



Public Health  
England

Protecting and improving the nation's health

# **A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice**

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## Conflicts of interest

Melanie Davies, Kamlesh Khunti, Thomas Yates, Nuzhat Ashra and Laura Gray are authors of the Let's Prevent and Walking Away studies.

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# Executive summary

## Introduction

This review updated and extended a previously conducted systematic review and meta-analysis which assessed the effectiveness of 'real-world' interventions for the prevention of type 2 diabetes mellitus (T2DM) in high risk populations. This was achieved through the following research questions:

1. What is the effectiveness of diabetes prevention programmes on delaying the onset and reducing the incidence of T2DM and reducing weight and glucose in high risk populations in practice?
2. In which population groups are the models identified the most effective – age, gender, BMI and ethnicity?
3. What are the key identifiable elements across the most efficacious interventions that constitute a successful programme?

## Methods

We updated the review by Dunkley et al. Further studies, published after July 2012 were identified via electronic searches of online published databases EMBASE, MEDLINE and The Cochrane Library. In addition, unpublished grey literature was considered for inclusion utilising the search engine Open Grey. We also contacted international and UK based experts within the field of diabetes prevention to collect previously unpublished data from both newly completed research projects and from the evaluation of programmes that are currently active in England. Experimental and observational studies which considered the effectiveness of a lifestyle intervention, whether diet or physical activity alone or in combination, and whether standalone or compared to a control group; where the stated aim of the intervention was diabetes risk reduction or prevention of T2DM were included in the systematic review. In addition included studies all had a primary focus of translating evidence from previous diabetes efficacy trials into routine healthcare, or a community setting. For studies to be eligible for inclusion, they included adults (>18 years old) identified as being at high risk of developing T2DM (for example, obese, sedentary lifestyle, family history of diabetes, older age, metabolic syndrome, impaired glucose regulation, pre-diabetes, or elevated diabetes risk score); had a minimum follow-up of 12 months; and reported one of the outcomes of interest. The primary endpoint examined was incidence of T2DM at the latest time point at which it was reported in the study. Secondary endpoints assessed weight, HbA1c levels, fasting glucose and 2-hour glucose changes from baseline to between 12 to 18 months follow-up.

Data was pooled using random effects models to take into account heterogeneity. Data was pooled in two ways:

- to assess if diabetes prevention programmes work, the data from intervention arms from RCTs and non-RCTs was pooled
- to assess the added benefit of diabetes prevention programmes over usual care, the data comparing the intervention arms to control from the RCTs only was assessed.

To assess in whom the programmes work best and which programme elements are associated with success, we conducted a number of meta regression and subgroup analyses. These analyses were conducted in the RCTs only, and assessed the difference between intervention and control.

## Results

Data from 36 studies was included in this review. A total of 16 studies (18 intervention arms) reported incidence of T2DM. Of these 16 studies, 11 were RCTs consisting of 13 intervention vs. control comparisons. Weight change data at 12 to 18 months follow up was available for 35/36 studies (38 study arms, 20 were RCT intervention arms). Fasting glucose was reported across 24 studies (27 intervention arms), of which 14 studies (16 intervention arms) were RCTs. A total of 14 studies (15 intervention arms) reported changes in 2-hour glucose outcomes at 12-18 months follow up. Ten of the 15 intervention arms were from RCTs. HbA1c levels were available for ten studies (11 intervention arms), of which nine were RCT intervention arms.

The incidence of T2DM was 75 cases per 1000 person years across all intervention arms. The pooled incidence rate of T2DM was 26% (95% Confidence Interval (CI): 7% to 42%) lower in those receiving a diabetes prevention programme compared with usual care. Attending a diabetes prevention programme corresponded to an overall 2.46kg mean weight loss at 12 to 18 months follow up. When compared with usual care the pooled mean weight loss was 1.57kg higher in those who received the intervention. The pooled reduction in fasting glucose was 0.09mmol/l across all arms. When compared with usual care there was a 0.06mmol/l greater reduction in fasting glucose; this was not statistically significant. The pooled reduction in 2-hour glucose was 0.38mmol/l. Across RCTs, the pooled reduction in 2-hour glucose was 0.28mmol/l in intervention arms when compared to control arms across RCTs. However this was not a significant reduction. The pooled reduction in HbA1c was 0.07 percentage-points. When comparing attending a diabetes prevention programme with usual care, an overall reduction in HbA1c of 0.04 percentage-points was seen.

