 SD 8.0 vs 15.3 SD 5.4; $p<0.0005$), anxiety (HADS 5.4 SD 4.0 vs 3.6 SD 3.3; $p<0.0005$) and depression (HADS 4.1 SD 3.9 vs 2.8 SD 2.9; p=0.014).

Saaristo *et al* (2010) reported an average 2.9 visits per participant over 12 months, with 29.1% achieving at least three visits. This group were more likely to have a higher BMI (32.6

kg/m^2 SD 5.6 compared with 31.3 kg/m^2 SD 5.1 for two or more visits and 30.9 kg/m^2 SD 5.0 for one or no visits; p<0.05). A lower proportion of participants attended two sessions than one or ≥ 3 (12.9% vs 26.1% and 29.1% respectively). The rate of attendance did not differ by age or gender. However, weight loss was associated with more intervention visits, with the group achieving the ≥ 5kg weight loss goal attending an average of 3.5 sessions compared to 2.9 in those maintaining weight (p<0.001). There was no difference in mean number of intervention visits between those maintaining weight and those losing 2.5 – 4.9% weight.

There appears to be a trend in the three studies based on the DPS for more frequent session attendance or programme intensity to be associated with greater weight loss (Absetz *et al* 2009; Laatikainen *et al* 2007; Saaristo *et al* 2010).

Evidence statement 27:

Translational studies based on the DPS

Participation / Attendance

There was moderate evidence [+] from 3 pre-test / post test single group studies based on the DPS of reasonable to good attendance rates.

One study (Absetz *et al* 2009 + Finland) reported that 57% of the participants attended all six sessions with the final session being least well attended (81% compared to 90%). Laatikainen *et al* (2007 + Australia) reported that 43% of participants attended all six sessions with reasons for non-attendance given as lack of transport, fuel costs, time constraints, low literacy and health conditions. Saaristo *et al* (2010 + Finland) reported 29.1% of participants achieving at least 3 visits. In this study, weight loss was associated with more intervention visits (p<0.001).

Sustainability

Absetz *et al* (2010) reported that weight loss achieved at year one (0.8 kg SD 4.5) was sustained at year three (0.1 kg SD 5.6). Similarly, they report sustained change in BMI with a loss of 0.3 kg/m^2 (SD 1.6) at year one and a loss of 0.5 kg/m^2 (SD 2.1) at year three.

Laatkainen *et al* (2007) reported sustained changes from 3 months to 12 months in weight loss (2.38 kg; 2.52 kg), BMI (0.88 kg/m^2; 0.93 kg/m^2), and waist circumference (3.16 cm; 4.17 cm).

Saaristo *et al* (2010) reported 12 month follow up only.

Evidence statement 28:

Translational studies based on the DPS

Sustainability

There is moderate evidence [+] from one DPS based study relating to sustainability of outcomes beyond the 12 month follow-up.

Only one pre-test / post test single group study (Absetz *et al* 2009 + Finland) had a follow up longer than 12 months. Whilst weight loss (0.8 kg) and BMI reduction (0.3 kg/m^2) at 12 months was maintained at 3 years (1.0 kg and 0.5 kg/m^2), waist circumference reduction at 12 months (1.6 cm) was not sustained (0.1 cm).

Table 6. Results of studies translated from DPP and the DPS

Study	Incidence of type 2 diabetes	Secondary outcomes					
		Changes in mean Blood Glucose	Weight change (%)	Mean weight loss	Change in mean BMI	Change in mean waist circumference	Other reported changes
DPP **N = 3234** **Follow up 12 months**	**58% more reduction (95% CI 48-66) compared to control at 12 months.**	**Lifestyle group: HbA1c reduced from 5.9% to 5.8%.** **Control group: HbA1c increased from 5.9% to 6.0% at 12 months.**	**NR**	**7 kg over 12 months, then gradual regain to 2 kg at 10 years.**	**NR**	**NR**	**NR**
Ackermann 2008 + N = 92 Follow up 12-14 months	NR	At 12 months: HbA1c: -0.1% intervention; no change in controls (p=0.28).	-6.0% (95% CI=3.8, 8.3) in intervention participants and -1.8% (95% CI= +0.3, −3.9) in controls (p=0.008) compared to baseline.	6.0 kg (12.5 lbs) for intervention participants and 1.8 kg (3.6 lbs) for controls. (p=0.008)	At 12 months -6.7 kg/m2 intervention -1.4 kg/m2 control (p=0.002).	NR	At 12 months: Change in total cholesterol concentration: -13.5 mg/dl (95% CI -24.3 to -2.8) intervention +11.8 mg /dl (95% CI 1.3 to 22.4) control (p=0.002) at 12 months HDL: +1.9 mmol/l (95% CI -1.0 to 4.7) intervention; -1.4 mmol/l control (p=0.10). Systolic BP: -1.6 (95% CI -7.3 to 4.1)intervention -2.7 (95% CI -8.0 to 2.7) control (p=0.78).
Almeida 2010 ++ n = 1,520 (760 matched pairs) Follow up 12 months	NR	NR	Intervention > -5% body weight compared to controls and adjusting for baseline (22% vs 15%, *P* = .001). 1.5 (95% CI, 1.2-2.0) times more likely to lose at least 5% of their	Intervention: 1.4 kg (95% CI 1.6 kg to 1.1 kg). Controls: 0.6 kg, 95% CI, 0.9 kg (2.0 lbs) to 0.4 kg (0.8 ibs); *P* < .001).	NR	NR	NR

Study	Incidence of type 2 diabetes	Secondary outcomes					
		Changes in mean Blood Glucose	Weight change (%)	Mean weight loss	Change in mean BMI	Change in mean waist circumference	Other reported changes
			body weight than matched controls.				
Amundsen 2009 + N = 355 Follow up 16 weeks	NR	NR	97% lost weight; 45% achieved 7% weight loss goal, 67% achieved at least 5% weight loss	6.7 kg (SD 4.0) no other details reported. .	-2.4 kg/m2 at week 16 (*P* < .001).	NR	Physical activity: mean 232 minutes (SD 128) per week after 16 weeks. Activity increased by mean 80 minutes from week 6 to week 16.
Davis-Smith 2007 + 150 adults and children Follow up 12 months	NR	Mean Fasting Serum Glucose levels were 100 mg/dL. At 12 months (-9mg /dl from baseline).	For individual participants, weight loss ranged from 0.2-12.3 kg (0.5-27.2 lbs) after the six-week intervention.	4.0, 3.0 and 4.8 kg immediately after the intervention, and at six- and 12-month follow-up, respectively. No other details reported.	The average decrease in BMI from the initial session to the 12-month follow-up was 1.9 kg/M2.	NR	NR
Faridi 2010 – Intervention n=83 Control n=78 Follow up 12 months	NR	NR	NR	Intervention +0.32lbs (0.15 kg) (SD 25.92) Control +0.82 (SD 19.30) (0.37kg)	Intervention -0.63 (SD 6.72) Control +0.13 (SD 3.18)	NR	Energy expenditure (kcal/kg/week) improved significantly in control group compared to intervention (131.31 SD 326.3 compared to 14.75 SD 117.43 7; p=0.0040).
Kramer 2009 + N =51 phase 1 N=42 phase 2 Follow up 12 months	NR	-1.5 mg / dl (-0.08mmol/l) or -1.4% (p=0.52) at 12 months	-4.9% at 12 months. Estimated loss 0.5 kg (1 lb) per week (*p*<0.001) at 12 months	Phase 2: -4.5 kg (9.9 lbs), [*p*<0.001].	Phase 2: BMI -1.6 kg/m2, (4.9%, *p*<0.001) at 12 months	Phase 2: -4.3 cm (-1.7 ins) [-4.2%, p<0.001] at 12 months.	Decrease in total cholesterol (-6.6 mg/dl; -3.6%, p=0.09), an increase in non-HDL cholesterol (+2.7 mg/dl; +6.1%, p=0.007). Decrease in systolic BP (-13.0 mmHg; -10.5%, p<0.001), diastolic BP (-4.3 mmHg; -5.5%, p=0.002) All at 12 months.
Kulzer 2009 ++ RCT (PREDIAS) 12 months	NR	FBG – 4.3 SD 6.0) (p=0.001). HbA1c 0.0% OGTT -7.3 (SD	NR	-3.8 kg (SD 5.2) (p<0.001)	-1.3 kg/m2 (SD 1.7) at 12 months.	-4.1 cm (SD 6.0) at 12 months.	Physical activity Control 17.9 (SD 63.8) p=0.035 Intervention 46.6 (SD 95.5) p<0.001

Study	Incidence of type 2 diabetes	Secondary outcomes					
		Changes in mean Blood Glucose	Weight change (%)	Mean weight loss	Change in mean BMI	Change in mean waist circumference	Other reported changes
N=182		30.8) at 12 months.					
Mc Tigue 2009a + N = 155 Follow up 12 months	NR		Weight loss of ≥7% in 27% of enrollees compared to 6% non-enrollees (p=0.001).	5.19 kg (CI, –7.71 to –2.68) among WiLLoW enrollees and +0.21 kg (CI, –1.50 to 1.93) among the nonenrollees with follow-up data (P < .001).	NR	NR	NR
Mc Tigue 2009b + N = 50 Follow up 12 months	NR	NR	31% had at least a 5% weight loss and 18% at least a 7% weight loss at the end of 1 year.	4.79 kg (95% CI: -7.36 to -2.22)	NR	NR	Mean change in systolic BP -7.33 mmHg (95% CI -10.75 to -3.92). Mean change in diastolic BP +0.44 mmHg (95% CI -2.74 to +2.83)
Seidel 2008 + N = 88 Follow up 6 months	NR	Proportion with glucose ≥100 mg/dl increased over time (baseline: 42% [21]; 3 months: 51% [25]; 6 months: 61.2% [30], P for trend = 0.06, adjusted P = 0.01).	46.4% (32) lost ≥ 5% body weight; 26.1% (18) lost ≥ 7% at 3 months. 87.5% (28) and 66.7% (12) sustained the 5% and 7% reduction, respectively, at the 6-month reassessment.	NR	NR	Proportion with abdominal obesity decreased significantly over time (baseline: 90% [45]; 3months: 82% [41]; 6 months: 68% [34]; P for trend = 0.006).	Proportion with hypertension ≥130/85 mmHg decreased over time (baseline: 68% [34]; 3 months: 58% [29]; 6 months: 48% [24], P for trend = 0.04, adjusted P = 0.04). Proportion with triglycerides ≥150 mg/dl changed over time (baseline: 58% [29]; 3 months: 32.7% [16]; 6 months: 36.7% [18], P for trend = 0.006, adjusted P = 0.6).
Vadheim 2010 + N= 13 on-site M= 16 telehealth Follow up 16 weeks	NR	NR	>40% both groups achieved 7% weight loss goal.	Telehealth group 6.7kg (SD 3.7) On-site group 6.5kg (SD 3.1) P=0.85	Telehealth group -2.7 kg/m2 (SD 1.3) On-site group -2.5 kg/m2 (SD 1.0) P=0.62	NR	Goal achievement: Fat: Telehealth group 38% [5]; On-site group 54% [7] p=0.49 7% weight loss: Telehealth group 50% [7]; On-site group 46% [6] p=0.84 Mean weekly physical activity: Telehealth group197 minutes (SD 103); On-site group 243 minutes (SD 146) p=0.37

Study	Incidence of type 2 diabetes	Secondary outcomes					
		Changes in mean Blood Glucose	Weight change (%)	Mean weight loss	Change in mean BMI	Change in mean waist circumference	Other reported changes
Whittemore 2009 ++ N = 58 Follow up 6 months	NR	Trend for change in OGTT 0.28 mg/dl per month intervention group versus 1.50 mg/dl in control group.	25% of intervention group achieved 5% weight loss compared to 11% of control group	6 months: 1.5% in intervention group (p=0.8), 0.0% in control group (p=0.45). .	NR	NR	Behavioural goals: Both groups improved nutritional behaviour over time in (p=0.001). Both showed monthly increase in physical activity (p=0.001). Trend toward greater improvement in intervention group (0.10 minutes vs 0.05 minutes each month) (p=0.8). Physical activity goal met by 29% intervention group at baseline and 46% at 6 months. In control group, percentage meeting goals changed from 39% to 40%.
DPS **Follow up 3 years**	**22 (9%) in the intervention group and 51 (20%) in the control group developed diabetes (P = 0.0001)**	**Fasting plasma glucose at 12 months:** **Intervention: -4mg/dl (-0.2 mmol/l) (SD 12) (95% CI -6 to-2)** **Control: +1mg/dl (-0.05 mmol/l)(SD 12)(95% CI 0-2).** **(p< 0.001)**	**4.7% decrease in intervention, 0.9% in controls at 12 months.** **(p< 0.001)**	**-4.2 kg (SD 5.1) intervention; -0.8 kg (SD 3.7) in controls after 12 months** **(p< 0.001)**	**NR**	**At 12 months:** **Intervention: -4.4 cm (SD 5.2) (95% CI 5.1-3.9)** **Control: -1.3 cm (SD4.8) (95% CI 1.9-0.7)** **(p< 0.001)**	**NR**
Absetz 2009 + N = 352 Follow up 1 year (n=312) and 3 years (n=266)	Of 193 with NGT at baseline, 10.9% had IGT and 1.6% had diabetes at year 3. Of 65 with IGT at baseline, 12% had diabetes and 43% had returned to normal by year 3.	At 12 months: Fasting plasma glucose: +0.1 mmol/l (SD 0.6)(p<0.001) OGGT: +0.1 mmol/l (SD 1.7)(not significant) At 3 years: Fasting plasma glucose:	NR	At 12 months: -0.8 kg (SD 4.5) (p=0.002) At 3 years: -1.0 kg (SD 5.6) (p<0.003)	At 12 months: -0.3 kg/m2 (SD 1.6) (p=0.003) At 3 years: -0.5 kg/m2 (SD 2.1) (p=0.001)	At 12 months: -1.6 cm (SD 4.8) (p=0.001) At 3 years: +0.1 cm(SD 6.4) (not significant)	At 12 months: Serum lipids: Total cholesterol -0.1 mmol/l (SD 0.9) (p<0.034) HDL: no change (not significant) Triglycerides: -0.07 mmol/l (SD 0.63) (not significant). Systolic blood pressure: -1.0 mmHg in females; -3.0 mmHg in males (not significant in either case). Diastolic blood pressure: -1.0 mmHg in females (not significant); -4.0 mmHg in males (p<0.01).

Study	Incidence of type 2 diabetes	Secondary outcomes					
		Changes in mean Blood Glucose	Weight change (%)	Mean weight loss	Change in mean BMI	Change in mean waist circumference	Other reported changes
		0.0 1 mmol/l (SD 0.8) (not significant) OGGT: +0.1 (SD 1.9) (not significant)					At 3 years: Serum lipids: Total cholesterol -0.4 mmol/l (SD 1.1) (p<0.001) HDL: no change (not significant) Triglycerides: -0.14 mmol/l (SD 0.61) (p<0.001).
Laatikainen 2007 + N = 311 Follow up 12 months (N=237)	At baseline, 65.9% had normal glucose values and 34.1% had IGR (IFG 9.5%, IGT24.6%). At 12 months 78.0% had normal glucose values and 19.8% had impaired values (IFG 6.5%, IGT 13.4%). Of 79 with IGR at baseline, five (2.2%) developed diabetes during the intervention and 42 (18.1%) reverted to normoglycemia.	At 12 months: Fasting Plasma Glucose: -0.14 mmol/l (95% CI -0.20 to -0.07) Change of -2.5% OGTT: -0.58 (95% CI -0.79 to -0.36) Change of -8.6%	At 12 months: -2.7% change 68% experienced weight reduction.	At 12 months: -2.36 (95% CI -3.19 to -1.85)	At 12 months: **-0.93** kg/m^2 (95% CI -1.17 to -0.69) Change of -2.8%	At 12 months: -4.17 cm (95% CI -4.87 to -3.48) Change of -4.0% 75% experienced some reduction in waist circumference.	At 12 months: Serum lipids: Total cholesterol -2.9 mmol/l (95% CI -0.40 to -0.18) Change of -5.1% HDL: +0.06 mmol/l (95% CI 0.03 to 0.09) Change of +4.4% Triglycerides: -0.15 mmol/l (95% CI -0.24 to -0.05) Change of -7.6% Systolic blood pressure: -1.01 mmHg (95% CI -2.60 to 0.58). Change of -0.8% Diastolic blood pressure: -2.14 mmHg (95% CI -3.33 to -0.94) Moderate improvements in SF-36v2 domains of vitality and general health. Small but statistically significant improvements in the domains of bodily pain, physical functioning and mental health as well as for measures of psychological distress.
Saaristo 2010 + N **=** 2,798 Follow up 12 months	Mean follow up 14 months: **In those with NGT at baseline:** 2.0% in males 1.2% in females **In those with**	NR	At 12 months: 17.5% lost ≥5% weight; 19.6% gained ≥2.5% weight. Average weight loss during the 1-year follow-up	At 12 months: **Males:** -1.2 kg (SD 5.3) (p<0.0001) **Females:** -1.1 kg (SD 5.8) (p<0.0001)	At 12 months: **Males:** **-**0.4 kg/m^2 (SD 1.5)(p<0.0001) **Females:** **-**0.4 kg/m^2 (SD 2.1)(p<0.0001)	At 12 months: **Males:** - 1.3 cm (SD 4.9) (p<0.0001) **Females:** - 1.3 cm (SD 5.9) (p<0.0001)	At 12 months: **Males:** Serum lipids: Total cholesterol -0.25 mmol/l (SD 0.86)(p<0.0001) HDL: +0.02 mmol/l (SD 0.22) (p=0.0030) Triglycerides: -0.11 mmol/l (SD1.12) (p=0.0050)

Study	Incidence of type 2 diabetes	Secondary outcomes					
		Changes in mean Blood Glucose	Weight change (%)	Mean weight loss	Change in mean BMI	Change in mean waist circumference	Other reported changes
	IGT at baseline: 16.1% in males 11.3% in females		was ~1 kg				Systolic blood pressure: -0.8 mmHg (SD 14.8) (p=0.0932) Diastolic blood pressure: -1.5 mmHg (SD 8.9) (p<0.0001) **Females:** Serum lipids: Total cholesterol -0.14 mmol/l (SD 0.79)(p<0.0001) HDL: +0.04 mmol/l (SD 0.31) (p=0.0001) Triglycerides: -0.03 mmol/l (SD 0.64) (p=0.0769) Systolic blood pressure: -1.9 mmHg (SD 14.8) (p=0.0001) Diastolic blood pressure: -1.6 mmHg (SD 8.4) (p<0.0001)

Differences in achievements between translational studies and the DPP / DPS

Whilst the DPP and DPS aims were to reduce incidence in type 2 diabetes, this was not a primary outcome for translational studies. The main outcome (measured in all studies) was weight loss. The 10 year follow up of the DPP (DPPRG 2009) reported an association between weight loss and diabetes prevention, and Hamman *et al* (2006) specified that a 16% reduction in risk for diabetes was associated with every kilogram of weight lost, after adjusting for changes in diet and physical activity.

The DPP (Knowler *et al* 2002) reported a mean weight loss of 7kg at 12 months and 5.6 kg at 3 year follow up in the intervention arm, compared to less than 1kg and 0.12 kg respectively in the control group. The DPS (Tuomilheto *et al* 2001) reported a mean weight loss of 4.2 kg (SD 5.1) at 12 months and 3.5 kg (SD 5.5) at 2 years in the intervention arm compared to 0.8 kg (SD 4.4) in the control group. At three years mean weight loss was reported as 4.5kg for lifestyle intervention and 3.5kg in controls.

Three of the DPP based translational studies were randomised controlled trials (Ackermann *et al* 2008; Kulzer *et al* 2009; Whittemore *et al* 2009). Two studies were pilots with small samples (Ackermann *et al* 2008; Whittemore *et al* 2009) and one had a follow up of only 6 months (Whittemore *et al* 2009). One trial was based on both the DPP and DPS curriculum (Kulzer *et al* 2009).

Those receiving the lifestyle intervention in a YMCA based trial (Ackermann *et al* 2008) achieved weight loss of 6.0kg at 12 months compared to 1.8 kg in the control group. Kulzer *et al* (2009) reported a weight loss of 3.8 kg in a German primary care intervention based on both the DPP and the DPS compared to a loss of 1.4kg in controls. Whittemore *et al* (2010) reported weight loss of 1.5% in the nurse practitioner delivered intervention compared to 0.0% in controls at 6 months.

In non-randomised controlled studies, a trend for greater weight loss in the intervention arm was found in all but one in study (Faridi *et al* 2009). Almeida *et al* (2010) reported a significant difference in weight loss between the intervention (1.4kg) and control group (0.6kg) of matched pairs at one year follow up. One in five of the intervention group achieved a weight loss of at least 5%. The authors extrapolated their findings to suggest that the weight loss achievement related to a delay of diabetes in 2% of the sample. There were

no significant differences between results of the two comparators (tele-health and on-site intervention) in the Vadheim study. Overall, mean weight loss was more than 6.4 kg which compares well with the DPP. However, follow up was short at 16 weeks, the sample size was small and both comparators received a lifestyle intervention. McTigue *et al* (2009a) compared outcomes from the primary care based WiLLoW programme with measurements of those that did not enrol on the programme and reported a weight loss of 5.19kg in the intervention group at 12 months compared to a weight increase of 0.21 kg in controls. Authors of one study that did not achieve weight loss in either the church based intervention for an African American population or the matched control (Faridi *et al* 2009) at 12 months concluded that this was likely due to differences in baseline characteristics between groups, difficulty recruiting voluntary workers and loss to follow up. Weight gain was less than 0.5kg in both groups, and was lower in the intervention group (0.14kg versus 0.37kg).

In studies that did not have a comparator, mean weight loss was reported as 6.7kg at 4 months (Amundsen *et al* 2009), 5.7kg at 3 months and 5kg at 12 months (Kramer *et al* 2009), 4.8kg at 12 months for a church based intervention (Davis-Smith 2007), and 4.79kg at 12 months for an internet-based intervention (McTigue *et al* 2009b). A lifestyle balance intervention achieved 5% weight loss in almost half of participants and 7% in more than a quarter at 3 months. This was sustained at 6 months by 87.5% of those achieving 5% loss and 66.7% of those achieving 7% loss or more.

Studies based on the DPS did not include comparators; weight change over 12 months ranged from -0.8kg to -2.36kg across three studies (Absetz *et al* 2009; Laatikainen *et al* 2007; Saaristo *et al* 2010). At three years, one study (Absetz *et al* 2009) reported a sustained change from -0.8kg to -1.0kg.

Evidence statement 29:

Weight loss achievement in translational studies compared with the DPP and DPS.

There was strong evidence [+; ++] for similar trends in weight loss achievements in randomised controlled translational studies to those achieved in the DPP and DPS at 12 months, though effects were generally weaker.

None of the translational studies achieved the 7kg weight loss of the DPP at one year follow-up, though one pilot randomised controlled trial utilising YMCA facilities (Ackermann *et al* 2008 + US) reported a loss of 6.0kg in the intervention arm. One RCT based on both the DPP and DPS (Kulzer *et al* 2009 + Germany) achieved 3.8kg weight loss in the intervention arm.

There was strong mixed evidence [+; ++] from non-randomised translational studies for weight losses ranging from 1.4kg in a primary care based intervention compared to 0.6kg in the control group (Almeida *et al* 2010 ++ US) to 5.19kg compared to a weight increase of 0.21 kg in controls (McTigue *et al* 2009a + US) at 12 months. One church based intervention that targeted African American communities (Faridi *et al* 2009 - US) did not report weight loss in either intervention or control groups, though the increase was less than 0.5kg in both groups and was greater in the control group.

There was moderate evidence from three translational studies based on the DPS [+] for a trend in weight loss at 12 months, though the effect was weaker than in the DPS.

The three studies based on the DPS (Absetz *et al* 2009 Finland +; Laatikainen *et al* 2007 + Australia; Saaristo *et al* 2010 + Finland) did not include controls or comparators. None achieved the 4.2 kg (SD 5.1) weight loss at 12 months reported from the DPS. Weight change ranged from -0.8kg to -2.36kg across the three studies. At three years, one study (Absetz *et al* 2009 + Finland) reported a sustained change from -0.8kg to -1.0kg.

7. DISCUSSION

Part One: Review of reviews of intervention components

For question one of this review, thirteen review level papers were assessed that described successful components of lifestyle interventions for the prevention of type 2 diabetes in at risk populations identified as being at risk. In terms of review methods, the papers were generally rated good quality. However, primary studies that were included within the reviews were typically deemed to have a high rate of bias by the review authors.

There was a large overlap between included studies for each paper. Some papers only reviewed RCTs, therefore the major diabetes prevention trials were included in several reviews. Other less systematic reviews also included smaller and non-randomised studies. The overlap in inclusion was not seen to be an issue since we were identifying successful components rather than measuring effectiveness. Nevertheless, we required caution in order not to over-emphasise components of trials that were identified by a number of reviews.

It was not possible to identify components that were clearly better than any other since these were not compared in any statistical way. Rather, reviews tended to describe those components that were a feature of studies that had shown effectiveness in reduction of diabetes incidence, or achievement of weight management. Therefore, there is a need for research that directly compares the components of interventions, such as mode of delivery and content, to assess whether there are detectable differences in outcomes.

Interventions that were successful in reducing the incidence of type 2 diabetes were delivered by qualified individuals, including nurses, psychologists, diabetes educators, as well as physical activity and nutrition specialists. The interventions included both dietary and physical activity components. The most commonly given dietary advice was to lower the intake of fat, particularly saturated fat, and increase the amount of fibre, fruit and vegetables. Moderate level physical activity of at least 30 minutes daily was found to be beneficial in achieving weight loss goals, though for sedentary individuals 10 minutes was beneficial. Although optimum dietary and physical activity advice is available, it is important for participants to set their own goals within limits and preferences. Interventions were mainly delivered intensively by skilled personnel to at risk individuals. Recipients benefitted from self-monitoring as well as motivating interactions with staff. Interventions that were most effective followed a progressive, gradual approach with support from staff and family.

There was little evidence relating to outcome differences between groups, though men were shown to be more likely to self-monitor their activities and to achieve physical activity goals. Older people were also reported to be more likely to complete their goals – this may be due

to increased time available. Comparisons between ethnic and socio-economic groups were not reported.

Behavioural strategies were described that utilised psychological theories relating to motivation and adherence. However, particular theories were not explicitly described within primary papers. The importance of behavioural strategies in eliciting behaviours that might improve health was the focus of one included review. In addition, a review that was outside our scope in terms of target population also emphasises the role of behavioural components.

Greaves Review of Reviews (Greaves et al 2011)

A recently published review of reviews (Greaves *et al* 2011) examined evidence relating the content of interventions for promoting dietary and /or physical activity change to their effectiveness in producing weight and behaviour change. The review focused on evidence relating to individuals at risk of type 2 diabetes due to lifestyle (e.g. inactivity), or individuals with a wider group of clinical risk factors (e.g. overweight, elevated blood pressure), and therefore had a broader scope than specified by NICE for this review. The work is thus a very important contribution to this field, and will be discussed in comparison with our findings.

Greaves *et al* (2011) examined the theoretical basis, behaviour change techniques used, mode of delivery, intervention provider, intensity, characteristics of the target population and setting of interventions. Thirty studies of good quality met the inclusion criteria. There was mixed evidence for the benefit of interventions having a theoretical underpinning, with stronger evidence for the use of self-regulatory techniques such as goal planning, self-monitoring, and provision of feedback.

The Greaves *et al* (2011) review concluded that interventions should include both diet and physical activity components using well established behaviour techniques. Interventions can be delivered by a wide range of trained personnel in a wide range of settings. Social support from friends and family is an important aspect in engaging participants. Group or individual modes of delivery can be used; maximum frequency of contact with participants should be included. There were no specific adaptations recommended for particular groups, though increased recruitment of men is required. The main findings in our review are, therefore, supported by Greaves' evidence from a broader range of studies that included those from high risk populations, but without necessarily having pre-diabetes.

In terms of applicability, there was scarce primary research carried out within the UK, therefore applying diabetes prevention protocols within the NHS may differ in practice from the original studies. Major trials would also be challenging to carry out within the NHS due to resource issues.

However, protocols have been adapted to smaller international settings to explore the possibility of diabetes prevention on a smaller scale, with adaptations to increase feasibility. The second part of this review focused on a number of these studies.

Part Two: Review of primary translational studies.

Assessment of the translation of major diabetes prevention trials to smaller community settings was carried out. A total of fifteen papers of generally good quality were identified that described eleven studies based on the DPP, three based on the DPS and one that utilised a combination of both trial protocols. None of the studies was based in the UK, therefore applicability is limited. However, there are promising trends that might be transferred to the UK since the findings were in the main positive in terms of achieving weight loss and management as well as for a range of secondary outcomes such as reductions in mean BMI and waist circumference.

The findings were not as strong as those achieved in the DPP or DPS, particularly in respect to the reduction of diabetes incidence which was the primary outcome for these major trials. Translational studies typically showed fluctuating blood glucose levels over a short follow-up. However, mean weight loss was reported in all but one of the included papers and was quite substantial in some translational studies. For example, one pilot randomised controlled trial utilising YMCA facilities reported a mean loss of 6.0kg for the intervention arm at 12 months compared to an initial 7kg in the DPP. The intervention group participating in another RCT based on both the DPP and DPS achieved a mean of 3.8kg weight loss at 12 months.

These are promising results given that the interventions were adapted for smaller scale samples, with limited resources and shorter follow up. The results from one church based study were not so promising, with no weight loss reported. The gain in weight was lower in the intervention group and BMI was reduced in the intervention group but not in the control group. The authors of this paper (Faridi et al 2010) consider that allowing Health Advisors to be perhaps too flexible with the intervention content and mode of delivery may have contributed to this result. The study also differed from other DPP and DPS based studies in that qualified personnel were not recruited to deliver the intervention. Rather, members of the church congregation were trained to carry out this work.

General weaknesses of the included studies were a lack of adequate control or comparator. Only three of the studies were RCTs, with two of these having small samples and one a short follow-up. Only one study had a follow up of more than 12 months, therefore

sustainability was difficult to assess. No consensus as to which intervention components were most effective could be made due to the heterogeneity of study design. However, one study described an association between the number of intervention attendances and weight loss. Since weight loss has also been reported as associated with a reduced diabetes incidence, an indirect inverse association between intervention attendance and diabetes incidence may be postulated.

The findings of this review are supported by two systematic reviews of translational studies by Cordona-Morrell *et al* (2010) and by Jackson *et al* (2009). The two reviews differ from the current review in that they did not only assess studies that were based on diabetes prevention protocols. The authors reported that results are in a positive direction and therefore are encouraging. As in this review the authors could not identify evidence for which components of the studies that might be most beneficial. This was mainly due to the study designs as well as the lack of reporting of component effectiveness within individual studies. In addition, for Jackson *et al* (2009), sustainability was not addressed due to short follow-up. However, there was an apparent trend toward more positive results with more frequent attendance.

Comparison of findings from the review of reviews and the review of translational studies.

Though no specific components of major diabetes prevention trials have been compared statistically, some trends can be observed from the reviews of these trials as well as the evaluations of translational programmes.

Firstly, the major trials were designed to incorporate behavioural strategies rather than merely deliver an intervention. Aspects such as the encouragement of self-monitoring appear from reviews of the trials to increase adherence to the programme with subsequent improvement in outcomes. Whilst translational papers did not particularly describe behavioural strategies, there appeared to be fidelity to the original DPP or DPS protocols when translating the programmes to primary care. Fidelity was less pronounced in one church based study, however, and the authors of this study state that lack of fidelity may be one contributor to a lack of desired outcome.

Secondly, translational studies have highlighted an association between improved outcomes and number of contacts between participants and those delivering the intervention and / or providing support (Saaristo *et al* 2010). Saaristo et al (2010) reported that weight loss was

associated with increased number of visits, with mean reduction in weight being most pronounced in participants attending an average of 3.5 sessions. This supports the finding in one review of dietary support interventions that access to such support needs to be made available at least every 3- 6 months (Nield *et al* 2008).

Conclusion

From the findings, a potential tension exists between achieving optimal outcomes and adapting diabetes prevention programmes into the 'real world'. In primary care and community settings the populations are diverse and resources are limited, which restricts the extent to which interventions can be tailored to meet individual preferences and be culturally sensitive. In addition, tailoring may limit the extent to which protocol fidelity can be maintained. This has an impact on the evaluation and comparisons of outcomes in translational studies.

However, reviews of major trials and the review of translational studies both show that diabetes prevention and weight loss are achievable in intense research settings and that significant weight loss can be achieved at least in up to twelve months of follow up in 'real world' settings. Outcomes from longer follow up of translational studies are needed to evaluate whether these results can be sustained.

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9. APPENDICES

Appendix 1: Search strategy

Overarching Search

Sample search Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1950 to Present

1. *prediabetic state/

2. (pre-diabetes or pre diabetes or raised glucose intolerance or impaired glucose level$ or impaired glucose tolerance or IGT or impaired fasting glucose or IFG or FPG or fasting plasma glucose or impaired glucose regulation or impaired glucose metabolism or raised glycated haemoglobin or raised glycated hemoglobin or high glycated Hb or hyperglycaemia or hyperglycemia).ti.

3. (prevention adj3 (type II diabetes or type 2 diabetes or T2D)).ti.

4. 1 or 2 or 3

5. *body mass index/

6. *obesity/

7. (south asia$ or black africa$ or black caribbean$ or pakistan$ or bangladesh$ or india$ or ethnic minorit$ or chinese or obes$ or waist circumference or "bmi > 3?" or BMI).ti.

8. 5 or 6 or 7

9. *Hemoglobin A, Glycosylated/ or *Mass screening/ or *Risk assessment/

10. (((risk assessment or monitoring or screening) adj2 diabetes) or HBA1C).ti.

11. 9 or 10

12. *Exercise/ or *Exercise therapy/ or *Diet therapy/

13. (lifestyle intervention$ or slimming club$ or diet or low glycaemic index or low glycemic index or reduced fat or low carbohydrate or low calorie or physical activit$ or exercise or cardiorespiratory training).ti.

14. (Motivational support adj5 diet).ti,ab.

15. 12 or 13 or 14

16. 8 or 11 or 15

17. 4 and 16

Search Strategy Review Three

Sample search Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1950 to Present

1. ((prevent$ or reduc$ or protect$ or limit$ or control$ or delay$) adj5 (diabetes or pre-diabetes or pre diabetes or raised glucose intolerance or impaired glucose level$ or impaired glucose tolerance or IGT or impaired fasting glucose or IFG or FPG or fasting plasma glucose or impaired glucose regulation or impaired glucose metabolism)).ti,ab.

2. *prediabetic state/

3. (prevent$ or reduc$ or protect$ or limit$ or control$ or delay$).ti,ab.

4. 2 and 3

5. *Diabetes Mellitus, Type 2/pc [Prevention & Control]

6. 1 or 4 or 5

7 Meta-Analysis as Topic/

8 meta analy$.tw.

9 metaanaly$.tw.

10 Meta-Analysis/

11 (systematic adj (review$1 or overview$1)).tw.

12 exp Review Literature as Topic/

13 7 or 8 or 9 or 10 or 11 or 12

14 cochrane.ab.

15 embase.ab.

16 (psychlit or psyclit).ab.

17 (psychinfo or psycinfo).ab.

18 (cinahl or cinhal).ab.

19 science citation index.ab.

20 bids.ab.

21 cancerlit.ab.

22 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21

23 reference list$.ab.

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

24 bibliograph$.ab.

25 hand-search$.ab.

26 relevant journals.ab.

27 manual search$.ab.

28 23 or 24 or 25 or 26 or 27

29 selection criteria.ab.

30 data extraction.ab.

31 29 or 30

32 Review/

33 31 and 32

34 Comment/

35 Letter/

36 Editorial/

37 animal/

38 human/

39 37 not (37 and 38)

40 34 or 35 or 36 or 39

41 13 or 22 or 28 or 33

42 41 not 40

43 6 and 42

44 limit 43 to (english language and humans and yr="1990 -Current")

Appendix 2: Included Studies

Review level evidence

Baker MK., Simpson K., Lloyd B., Bauman AE., Singh MAF. Behavioural strategies in diabetes prevention programs: A systematic review of randomized controlled trials. *Diabetes Research and Clinical practice* 2011; 91: 1-12

Burnet DL, Elliott LD, Quinn MT, Plaut AJ, Schwartz MA, Chin MH *et al*. Preventing diabetes in the clinical setting. *J Gen Intern Med* 2006; 21(1):84-93.

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Yates T., Khunti K., Bull F., Gorely T., Davies MJ. 2007 The role of physical activity in the management of impaired glucose tolerance: a systematic review. *Diabetologia* 2007; 50: 1116-1126

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Primary level evidence

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Ackermann RT., Finch EA., Brizendine E., Zhou H., Marrero DG. Translating the Diabetes Prevention Program into the Community: The DEPLOY Pilot Study. *Am J Prev Med.* 2008 35(4): 357–363.

Almeida FA, Shetterly S, Smith-Ray RL, Estabrooks PA, Reach and effectiveness of a weight loss intervention in patients with pre-diabetes in Colorado. *Preventing Chronic Disease* 2010; 7(5):A103

Amundson HA, Butcher MK, Gohdes D, Hall TO, Harwell TS, Helgerson SD *et al*. Translating the Diabetes Prevention Program into Practice in the General Community Findings From the Montana Cardiovascular Disease and Diabetes Prevention Program. *Diabetes Educ* 2009; 35(2):209-223

Davis-Smith MD. Implementing a Diabetes Prevention Program in a Rural African-American Church. *Journal of the National Medical Association*. 2007; 99 (4): 440-446

Faridi Z., Shuval K., Njike VY., Katz JA., Jennings G., Williams M., Katz DL., and PREDICT Working Group. Partners reducing effects of Diabetes (PREDICT): a diabetes prevention physical activity and dietary intervention through African-American churches. Health Education Research 2010 25 (2) 306-315

Kramer MK, Miller RG, Orchard TJ Translating the Diabetes Prevention Program: a comprehensive model for prevention training and program delivery. *American Journal of Preventive Medicine*. 2009 37(6):505-11

Kulzer B., Hermanns N., Gorges D., Schwarz P., Haak T. Prevention of diabetes self-management program (PREDIAS): effects on weight, metabolic risk factors, and behavioural outcomes. Diabetes Care 2009 32 (7) 1143-46

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Appendix 3: Excluded studies

Studies excluded after review of full paper

Author	Reason for exclusion
Angermayr	Includes those diagnosed with T2D. No evidence on components.
#454 Astrup	No interventions described
#115 Bellamy	No findings relevant to research question
#270 Case	No findings relevant to research question
#601 Cao	Focus on dietary science – some animal testing included
#1403 Caperchione	Use as reference source for R4
#1832 Coffin	Good for background on bariatric surgery procedures
#370 Curtis	All studies focusing on pharma
#57 Di Cianni	No findings relevant to research question
#705 Emini Sadiku	May be useful for background / discussion – not a systematic review
#1869 England	May be useful for background / discussion – not a systematic review
#4 Esposito	Most of populations studied diagnosed with diabetes
Eves 2006	Population with T2DM
#1340 Fleming	Not focussed on T2D related outcomes, though does give some synthesis on components.
#1036 Franz	Not systematically reported. Focus on effects of dietary and physical activity components rather than interventions.
#811 Franz	Position statements rather than review (linked to #1036)
#215 Galani	Not PD population. No findings relevant to research question
#258 Gillies	Interventions but effectiveness data only
#1898 Greaves	RCT
#1412 Hjelm	Nurse education paper
#1458 Hudon	Populations with T2D and / or other chronic conditions
#256 Jeon	Association papers (physical activity with lowered T2D risk)
#546 Korkiakangas	Looking at BFs to physical activity – use for refs in R4
#214 Lauritzen	All studies focusing on pharma
#1004 Lim	Population with T2DM
#1787 Lindstrom	Commentary paper
#634 Lirusi	Focuses on population with T2D
#1385 Mann	Focuses on dietary elements not interventions
McTigue *et al* 2003	Not prevention of T2DM / progression to T2DM.
McTigue *et al* 2006	Not focussed on T2 prevention
#922 Opperman	Focuses on dietary elements not interventions
#167 Orozco	Doesn't discuss components of interventions
#1314 Parez	Populations with diabetes
#198 Priebe	Doesn't discuss components of interventions
#59 Renzaho 2009	Most of populations T2DM or non-adults
Rosenberg & Lawrence 2000	Most of studies focus on obesity / CVD. No new information re prevention of type 2 diabetes
Schulze 2005	Small section on successful aspects; epidemiological data
#1035 Sherwin	Position statement
#15 Swanson	All studies focusing on pharma
#593 Wang	Clinical research
#1550 Wyeness	Not assessing interventions
#337 Yamaoka	No findings relevant to research question
#1549 Yates	Commentary but good background and potential for R4

Studies excluded after review of full paper (Primary)

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Author	year	Ref ID	Reason for exclusion
Benjamin *et al*	2004	2699	Conference abstract only
Boltri *et al*	2010	2659	Conference abstract only
Bowman *et al*	2003	2490	Review
Brown *et al*	2010	2658	Population youth
Burr *et al*	2010	2163	Review
Chiasson *et al*	2005	2422	Review
Colagiuri *et al*	2010	2661	Review
Delahanty *et al*	2008	2297	Review
Delahanty *et al*	2004	1853	Review
Delagadillo *et al*	2010	2132	Description only
Engelgau *et al*	2003	2501	Review
Ershow	2009	2197	Review
Escobar *et al*	2008	2268	T2DM population
Fain	2009	2238	Editorial
Finch *et al*	2009	2235	Description
Gailvan *et al*	2007	2330	Review
Goodman *et al*	2008	2311	Recommendations
Gruber *et al*	2006	2394	Commentary
Icks *et al*	2007	2343	Cost-effectiveness
Inzicchi *et al*	2005	2443	Review
Ivy *et al*	1999	2573	Review
Ivy	1997	2590	Review
Jackson	2009	2234	Review
Jortberg *et al*	2004	2698	Conference abstract only
Karter *et al*	2003	2499	Cost-effectiveness
Kelly *et al*	2004	2469	Discussion paper
Kilkhinen *et al*	2007	2350	Brief report (same study as Laitikanen)
Lindstrom *et al*	2010	2169	Toolkit / guidelines
Marrero	2009	2196	Review
Matvienko *et al*	2009	2213	Population with T2DM
Mau *et al*	2010	2170	Minority population (Native Hawaian)
McBride *et al*	2008	2258	Population with T2DM
Merriam *et al*	2009	2233	Population non-applicable (Latino)
Myers *et al*	2010	2662	Conference abstract only
Pagoto *et al*	2008	2907	Includes T2DM population
Pepe	2006	2397	Commentary
Porterfield *et al*	2010	2141	Recommendations
Rosal *et al*	2008	2304	Implementation information
Roubideaux *et al*	2008	2675	Population non-applicable (American Indians / Native Alaskan)
Ruggiero *et al*	2007	2687	Population non-applicable (Latino)
Ryan	2003	2504	Review
Schwarz *et al*	2007	2315	Review
Schwarz *et al*	2007	2325	Review
Schwarz *et al*	2008	2298	Study plan of action
Simmons *et al*	2008	2263	Population non-applicable
Simpson *et al*	2003	2513	Review
Staten *et al*	2005	2446	Not diabetes specific
Williams	2010	2176	Commentary
Yates	2009	2212	Review
Zimmet *et al*	2003	2701	Commentary
Zinman *et al*	2006	2382	Medication

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Appendix 4: Review screening form

Study identification Include author, title, reference, year of publication	
Programme/intervention topic	**Key question no:**
Checklist completed by:	
SCREENING QUESTIONS	
In a well-conducted systematic review:	**In this review this criterion is met:** **(Circle one option for each question)**
1 Does the review address an appropriate and clearly-focused question that is relevant to one or more of the guidance topic's key research question/s?	Yes No Unclear
2 Does the review include the types of study/s relevant to the key research question/s?	Yes No Unclear
3 Is the literature search sufficiently rigorous to identify all the relevant studies?	Yes No Unclear
4 Is the study quality of included studies appropriately assessed and reported?	Yes No Unclear
5 Is an adequate description of the analytical methodology used included, and are the methods used appropriate to the question?	Yes No Unclear

Appendix 5: Quality assessment

Review level evidence

1. Did the review ask a clearly focused question?
2. Did the review incorporate primary studies of appropriate study design?
3. Were the search methods used to find evidence on the primary research question stated?
4. Was the search for evidence reasonably comprehensive?
5. Were the criteria used for deciding which studies to include reported?
6. Was bias in the selection of studies avoided? (e.g. language restrictions not applied, unpublished trials included)
7. Was there duplicate study selection and data extraction?
8. Were the criteria used for assessing the validity of the included studies reported?
9. Was the validity of all studies referred to in the text assessed using appropriate criteria?
10. Were the characteristics of the included studies provided?
11. Were the methods used to combine the findings of the relevant studies reported?
12. Were the findings of the relevant studies combined appropriately relative to the primary question of the overview?
13. Were the conclusions made by the author(s) supported by the data and/or analysis reported in the overview?
14. Can the results be applied to the UK population/population group?