The mean age of participants at baseline or varying age inclusion criteria across studies was not significantly associated with incidence of T2DM, weight change or glucose outcomes. A one percentage-point increase in baseline percentage of males was found to be associated with a 3% higher incidence rate of T2DM and a borderline significant 0.05kg weight gain across intervention arms when compared with control arms. Studies which utilised BMI inclusion

criteria of  $\geq 25\text{kg/m}^2$  were associated with an additional 51% reduction in T2DM incidence and 3.07kg weight loss in prevention programme arms when compared with control arms, than studies which used no BMI inclusion criteria. The mean percentage of non-Caucasian participants at baseline or varying ethnic make-up of study participants was not significantly associated with incidence of T2DM, weight change or glucose outcomes. Some subgroups contained very few studies, so caution in interpretation is advised.

Intervention content was coded in relation to the recommendations for lifestyle interventions for the prevention of diabetes provided by both the IMAGE project (Development and Implementation of a European Guideline and Training Standards for Diabetes prevention) and NICE. A one-point increase in NICE score resulted in a larger intervention effect on weight loss (-0.47kg) and decrease in fasting glucose levels (-0.03mmol/l), when compared with control arms. Adhering to 9 to 12 NICE guidelines resulted in an additional 3.24kg weight loss and 0.17mmol/l reduction in fasting glucose in intervention arms compared to usual care, than adhering to 5 to 8 guidelines. A one-point increase in IMAGE score resulted in a larger intervention effect on weight loss (-1.04kg) when compared to control arms. Scoring an IMAGE score of 5 to 6 also resulted in an added weight loss of 3.36kg in intervention arms in comparison with usual care than a score of up to 2 points.

Utilising a combined diet and PA intervention was associated with greater weight loss of 1.93kg in intervention arms when compared with usual care, than using a PA only intervention. Spreading programme sessions across 9 to 18 months resulted in a 47% greater reduction in T2DM incidence rate in intervention arms than usual care, whilst not spreading the intervention across the same time-frame resulted in 2.32kg greater weight loss in intervention arms compared to usual care. Sessions of 1-2 hours in length resulted in an extra 2.20kg of weight loss in intervention arms compared to control arms, than using a session length of less than an hour. Offering 13 or more contacts over the first 18 months was associated with a 3.15kg greater weight loss in intervention arms compared to control arms, than offering less than eight contacts. A one-hour increase in contact time corresponded to a 0.1kg greater weight loss in intervention arms compared to usual care. Providing 16 or more hours of contact time resulted in an additional 3.38kg weight loss and 0.18mmol/l decrease in fasting glucose in intervention arms. Studies offering only one contact produced a 0.02kg weight gain in intervention arms compared to usual care than providing weekly contacts. Providing bi-monthly contacts resulted in a smaller weight loss of 0.41kg and an increase in fasting glucose of 0.03mmol/l in intervention arms compared to usual care than weekly contact.

Incorporating three or more behaviour change techniques into the prevention programme resulted in smaller reductions in 2-hour glucose in intervention arms (-0.15mmol/l) than using fewer than three techniques (-1.17mmol/l). Similarly use of self-regulatory techniques was associated with a smaller reduction in 2-hour glucose (-0.15mmol/l) in intervention arms when compared to usual care than not using such methods (-1.17mmol/l). Use of empathy building approaches was associated with a smaller weight loss (-0.80kg) and 2-hour glucose reduction (-0.03mmol/l) in prevention programme arms than not using these techniques (-2.73kg and -

0.77mmol/l respectively). Encouraging engagement of social support outside of intervention groups resulted in an additional 0.25mmol/l decrease in fasting glucose in intervention arms compared to control arms.