Y – item addressed; N – no; P – partially; U – not enough information or not clear; NA – not applicable

Study	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**Quality**
Baker 2011	Y	Y	Y	Y	Y	N	Y	Y	Y	P	Y	Y	Y	Y	12/14 ++
Burnet 2005	Y	Y	Y	Y	Y	U	U	N	N	Y	NA	Y	Y	P	8 / 14 +
Davies 2004	Y	Y	U	U	N	U	U	N	N	Y	N	Y	Y	Y	6 / 14 +
Davis 2009	Y	P	U	U	N	U	U	N	N	P	N	P	Y	U	2 / 14 -
Madden 2008	Y	Y	Y	P	P	U	U	N	U	Y	N	Y	Y	P	6/14 +
Nield 2008	Y	P	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	P	U	10 /14 ++

Norris 2007.	Y	P	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	U	11/14 ++
Paulweber 2010	Y	Y	Y	P	Y	U	Y	Y	Y	Y	NA	Y	Y	P	10/14 ++
Roumen 2009.	Y	Y	NR	NR	N	U	NR	NR	N	Y	N	P	Y	U	4/14 -
Walker 2010	Y	Y	Y	Y	Y	U	U	U	U	P	N	U	Y	U	6 /14 +
Waugh / Gillett 2010	Y	Y	Y	Y	Y	U	Y	Y	P	Y	NR	Y	Y	P	10/14 ++
Yates 2007	Y	Y	Y	Y	U	Y	N	N	N	Y	N	Y	Y	U	8/14 +
Yuen *et al* 2010.	Y	Y	Y	Y	Y	Y	Y	Y	N	P	P	Y	Y	U	10/14 ++

Primary level evidence

1. Is the source population or source area well described?
2. Is the eligible population or area representative of the source population or area?
3. Do the selected participants or areas represent the eligible population or area?
4. How was selection bias minimised?
5. Were interventions (and comparisons) well described and appropriate?
6. Was the allocation concealed?
7. Were participants and/or investigators blind to exposure and comparison?
8. Was the exposure to intervention and comparison adequate?
9. Was contamination acceptably low?
10. Were the other interventions similar in both groups?
11. Were all participants accounted for at study conclusion?
12. Did the setting reflect usual UK practice?
13 Did the intervention or control comparison reflect usual practice?
14. Were outcomes measures reliable?

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

15. Were all outcome measurements complete?
16. Were all the important outcomes assessed?
17. Were all outcomes relevant?
18. Were there similar follow up times in exposure and comparison groups?
19. Was follow-up time meaningful?
20. Were exposure and comparison groups similar at baseline?
21. Was intention to treat (ITT) analysis conducted?
22. Was the study sufficiently powered to detect an intervention effect (if one exists)?
23. Were the estimates of effect size given or calculable?
24. Were the analytical methods appropriate?
25. Was the precision of intervention effects given or calculable? Were they meaningful?
26. Are the study results internally valid (i.e. unbiased)?
27. Are the findings generalisable to the source population (i.e. externally valid)?

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	Quality
Absetz 2007; 2009	Y	Y	Y	NA	Y	NA	NA	Y	U	NA	U	P	P	U	Y	Y	Y	NA	Y	NA	U	Y	Y	Y	P	U	U	12 / 27 +
Ackermann 2008	Y	Y	Y	N	Y	NA	N	Y	U	Y	Y	P	P	U	Y	Y	Y	Y	P	P	U	NR	Y	Y	Y	U	P	14 / 27 +
Almeida 2010	Y	Y	Y	NA	Y	Y	NA	NA	Y	U	Y	P	Y	Y	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	U	U	19 / 27 ++
Amundsen 2009 / Vanderwood 2010	Y	Y	Y	NA	Y	NA	NA	Y	Y	NA	U	P	P	Y	P	Y	Y	NA	Y	NA	U	U	Y	Y	Y	U	U	13 /27 +
Davis-Smith 2009	Y	Y	Y	NA	Y	NA	NA	Y	NA	NA	Y	N	N	Y	Y	Y	Y	NA	Y	NA	NR	NR	N	P	N	U	P	11 / 27 +
Faridi 2010	Y	Y	P	U	P	NA	NA	U	Y	U	Y	P	P	U	Y	Y	N	Y	Y	N	U	U	Y	P	N	U	P	9/27 -
Kramer 2009	P	U	Y	NA	Y	NA	NA	Y	U	Y	Y	P	Y	Y	Y	Y	Y	Y	Y	NA	Y	Y	Y	Y	Y	U	U	17/ 27 +
Kulzer 2009	Y	Y	Y	Y	Y	NA	NA	Y	Y	Y	Y	P	P	Y	Y	Y	Y	Y	Y	Y	NR	Y	Y	Y	Y	P	P	20 / 27 ++
Laatikainen 2007	P	Y	Y	NA	Y	NA	NA	Y	NA	NA	Y	P	P	Y	Y	Y	Y	NA	Y	NA	U	Y	Y	Y	Y	U	U	14 / 27 +
McTigue 2009a	P	Y	P	NA	Y	NA	NA	Y	U	N	Y	P	P	Y	P	Y	Y	Y	Y	Y	NR	NR	Y	Y	Y	U	P	13 / 27 +
McTigue 2009b	Y	Y	Y	NA	Y	NA	NA	Y	NA	NA	Y	P	P	Y	Y	Y	Y	NA	Y	NA	NR	NR	Y	Y	Y	U	P	14 / 27 +
Saaristo 2007; 2010	Y	Y	Y	NA	Y	NA	NA	Y	NA	NA	U	P	P	Y	Y	Y	Y	NA	Y	NA	U	Y	Y	Y	Y	U	U	14 / 27 +
Seidal 2008	Y	Y	Y	NA	Y	NA	NA	Y	NA	NA	Y	P	P	Y	Y	Y	Y	NA	P	NA	NR	NR	N	P	N	U	U	10 / 27 +
Vadhelm 2010	Y	Y	Y	NA	Y	NA	NA	Y	N	Y	Y	P	Y	U	Y	Y	Y	Y	Y	Y	N	N	N	Y	Y	N	P	16 / 27 +
Whittemore 2009	Y	Y	Y	Y	Y	U	N	Y	U	Y	Y	P	Y	Y	Y	Y	Y	Y	P	Y	U	Y	Y	Y	P	P	U	18 / 27 ++

NR = Not Reported, NA = Not Applicable; U = Unclear; P = Partial

Appendix 6: Evidence tables for the most effective components of studies reported in reviews focusing on lifestyle interventions

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Baker *et al* 2011 **Type**: Systematic review (RCTs) **Focus**: Behavioural strategies in diabetes prevention programs **Quality: ++**	**Databases and websites searched:** Medline, PreMedline, CINAHL, EMBASE, PsychINFO, Cochrane Register of Controlled Trials **Other search methods undertaken:** NR **Years searched:** 1966 - 2009 **Study type inclusion criteria:** RCTs Full text English language **Study type exclusion criteria:** Non-RCTs **Number of studies included:** 7 **Method of synthesis**: Systematic and critical review	**Included population/s:** Adults at risk of T2DM (dysmetabolic / IGT) **Excluded population/s:** **Setting of included studies:** **Population**: **Interventions:** Exercise training / physical activity / dietary intervention **Primary outcome:** Incidence of T2DM **Exclusions:** Non-English language Diagnosis of T2DM	**Intervention/s description:** Lifestyle interventions (physical activity / dietary intervention) Characteristics of those delivering the intervention Highly trained, e.g physicians and nurses (JDPP, IDPP, DQS, ADPP). Registered dieticians (DPS, DPP). Multidisciplinary team (VIP). Mode of delivery Individual counselling apart from DQS and ADPP (groups). Characteristics of recipients Mean cohort age 42 (SD 9) – 56 (SD 6) 3 studies had minimum BMI (DPP 24, DPS 25, VIP 27) JDPP males only Broad range of ethnic groups Setting Clinical outpatients (JDPP, IDPP, DQS, ADPP). Intensity / Duration Number of contacts (not including supervised physical activity) over first 12 months ranged from 6 (JDPP / ADPP) to > 22 (VIP / DPP). Adherence/ loss to follow up No data on rate of attendance. Loss to follow up low (6.9% - 13.4%) Intervention content All studies included combined physical activity (moderate intensity aerobic) and dietary	**Primary Outcomes** All studies successful in lowering incidence of T2D. RRR 75% in ADPP; 74% in VIP; 58% in DPP and DPS; 38% in DQS; 29% in IDPP compared to controls. NNT relatively low (range 4.6 in DQS to 18.5 in ADPP). **Secondary outcomes:** None **Follow-up periods:** NR **Methods of analysis**: NR	Highly skilled Staging of information provision Individual tailoring of programme components Multiple sessions, reinforcement, specified small group size; individual or group programmes. Written materials to reinforce verbal advice Nutritional change: Small steps Vicarious and observational learning Identification of barriers to change and problem solving Learning to deal with relapse Increasing confidence to change Physical activity change: Prescriptive approach with progressive increase in volume and frequency Self-monitoring Building problem solving and decisional balance into increasing motivation for activity Direct supervision (3 studies) Resource intensive during induction Moderate to very large number of face-to-face contacts over first 12 months. Contacts in person / by phone at regular intervals for duration of programme. Similar results were achieved with 9 versus 22 individual contacts in the DPS and DPP respectively. 2 studies with obese cohorts (DPS; DPP) provided free	**Limitations identified by author:** None **Limitations identified by reviewers:** **Evidence gaps and/or recommendations for future research:** Implementation studies to document adherence, optimal number of contacts. **Source of funding:** Nil

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
			(reduction in fat intake to 20-30% total energy) interventions. No study specified a particular behavioural theory.		exercise classes for the duration of the trial. Self-management and monitoring through log books on physical activity and diet Physical activity change: Structured programmes (observational learning and modelling of behaviour) Achievable, modest changes across multiple lifestyle goals Two studies were significantly related to type 2 prevention, DPS – positive lifestyle changes such as achieving a high number of diet and exercise goals, lower fat intake, higher fibre intake, and a greater volume of physical activity were all associated with a reduction in diabetes risk suggesting a dose-response relationship. Greater success in achieving lifestyle goals related to weight loss, fat reduction, and exercise was also independently related to risk reduction in the DPP. This suggests that a behavioural change strategy that focuses on achievable, modest changes across multiple lifestyle goals may be the key to diabetes prevention.	

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Burnet *et al* 2005 **Type**: Review **Focus**: To review, from the perspective of practicing clinicians, available evidence on lifestyle interventions (or medication) to prevent or delay the onset of type 2 diabetes. **Quality: +**	**Databases and websites searched:** Medline **Other search methods Undertaken:** NR **Years searched:** 1980-2004 **Study type inclusion criteria:** Clinical trials with longitudinal follow up. **Study type exclusion criteria:** **Number of studies included:** 4 **Method of synthesis**: Narrative	**Included population/s:** IGT **Excluded population/s:** NR **Setting of included studies:** NR **Primary outcome:** Onset of T2DM **Exclusions:** NR	**Intervention/s description:** Lifestyle (medication) **Characteristics of those delivering the intervention:** MDs, nurses, technicians (DPP; Da Qing). Dietician, nurse, physiotherapist, MD (Malmo). **Mode of delivery**: Intensive interaction; individual counselling **Characteristics of recipients**: IGT **Setting:** NR **Intensity / Duration**: See individual studies **Adherence/ loss to follow up:** Vigorous follow up efforts. Intervention content Behavioural counselling sessions **Control/comparison/s description:**	**Primary Outcomes** Prevention or delay of T2DM **Secondary outcomes:** NR **Follow-up periods:** Varied **Methods of analysis**: Any	Lifestyle interventions more effective than medication in the DPP. Staff qualifications and training. Behavioural contracting around self-derived goals. Recipients used individualised counselling to set own goals following those set by protocol. Study staff assisted in tailoring and modifying goals progressively to achieve success. Recipients documented goals. Patient empowerment and self-efficacy enhanced through promotion of self-monitoring through use of weighing scales and measuring cups for diet. Diet and physical activity levels recorded by recipients. Importance of family and social context. Spouses encouraged to participate in counselling sessions in DPP, DPS and Malmo. Family is a key source of social support. Vigorous follow up efforts were made including computer monitoring adherence and triggering actions for the recovery of those failing to reach goals. Moderate intensity (e.g. brisk walking) physical activity most days of the week; the type of which tailored to individual needs. Sustainability can be achieved if activity is enjoyable and recipient is able to make it a priority. Encourage increased physical activity in daily routine. Previously inactive recipients begin activity slowly (e.g. 10	**Limitations identified by author:** NR **Limitations identified by reviewers:** Only one database searched. **Evidence gaps and/or recommendations for future research:** Further research on translating to practice. **Source of funding:** National Institute of Diabetes and Digestive and Kidney Diseases Diabetes Research and Training Centre. Career Development award.

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
					mins per day) with gradual increase. Emphasise that total calories matter. Fat < 25% of total intake, minimise saturated and trans fat intake. Fibre 20-30g / day, high in whole grains, fruits and vegetables, beans and nuts. Encourage portion size awareness and reading food labels. Goal set with gradual changes. Encourage self reward for meeting goals. Help recipients anticipate potential barriers to physical activity and solutions to these. Emphasise that relapse is the norm, encourage to overcome after exploring what led to the relapse.	

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Davies *et al* 2004. **Type:** Review **Focus**: Prevention of type 2 diabetes mellitus in a UK setting. **Quality:+**	**Databases and websites searched:** NR **Other search methods undertaken:** NR **Years searched:** NR **Study type inclusion criteria:** Large international trials **Study type exclusion criteria:** NR **Number of studies included:** 9 **Method of synthesis**: Narrative	**Included population/s:** IGT **Excluded population/s:** NR **Setting of included studies:** Various	**Intervention/s description:** Lifestyle interventions **Characteristics of those delivering the intervention**: Committed to achieving results. Those with lowest level of emotional support had an increased risk of diabetes. **Mode of delivery:** Sustained **Characteristics of recipients**: Different cultural, social and economic situations. **Setting:** Varied **Intensity / Duration**: Intensive **Adherence/ loss to follow up** Need for sustained effort to prevent regain of weight. **Intervention content** Increased physical activity and decreased consumption of energy-dense foods.	**Primary Outcomes** Prevention of T2DM **Secondary outcomes:** Weight loss surrogate marker for dietary or physical activity change (difficult to tease one from the other). Weight loss / weight stabilisation is essential. Benefits most pronounced in those who made most lifestyle changes (DPS). **Follow-up periods:** Varied **Methods of analysis**: Varied **Attrition details:** NR	One-to-one dietary and physical activity sessions. Target: 30 minutes physical activity each day or 150 mins / week. Need for sustained input in dietary intervention (NZ) to maintain weight loss. At least 7 dietary / physical activity sessions over first year then individual or group sessions every 3 months over the remainder of the study. Physical activity seems to be major contributing factor to non-progression from IGT to T2DM. (Da Qing). Outcomes / Recommendations RRR Diet 31%, physical activity 41%, combination 42% (Da Qing) Need for culturally sensitive, individualised and sustained interventions. The trials that have produced significant results targeted people at high risk of diabetes, had intensive on-going interventions and were organised and co-ordinated by people committed to achieving results.	**Limitations identified by author:** None of the major evidence replicated in the UK. **Limitations identified by reviewers:** Difficult to assess exactly which papers included as no list. **Evidence gaps and/or recommendations for future research:** UK research. **Source of funding:** .NR

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Davis *et al* 2009. **Type:** Review **Focus:** Role of obesity and lifestyle interventions in the prevention and management of type 2 diabetes. **Quality: -**	**Databases and websites searched:** NR **Other search methods Undertaken:** NR **Years searched:** NR **Study type inclusion criteria:** Major studies, translational studies, weight loss studies **Study type exclusion criteria:** NR **Number of studies included:** 5 trials; 4 translational studies, 5 weight loss **Method of synthesis**: Narrative	**Included population/s:** NR **Excluded population/s:** NR **Setting of included studies:** NR	**Intervention/s description:** Lifestyle interventions **Characteristics of those delivering the intervention** See individual studies **Mode of delivery** Not listed **Characteristics of recipients** Not listed **Setting** NR **Intensity / Duration** Not listed **Adherence/ loss to follow up:** NR **Intervention content:** As Da Qing, DPS, DPP	**Primary Outcomes** Prevention of T2 DM **Secondary outcomes:** No significant weight loss between intervention and control (Da Qing). Weight loss 5.6kg in lifestyle intervention compared to placebo and metformin (0.1 and 2,1kg) (DPP). **Follow-up periods:** As individual studies **Methods of analysis**: NR	Importance of weight loss as well as prevention as an outcome. Weight loss of 9kg associated with 1.67% reduction in HbA1c over 6 months. No optimal dietary strategy for prevention of T2DM. Success is reliant on the individual ability to follow diet. Modest weight loss of 4-7% significant in reducing diabetes incidence.	**Limitations identified by author:** NR **Limitations identified by reviewers:** More detail required. **Evidence gaps and/or recommendations for future research:** NR **Source of funding:** .NR

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Madden *et al* 2008 **Type:** Integrative review **Focus:** Review of lifestyle interventions for the prevention of type II diabetes mellitus. **Quality: +**	**Databases and websites searched:** Medline, CINAHL, Cochrane Database **Other search methods undertaken:** Examination of reference lists. **Years searched:** 1996 - 2007 **Study type inclusion criteria:** Diabetes Prevention Programmes **Study type exclusion criteria:** Non-English language Non-peer reviewed. Medication studies. **Number of studies included:** 12 **Method of synthesis**: Narrative	**Included population/s:** Adults **Excluded population/s:** Diagnosed T2 DM **Setting of included studies:** NR	**Intervention/s description:** Lifestyle interventions **Characteristics of those delivering the intervention** **Mode of delivery** NR **Characteristics of recipients** One study – lean vs overweight. **Setting**: NR **Intensity / Duration**: NR **Adherence/ loss to follow up** Follow up one to six years. Five out of 8 trials participants unable to maintain initial results **Intervention content** Five studies evaluated diet (3 d*iet al* one, the other 2 included physical activity and /or diet). Three studies focused on caloric restriction; one of these on reduced intake late at night (Watanabe). One focused on low fat intake and one on a balanced diet. Three focused on physical activity alone; one involved supervised walking. Seven assessed diet plus physical activity. Nutritional and behavioural counselling in 3 studies.	**Primary Outcomes** Prevention of T2DM **Secondary outcomes:** Weight / BMI reduction **Follow-up periods:** One to seven years. Only one study reported sustained results at six years. Two studies reported significant weight loss at 2 years but this was not sustained. **Methods of analysis**: NR	Only males were involved in the trial that , in this review, resulted in the lowest incidence of T2DM (Kosaka 2005) Benefits from sustained intervention Low fat and low calorie diet had greatest results with mean weight loss 5.6kg (Wing). Balanced diet demonstrated lowest T2DM incidence in IGT participants over 4 years (Wein). Highest mean weight loss found in physical activity intervention that involved behavioural counselling via e-mail (Tate), though no follow up after 1 year. The greatest weight change overall followed a strict caloric intake of 800 – 1200 kcal / day and physical activity of 1-2 50-60 min supervised walks per week gradually increasing to 1500 kcal / week (Wing). Lowest T2DM incidence in diet plus physical activity intervention of healthy diet and moderate physical activity 30-40 mins / day (Kosaka). Sustaining the interventions appears to be difficult for individuals. One reason may be that it is difficult to direct people consistently to make healthy lifestyle choices. Programme selection should be a joint decision by patient and clinician. Outcomes / Recommendations Five studies focusing on physical activity showed a statistically significant reduction in weight and/ or BMI.	**Limitations identified by author:** Only 3 databases searched. **Limitations identified by reviewers:** Could be more detailed. **Evidence gaps and/or recommendations for future research:** NR **Source of funding:** NR

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Nield *et al* 2008 **Type:**Cochrane Systematic Review **Focus**:Dietary advice for the prevention of type 2 diabetes mellitus in adults **Quality ++**	**Databases and websites searched:** Medline, EMBASE, CINAHL, AMED, The Cochrane Library **Other search methods undertaken:** Biblographies. Author contact Ongoing trials **Years searched:** Up to 2007 **Study type inclusion criteria:** RCTs **Study type exclusion criteria:** <12 months duration **Primary outcome:** Incidence of T2DM **Number of studies included:** 5 **Method of synthesis**: Sub group Narrative	**Included population/s:** Adults IGT **Excluded population/s:** NR **Setting of included studies:** NR	**Intervention/s description:** Dietary advice interventions **Characteristics of those delivering the intervention** Da Qing: Physician for health check, nurses for discussion of intervention. **Mode of delivery** Da Qing: comprehensive health check every 3 months **Characteristics of recipients** IGT. Da Qing: age >25 years, BMI > 25kg/m2, living in Da Qing. ODES: From screening programme; age 41 – 50 years, relatively inactive, BMI > 24kg/m2. **Setting** Dietary advice given at a clinic (Pan) or university hospital (Torjesen). **Intensity / Duration** Da Qing: counselling weekly for first month, monthly for three months and 3 monthly until end (6 years). ODES: Baseline and 12 month follow up. **Adherence/ loss to follow up** NR **Intervention content** ODES: Diet, physical activity, combined diet and physical activity, control arms. Da Qing: Diet, physical activity, combined diet and physical activity arms	**Primary Outcomes** Incidence of T2DM Blood glucose measures Time to development of T2DM **Secondary outcomes:** QoL Mortality Morbidity Weight BMI Cost Lipids BP Maximal exercise capacity Adverse effects **Follow-up periods:** Minimum 12 months **Methods of analysis**: NR	Dietary advisors. High-risk recipients Support and guidance provided at least 3-6 monthly Energy-controlled diet with increase in fresh fruit and vegetables, and a decrease in simple sugars. Benefits in following diet as above. Over-riding factor was the frequency of support and guidance.	**Limitations identified by author:** **Limitations identified by reviewers:** **Evidence gaps and/or recommendations for future research:** **Source of funding:** Cochrane

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Norris *et al* 2007. **Type:**Cochrane Systematic Review **Focus**: Long-term non-pharmacological weight loss interventions for adults with pre-diabetes. **Quality: ++**	**Databases and websites searched:** Medline, EMBASE, CINAHL, ERIC, PsychINFO, Web of Science, Biosis, Nutrition Abstracts and review, The Cochrane Library **Other search methods undertaken:** Hand searches of a range of relevant journals. **Years searched:** Up to 2004 **Study type inclusion criteria:** RCTs published / unpublished) Any language **Study type exclusion criteria:** <12 months duration **Primary outcome:** Incidence of T2DM **Number of studies included:** 9 **Method of synthesis**: Meta-analysis	**Included population/s:** IFG /IGT Adults **Excluded population/s:** NR **Setting of included studies:** NR	**Intervention/s description:** Dietary, physical activity, Behavioural Characteristics of those delivering the intervention Most used a dietician. Mode of delivery Individual and group sessions. Characteristics of recipients Pre-diabetes Overweight or obese Setting NR Intensity / Duration Four weeks to 10 years duration. Total contacts ranged from 4 to a 28 day residential. Adherence/ loss to follow up Mean attrition 9.6% Intervention content Dietary, physical activity or behavioural strategies for weight loss or control.	**Primary Outcomes** Weight loss / control Statistically significant weight loss of 2-3kg in intervention groups at one and two year follow up. One 10 year study found sustained weight loss. **Secondary outcomes:** Characteristics of studies correlating with weight loss Characteristics of populations correlating with weight loss Lipids BP Glycaemic control Morbidity Mortality QoL **Follow-up periods:** At least one year **Methods of analysis**: NR	Prolonged, frequent contacts, low attrition rates, evidence of persistent behaviour change. One residential treatment programme with close supervision and 2.5 hours physical activity per day was very successful. High risk overweight and obese Number of intervention contacts significantly correlated with weight loss. Diet, physical activity or combination Sustained, long-term, intensive, multi-component interventions required to decrease incidence of T2DM.	**Limitations identified by author:** Only published literature included; no further information could be obtained. **Limitations identified by reviewers:** **Evidence gaps and/or recommendations for future research:** Evidence for translation and implementation in community settings. **Source of funding:** Cochrane
Paulweber *et al*	**Databases and**	**Included**	**Intervention/s**	**Primary**	Monitor co-morbidities and taken	**Limitations identified**

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
2010 **Type:** Systematic review **Focus**: Review of lifestyle modification interventions fro the prevention of type 2 diabetes **Quality: ++**	**websites searched:** Medline **Other search methods undertaken:** Search of cited references **Years searched:** 1979-2008 **Study type inclusion criteria:** RCTs, SRs. **Study type exclusion criteria:** <12 months duration **Primary outcome:** Incidence of T2DM **Number of studies included:** 5 **Method of synthesis**: Narrative	**population/s:** NR **Excluded population/s:** T2DM **Setting of included studies:** Clinics, hospitals	**description:** Lifestyle modification Characteristics of those delivering the intervention Only one study reporting; nurse/ practitioner. Mode of delivery Individual counselling; 16 session core protocol; telephone contacts. Characteristics of recipients All mean BMI ≥ 24 kg / m2 Ages 30-60 years Setting Clinics; Hospital Intensity / Duration Varies across studies and interventions Adherence/ loss to follow up 1.5% - 9% drop out over 1-20 years **Description of the intervention content** All diet and physical activity interventions. Diet: increased vegetables, fibre, decreased sugar, alcohol, saturated fat. Physical activity: ≥ 30 mins slow walking / 20 mins fast walking / cycling / day or 150 mins / week.	**Outcomes** Incidence of T2DM **Secondary outcomes:** NR **Follow-up periods:** Varied **Methods of analysis**: NR	into account when planning diet. Encourage to change diet and increase physical activity. Sustained weight reduction by 5-7%. Diet high in fibre (≥ 15g per 1000kcal), moderate fat (≤ 35% total energy), reduced saturated and trans fat (≤10% total energy). Increase in physical activity at 30 minutes per day moderate exercise Outcomes / Recommendations Weight reduction essential element.	**by author:** Limited primarily to EU environment. Does not address specific requirements of ethnic minority groups. **Limitations identified by reviewers:** **Evidence gaps and/or recommendations for future research:** NR **Source of funding:**
Roumen *et al* 2009.	**Databases and websites**	**Included population/s:**	**Intervention/s description:**	**Primary Outcomes**	Need to know the behavioural stage of the recipient.	**Limitations identified by author:**

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
Type: Review **Focus**: Lifestyle intervention for prevention of diabetes. **Quality: -**	**searched:** NR **Other search methods undertaken:** NR **Years searched:** NR **Study type inclusion criteria:** Any **Study type exclusion criteria:** < 12 months duration **Number of studies included:** 16 **Method of synthesis**: Narrative	IGT **Excluded population/s:** **Setting of included studies:** Country only	Lifestyle interventions to prevent type 2 diabetes in IGT subjects. **Characteristics of those delivering the intervention** NR **Mode of delivery** NR **Characteristics of recipients** IGT Differences in baseline characteristics such as waist circumference, fasting glucose, insulin levels and % engaging in physical activity may have effect on outcomes **Setting** NR **Intensity / Duration** Physical activity typically 30 min moderate activity at least 5 days a week **Adherence/ loss to follow up** NR **Intervention content** Encouragement in physical activity Walking / jogging Healthy diet encouragement or education 8 studies encouraged weight/body loss ≥ 5% Other common features include dietary advice for proportion of energy consumption: carbohydrates app. 55% total fat < 30% Saturated fat ≤ 10% Cholesterol <33g/mj day Protein 10-15 %	T2DM incidence **Secondary outcomes:** Changes in plasma glucose **Follow-up periods:** One to 20 years **Methods of analysis**: NR	Need to be aware of the clinical significance of IGT and reducing risk by targeting interventions. Practitioners skilled in assessment of dietary history and physical activity counselling or the willingness to refer. As there is high heterogeneity among high risk individuals in terms of co-morbidities and muscle strength, physical activity needs to be individually tailored to increase therapeutic value. Motivational interviewing may be beneficial to assist in positive attitude towards diet and physical activity Need to be aware of increased risk for diabetes and own lifestyle. This can be achieved in general practice by asking questions of at risk individuals. Those with lower BMI seem more able to achieve activity goals. However, even small but sustained increases in activity are beneficial in the long term. Increasing motivation, self-efficacy and social activities, decreasing stress, emphasising the importance of prevention and tailoring advice may increase adherence. There are indicators that moderate to vigorous physical activity helps prevent T2DM. Combined aerobic and resistance training showed greatest improvement on HbA1c. A high fibre, low fat diet predicts weight loss and prevention of T2DM.	NR **Limitations identified by reviewers:** The review does not report systematic methods for searching, or quality assessment. **Evidence gaps and/or recommendations for future research:** More large studies required to identify how major modulators interact with lifestyle effects. Future publications should include concise and conclusive reporting on risk genotypes and reasons for non-adherence for one or both of the following reasons: 1) so lifestyle interventions can be adjusted for those less likely to adhere to and benefit from them; or 2) so the environment can be adjusted to increase adherence and compliance, especially for the lower socioeconomic classes. **Source of funding:** NR

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
			Fibre 3g / mj day Physical activity 30 min moderate at least 5 days per week.		Outcomes / Recommendations Most but not all studies show beneficial effect of lifestyle interventions on glucose tolerance. Weight reduction the dominant predictor of reduced diabetes risk. Physical activity contributes to improvement in glucose metabolism independent of weight loss, so seems to have an additive effect on prevention	
Walker *et al* 2010 **Type:** Review **Focus:** Diet and exercise in the prevention of diabetes. **Quality: +**	**Databases and websites searched:** Medline, EMBASE, The Cochrane Library, The Cumulative Index to Nursing and Allied Health literature **Other search methods undertaken:** NR **Years searched:** 1999-2008 **Study type inclusion criteria:** Systematic reviews and large original studies (>100 participants). **Study type exclusion criteria:**	**Included population/s:** IGT (trials). SRs – not specified. **Excluded population/s:** NR **Setting of included studies:** NR	**Intervention/s description:** Lifestyle **Characteristics of those delivering the intervention** **Mode of delivery** **Characteristics of recipients** **Setting** **Intensity / Duration** **Adherence/ loss to follow up Intervention content** All above reported ad hoc.	**Primary Outcomes** Prevention of T2DM **Secondary outcomes:** NR **Follow-up periods:** 2.5 years – 20 years **Methods of analysis**: NR	Mediterranean diet is particularly effective in women compared to a low fat diet. Effects of lifestyle intervention increase in those severely overweight (One unit increase in baseline BMI leads to a decrease in HR of 7.3%. Mediterranean diet seems to have a long term impact on weight loss	**Limitations identified by author:** NR **Limitations identified by reviewers:** Includes studies outside the criteria in discussion of interventions and components; difficult to see the evidence base. **Evidence gaps and/or recommendations for future research:** To develop public health approaches to support integration of lifestyle changes into daily life. **Source of funding:** Australian Department of Health and ageing.

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
	Cohort studies < 12 months duration **Number of studies included:** 4 major intervention trials (DPP, DPS, Da Qing, Indian DPP) and 3 follow up studies. SRs 4 systematic reviews. **Method of synthesis**: Narrative					
Waugh / Gillett *et al* 2010 **Type:** Systematic review and economic evaluation (in progress). **Focus:** Non-pharmacological interventions to reduce the risk of diabetes in people with impaired glucose regulation. **Quality: ++**	**Databases and websites searched:** Medline, EMBASE, The Cochrane Library, Science Citation Index, The National research Register, UKCRN. **Other search methods undertaken:** NR **Years searched:** Up until 2007 **Study type inclusion criteria:** RCTs ≥ 2 years duration **Study type exclusion criteria:** RCTs < 2 years	**Included population/s:** IGT / IFG **Excluded population/s:** People with diabetes **Setting of included studies:** NR	**Intervention/s description:** Lifestyle (weight loss, physical activity, diet; alone or combinations) **Characteristics of those delivering the intervention** **Mode of delivery** **Characteristics of recipients** **Setting** **Intensity / Duration** **Adherence/ loss to follow up** **Intervention content** Reported individually; no table	**Primary Outcomes:** Progression toT2DM; weight loss; adverse events; changes in blood glucose; changes in diet and physical activity; changes in blood cholesterol. **Secondary outcomes:** NR **Follow-up periods:** As per individual study **Methods of analysis**: NR	Goals more likely to be achieved by those at least risk. Physical activity increase was associated with older age groups (>60 years compared with 25-4 years) at 1 and 2 years (DPP). 80% of DPP participants were eliminated between screening and OGTT testing. 150 mins moderate physical activity per week (DPP) Greater reduction in energy intake after one year in lifestyle intervention group compared to metformin or placebo groups. Much of the diabetes incidence reduction was related to weight loss, though there was also 50% reduction in those that met physical activity goals.	**Limitations identified by author:** **Limitations identified by reviewers:** **Evidence gaps and/or recommendations for future research:** **Source of funding:** HTA

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
	duration Non-RCTs **Number of studies included:** 9 RCTs; 5 SRs **Method of synthesis**: Narrative					
Yates *et al* 2007 **Type:**Systematic review. **Focus**: The role of physical activity in the management of impaired glucose tolerance. **Quality: +**	**Databases and websites searched:** MEDLINE (1966–2006) and EMBASE (1980–2006) **Other search methods undertaken:** NR **Years searched:** As above **Study type inclusion criteria:** Randomised and non-randomised controlled trials were included. **Study type exclusion criteria:** Interventions that provided brief written or verbal advice only. Evaluations of a single episode of physical activity / training.	**Included population/s:** Adults (18 years and over) with pre-diabetes (IGT and / or IFG). Except for one trial that involved only men (n=188), all trials included both men and women. In the included studies a total of 40% of participants were men. **Excluded population/s:** **Setting of included studies:**	**Intervention/s description:** Physical activity programmes (actively promoted / supported physical activity or structured exercise training). Regular encouragement and counselling (6 studies). Supervised physical activity classes (2 studies). Discounted access to local gym (1 study). Initial 1 month stay at wellness centre followed by planning for healthy lifestyle (1 study) **Characteristics of recipients** Sample sizes 62 – 2,161 All with IGT One trial male only (Malmo). **Intensity / Duration** Encouragement to increase in physical activity to ~150 mins moderate – vigorous per week (6 studies) Diet counselling at least once every 3 months (6 studies). **Intervention content** 7 used multi-component lifestyle interventions. One used structured gym-based training of 180 mins aerobic per week (Carr 2005). 6 encouraged weight loss through energy-restricted diet	**Primary Outcomes** Measure of physical activity and related clinical outcomes (progression to T2DM / measure of 2hr – glucose or FPG). Four studies included the incidence of diabetes as the main outcome, and four used 2-h plasma glucose levels as a direct measure of glucose control. All the studies using the incidence of diabetes as their main outcome were based on a multi-component lifestyle intervention. **Secondary outcomes:** Insupport of the importance of exercise. **Follow-up periods:** NR **Methods of analysis**: NR	Greater reduction in incidence of T2DM in physical activity group than either diet or physical activity alone, or in combination. Physical activity alone not associated with greater weight loss. Aerobic training at 3hr / week did not lower blood glucose but did improve insulin sensitivity at 6 and 24 months. Outcomes / Recommendations Four studies found lowered incidence of T2DM by app. 50% in intervention groups. Non-significant to small changes in physical activity for intervention group (3 studies; self-reported activity). 6 studies reported significant weight loss. 150 min/week of moderate to vigorous intensity exercise unlikely to be sufficient to reduce risk of T2DM in those with IGT independently of other lifestyle changes.	**Limitations identified by author:** It is not possible to make recommendations as to the intensity and duration of exercise needed to improve glucose tolerance and/or reduce the risk of diabetes in individuals with IGT, independently of other lifestyle changes. All studies included in will apply to the majority of individuals with pre-diabetes. **Limitations identified by reviewers:** **Evidence gaps and/or recommendations for future research:** More evidence from rigorously designed randomised controlled trials with objective measures of physical activity is needed. **Source of funding:** NR

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
	Number of studies included: 8 **Method of synthesis**: Narrative					
Yuen *et al* 2010. **Type:** Systematic review **Focus:** Lifestyle and medication interventions for the prevention or delay of type 2 diabetes mellitus in pre-diabetes. **Quality: ++**	**Databases and websites searched:** Cochrane Register of Controlled Trials, MEDLINE, EMBASE, CINAHL, PsycINFO, Web of Science, BIOSIS and LILACS databases. Trial registries. **Other search methods undertaken:** Reference lists of included studies and relevant reviews and meta-analyses. Attempts to contact authors. No language restrictions were imposed. **Years searched:** NR **Study type inclusion criteria:** RCTs that followed participants for at	**Included population/s:** **Excluded population/s:** **Setting of included studies:** **Population**: **Interventions:** **Included studies:** 4 **Inclusions:** **Study type:** RCTs **Population**: Pre-diabetes **Interventions:** Lifestyle vs medication; Lifestyle and medication aiming to prevent, delay or revert T2DM **Primary outcome:** Incidence of T2DM; reversion to NGT using OGTT / FPG **Exclusions:** Follow up < 12 months	**Intervention/s description:** **Characteristics of those delivering the intervention** Case managers Dieticians Hospital staff **Mode of delivery** NR **Characteristics of recipients** IGT Possibly more motivated as self selected in 2 studies **Setting** NR **Intensity / Duration** Average duration of studies 3-5 years. Intensity differed across studies. **Adherence/ loss to follow up** Unsure whether the effects of these interventions are lasting. **Intervention content** Varied across trials; lifestyle education, instruction on diet and physical activity, individualised advice. Medication (Metformin; Acarbose). See http://lifeinthefastlane.com/resources/research-tables/ For more information	**Primary Outcomes:** Incidence of T2DM and normal glucose tolerance (NGT). We included studies that identified T2DM or NGT using ranges of two hour plasma glucose (2hPG) and fasting plasma glucose (FPG) that were specified in detail. **Secondary outcomes:** Mortality (Total deaths or rate of death) Incidence of CVD morbidity (Number or rate of events) Glycaemic control (Glycated haemoglobin levels (%));Fasting blood glucose levels (mmol/L); 2 hour plasma glucose levels (mmol/L) Plasma lipids (Total cholesterol; High-density lipoprotein (HDL) (mmol/L); Low-density lipoprotein (LDL) (mmol/L); Triglycerides (mmol/L) Blood pressure (Diastolic blood pressure (mmHg); Systolic blood pressure (mmHg)) Insulin (Fasting insulin (pmol/L) Postload insulin (pmol/L) Body weight (kg) BMI (kg/m2) Waist circumference (cm) Waist to hip ratio (WHR)	Unclear how capable health care systems are around the word to provide adequate lifestyle interventions. None of participants in the DPP were in the pre-contemplative phase. Lifestyle advice needs to be re-reinforced regularly. DPP found that initial attainment of physical exercise and weight loss goals predicted future success; may be beneficial to employ an initial period of regular contact. Not possible to draw conclusions on which interventions were most effective in delaying T2DM May need more time to deliver interventions in the real world. Lifestyle advice needs to be reinforced regularly and yet in the IDPP-1 that alone was not be enough. Components such as enhancing social support, behaviour modification and having face to face contact may be required. DPP found that initial attainment of exercise and weight loss goals predicted future success.	**Limitations identified by author:** There were insufficient studies investigating reversion to NGT; most relied heavily on the incidence of T2DM to demonstrate effect. The external validity of the findings of this review is uncertain. It is likely that study participants were more motivated than other patients being self-selected in the two largest studies. DPP groups also reported being more physically active than the nationally representative sample with IGT in NHANES III Similarly, none of the IL participants were in the pre-contemplation stage of behavioural change in physical activity levels, a result markedly different to other populations. **Limitations identified by reviewers:** **Evidence gaps and/or recommendations for**

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.