RCT studies conducted outside of the UK reported 2.15kg greater weight loss as a result of intervention in comparison to usual care than those conducted in the UK (-0.21kg). Private intervention delivery corresponded to 5.50kg greater weight loss in intervention programme arms compared to control arms than primary care delivery. A group size of between 10 to 15 produced an additional 3.80kg weight loss in prevention programme arms compared to standard care than group sizes of less than ten (-0.71kg). Offering optional supervised PA sessions as part of the intervention produced a 1.17mmol/l greater decrease in 2-hour glucose in intervention arms compared to usual care than making PA recommendations alone. Use of calorie restriction targets produced a greater 3.92kg weight loss in intervention arms compared to usual care. Use of a risk score to identify individuals at high risk of T2DM was associated with a 39% increased incidence rate of T2DM in intervention arms in comparison to usual care, than using a glucose test. A one mmol/l increase in participant baseline fasting glucose resulted in a substantial 79% decrease in T2DM incidence rate in intervention arms when compared to control arms. Using an evidence base different to the major prevention programmes (DPS or DPP) resulted in smaller added weight loss in intervention arms (-0.24kg) when compared to using the DPP as the sole evidence base (-3.10kg).

## Conclusions

Our review supports previous research, demonstrating that diabetes prevention programmes can significantly reduce the progression to T2DM and lead to reductions in weight and glucose compared with usual care. Those developing prevention programmes should adhere to the NICE and/or IMAGE guidelines to increase efficacy.

## Introduction

A major drive towards diabetes prevention in the UK is paramount. With obesity and physical inactivity continuing to rise across the country and an estimated 62% of adults now overweight or obese, increases in diagnoses of type 2 diabetes mellitus (T2DM) and associated co-morbidities seem more likely than ever before. It is estimated that the cost of diabetes to the NHS is close to £10 billion each year, and the majority of this is due to preventable complications associated with diabetes.<sup>1</sup> As trends continue in an upward trajectory, with one in three adults expected to be obese by 2034 and one in ten adults diagnosed with T2DM, prevention is certainly better than cure and may be more easily implemented.<sup>2</sup> Large randomised controlled trials (RCTs) and systematic reviews have shown that modest changes in diet and physical activity (PA) levels can reduce incidence of T2DM by more than 50% for individuals with pre-diabetes.<sup>3</sup> Pre-diabetes is an umbrella term for impaired fasting glycaemia (IFG) and impaired glucose tolerance (IGT), a condition which is not diagnosed as T2DM but is also not considered to represent normal glucose regulation.<sup>4</sup> The condition, nevertheless, confers an increased risk of developing diabetes which is highly reversible via weight loss and an increase in PA levels.<sup>5,6</sup>

Although large-scale diabetes prevention programmes (DPP) have been implemented across the globe, most significantly the US DPP, Finnish diabetes prevention study (DPS), Chinese Da Qing Study as well as the Indian DPP, translating such costly interventions into routine practice remains a challenge.<sup>7-10</sup> Still, increasing attempts have been made to tailor these interventions for use in community or 'real-world' settings with the aim of achieving pragmatic delivery of intervention whilst retaining a measurable degree of effectiveness.<sup>4</sup> To date, systematic reviews of prevention programmes have been conducted, yet they have not been as far-reaching as hoped. Several reviews did not include a meta-analysis,<sup>6,11-15</sup> whilst others did not focus on translational interventions.<sup>6,12,13,16-18</sup> More comprehensive reviews and meta-analyses conducted in 2010 and 2012 focused on translation, however the former focussed on interventions delivered only in health-care settings, excluding 15 studies as a result, whilst the latter concentrated on implementation of the US DPP in routine practice.<sup>19,20</sup>

A recent systematic review and meta-analysis conducted by Dunkley et al was comprehensive in its consideration of studies across different countries and settings.<sup>21</sup> However, for an effective national diabetes prevention service to be implemented in England, a wider search including previously unpublished studies, as well as ongoing prevention programmes is required, in order to fully assess the variation in effectiveness between interventions. It is accepted that low intensity interventions encourage reduced levels of weight loss than their more intensive counterparts.<sup>19</sup> However, it is important to identify the components of lifestyle interventions that correspond to increased effectiveness, in order to implement the most efficient and cost-effective diabetes prevention programme.

## Aim

The objective is to update and extend a previously conducted systematic review and meta-analysis assessing the effectiveness of 'real-world' interventions for the prevention of T2DM in high risk populations.<sup>21</sup>

This will be achieved through answering the following research questions:

1. What is the effectiveness of diabetes prevention programmes on delaying the onset and reducing the incidence of type 2 diabetes and reducing weight and glucose in high risk populations in practice?
2. In which population groups are the models identified the most effective – age, gender, body mass index (BMI) and ethnicity?
3. What are the key identifiable elements across the most efficacious interventions that constitute a successful programme?