Study	Review search parameters	Review population and settings	Intervention/s	Outcomes and method of analysis	Findings (Successful components)	Notes
	least one year, investigating IGT or IFG or both **Study type exclusion criteria:** **Number of studies included:** 4 (DPP, STOP-NIDDM, IDPP-1. Fang *et al* 2004) Total sample: 5,196 (range 178 to 3,234 participants). **Method of synthesis**: Narrative			Adverse effects Compliance Quality of life **Follow-up periods:** NR **Methods of analysis**: NR		**future research:** None of the included studies gave resistance training. **Source of funding:** NR

Evidence tables for primary translational studies

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and methods of analysis	Results	Notes
Author: Absetz **Year:** 2007 (one year follow up) 2009 (three year follow up) **Setting / country:** Finland **Aim of study:** To study the effectiveness of the GOAL Lifestyle Implementation Trial at the 36-month follow-up **Study design:** Single group pre-test and post-test **Funding:** The Academy of Finland and the Finnish Ministry of Health. **Quality score: +**	**Source population/s:** Primary Health Centre patients. **Eligible population:** Patients aged 50–65 years with risk factors (obesity, hypertension, elevated blood glucose, or lipids). **Selected population:** 352 participants risk assessed by mean FINDRISC score 16.2 ±3.3). 312 (88.6%) attended at year 1 and 271 (77.0%) at year 3. Eight participants responded at year 3 but not at year 1. **Excluded population/s:** **Setting:** Primary health care	**Method of allocation**: The inclusion criterion was set at FINDRISC score ≥12 (17% 10-year risk). 405 patients were recruited. Exclusions: *1*) Mental health problems / substance abuse likely to interfere with participation (*n*=3). *2*) Acute cancer (*n* =6). *3*) Type 2 diabetes requiring medical treatment (*n*=7). *4*) Myocardial infarction during past 6 months (*n* =0). **Intervention/s description: control/comparison/s description:** The Good Ageing in Lahti Region (GOAL) Lifestyle Implementation Trial was designed to replicate results from the DPS under more "real world" conditions with a modest program delivered by existing health care personnel. Five key lifestyle change objectives (as for DPS): 1. Less than 30% of total energy intake from fat; 2. Less than 10% of total energy intake from saturated fat; 3. At least 15 g of fibre/1,000 kcal; 4. At least 4 h/week moderate level physical activity; and 5. More than 5% weight reduction. **Modifications from DPS:** Intervention delivered as six	**Primary outcomes:** Weight loss Blood Glucose **Secondary outcomes:** BMI Waist circumference Lipids BP Dietary intake Physical activity levels **Other:** Level of education, employment status, marital status. Program participation at follow-up. Fidelity of program delivery. **Measurement points:** 1 month; 9 months; 1 year; 3 years. **Methods of analysis:** Differences between respondents and those lost to follow-up (x2 tests and independent-samples *t* tests). Risk factor changes from baseline to years 1 and 3 (paired-sample *t* tests), Effect of medication use on cholesterol changes (repeated measures ANOVA). SPSS for Windows version 15.0. The RE-AIM (Reach, Efficacy/Effectiveness, Adoption, Implementation,	**Attrition details:** 462 patients screened: 37 women and 20 men did not fulfill the risk status criteria. Of remaining 405, 389 participants (103 men and 286 women) were recruited to the intervention following screening for other conditions. In the baseline group, 14 men (14%) and 18 women (6.4%) had type 2 diabetes after a 2-hOGTT, and 2 men and 3 women did not take OGTT. All participated in counselling but were excluded from the analyses, leaving 352 study participants assigned to 36 groups. 1 month pre-intervention questionnaire data gave response rate 97.5%, at 9 months 81%, and at 12 months 83%. Fifty-seven percent of the participants reported having attended all six counselling sessions. Attendance in the first five sessions remained over 90% but dropped to 81% in the last session. Seven men and 26 women dropped out of the study during the follow-up. Those completing the study were more likely to be married or cohabiting than the dropouts (73 vs. 51%, x2 = 6.501, *P* = 0.05). No statistically significant socioeconomic differences were found in the drop-out rates. <u>Three Year follow up:</u> Participants who completed the study (*n* = 271) differed from participants who were lost to the 3-year follow- up (*n* =81) in employment status (x2 = 6.447, *P* = 0.040), by being more often retired (50.0 vs. 39.5%) and less often unemployed (11.5 vs. 22.4%). At baseline, the completers also had a lower mean BMI (32.3 ± 5.0 vs. 33.7 ± 4.8 kg/m2, *t* = 2.064, *P* = 0.040) and waist circumference (104.6 ±12.3 vs 107.9 ±11.9 cm, *t* = 2.105, *P* = 0.036). At year 1, the differences did not yield significance (31.9 ± 4.9 vs. 33.1±4.7 kg/m2, NS, for BMI; 102.7± 11.9 vs. 105.6 ± 13.0 cm, NS, for waist circumference). **Sample Characteristics:** *n* Female =265 Male = 87 Age (years) Female 58 ± 4.3 Male 59 ± 3.7	**Limitations identified by author**: The unemployed were more likely to drop out from the study during the post-intervention follow-up, limiting the conclusions that can be drawn of the long-term effectiveness of the intervention in this group of people. See: http://www.palmenia.helsinki.fi/kihyva/InEnglish.html. For further details.

		sessions by public health nurses over a period of 8 months. Protocol included no other post-intervention contact with participants, except follow-up measurements at years 1 and 3. **Data Collection and Outcomes** 12 months anthropometric measurements, laboratory tests, and a 3-day food diary. Questionnaire data at 1 month pre-intervention, 9 months and 12 months. Key lifestyle measures at 12 months were total fat intake (%E), saturated fat intake (%E), fibre intake (g/ 1,000 kcal), physical activity (min/day), and relative weight change from baseline (%). **Control**: NA **Baseline comparisons:** Clinical data at baseline, year 1 and 3. Self-reported demographic background data in baseline questionnaire. Risk factor changes from baseline to years 1 and 3. Laboratory tests at year 3. **Study sufficiently powered?**	Maintenance) evaluation framework for complex implementation trials was utilized to analyze the reach, effectiveness, adoption, and implementation of the intervention. Comparison of the "success rates" between DPS and GOAL participants for each lifestyle objective (x^2) at 12 months.	Basic education (missing values female n=5; male n=2) Elementary Female 164 (63%) Male 63 (74%) Secondary Female 65 (25%) 17 (20%) High school Female 31 (12%) 5 (6%) Employment (missing values female n=4; male n=2) Employed Female 98 (38%) Male 35 (41%) Unemployed Female 39 (15%) Male 9 (11%) Retired Female 124 (47%) Male 41 (48%) Marital status (missing values female n=5; male n=2) Married or cohabited Female 183 (69%) Male 66 (76%) Glucose tolerance (Plasma glucose after 2-h challenge: normal ≤7.8 mmol/l and impaired =7.8 – 11.0 mmol/l) Normal Female 205 (77%) Male 57 (66%) Impaired Female 60 (23%) Male 30 (34%) 70% of participants were obese (BMI≥30 kg/m2). Mean waist circumference was >100 cm among women and 110 cm among men. Mean blood lipid levels and blood pressure were only slightly elevated. On average, participants had normal glucose levels. 30% of men and 21% of women were found to have impaired glucose tolerance. Except for lower blood glucose levels and higher BMI, mean risk factor levels were similar to the DPS sample. GOAL participants not meeting lifestyle objectives at baseline: *n* 281 Total fat ≤30 E% 44 Saturated fat ≤10 E% 29 Fibre ≥15 g /1,000 kcal 47 Moderate-intensity physical activity ≥30 min/day 60 Weight reduction ≥5% 11 Four to five objectives attained 14 GOAL participants meeting lifestyle objectives at baseline: n =71 Total fat ≤30 E% 61 Saturated fat ≤10 E%‡ 55 Fibre ≥15 g /1,000 kcal 73 Moderate-intensity physical activity≥30 min/day 86 Weight reduction ≥5% 18 Four to five objectives attained 38	

				GOAL total sample: n = 352 Total fat ≤30 E% 48 Saturated fat ≤10 E% 34 Fibre ≥15 g /1,000 kcal 52 Moderate-intensity physical activity ≥30 min/day 66 Weight reduction ≥5% 12 Four to five objectives attained 20 DPS intervention sample: n = 265 Total fat ≤30 E% 47 Saturated fat ≤10 E% 26 Moderate-intensity physical activity ≥30 min/day 86 Fibre ≥15 g /1,000 kcal 25 Weight reduction ≥5% 43 **Primary outcomes:** **Weight loss** Reduction in weight and BMI achieved by year 1 were maintained also at year 3. Between years 1 and 3, an average regain of 1 kg was found in the DPS, resulting in a -3.5 ± 5.1 kg weight reduction from baseline to 3 years, whereas in the GOAL trial, the weight decrease achieved at year 1 was maintained throughout follow-up. **Blood Glucose** Of 193 participants with normal glucose tolerance at baseline, 10.9% had impaired glucose tolerance (IGT) and 1.6% had diabetes at year 3. Of 65 participants who had had IGT at baseline, 12% had diabetes and 43% had returned to normal by year 3. **Attainment of the lifestyle change objectives.** At baseline, 71 participants (20% of the total sample) showed both nutrient intake and physical activity levels compatible with study objectives. 281 participants failed to meet one or more of the objectives. Significant differences in attainment of objectives were found at 1-year, with highest success rates in those who had already met objectives at baseline. Compared to DPS, success rate in GOAL total sample was significantly lower for physical activity objective , but significantly higher for the fibre objective. In the fat intake objectives, no significant differences were found. Success rate for four to five lifestyle	

				change objectives was equal in both studies, though weight loss attainment as the final outcome was significantly lower in GOAL compared with DPS. **Risk factor changes from baseline to follow-up** At 1-year, several risk factors had decreased significantly, with a stronger effect for men. Diastolic blood pressure, weight and BMI (only men), and waist circumference (both sexes) decreased. Mean fasting plasma glucose level increased slightly, but statistically significantly, among women. Despite the increase, it remained within normal range. **Females** Baseline n = 270 Weight 86.0 ± 13.2 85.5 _ 13.3 BMI 32.5 ±4.6 Waist circumference (cm) 102.8± 10.7 Plasma glucose (mmol/l) Fasting glucose 5.6 ± 0.8 NS 2-h tolerance test 6.5 ± 1.7 NS Serum lipids (mmol/l) Total cholesterol 5.5 ± 1.0 NS HDL cholesterol 1.5 ± 0.4 NS Triglycerides 1.6 ± 0.8 NS Blood pressure (mmHg) Systolic 141 ± 17 NS Diastolic 87 ±9 NS Follow up n = 226 Weight 85.5± 13.3 BMI 32.3± 4.7 Waist circumference (cm) 101.6 ± 10.9 ($P < 0.001$) Fasting glucose 5.7 ± 0.7 ($P < 0.01$) 2-h tolerance test 6.6 ± 1.9 NS Serum lipids (mmol/l) Total cholesterol 5.5 ± 0.9 NS HDL cholesterol 1.5 ± 0.4 NS Triglycerides 1.5 ± 0.7 Blood pressure (mmHg) Systolic 140 ± 18 NS Diastolic 86±9 NS **Males** Baseline n = 99 Weight 100.0 ± 18.1 BMI 32.0± 5.3 Waist circumference (cm) 110.6 ±12.6	

				Fasting glucose 5.9 ± 0.7 2-h tolerance test 6.9 ± 1.8 NS Serum lipids (mmol/l) Total cholesterol 5.3 ± 0.9 NS HDL cholesterol 1.3 ± 0.3 NS Triglycerides 1.6 ± 0.8 NS Blood pressure (mmHg) Systolic 146 ± 20 NS Diastolic 91 ± 11 Follow up n = 226 Weight 98.5 ± 18.1 *(P*< 0.01) BMI 31.5± 5.2 Waist circumference (cm) 108.3 ± 13.1 (*P* < 0.001) Plasma glucose (mmol/l) Fasting glucose 6.1 ± 0.8 NS 2-h tolerance test 6.8 ± 2.3 NS Serum lipids (mmol/l) Total cholesterol 5.1 ± 0.8 NS HDL cholesterol 1.4 ± 0.3 NS Triglycerides 1.6 ± 1.0 NS Blood pressure (mmHg) Systolic 143 ± 16 NS Diastolic 87 ± 8 9 (*P* <0.01) **Costs:** NR	
Author: Ackermann RT., Finch EA., Brizendine E., Zhou H., Marrero DG. **Year:** 2008 Translating the Diabetes Prevention Program into the Community The DEPLOY Pilot Study Am J Prev Med. 35(4): 357–363. **Setting / country:**	**Source population/s:** Two YMCA populations (semi-urban, with similar ethnic and SES characteristics) 7500 randomly selected households within approximately 5 miles of each YMCA facility. **Eligible population:** Adults with diabetes risk factors invited to attend a community-based screening and education event at the YMCA. (2) a determination of BMI.	**Method of allocation**: Randomisation **Intervention/s description: control/comparison/s description:** One of two YMCA sites randomly assigned to receive training and support for delivering a group based adaptation of the DPP lifestyle intervention. **Control**: YMCA offered information about existing wellness programmes. Participants in both groups received similar testing, counselling, educational materials, limited access to the YMCA, and repeat testing and counselling	**Primary outcomes:** Weight change **Secondary outcomes:** **Measurement points:** 4-6 months 12-14 months **Methods of analysis:** Ordinary least squares multivariate regression. SAS version 9.1 Analysis of all participants who completed data collection, regardless of their level of intervention participation.	**Uptake / Attrition details:** Of 46 participants in intervention arm, 35 (76%) participated in at least one of the sessions. These 35 participants completed an average of 75% of the 16 core curriculum visits. The 46 participants allocated to the intervention arm attended an average of 57% (76% × 75%) of the maximum possible core curriculum sessions. The 4–6-month follow-up visit was completed by 85% of intervention participants and 83% of controls. **Sample Characteristics:** NR **Primary outcomes:** **Weight loss** At 4–6-month follow-up, clinically significant between-group difference was found in percent change in body weight. Compared to baseline levels, body weight decreased by 6.0% (95% CI=4.7, 7.3) in intervention participants and 2.0% (95% CI=0.6, 3.3) in control	

US: Indeanapolis **Aim of study:** To evaluate the delivery of a group-based DPP lifestyle intervention in partnership with the YMCA **Study design:** Pilot cluster-randomized trial **Funding:** National Institute of Diabetes and Digestive and Kidney Diseases (R34 DK70702-02) **Quality score:**	(3) Completion of 7-item ADA risk score. (4) Collection of a drop of whole blood (CCBG) concentration for those with a BMI ≥24 kg/m2 and an ADA risk score ≥1 **Selected population:** 535 adults assessed during the YMCA-based diabetes risk screening events. 143 had a high-risk ADA score and met the glucose-level criteria for the study. After the exclusion of 12 participants because of conditions that might preclude participation 131 were eligible and 92 (70%) enrolled. At baseline, intervention and control participants were similar with respect to age, but control participants were more often female (61% vs 50%) and of non-white race (29% vs 7%) **Excluded population/s:** **Setting:** YMCA	at 6 and 12 months. Only participants at the intervention site were offered free access to a new group-based diabetes prevention intervention. **Modifications from DPP** Group-based program modelled on DPP materials, with some adaptation to improve sustainability by the YMCA. Maintenance activities following the core curriculum sessions involved monthly, large-group meetings at the YMCA, where guest presenters discussed healthy restaurant eating and food shopping. YMCA staff completed a structured two-and-one-half day group-instructor training administered by experienced DPP investigators. Instructor s were selected based on good communication skills and prior experience in group education or programming. **Data Collection and Outcomes** **Baseline comparisons:** Attendance; Weight **Study sufficiently powered?**		participants (p<0.001). Mean weight loss of 5.7 kg (12.5 lbs) for intervention participants and 1.8 kg (4.0 lbs) for controls. At 12–14-month follow-up, significant between-group difference in percent change in body weight. Compared to baseline levels, follow-up body weight decreased by 6.0% (95% CI=3.8, 8.3) in intervention participants and 1.8% (95% CI= +0.3, −3.9) in controls (p=0.008 for between group difference). Mean weight loss of 5.7 kg (12.5 lbs) for intervention participants and 1.6 kg (3.6 lbs) for controls. **Costs:** NR	
Author: Almeida **Year:** 2010	**Source population/s:** Integrated health	**Method of allocation**: **Intervention/s description:**	**Primary outcomes:** Weight measured by clinical staff during routine	**Attrition details:** Of 12,468 eligible members, 1,030 took part, representing a participation rate of approximately 8%.	**Limitations identified by author**: NR

Setting / country: Denver, Colorado US **Aim of study:** To investigate the effectiveness of a theory-based, brief, small-group weight loss intervention for diabetes prevention. To determine the potential reach of the intervention. **Study design:** Matched-cohort longitudinal study **Funding:** Department of Preventive Medicine at KPCO. **Quality score:** **++**	care organization (Kaiser Permanente Colorado) (KPCO) **Eligible population:** Newly diagnosed pre-diabetes (impaired fasting glucose measurements of 100 to 125 mg/dL. IFG values). **Selected population:** 18 years or older, a member of the health care organization for at least 6 months before the study start date of February 2004. **Excluded population/s:** 1) an IFG measurement of 126 mg/dL or higher 2) a diabetes diagnosis in the first 30 days after the IFG measurement 3) a dietician contact in the 6 months before the study period **Setting:** Health care	**control/comparison/s description:** Single 90-minute small-group session with 10 to 20 participants. Presentation by a dietician or weight loss specialist. Information about pre-diabetes and diabetes, recommendations for a healthful diet and regular physical activity, and information on how diet, physical activity, and weight loss delay the onset of diabetes. Four to 6 classes offered monthly **Control** ; Electronic medical records to select 1 or 2 controls for each member who attended a small-group session. Matching based on the exact match on month and year of IFG measurement, exact match on sex, within 5 years of age, within 2 (BMI) units, and within 5 mg/dL for initial IFG measurement. **Baseline comparisons:** Weight measurement obtained closest to the date of participation in the small-group session **Study sufficiently powered?**	medical visits. **Secondary outcomes:** **Measurement points:** Follow-up 12 months after initial class attendance (recorded up to 30 days after the end of the 12-month period). **Methods of analysis:** Mixed models analyses .	60 matched controls eliminated due to lack of 12-month follow-up weight measurements within the 30-day window. This gave 760 matched pairs for final analyses (n = 1,520; 8% participation). **Sample Characteristics:** Mean age : 62 Intervention 63 [SD 10] controls 53% women Ethnic characteristic data were not available Small-group sessions (N = 760) had an average weight of 188.3 lbs and average BMI of 29.8 kg/m2. $\chi 2$ and *t* test results confirmed that small-group participants did not significantly differ from their matched controls in demographic or weight attributes. **Primary outcomes:** Body weight at 12 months decreased significantly more for intervention group compared to matched controls (mean weight loss for small-group participants, −3.0 lbs; 95% confidence interval [CI], −3.6 to −2.4; for controls, −1.4 lbs, 95% CI, −2.0 to −0.8; *P* < .001). A significantly higher proportion of intervention group lost at least 5% of their body weight compared to controls (22% vs 15%, *P* = .001). Intervention group 1.5 (95% CI, 1.2-2.0) times more likely to lose at least 5% of their body weight than controls. **Author Conclusions**: A single-session, theory-based weight loss program can be modestly effective but may not have sufficient reach to be effective as a population approach.	**Evidence gaps and/or recommendations for future research**: Cost-effectiveness of brief small-group interventions in comparative effectiveness trials with more intensive interventions and with interventions supplemented with follow-up through interactive technology.
Author: Amundsen **Year:** 2009 **Setting / country:**	**Source population/s:** See settings. **Eligible population:** Adults aged 18 years and older	**Method of allocation**: No comparators. **Intervention/s description:** **control/comparison/s description:** DPP core lifestyle intervention	**Primary outcomes:** Self monitored fat intake and physical activity Weight loss **Secondary outcomes:**	**Attrition details:** 355 participants enrolled, and 293 (83%) completed the 16-week protocol. Participants attended an average of 14.5 ± 2.0 sessions. Forty-three percent of participants attended all 16 sessions, and 91% attended 12 or more sessions. No significant associations between number of classes	**Limitations identified by author**: A time-series valuation was conducted, and there was no comparison group. Second, self-reported physical activity and diet measures were

Montana, US; Primary care **Aim of study:** To evaluate the feasibility of translating the Diabetes Prevention Program (DPP) lifestyle intervention into practice in the general community. **Study design:** Pre-test / post-test single group. **Funding:** Montana State Legislature and cooperative agreement with the Centres for Disease Control and Prevention, Division of Diabetes Translation (U32/CCU822743-05), Atlanta, Georgia. **Quality score: +**	BMI ≥25 (kg/m2) 1 or more risk factors for diabetes or cardiovascular disease (previous diagnosis of pre-diabetes, impaired glucose tolerance or impaired fasting glucose, high blood pressure (≥130/85 mm Hg or treatment) or dyslipidemia (triglycerides >150 mg/dL, low-density lipoprotein cholesterol >130 mg/dL or treatment, or high-density lipoprotein [HDL] cholesterol <40 mg/dL for men and <50 mg/dL for women), a history of gestational diabetes (GDM), or having given birth to a baby of greater than 9 lb (4.1 kg). **Selected population:** **Excluded population/s:** Those with T2DM, unstable cardiac disease, cancer and currently undergoing treatment, end-stage renal disease or currently on dialysis, unable to participate in regular moderate physical activity, or were pregnant or planning to become pregnant in the next	adapted as a group-based program, with the protocol delivered over16 weekly sessions. **Data Collection and Outcomes** Self-monitoring and documentation of daily fat intake and weight, beginning at session 2, physical activity at session 5, and, if necessary, calories at session 7, as DPP monitoring guidelines. Measures were collected weekly and included fat gram intake, calorie intake, physical activity minutes, and weight. Values were reported as a weekly average. Participants who self-monitored their weight, fat grams, physical activity minutes, and calorie intake 4 or more days per week were considered regular self-monitors. The lifestyle coach weighed each participant at the beginning of each core and follow-up session. **Control**: **Baseline comparisons:** Height, weight, and blood pressure. Referring physicians provided information regarding blood glucose, lipid values, current medications for hypertension and dyslipidemia, and current medications for weight loss or pre-diabetes. **Study sufficiently powered?**	**Measurement points:** Following 16-week sessions and after completion of the 6 monthly group follow-up visits. **Methods of analysis:** Self monitoring score for each component (eg, fat grams, calories, and weight). Final weight defined as the last weight assessed during the 16-week core protocol. Data analyses completed using Statistical Analysis Software Version 9 (Cary, NC). Paired *t* tests to assess weight loss from initial weight to final weight at the end of the 16-week protocol. Chi-square statistics to compare weight loss and physical activity goal achievement by gender, BMI (25-29 kg/m2, 30-34 kg/m2, 35-39 kg/m2, and 40+ kg/m2), age group (<60 years, 60+ years), and risk factors. Logistic regression models to determine variables independently associated with achieving the 7% weight loss goal.	attended and age, sex, or BMI. Mean ± SD age of participants was 53.6 ± 9.7 years, 20% were men, the mean weight at baseline was 99.3 ± 20.0 kg, and the mean BMI was 35.9 ± 6.5 kg/m2. Seven percent of participants were taking a weight loss medication at baseline (n = 21). Participants not completing the lifestyle intervention (62 of 355) were significantly less likely to have been diagnosed with hypercholesterolemia (*P* = .01); less likely to have had a previous diagnosis of pre-diabetes, impaired glucose tolerance, or impaired fasting glucose (*P* = .002); and less likely to have had elevated total cholesterol levels (*P* = .004), and they were significantly more likely to have had lower HDL levels at intake (*P* = .004) compared with participants completing the lifestyle intervention . **Sample Characteristics:** Mean age 53.6 (SD10.5) Mean BMI35.9 (6.5) Mean weight (kg) 99.3 (19.7) Females 80% (n = 233) Males 20% (n = 60) Family history of diabetes 39% (n=111) History of gestational diabetes 7 %(n=19) History of baby >9 lb (4.1 kg) 14 % (n=41) Prediabetes, impaired fasting glucose, impaired glucose tolerance 52% (n=141) Diagnosed hypertension 54% (n=150) **Primary outcomes:** **Self-monitoring** records of dietary fat intake were complete for an average of 10.1 ± 4.0 weeks (range, 0-14 weeks). Men were significantly more likely to complete dietary fat records compared with women (mean, 11.6 ± 3.2 weeks vs 9.7 ± 4.1 weeks, *P* = .001). Age associated with self-monitoring of dietary fat; adjusting for gender, participants 60 years or older completed significantly more dietary fat self-monitoring records (11.5 ± 4.1 weeks) than did participants younger than 60 years (10.3 ± 4.7 weeks, *P* = .02). Participant BMI at baseline was not associated with mean number of dietary fat records completed. Mean daily fat intake decreased significantly: –6.0 ± 18.2 g (range, –3.7 to –12.1 g) from week 3 to the last reported fat gram intake. A mean of 232 ± 128 minutes of physical activity per	collected as part of the intervention. Although these data sources may be biased, participant weight loss was similar to that found in other studies. Third, our initial findings include only the shortterm follow-up, and it is likely that participants will experience some weight regain after the intense intervention, similar to what has been found in the DPP. However, both the Finnish Diabetes Prevention Study and the Da Quing Study from China found long-term benefits after their initial lifestyle interventions. **Evidence gaps and/or recommendations for future research**: NR

	6 months. **Setting:** Four health care facilities associated with diabetes education programs (ADA recognised) and meeting National Standards for Diabetes Self-management Education. Three facilities located in small urban counties with populations ranging from 55 716 to 129 352.20. Fourth facility in frontier county with a population of 11 696. One site a collaboration between local hospital, a local health department, and a federally qualified community health centre. A second site is a collaboration between the local health care facility and the YMCA.			week reported at the end of core protocol. Seventy percent of participants achieved the goal of ≥150 minutes per week, based on mean physical activity at the end of the core sessions. Mean physical activity minutes increased significantly from 210 ± 160 minutes at week 6 to 290 ± 192 minutes at week 16 ($P < .001$). Men averaged 280 ± 152 minutes of physical activity per week, significantly higher than women (219 ± 118 minutes per week, $P = .005$). Eighty-five percent of men (50 of 59) achieved the goal of ≥150 minutes per week versus 67% of women (150 of 225, $P = .007$). After adjustment, gender and self-monitoring behaviour were independently associated with success at achieving the physical activity goal. Men were twice as likely to have met the physical activity goal compared with women (odds ratio [OR], 2.43; 95% confidence interval [CI], 1.10-5.35). Participants who self-monitored dietary fat for at least 14 weeks were 7 times more likely to have met the physical activity goal (OR, 7.00; 95% CI, 2.75- 17.78), and participants who self-monitored for 7 to 13 weeks were 3 times more likely to have met the physical activity goal (OR, 3.07; 95% CI, 1.54-6.11) than participants who monitored dietary fat less often. **Weight loss** Mean participant weight at baseline 99.3 ± 19.7 kg (range, 58.2-180.1 kg). At the end of the core protocol, mean weight was 92.6 ± 18.8 kg ($P < .0001$). Mean weight loss per participant 6.7 ± 4.0 kg (range, –18.0 kg to +2.8 kg), or 6.7% of initial body weight. Significant reduction in BMI from 35.9 ± 6.5 kg/m2 at baseline to 33.5 ± 6.3 kg/ m2 at week 16 ($P < .001$). 97% of participants lost weight (285 of 293). 45% (133 of 293) achieved 7% weight loss goal, and 67% (195 of 293) achieved at least 5% weight loss. Men lost an average of 8.7 ± 4.2 kg, or 7.9% of initial body weight, significantly more than did women, who lost an average of 6.2 ± 6.0 kg, or 6.3% of initial body weight ($P = .02$). Men were twice as likely to have met the 7% weight loss goal as compared with women (OR, 1.83; 95% CI, 1.03-3.26). Participants who achieved the physical activity goal were twice as likely to also achieve the weight loss goal, as were participants who did not achieve the physical activity goal (OR, 2.1; 95% CI, 1.43-5.02).	

				Participants who self-monitored dietary fat intake every week were 8 times more likely to achieve the weight loss goal (OR, 7.60; 95% CI, 2.75-21.01), and participants who self-monitored fat for 7 to 13 weeks were 4 times more likely to achieve the weight loss goal (OR, 3.75; 95% CI, 1.54-9.20) than were participants who self-monitored fat less frequently.	
Author: Davis-Smith MD **Year:** 2007 Implementing a Diabetes Prevention Program in a Rural African-American Church Journal of the National Medical Association. 99 (4): 440-446 **Setting / country:** US: African American Church. **Aim of study:** To determine the feasibility of implementing a diabetes prevention programme (DPP) in a rural African-American church. **Study design:** Evaluation **Funding:** NR	**Source population/s:** African- American church in a rural Georgia town. The church's roster included 407 members with a 3:1 ratio of women to men. **Eligible population:** At risk, as measured by the seven item Diabetes Risk Assessment instrument. **Selected population:** Announcement of programme one week prior to start. Project explained during service on the following Sunday by a research team member. All adults >18 years old invited to complete risk assessment. (Cut off ≥ 10), which was performed during two separate Sunday services to maximize participation. Each service had in attendance an estimated 150 adults	**Method of allocation**: **Intervention/s description: control/comparison/s description:** Six sessions presented over 7 weeks following a schedule determined by the participants. Each session led by volunteer healthcare professionals. Session leaders attended a 60-minute training session led by the research team. Each session started with a prayer. Diet and physical activity logs were reviewed by the group and the leader. Using handouts, the leader guided the discussion, emphasizing participation by all participants. After the presentation and discussion, individuals set goals for diet, exercise and behaviour change for the subsequent week. A prayer concluded the session. . **Modifications from DPP** A six-session program was designed from the 16-session intensive lifestyle arm of the DPP. Two sessions from each of three DPP categories (nutrition, physical activity and behaviour change) were chosen to make up the six sessions. **Control**: NA	**Primary outcomes:** Weight change **Secondary outcomes:** BMI Blood glucose **Measurement points:** Baseline, end of intervention, 6 months and 12 months. **Methods of analysis:** SPSS® version 15.0. Pre-to-post comparison was made for each participant using intention-to-treat analysis. Differences between pre-intervention and post-intervention data for the continuous variables, including weight, BMI, blood pressure and fasting glucose were assessed using independent t tests.	**Uptake / Attrition details:** Risk score completed by 99 adult church attendees (66%) over two church attendances (74 at first session and 25 at the second). Twenty nine (28.3%) participants identified as high risk for diabetes (risk assessment score of ≥10). All 29 high-risk participants (100%) returned for a FSG, with 3-4 attending each of the eight FSG screenings. Of 29 identified as high risk for diabetes, 11 (37.9%) were found to have pre-diabetes. One participant had a FSG .126 mg/dl and was referred to a primary care physician. The remaining 17 (58.6%) had FSG <100 mg/dL. Of 11 participants identified with pre-diabetes, 10 agreed to participate; a visitor from out of town was excluded from the analysis. Attendance rate for the six-session program was 47/60 (78%). Data were collected on nine (90%) of the participants at the six- and 12-month follow- up. One participant could not be located at 6 months, and another moved out of state prior to the 12-month follow-up. **Sample Characteristics:** The initial mean group FSG was 108 mg/dL. **Primary outcomes:** **Weight loss** After the final session, and at six- and 12-month follow ups, the mean FSG levels were 102-, 99- and 100 mg/dL, respectively. For individual participants, weight loss ranged from 0.5-27.2 lbs after the six-week intervention. Overall mean weight loss for the combined group when compared to the initial weight was 8.8-, 6.5- and 10.6 lbs immediately after the intervention, and the six- and 12-month follow-up, respectively. Mean decrease in BMI from the initial session to the 12-month follow-up was1.9 kg/M^2. Mean change in variables over time	

Quality score:	and children. **Excluded population/s:** **Setting:**	**Baseline comparisons:** Measurements included fasting glucose (mg/dL), blood pressure (mmHg), height (inches) and weight (pounds). **Study sufficiently powered?**		Initial Weight (lbs) 231 a (±55.7) BMI (kg/m^2) 35.70 Finger-stick glucose (mg/dL) 1 09a (± 8.3) End of Intervention Weight (lbs) 222.2b (±50.7) BMI (kg/m^2) 34 Finger-stick glucose (mg/dL) 1 02b (±7.5) 6-Month Follow-Up Weight (lbs) 224.5b (±60) 220.4 (±34.7) BMI (kg/m^2) 34.9 Finger-stick glucose (mg/dL) 99c (±9.8) 12-Month Follow-Up Weight (lbs) 220.4 (±34.7) BMI (kg/m^2) 33. Finger-stick glucose (mg/dL) 100 (±5.8) **Costs:** Materials for the project cost $1,075.09. This included paper for handouts, food, scales, supplies, items distributed to participants, postage, etc. This does not include the research assistant's salary. Session leaders volunteered their time and the space was donated by the church.	
Author: Fariidi **Year:** 2010 **Setting / country: US** **Aim of study:** To test the impact of a Community Health Advisor led diabetes prevention intervention targeting an African American church congregation compared to no intervention (PREDICT).	**Source population/s:** African American church congregations **Eligible population:** **Selected population:** **Excluded population/s:** **Setting:** Churches in 2 areas of Connecticut, US.	**Method of allocation**: Randomisation **Intervention/s description: control/comparison/s description:** Intervention adapted from the DPP and utilising delivery by CHAs. CHAs were members of the congregation who received 10 weeks training focussing on diabetes knowledge, awareness of risk factors. Topics included improved physical activity and diet, food labels, portion control, healthful cooking, weight loss programmes, social support and empowerment. Intervention methods were	**Primary outcomes:** Physical activity and dietary patterns. **Secondary outcomes:** Anthropological measures Social support Diabetes knowledge Nutrition and physical activity self-efficacy. **Measurement points:** Baseline 12 months **Methods of analysis:** Chi square for categorical variables ANOVA to assess intra-individual differences. Pared t-tests to assess	**Attrition details:** 68.5% of intervention and 62.9% of control group completed the pre and post surveys. **Sample Characteristics:** All African American Most female (intervention 85%, control 78%) 50% were aged between 18 and 49 Mean BMI 33.8 kg /m2 (SD 8.4) intervention and 31.9 (SD 7.1) in control. Age, weight, BMI, support, diabetes knowledge, self efficacy all comparable between intervention and control sites. Higher levels of education and higher household income in control compared to intervention (p= 0.0098 and p= 0.0105 respectively). Higher social support in intervention (p=0.0329). **Primary outcomes:** No statistically significant differences between	**Limitations identified by author**: Possible explanations for lack of change include differences in baseline characteristics , difficulty recruiting CHAs, variability in CHA interventions and loss to follow up. Blood glucose measurements were not allowed by the church leaders. **Evidence gaps and/or recommendations for future research**:

Study design: Non-randomised controlled trial **Funding:** Connecticut Health Foundation and a grant from the Centres for Disease Control and Prevention. **Quality score: -**		chosen by the CHAs and were tailored to individual preferences. Thus, both group (church) and individual (outreach) sessions were delivered. Awareness raising was also included. **Control**: No intervention in similar settings. **Baseline comparisons:** **Study sufficiently powered?** Alpha 0.05 with 80% power to detect minimal difference between control and intervention of 20% improvement in physical activity and 5.0 point improvement in diet patterns.	mean changes. Logistic regression.	intervention and control in relation to weight, BMI, social support, diabetes knowledge, self-efficacy or consumption of saturated fat and carbohydrates. Energy expenditure(kcal/kg/week) improved significantly in control group compared to intervention (14.75 SD 117.43 compared to 131.31 SD 326.37; p=0.0040). Within the intervention group there were statistically significant improvements in diabetes knowledge (2.4 p=0.0496), total calories (-554.0 p= 0.0086), total carbohydrates (-94.5 p= 0.0051, transfat (-13.3 p= 0.0363). In controls there was statistically significant improvement in energy expenditure (131.31 p=0.0007) and nutritional self-efficacy (0.64 p=0.0485). **Author Conclusions**: Whilst it is important to maintain cultural sensitivity, a high degree of variability in the content between interventions impedes implementation and evaluation.	
Author: Kramer **Year:** 2009 **Setting / country:** Diabetes Prevention Support Centre, Pittsburg, US **Aim of study:** to develop a comprehensive model for diabetes prevention translation using a modified DPP lifestyle intervention **Study design:** A nonrandomized	**Source population/s:**) Phase 1: Primary Care practices (pilot) Phase 2: Diabetes Prevention Support Centre and Additional Practices **Eligible population:** Age 25–74 years without diabetes BMI ≥25 kg/m^2 metabolic syndrome Phase 2: the inclusion criteria were expanded to include age ≥18 years and those with pre-diabetes (fasting glucose 100–125 milligrams pre deciliter [mg/dL]).	**Method of allocation**: **Intervention/s description: control/comparison/s description:** Group rather than individual delivery. Number of sessions was reduced from 16 to 12. Other modifications included concentrating on healthy-food choices rather than the food pyramid specifically, a focus on energy as well as fat intake from the beginning of the intervention and an enhanced emphasis on pedometer use. The manual was updated from the 1996 DPP version to reflect current standards. Group Lifestyle Balance program participants attended 1-hour weekly sessions and received handouts for each session. They received a commercially	**Primary outcomes:** Weight loss **Secondary outcomes:** Weight Waist circumference BMI Cholesterol levels BP **Measurement points:** Baseline and 12 months **Methods of analysis:** Analyses were carried out using the SAS statistical package, version 9.1. Primary analyses were conducted on an intention-to treat basis. Secondary subgroup (per protocol) analyses were performed for those	**Attrition details:** 2167 screening invitations 388 (18%) attended screening from which 106 (27%) met eligibility criteria for the intervention Of 106 eligible individuals, 55 declined participation, yielding a study population of 51 across the four practices. Reasons for nonparticipation are unavailable as the screening component was not part of this consented research evaluation. Phase 2: A total of 74 referrals were received; 56 (76%) met the eligibility criteria, of which 42 (75%) enrolled. In Phase 2, a total of 40 participants (95.2%) attended at least half (mean number of sessions attended was 10.0). Participants who were over the median age (58 years) had better attendance than younger participants (mean sessions attended 10.7 vs 9.2, respectively; *p*=0.03) in Phase 2; however, in Phase 1 there was no significant attendance difference by age. In both phases, the number of sessions attended was positively correlated with weight loss (Phase 1: *r* _0.43, *p*=0.002; Phase 2: *r* =0.53, *p*=0.0003) and with physical activity minutes (Phase 1: *r* =0.37, *p*=0.03; Phase 2: *r* =0.38, *p*=0.01).	**Limitations identified by author**: Unavailability of information regarding participant decision to decline participation as well as the modest sample size and the attrition of participants in Phase 1. In addition, only a small number of men took part, as did only a few nonwhites Because missing values were handled by carrying forward the last value for analysis, it is possible that weight loss could have been overestimated. A more comprehensive cost analysis would provide useful information for implementation.

prospective one-group design **Funding:** U.S. Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick MD, Award Number W81XWH-04-2-0030 and the Frank E. Rath/Spang and Company Charitable Trust. **Quality score: +**	**Selected population:** BMI ≥25 kg/m2 Metabolic syndrome **Excluded population/s:** With T2DM **Setting:** Primary care practices (2 urban, 2 rural, near Pittsburg).	available fat- and calorie-counting book, self-monitoring books for recording food intake and physical activity, a pedometer, and a chart for self-monitoring weight. All were asked to self-monitor their weight two times weekly , as well as food intake and physical activity levels daily. Feedback on progress was offered each week. In Phase 2 monthly support meetings were offered for a period of 9 months after completion of the intervention. **Joint aspects of DPP and GLB interventions.** Goal**:** 7% weight loss and increase physical activity to 150 minutes/week Safe and appropriate intervention that incorporates nutrition, physical activity, and behaviour change Intervention delivered by appropriately trained group Leader. Strong focus on use of self-monitoring tools with feedback. Use of problem-solving techniques to address barriers to healthy eating and physical activity. **Modifications from DPP** 12 weekly 1-hour sessions delivered over 12–15 weeks. Group classes. Primary focus on healthy food choices. Initial emphasis on fat intake and calories. Pedometer introduced during core sessions. Use of inexpensive food samples and incentives. Prevention training conducted by DPSC faculty via 2-day	who attended at least 50% of the intervention sessions and the follow-up assessment visits.	**Sample Characteristics:** Median age 58 years Phase 1 and Phase 2 respectively: Women/total group 42/51 (82%) 33/42 (79%) Nonwhite 14/51 (27%) 0/42 (0%) Age 52.9 (12.3) 57.2 (9.7) Age range 27-74 years 24-73 years Weight (pounds) 216.0 (42.3) 208.4 (37.2) Waist (inches) 43.2 (5.6) 41.2 (5.1) BMI 36.6 (7.4) 34.6 (5.4) Total cholesterol (mg/dL) 191.3 (31.4) 185.8 (30.0) HDLC (mg/dL) 41.6 (11.4) 44.4 (10.9) Non-HDLC (mg/dL) 149.7 (31.2) 142.4 (27.6) Blood glucose (mg/dL) 98.8 (17.9) 108.1 (12.2) Systolic blood pressure (mmHg) 125.4 (16.4) 122.8 (11.8) Diastolic blood pressure (mmHg) 79.1 (9.9) 79.0 (7.1) **Primary outcomes:** **Weight loss** Significant decreases in weight (-9.9 pounds, -4.9%, *p*<0.001); waist circumference (-1.7 inches, -4.2%, *p*<0.001); and BMI (-1.6 kg/m2, 4.9%, *p*<0.001) were also observed from baseline to post-intervention in the Phase-2 cohort (N=42). In addition, significant decreases in total cholesterol (-14.9 mg/dL, -7.6%, *p*=0.001); non-HDL cholesterol (-14.1 mg/dL, -9.4%, *p*=0.001); systolic blood pressure (-8.6 mmHg, -6.8%, *p*<0.001); and diastolic blood pressure (-3.1 mmHg, -3.7%, *p*=0.04) were noted. Using mixed models analysis, participant weight loss in the Phase-2 cohort was estimated at 1 pound per week (*p*<0.001) after adjusting for baseline weight and clinic. At 12 months, a significant decrease from baseline continued to be observed for all of the above noted measures, with the exception of total cholesterol (-6.6 mg/dL, -3.6%, *p*=0.09). In addition, a significant increase in HDL (+2.7 mg/dL, +6.1%, *p*=0.007) was noted. Weight loss per protocol at 3 (*n*=39); 6 (*n*=35); and 12 months (*n*=30) was significant, with an average decrease of 10.6 pounds (-5.1%, *p*<0.001); 12.5 pounds (-6.0%, *p*<0.001); and 11 pounds (-5.3%, *p*<0.001), respectively. Achievement of weight loss in both phases as well as the combined data following a per-protocol analysis (*n*-	

		workshop. Ongoing support for implementation provided by DPSC. **Data Collection and Outcomes** **Control**: **Baseline comparisons:** Two groups enrolled at the Diabetes Prevention Support Centre In addition, five University of Pittsburgh Medical Centre primary care practices also offered the intervention **Study sufficiently powered?** Based on previous local DPP weight-loss experience and using this variance estimate, it was estimated that for paired analysis 21 subjects were needed to detect a 7% weight loss with á =0.05 and 90% power.		67); 16 participants (23.8%) reached 7% weight loss at the 3-month post-intervention assessment, while 35 (52.2%) and 40 (59.7%) achieved 5% and 3.5%, respectively. No change was found in global CVD risk (mean pre-intervention 10-year risk=5.0% [SD=6.0%] vs 6.0% [SD=7.0%] post-intervention, *p*=0.70) during Phase 1. In Phase 2, there was a marginal reduction in the 10-year CVD risk after completion of the intervention (mean pre-intervention 10-year risk -3.0% [SD=3.0%] vs 2.0% [SD=3.0%] post-intervention, *p*=0.09). **Costs:** No formal cost evaluation was completed. Cost of Group Lifestyle Balance program delivery was calculated using program material expenses and a rate of $30/hour of prevention professional time (based on their report, each session required about 3 hours, including prep and class time). Cost for provision of healthy foods for taste testing and small incentives was also included. The cost of a 1-year program including 12 sessions and nine monthly follow-up meetings was calculated at approximately $300 per participant, with eight participants per group.	
Author: Kulzer **Year:** 2009 **Setting / country:** Germany **Aim of study:** To evaluate the efficacy of the group diabetes prevention programme PREDIAS **Study design:** **Funding:** Roche diagnostics,	**Source population/s:** **Eligible population:** 20-70 years BMI ≥ 26 kg/m2 IGT / IFG Ability to read and understand German **Selected population:** Diabetes Risk score 10 or risk assessment by physician **Excluded population/s:** T2DM Serious illness	**Method of allocation**: Block randomisation (1:1) **Intervention/s description: control/comparison/s description:** 12 lessons 90 minutes each. Eight core sessions in first 8 weeks then 4 bimonthly sessions. PREDIAS based on self-management theory, conducted in small groups (median 7 people). Delivery by psychologists or diabetes educators. Transparencies in sessions; written information. Table of caloric values and worksheets for each activity. **Control**: Written materials	**Primary outcomes:** BMI Weight Waist circumference **Secondary outcomes:** Fasting glucose A1c Lipids, BP, cholesterol **Measurement points:** Baseline 12 months **Methods of analysis:** Intention to treat paired t tests independent t tests	**Attrition details:** 17 lost to follow up **Sample Characteristics:** 182 participants Age mean 56.3 years (SD 10.1) 43% female Mean BMI 31.5 (SD 5.3) Mean fasting glucose 105.7 mg / dl (SD 12.8) No significant differences between groups **Primary outcomes:** **Changes at 12 months:** BMI Control -0.5 (SD 1.4) p=0.002 Intervention -1.3 (SD 1.7) p<0.001 Weight Control -1.4 kg (SD 4.0) p=0.002 Intervention -3.8 (SD 5.2) p<0.001 Waist circumference Control -0.4 (SD 6.2) p=0.559	**Limitations identified by author**: NR **Evidence gaps and/or recommendations for future research**:

Germany **Quality score: ++**	**Setting:** Primary care	**Baseline comparisons:** **Study sufficiently powered?** 73 participants per group needed to show weight reduction of 2.5 ± 4.6 kg and a power of 0.90 (two sided α = 0.50). Nonevaluable rate of maximum 20% a total of 182 in each group needed.		Intervention -4.1 (SD 6.0) p<0.001 Fasting glucose Control 1.8 (SD 13.1) p=0.211 Intervention -4.3 (SD 11.3) p=0.001) A1c Control 0.1 (SD 0.4) p=0.165 Intervention 0.0 (SD 0.3) p=0.203 Physical activity Control 17.9 (SD 63.8) p=0.035 Intervention 46.6 (SD 95.5) p<0.001 **Author Conclusions**: Significant effect of intervention on body weight BMI and waist circumference. Both groups increased physical activity but increase greater in intervention group. Significant effect of intervention on fasting glucose but not on OGTT and A1c.	
Author: Laatikainen **Year:** 2007 **Setting / country:** Australia **Aim of study:** To determine whether lifestyle modification programmes are feasible in primary health care. **Study design:** Pre-test post-test **Funding:** The Australian Government Department of Health and Ageing, Canberra,	**Source population/s:** Patients presenting at local General Practices. Opportunistic screening by study nurses in reception and waiting areas. **Eligible population:** The Diabetes Risk Score tool used to identify patients at high risk of type 2 diabetes. A score of 12 or more was used as a recruitment criterion. **Selected population:** **Excluded population/s:** Individuals with cancer, recent myocardial infarction or stroke, cognitive	**Method of allocation**: **Intervention/s description: control/comparison/s description:** Based on the diabetes prevention project in the Finnish GOAL study. Six structured 90 minute group sessions over eight months using the Health Action Process Approach. First five sessions occurred within first three months, with two week intervals between sessions. The last session took place at eight months. The sessions were facilitated by specially trained study nurses, dieticians and physiotherapists. A goal setting approach was used to motivate individuals to progress from intention to actual behaviour change. Regular self-assessment was used to empower participants to take responsibility for their own decisions and to make informed choices. Session	**Primary outcomes:** Weight BMI Waist circumference Blood Glucose measures **Secondary outcomes:** Lipids BP SF-36v2 Differences between completers and non-completers **Measurement points:** Baseline, 3 months and 12 months. **Methods of analysis:** SPSS Version 14. Paired t-tests to test differences between baseline and follow-up. Wilcoxon rank sum tests were performed for psychological tests. Effect sizes calculated for changes in psychological and general health	**Attrition details:** More than 1,500 people were approached, of whom approximately two thirds were willing to be screened. Of the 523 subjects whose score was ≥12, 343 subjects (65.6%) were willing to participate in the study. Those (n = 32) who were diagnosed with type 2 diabetes based on their baseline fasting plasma glucose value (≥7.0 mmol/l) and/or two-hour oral glucose tolerance test (>11.0 mmol/l) were excluded from the analyses . Of 311 who started in the intervention, 237 (65 males and 172 females) attended both the baseline and 12 month clinical tests and at least one group session. This was the definition of completion. Forty-three percent of completers participated in all six sessions and only 9.7% in three or less sessions. Reasons for non-completion were: Lack of transport, fuel costs, time constraints, poor literacy and health conditions. Compared with completers, non-completers had significantly higher waist circumferences, lower levels of education and higher scores on measures of psychological distress, anxiety and depression. In most domains of the SF- 36v2, non-completers reported poorer health. **Sample Characteristics:** 311 participants (88 males and 223 females) aged 40–	**Limitations identified by author**: NR

Australia. **Quality score: +**	impairment, substance abuse, pregnancy or a previous type 2 diabetes diagnosis. **Setting:** Greater Green Triangle of Southwest Victoria and Southeast South Australia in 2004–2006 using General Practices in Hamilton, Horsham and Mount Gambier	content for diet and physical activity was based on Dietary Guidelines for Australian Adults and National Physical Activity Guidelines for Adults. **Modifications from DPP Data Collection and Outcomes** **Control**: NA **Baseline comparisons:** Height, weight, waist, hip and blood pressure **Study sufficiently powered?** Sample size calculations to detect a 5% reduction in main outcome variables such as weight, serum cholesterol, blood glucose etc. with 80% power at the 5% significance level were carried out.	measures by dividing the change in means by the standard deviation of the baseline mean.	75 years were eligible to participate. Mean risk score for eligible participants = 15.7 Completers: Age (yr) 56.7 (8.7) Weight (kg) 91.7 (17.7) Body-mass index (kg/m2) 33.5 (5.9) Waist circumference (cm) 104.9 (13.0) Hip circumference (cm) 115.7 (12.5) Plasma glucose (mmol/l) Fasting 5.53 (0.54) 2 Hr oral glucose challenge 6.71 (1.68) Total cholesterol (mmol/l) 5.67 (1.15) Low-density lipoprotein cholesterol (mmol/l) 3.44 (0.99) Highdensity lipoprotein cholesterol(mmol/l) 1.34 (0.37) Triglycerides (mmol/l) 1.94 (1.05) Blood pressure (mm Hg) Systolic 132.1 (17.1) Diastolic 81.0 (9.9) HADS anxiety 3.6 (3.3) HADS depression 2.8 (2.9) Kessler 10 (psychological distress) 15.3 (5.4) SF-36 v2 Physical functioning 78.3 (18.6) Role limitation physical 78.6 (22.4) Bodily pain 63.0 (23.9) General health perception 65.9 (18.6) Vitality 56.4 (19.2) Social functioning 83.2 (20.3) Role limitation emotional 85.4 (21.0) Mental health 75.7 (17.0) Years of education 12.1 (3.4) Non-completers: Age (yr) 57.2 (9.5) p= 0.705 Weight (kg) 95.3 (19.6) p= 0.145 Body-mass index (kg/m2) 34.7 (6.9) p=0.144 Waist circumference (cm) 109.6 (14.9) p=0.009 Hip circumference (cm) 117.6 (13.9) p= 0.257 Plasma glucose (mmol/l) Fasting 5.46 (0.51) p=0.298 2 Hr oral glucose challenge 6.61 (1.72) p=0.644 Serum lipids (mmol/l) Total cholesterol 5.42 (0.98) p= 0.102 Low-density lipoprotein cholesterol 3.25 (0.80) p=0.097 Highdensity lipoprotein cholesterol1.26 (0.34) p=0.082 Triglycerides 2.02 (1.14) p=0.569 Blood pressure (mm Hg)	

				Systolic 135.0 (18.8) p=0.216 Diastolic 82.6 (11.7) p=0.265 HADS anxiety 5.4 (4.0) <0.0005 HADS depression 4.1 (3.9) p=0.014 Kessler 10 (psychological distress) 19.0 (8.0) <0.0005 SF-36 v2 Physical functioning 66.3 (26.3) p=0.001 Role limitation physical 67.3 (29.6) p=0.008 Bodily pain 57.8 (27.5) p=0.107 General health perception 61.0 (18.9) p=0.034 Vitality 50.1 (23.8) p=0.023 Social functioning 75.2 (27.3) p=0.055 Role limitation emotional 76.9 (27.3) p=0.026 Mental health 66.5 (20.5) <0.0005 Years of education 10.7 (3.1) p= 0.002 **Primary outcomes:** Between baseline and 12 months, statistically significant improvements were observed in mean clinical indicators except systolic blood pressure. Greatest improvement (8.6%) seen in plasma glucose after two hours oral glucose challenge. Total cholesterol decreased 5.1%, LDL cholesterol 7.3% and triglycerides 7.6%, whilst HDL cholesterol increased 4.4%. Waist, weight and diastolic blood pressure decreased 4.0%, 2.7% and 2.6%, respectively. 75% experienced some waist reduction and 68% experienced weight reduction. Statistically significant improvements to weight, waist, total and LDL-cholesterol evident at 3 months. These changes were sustained at 12 months. Although not observed at 3 months, statistically significant improvements were found in fasting glucose, HDL-cholesterol, triglycerides and diastolic blood pressure at 12 months. At baseline, 65.9% of participants had normal glucose values and 34.1% had impaired glucose values (IFG 9.5%, IGT 24.6%). At the 12 month clinical test, 78.0% had normal glucose values and 19.8% had impaired values (IFG 6.5%, IGT 13.4%). Out of 79 participants who had impaired values at baseline, five (2.2%) developed type 2 diabetes during the intervention and 42 (18.1%) reverted to normoglycemia. **Changes from baseline:** Weight (kg) Baseline 237 91.7 (17.7) 3 months -2.38 (-2.79,-1.98) 12 months -2.52 (-3.19,-1.85) Total 12 months -2.7	

				Body-mass index (kg/m2) 237 33.5 (5.9) 3 months -0.88 (-1.03,-0.74) 12 months -0.93 (-1.17,-0.69) Total 12 months -2.8 Waist circumference (cm) 236 104.9 (13.0) 3 months -3.16 (-3.72,-2.60) 12 months -4.17 (-4.87,-3.48) Total 12 months -4.0 Hip circumference (cm) 236 115.7 (12.5) -3 months 1.56 (-2.04,-1.07) 12 months -2.65 (-3.26,-2.05) Total 12 months -2.3 Plasma glucose (mmol/l) Fasting 237 5.53 (0.54) 3 months 0.00 (-0.07,0.08) 12 months -0.14 (-0.20,-0.07) Total 12 months -2.5 2 Hr oral glucose challenge 232 6.70 (1.69) 3 months – (NR) 12 months -0.58 (-0.79,-0.36) Total 12 months -8.6 Serum lipids (mmol/l) Total cholesterol 237 5.67 (1.15) 3 months -0.21 (-0.32,-0.09) 12 months -0.29 (-0.40,-0.18) Total 12 months -5.1 Low-density lipoprotein cholesterol 229 3.44 (0.99) 3 months -0.16 (-0.25,-0.07) 12 months -0.25 (-0.34,-0.16) Total 12 months -7.3 High-density lipoprotein cholesterol 237 1.34 (0.37) 3 months 0.01 (-0.02,0.03) 12 months 0.06 (0.03,0.09) Total 12 months +4.4 Triglycerides 237 1.90 (1.00) -0.10 (-0.20,0.01) 12 months -0.15 (-0.24,-0.05) Total 12 months -7.6 Blood pressure (mmHg) Systolic 236 132.1 (17.1) 3 months -1.67 (-3.3,-0.04) 12 months -1.01 (-2.60,0.58) Total 12 months -0.8 Diastolic 236 81.0 (9.9) 3 months -0.99 (-2.18,0.20) 12 months -2.14 (-3.33,-0.94) Total 12 months -2.6 **Costs:** NR	
Author: Mc Tigue KM., Conroy M B., Bigi L., Murphy C., Mc Neil M. **Year:** 2009a Weight Loss Through Living Well: Translating an Effective Lifestyle	**Source population/s:** Primary care records **Eligible population:** WiLLoW was made available to overweight or obese patients (BMI ≥ 25 kg / m^2) with or without diabetes.	**Method of allocation**: Voluntary enrolment / non-enrolment **Intervention/s description: control/comparison/s description:** 12-session, group-based version of the DPP lifestyle curriculum. Programme goals consistent with DPP: 7% weight loss and 150 minutes of moderate	**Primary outcomes:** Weight change **Secondary outcomes:** **Measurement points:** Baseline; 12 months **Methods of analysis:** T tests for weight change between the 2 groups. Analysis of covariance and linear regression with	**Uptake / Attrition details:** From March 8, 2005, to February 1, 2007, 166 patients referred to WiLLoW, and 49% enrolled. Of those referred, 12 were excluded. Of included patients, 93% of enrollees and 80% of non-enrollees had a follow-up weight recorded. **Sample Characteristics:** At baseline, those referred were aged 20 to 79 years, and enrolees were, on average, slightly older than non-enrolees (53.01 [SE, 1.34] versus 47.18 [SE, 1.46] years. Most referred patients were female (84%) and severely obese (66%). Sex, body weight distribution,	

Intervention Into Clinical Practice The Diabetes Educator 2009 35: 199 **Setting / country:** US **Aim of study:** To translate the Diabetes Prevention Program (DPP) lifestyle intervention into a clinical setting and evaluate its effectiveness. **Study design:** Controlled Cohort **Funding:** Division of General Internal Medicine, University of Pittsburgh. **Quality score: +**	**Selected population:** N = 155 (intervention n = 72; control n = 82) **Excluded population/s:** NR **Setting:** Primary Care	physical activity per week, with total fat reduction (to 25% of calories from fat) and calorie balance and restriction (with a goal of a 500- to 1000-calorie reduction diet). WiLLoW sessions led by a nurse educator. Each session included a discussion of a specific topic with opportunities to share personal experiences. Demonstrations (eg, healthy portion sizes, food labels). Behavioural techniques such as goal setting, self-monitoring, and problem solving. Monthly phase 2 sessions offered for those requiring further support. Weight monitored on a calibrated Detecto scale and recorded in the EMR, so physicians can monitor progress and provide support. **Control** Those who were referred to the programme but did not enrol. **Baseline comparisons:** Weight **Study sufficiently powered?**	follow-up weight as a predictor. Regression analyses adjusted for age and weighted by a value inversely proportional to the probability that an individual was in his or her actual group, adjusted for age. α^{2} for frequency of weight loss between groups .	and follow-up duration did not differ by enrolment status. **Primary outcomes:** Average of 357.81 (SD, 74.02) days of follow-up, mean weight change was –5.19 kg (CI, –7.71 to –2.68) among WiLLoW enrolees and +0.21 kg (CI, –1.50 to 1.93) among the non-enrolees with follow-up data ($P <$ .001). Effect size was similar when calculated using the age-adjusted analysis of covariance (–5.74 kg; CI, –8.82 to –2.66). Clinically significant weight loss (≥7%) was more common among enrolees (27%) than non-enrolees (6%) (α^{2} P = .001). Adjusted for age, enrolees had 4.38 times the odds of showing a clinically significant weight loss compared with non-enrolees (CI, 1.84 to 10.42). **Limitations:** Nonrandomized data may introduce bias. Cost of participating likely to have excluded those with lower socioeconomic status. Authors state that WiLLoW fees are lower than those of a local effective commercially available option ($100 vs $133 for 12 sessions). .	
Author: Mc Tigue KM., Conroy M B., Hess R., Bryce CL., Fiorillo AB., Fischer GS., Milas NC., Simkin-Silverman LR. **Year:** 2009b Using the internet to translate an evidence-based	**Source population/s:** From a single, academic general internal practice. **Eligible population:** Age 18–80, body mass index (BMI) ≥25 kg/m2, history of at least one weight-related cardiovascular risk factor (hypertension, dyslipidemia,	**Method of allocation**: **Intervention/s description: control/comparison/s description:** Baseline height, weight, and blood pressure measured. Pedometer and book detailing fat and calorie content of various foods to facilitate self-monitoring were provided. Five components accessed from a home page. Automated e-mail prompts reminded participants of pending lessons, and other tasks.	**Primary outcomes:** Change in body weight (kg). **Secondary outcomes:** Change in blood pressure and the frequency of clinically significant weight loss. **Measurement points:** Baseline and 12 months **Methods of analysis:** Descriptive statistics and	**Uptake / Attrition details:** 8% of participants' final log-in occurred within 45 days of enrolling, while 50% were still logging in at some time during the last 30 days of the 1-year evaluation period. Mean completion 12.80 (SD 7.29) lessons, with 44% completing 16 lessons and 16% completing more than 20 lessons. Among those who did not follow recommended lesson timeline, many worked through lessons at a slower rate over the year. 24% completed a lesson within the last 30 days of the program. On average, weight self-monitoring was recorded during 27.32 (SD 19.81) weeks over the year, with 40% of the sample reporting a weight in at least 40 weeks. Mean number of weeks in which fat	

lifestyle intervention into practice. Telemedicine and e-Health 15 (9); 851-858 **Setting / country:** US: Pittsburgh, Pensylvania **Aim of study:** To translate an evidence-based lifestyle programme into the clinical setting by adapting it for delivery via the Internet. **Study design:** **Funding:** Department of Defence [USAMRAA W81XWH-04-2-0030 Siminerio (PI)], through the University of Pittsburgh Diabetes Institute. **Quality score:**	diabetes, or impaired fasting glucose), and willingness to participate. Internet access via Microsoft Internet Explorer 6.0. Speakers or headphones that enable use of online audio files, and the ability to turn off system pop-up blockers. **Selected population:** Moderate physical activity was safe and medically appropriate, noting any specific health concerns that may influence lifestyle goals (e.g., diabetes, arthritis), and reporting any obesity-related comorbidities. **Excluded population/s:** If concern that moderate exercise was unsafe or inappropriate. Pregnancy. **Setting:** Internet based	Each 30–45-minute lesson was audio narrated and included an optional quiz. Sixteen weekly lessons comprised the core curriculum of the DPP Lifestyle Intervention, slightly modified for online delivery. They were followed by eight monthly lessons, adapted from relevant supplemental DPP materials. Coaches updated items and directed individuals as necessary. Other resources included links to Web-based information, such as recipes, materials from the Centers for Disease Control and Prevention, and locations of nearby farmers markets, parks, and trails. **Control** NA **Data Collection and Outcomes** Software generated quarterly progress reports including graphs of weight and behavioural progress. Coaches personalized reports with a brief update. Referring physicians could read the correspondence between patients and health coaches. Coaches could notify a practitioner if health concerns arose. **Baseline comparisons:** Major weight-related co-morbidities were assessed. Baseline blood pressure and weight were assessed at the orientation session. Follow-up measurements performed every 3 months (±2 weeks), by study staff, or during	estimated change in body weight at 12 months.	intake and physical activity were tracked was 17.62 (SD 17.60) and 14.52 (SD 17.28), respectively. **Sample Characteristics:** Mostly female. Age range 26–78 years. Mean BMI 36.43kg/m^2 (SD 6.78). Primarily white and non-smoking. Relatively well educated, though nearly one third reported difficulty paying for basics. Mean 1.74 (SD 0.80) weight-related cardiovascular risk factors, with total number of weight-related co-morbidities ranging from 1 to 5. Age 51.94 (10.82) Sex (% female) 38 (76) Race White 43 (86) African American 4 (8) Asian 2 (4) Other 1 (2) Ethnicity (% Hispanic) 0 (0) Education Some high school/GED 2 (4) Some college 14 (28) Completed college 9 (18) Graduate degree 25 (50) Ability to pay for basics Not at all hard 35 (70) Somewhat hard 13 (26) Very hard 2 (4) Currently smoking No 46 (92) Yes 2 (4) Not reported 2 (4) Baseline BMI (kg/m^2) Overweight (25.0–29.9 kg/m^2) 10 (20) Class 1 obesity (30.0–34.9 kg/m^2) 13 (26) Class 2 obesity (35.0–39.9 kg/m^2) 11 (22) Class 3 obesity (≥40 kg/m^2) 16 (32) Major weight-related co-morbidities Glucose intolerance 8 (16) Diabetes14 (28) Hypertension 32 (64)	

		routine medical care visits. Final evaluation between 50 and 56 weeks of follow-up. Participants completed an online survey with each outcome assessment. Software utilization data abstracted for 12-month evaluation. Information on the frequency of weight, dietary, and physical activity self-monitoring was evaluated across the same time frame. **Study sufficiently powered?**		**Primary outcomes:** At each follow-up visit, mean weight significantly lower than at baseline. Mean weight change among those who completed the 12-month weight evaluation (*n* = 45) was -4.79 kg (95% CI: -7.36 to -2.22); 31% of these had at least a 5% weight loss and 18% at least a 7% weight loss at the end of 1 year. A LOCF approach to self-reported data showed an effect size of -4.94 kg (95% CI: -7.39 to -2.48), with 30% and 18% having a ≥5% or ≥7% weight loss, respectively. Seven had medical conditions that potentially influenced weight change. Excluding these from the analyses did not change the overall findings (completers: -4.20 kg; 95% CI: -6.52 to -1.82; LOCF: -4.44 kg; 95% CI: -6.72 to -2.16). **Limitations:** The need for Internet access limits generalisability, especially for poor and minority populations. However, home access to the Internet is expanding rapidly, from 66% of the U.S. population in 2003 to 74.9% in 2004.	
Author: Saaristo **Year:** 2007 (Description) 2010 (Evaluation). **Setting / country:** Finland **Aim of study:** To investigate 1-year outcomes of a national diabetes prevention program. **Study design:** Pre-test post-test. **Funding:** Hospital districts of Pirkanmaa, Southern	**Source population/s:** 400 participating primary health care centres and occupational health care outpatient clinics. Age ≥ 18 years **Eligible population:** Opportunistic screening in primary health care centres and pharmacies and at public events. National advertising campaign. **Selected population:** Finnish Diabetes Risk Score (FINDRISC) scores	**Method of allocation**: NA **Intervention/s description: control/comparison/s description:** Either individual counselling visits or group sessions. Counselling based on DPS study and application of different stages of change. Focus of the visits was weight, meal frequency, fat intake, quality of fat, use of salt, fibre intake, use of alcohol, exercise, or smoking, based on individual preference. Group sessions varied from weight maintenance groups to exercise groups and lectures on diabetes and lifestyle changes. **Modifications from DPS**	**Primary outcomes:** Diabetes incidence Weight loss BMI Waist circumference **Secondary outcomes:** Lipids BP **Measurement points:** Baseline and 1 year (mean 14 months) **Methods of analysis:** Statistical analyses and data management were performed using SAS for Windows (version 9.2). association between incident diabetes and weight loss	**Attrition details:** 10,149 (3,379 men and 6,770 women) aged 18–87 years (53.6 ± 10.9 years fulfilling criteria were initially contacted. Of them, 8,353 had an oral glucose tolerance test (OGTT) at baseline and 5,523 had any follow-up data. One-year follow-up data available for 3,880 (70.3%) participants. Of these, 638 individuals did not have an OGTT at baseline. 444 had screening-detected diabetes at baseline and were excluded. 2,798 were non-diabetic at baseline and had 1-year follow-up data. 50% of the total cohort had any follow-up data. First loss to follow-up after screening; only 78% of the screened high-risk subjects had an OGTT. Second loss to follow-up after the OGTT; 69% who had an OGTT at baseline had any follow-up data. Altogether 70% of the cohort participating in follow-up had 1-year follow-up data available. **Sample Characteristics:** Men (n=919) Age 56.0 ± 9.9 years	**Limitations identified by author**: Attrition rate high.

Ostrobothnia, Northern Ostrobothnia, Central Finland, and Northern Savo, the Finnish National Public Health Institute, the Finnish Diabetes Association, the Ministry of Social Affairs and Health in Finland, Finland's Slottery Machine Association, the Academy of Finland (grant 129293), and the Commission of the European Communities, Directorate C-Public Health (grant agreement 2004310) in cooperation with the FIN-D2D Study Group and the Steering Committee **Quality score: +**	≥15. History of impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), an ischemic cardiovascular disease event, or gestational diabetes mellitus. **Excluded population/s:** Those with FINDRISC score < 15 **Setting:** Health care settings, and others such as pharmacies, weightwatchers etc.	Frequency of intervention visits varied among health centres, depending on local circumstances and resources. Default model for life-style interventions in FIN-D2D was group intervention 4 to 8 times during the course of the programme, either once a week or every other week, with a follow-up session one month after the final intervention session. Planning of programme to meet with patient empowerment principles. **Data Collection and Outcomes** **Control**: NA **Baseline comparisons:** Baseline visits 17 January 2004 and 28 August 2007. The 1-year visits between 17 January 2005 and 12 June 2008. Time window for 1-year visits was 9–18 months after the baseline visits. Mean follow-up time 14 months. In the primary health care setting, evaluation of risk factors and glucose tolerance, interventions, and follow-up took place as part of standard care. Measurements were done by local nurses. Glucose tolerance was classified according to the World Health Organization 1999 criteria. **Study sufficiently powered?** NA		Mean FINDRISC score (n-536) 16.6 ± 3.7 Weight (kg) 95.8 ± 15.9 BMI (kg/m^2) 30.9 ± 4.6 Waist (cm) 107.3 ± 11.4 Women (n = 1,879) Age 54.0 ± 10.7 years Mean FINDRISC score (n = 1,259) 17.2 ± 3.0 Weight (kg) 83.8 ± 15.4 BMI (kg/m^2) 31.6 ± 5.4 Waist (cm) 99.4 ± 12.4 **Primary outcomes:** **Change from baseline to one year:** Men (n=919) Weight (kg) -1.2 ± 5.3 BMI (kg/m^2) -0.4 ± 1.5 Waist (cm) -1.3 ± 4.9 (all p< 0.0001) Women (n = 1,879) Weight (kg) -1.1± 5.8 BMI (kg/m^2) -0.4 ± 2.1 Waist (cm) -1.3 ± 5.9 (all p< 0.0001) **Diabetes incidence** Incidence of diabetes during a mean follow-up of 14 months was 2.0% among men (*n* = 299) and 1.2% among women (*n* = 865) with normal glucose tolerance. Diabetes developed in 13.5% of men (*n* = 230) and in 7.4% of women (*n* = 272) who had IFG at baseline. Incidence of diabetes was higher in men (16.1%, *n* = 254) and in women (11.3%, *n* = 435) who had IGT at baseline. Abnormal glucose homeostasis increased the risk of diabetes by six- to nine-fold in these participants compared with those with normal glucose homeostasis at baseline. The relationship between weight loss and incidence of diabetes was almost stepwise. The relative risk of diabetes was 0.31 (95% CI 0.16–0.59), translating to 69% risk reduction in the group who lost ≥5% weight compared with the group who maintained weight. Relative risk was 0.72 (0.46–1.13; risk reduction of 29%) in the group who lost 2.5–4.9% weight and 1.10 (95% CI 0.77–1.58; risk increase 10%) in the group who gained 2.5% compared with the group who	

				maintained weight. 17.5% lost ≥5% weight. On average this equates to an 8.5-kg reduction in weight and a 6.6-cm reduction in waist circumference. During the follow-up, 16.8% lost 2.5–4.9% weight and 46.1% maintained weight. 19.6% gained ≥2.5% weight. Men were as successful as women in losing weight. **Intervention visits** Participants had a mean 2.9 intervention visits at 1-year follow up. Proportions of those who had three or more, two, and one intervention visit were 29.1, 12.9, and 26.1%, respectively. Those who had three or more visits were more obese at baseline than those who had only two or one or no intervention visits (BMI 32.6 ± 5.6, 31.3 ± 5.1, 30.7 ± 4.8, and 30.9 ± 5.0 kg/m^2, respectively, $P < 0.05$). Age and the proportion of men did not differ between the groups with different numbers of intervention visits. The group who lost ≥5% weight had a mean 3.5 intervention visits, whereas those who maintained weight had 2.9 intervention visits during the follow-up ($P < 0.001$). Mean number of intervention visits did not differ between the group who lost 2.5–4.9% weight and the group who gained ≥2.5% weight compared with the group who maintained weight (3.0 and 2.5 vs. 2.9, respectively). Altogether 32.0% had no recorded intervention visits. Among participants who had intervention visits, 51% had individual counselling visits only, 13% attended group sessions only, and 10% participated both in individual and group visits. The type of visits was not recorded in 26% of individuals who had intervention visits. **Costs:** NR	
Author: Seidel MC., Powell RO., Zgibor JC., Siminerio LM., Piatt GA. **Year:** 2008 Translating the Diabetes Prevention	**Source population/s:** 11 urban medically underserved neighbourhoods. **Eligible population:** Participants with a BMI ≥25 kg/m^2, physician consent to	**Method of allocation**: **Intervention/s description: control/comparison/s description:** Phase II: modified GLB intervention. Adaptation of the DPP lifestyle programme to group based. 16 sessions to 12 sessions while	**Primary outcomes:** 1) 5% or 7% weight loss from baseline to 3- and 6-month follow- up. 2) Improvement of at least one metabolic syndrome component from baseline to 3- and 6-month follow up.	**Uptake / Attrition details:** Phase One: 573 attended one of 35 screenings during 2005–2006. 69 provided 3-month data, yielding a response rate of 78.4%. 50 participants provided 6-month data, with a response rate of 56.8%. Those who did not complete the intervention were significantly older, and a greater proportion non-Caucasian in comparison to those who completed the intervention. There was no difference in education level between groups.	

Program Into an Urban Medically Underserved Community A nonrandomized prospective intervention study. *Diabetes Care* 31:684–689 **Setting / country:** US: Near Pittsburgh, Pennsylvania. **Aim of study:** To determine if a community-based modified Diabetes Prevention Program Group Lifestyle Balance (GLB) intervention, for individuals with metabolic syndrome, was effective in decreasing risk for type 2 diabetes and cardiovascular disease (CVD) in an urban medically underserved community, and subsequently to determine whether improvements in clinical outcomes could be sustained in the	exercise, and at least 3/5 metabolic syndrome components as defined by the National Cholesterol Education Program's Adult Treatment Panel III. **Selected population:** Former hub of the steel industry that experienced industrial downsizing in the 1980s. This led to increased unemployment and out-migration of the young and affluent, resulting in a predominately older socioeconomically depressed population with a high prevalence of chronic disease. African Americans 36% of the community compared with 13.1% in Allegheny county and 10.6% in Pennsylvania (U.S. Census Bureau, 2000 Census). Carried out in two phases: phase I, community-based screening to determine GLB intervention eligibility, and phase II, provision of the GLB intervention with 3- and 6-month re-assessments.	maintaining key concepts. As in DPP, goals of the GLB were to achieve and maintain a 7% weight loss and to progressively increase physical activity to 150 min/ week of moderately intense physical activity. **Modifications to the DPP:** 12 weekly sessions over 12–14 weeks, group classes, healthy food choices, emphasis on fat intake and calories, and more emphasis on pedometer. Two trained "preventionists" (one dietician and one exercise specialist) responsible for delivery, which took place in the 11 targeted neighbourhoods and was held weekly for 12 weeks and lasted around 90 minutes. Group size ranged from 5 to 13 participants. Providers attended a 2-day training workshop, delivered by the original DPP lifestyle team. Each participant received a copy of the GLB handouts, a fat and calorie counter, self-monitoring books for keeping track of food and physical activity, a pedometer, measuring cups and spoons, a chart for recording weekly weights, and a free 6-month membership to the local YMCA. All were asked to self-monitor food intake and physical activity throughout the 12-week intervention and were given feedback concerning progress. **Data Collection and Outcomes**	**Secondary outcomes:** Improvements in triglycerides, abdominal obesity, hypertension status, HDL cholesterol, and glucose levels. **Measurement points:** 3 months and 6 months **Methods of analysis:** All conducted at the individual level. Not "intent to treat," since not an RCT. Last response- carried-forward imputation conducted to estimate the impact of attrition on the results. Student's *t* tests and Pearson α2 tests used to determine differences between the GLB intervention population and the screening population. McNemar's test for discrete data were used to determine differences between baseline and 3- and 6-month re-assessment in the intervention population. α2 test for trend used to determine unadjusted trends over time. P values <0.1 were used to determine trends in the data. *P* <0.05 were considered statistically significant. SAS version 8.2 (SAS Institute, Cary, NC).	**Sample Characteristics:** 185 eligible participants. Of these, 88 enrolled to the intervention. Mean Age 54.0 years. Female = 84.1% Non-Hispanic white = 72.7% 77.4% had high school education 71.1% had a family history of diabetes. Nearly 60% of households had an annual income below 200% of the poverty level (<$41,300 for a family of four). Sixty-nine percent of subjects attended at least 75% of classes. No statistically significant differences apparent (age: GLB [54.0±10.5 years] vs. screening [53.7 ±15.6], *P* = 0.86; sex: GLB [% female: 84.1] vs. screening [75.2], *P* = 0.07; race: GLB [% non-Hispanic white: 72.7] vs. screening [72.3], *P* = 0.93). Abdominal obesity the most prevalent metabolic syndrome component at baseline (93.2%), followed by abnormal HDL cholesterol (84.1%), hypertension (68.2%), high triglyceride levels (47.7%), and increased glucose (40.9%). **Primary outcomes:** **Weight loss** In participants who provided data at 3 months, 46.4% (32) lost at least 5% of their body weight, whereas 26.1% (18) lost at least 7%. 87.5% (28) and 66.7% (12) of these sustained the 5% and 7% reduction, respectively, at 6-months. The proportion with abdominal obesity decreased significantly over time (baseline: 90% [45]; 3months: 82% [41]; 6 months: 68% [34]; P = 0.006). This significant reduction remained despite adjustment for age, sex, race, and the number of intervention classes attended (adjusted *P* =0.009). **Blood Glucose** The proportion with glucose ≥100 mg/dl increased over time (baseline: 42% [21]; 3 months: 51% [25]; 6 months: 61.2% [30], P = 0.06, adjusted P = 0.01)	

short term. **Study design:** Nonrandomized prospective one-group. **Funding:** U.S. Air Force, administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick, MD (award number W81XWH-04-2-003) **Quality score:**	**Excluded population/s:** Diagnosis of diabetes or a having current prescription for glucose-lowering medication. Pregnancy. Unable to walk a quarter of a mile without stopping. History of bariatric surgery. Currently using weight-loss medications. Unable to provide informed consent. **Setting:**	**Control**: **Baseline comparisons:** Height, weight, waist circumference, blood pressure. Blood samples following an 8-hour fast to determine glucose, triglycerides, and HDL cholesterol levels. **Study sufficiently powered?** The study was underpowered to detect significant differences in primary and secondary outcomes due to the small sample size. Initial sample size calculations estimated that 190 subjects would provide sufficient power to demonstrate valid changes in the proportion of subjects who decrease at least one parameter of metabolic syndrome.			
Author: Vadheim **Year:** 2010 **Setting / country:** Montana, US **Aim of study:** To assess the feasibility of delivering an adapted group-based version of the Diabetes Prevention Program's (DPP) lifestyle intervention through telehealth video conferencing.	**Source population/s:** Through general practices and newspaper advertisements. **Eligible population:** Medical clearance from primary care provider, 18 years or older, ready to make changes in their diet and physical activity level, overweight (body mass index [BMI] ≥25 kg/m^2), and possessed 1 or more risk factors for diabetes or cardiovascular disease (a previous diagnosis of pre-	**Method of allocation**: NR **Intervention/s description: control/comparison/s description:** Delivered by 2 lifestyle coaches (0.5 full-time equivalent each) who were staff members of American Diabetes Association (ADA) recognized diabetes self-management education programme. One paid support staff at the on-site facility (0.25 full-time equivalent). One lifestyle coach was a registered dietician and certified diabetes educator. Another lifestyle coach had training in the exercise sciences. Tele-health site coordinated by	**Primary outcomes:** Goal attainment **Secondary outcomes:** Weight BMI Lipids **Measurement points:** Baseline and following 16 week protocol. **Methods of analysis:** Statistical Analysis Software Version 9 (Cary, NC). Paired *t* tests used to assess weight loss from initial weight to final weight at the end of the 16-week protocol, as well as the change in BMI. Chi-squared statistics	**Attrition details:** NR **Sample Characteristics:** 13 and 16 eligible adults enrolled in the onsite and the telehealth program, and 13 (100%) and 14 (88%) participants completed the 16-week program. <u>Telehealth Group (N = 14)</u> Mean Age 50 (SD 7) Mean BMI (kg/m2) 38.7 (SD 8) Female 93 (13%) History of GDM 7 (1%) History of baby >9 lbs 36 (5%) Prediabetes, IFG, IGT 50 (7%) Diagnosed hypertension 71 (10%) Triglycerides >150 mg/dL 29 (4%) Low HDL 21 (4%) Elevated LDL 29 (4%) Elevated total cholesterol 36 (5%) <u>On-site Group (N = 13)</u> Mean Age 53 (SD 14) p = .44	**Notes:** Participants agreed to and signed a contract specifying what their personal responsibilities were and what they would receive from the lifestyle coaches and the program. Participants were also required to pay $150 to participate in the program, which was paid by the participant, their employer, or through a scholarship made available for anyone unable to pay. **Limitations identified by author**: Self-reported physical activity and diet measures. Sample size for both groups was too small to detect a

Study design: Non-randomised feasibility controlled trial **Funding:** Montana State Legislature, supported through a cooperative agreement with the Centres for Disease Control and Prevention (CDC), Division of Diabetes Translation (U32/CCU822743-05) in Atlanta, Georgia. **Quality score: +**	diabetes, impaired glucose tolerance or impaired fasting glucose, high blood pressure (≥130/85 mm Hg or treatment) or dyslipidemia (triglycerides >150 mg/dL, low-density lipoprotein cholesterol >130 mg/dL or treatment, or high-density lipoprotein [HDL] cholesterol <40 mg/dL for men and <50 mg/dL for women), a history of gestational diabetes (GDM), or having given birth to an infant of greater than 9 pounds (4.1 kg). **Selected population:** **Excluded population/s:** Pregnant or planning to become pregnant in the next 6 months. **Setting:** On-site group intervention delivered at Holy Rosary Healthcare, located in Custer County in south-eastern Montana. Custer County is designated as a frontier County (less than 6 people per square mile), with a 2000 census population of 11 696.	a health care professional (0.05 FTE) from the local medical facility. **Modifications from DPP** Adapted version of the DPP developed by the Healthy Native Community Partnership designed for group delivery. Lifestyle coaches were trained by individuals with experience in the original DPP trial at a 2-day training covering the DPP background, core and after-core protocol, and standardized procedures for collecting anthropometric measures. The coaches taught the 16 weekly core protocol sessions and the 6 monthly after-core sessions. Goals of the intervention were the same as the DPP (7% weight loss and moderately intense physical activity for ≥150 minutes per week). Each session was approximately 1 hour in length. The telehealth group simultaneously participated in weekly and monthly sessions via telehealth video conferencing. Each participant was provided With a manual covering each of the 16 weekly sessions, a log book to track daily fat and caloric intake and physical activity minutes, and a book that helps participants estimate the fat and caloric content of specific foods. 2 to 4 weekly supervised physical activity sessions were organised for the on-site participants. Weight was measured each week by the lifestyle coaches	used to compare weight loss and physical activity goal achievement, as well as intake demographic characteristics and risk factors for cardiovascular disease and diabetes. *T* tests used to compare age and BMI at intake between groups	Mean BMI (kg/m2) 34.0 (SD 7) .11 Female 69 (9%) p =.11 History of GDM 8 (1%) p =.96 History of baby >9 lbs 31 (4%) p = .79 Prediabetes, IFG, IGT 15 (2%) p =.06 Diagnosed hypertension 23 (3%) p = 01 Triglycerides >150 mg/dL 33 (4%) p =.79 Low HDL 55 (6%) p =.09 Elevated LDL 17 (2%) p =.47 Elevated total cholesterol 30 (3%) p = .77 The majority of participants in both groups were female. Both groups had multiple cardiometabolic risk factors. Participants in the telehealth group had a significantly higher prevalence of glycemic abnormalities and hypertension at baseline compared with participants in the on-site group. No statistically significant differences in the mean number of weeks of participation in the 16-week core protocol between the on-site group (mean = 14.2 weeks [SD 2.1]) and the telehealth group (mean = 14.7 weeks [SD 2.5], *P* = .53). **Primary outcomes:** <u>Goal achievement</u> Telehealth Group (N = 14) Met fat goal 38 (5%) Met 7% weight loss goal 50 (7%) Physical activity and weight loss Weekly physical activity minutes Mean achieved 197 (SD103) Mean Weight loss (kg) 6.7 (SD 3.7) Mean Reduction in BMI (kg/m2) 2.7 (SD 1.3) On-site Group (N = 13) Met fat goal 54 (7%) p= .49 Met 7% weight loss goal 46 (6%) p= .84 Physical activity and weight loss Mean Weekly physical activity minutes achieved 243 (SD 146) p=.37 Mean Weight loss (kg) 6.5 (SD 3.1) p=.85 Mean Reduction in BMI (kg/m2) 2.5 (SD 1.0) p=.62 No significant differences in the achievement of the weekly fat goals or the physical activity minutes per	significant clinical change from baseline. A qualitative evaluation to assess participant satisfaction with the program and to assess the delivery of the program through video conferencing was only completed by a subgroup of participants from the on-site and telehealth groups. **Suggestions for further Research**: An additional potential strategy to increase access to the DPP lifestyle intervention could include providing the protocol in an online format. McTigue and colleagues have pilot tested this approach by adapting the DPP protocol for Internet delivery.

	Telehealth site located in Baker, Montana (79 miles from Miles City), at the Fallon Medical Complex also in south-eastern Montana. Baker is located in Fallon County, with a 2000 census population of 2837.	and the telehealth coordinator. **Data Collection and Outcomes** **Control**: On-site intervention **Baseline comparisons:** Mean Age Mean BMI (kg/m2) Gender History of GDM History of baby >9 lbs Prediabetes, IFG, IGT Diagnosed hypertension Triglycerides >150 mg/dL Low HDL Elevated LDL Elevated total cholesterol **Study sufficiently powered?** Small sample		week between these groups. More than 40% of the on-site and telehealth group participants achieved the 7% weight loss goal, and the overall mean weight loss in both groups was greater than 6.4 kg. **Costs:** Average cost per participant enrolled in the on-site group was approximately $560.17 The addition of the telehealth participants reduced the average cost per enrolled participant to approximately $470.	

Reviewing mechanisms of successful interventions and evidence from studies that translate major trial evidence in practice.