## Methods

### Search strategy

As the search of databases sought to identify additional studies for inclusion in an existing systematic review, all searches were restricted to articles published after the end of July 2012, as articles from January 1998 up to this time point have been previously identified by Dunkley et al.<sup>21</sup> Studies included in the previous systematic review were restricted to those published after January 1998 to aid identification of studies which were informed by or translating evidence from previous diabetes prevention efficacy trials.<sup>7,8,10,22</sup> Further studies, published after July 2012, which were eligible for inclusion in the updated review, were identified via electronic searches of online published databases EMBASE, MEDLINE and The Cochrane Library. In addition, unpublished grey literature was considered for inclusion utilising the search engine Open Grey. Where data was not readily extractable for inclusion, every effort was made to contact the authors for summary data. We also contacted international and UK based experts within the field of diabetes prevention to collect previously unpublished data from both newly completed research projects and from the evaluation of programmes that are currently active in England.

### Inclusion/exclusion criteria

Experimental and observational studies which considered the effectiveness of a lifestyle intervention, whether diet or PA alone or in combination, and whether standalone or compared to a control group; where the stated aim of the intervention was diabetes risk reduction or prevention of T2DM were included in the systematic review. In addition included studies all had to have a primary focus of translating evidence from previous diabetes efficacy trials into routine healthcare, or a community setting. For studies to be eligible for inclusion, they included adults (>18 years old) identified as being at high risk of developing T2DM (for example, obese, sedentary lifestyle, family history of diabetes, older age, metabolic syndrome, impaired glucose regulation, pre-diabetes, or elevated diabetes risk score);<sup>23</sup> had a minimum follow-up of 12 months; and reported progression to diabetes (incidence or prevalence) or change in weight, glucose or HbA1c. As the focus of the review was primary prevention, studies where >10% of the population had established diabetes were excluded. Only studies published in English language were included.

The initial search strategy included a combination of MeSH terms and keywords specific to each bibliographic database. In order to avoid missing papers the final search strategy included only terms related to the intervention and the study design. An example search strategy (MEDLINE) is outlined in Appendix 1. Grey literature was not included in the search by Dunkley et al. therefore we widened the time window to 1998-present for this type of literature. An example search strategy of Open Grey is presented in Appendix 2.

Abstracts and titles were assessed by two independent reviewers for eligibility and potentially relevant articles were retrieved. Any differences in opinion were resolved by a third reviewer if necessary. Where published data was not sufficient for extraction, but inclusion criteria appeared to be met, authors were contacted for additional data and/or clarification. In an attempt to detect further papers not identified through electronic searching, reference lists of included papers and relevant reviews were examined.

## Summary endpoints

The primary endpoint examined was incidence of T2DM at the latest time point at which it was reported in the study. Secondary endpoints assessed weight, HbA1c levels, fasting glucose and 2-hour glucose changes from baseline to between 12 to 18 months follow-up.

## Data extraction and quality assessment

Data was extracted by one reviewer and a second reviewer checked for consistency. Data on sample size, population demographics, intervention details and length of follow-up was extracted. All papers relating to a particular study were retrieved, including those on design and methodology (if reported separately), and any supplementary online material.

The quality of studies was assessed using the UK's National Institute for Health and Clinical Excellence (NICE) quality appraisal checklist for quantitative intervention studies.<sup>24</sup> The checklist includes criteria for assessing the internal and external validity of experimental and observational quantitative studies (RCTs, non-randomised controlled trials, and before and after studies) and allows assignment of an overall quality grade (categories ++, + or -).

## Coding of intervention content

Intervention content was coded as it was previously by Dunkley et al,<sup>21</sup> in relation to the recommendations for lifestyle interventions for the prevention of diabetes provided by both the IMAGE project (Development and Implementation of a European Guideline and Training Standards for Diabetes prevention)<sup>25</sup> and NICE.<sup>23</sup> If available information was insufficient to allow coding, the data was coded as missing; where an intervention appeared to be well described but a particular component (e.g. engaging social support) was not mentioned or could not be implied from other text, it was assumed that the component was not used. In the analysis, it was assumed that missing values indicate that the guideline criterion was not met.

## Data analysis and synthesis

For the incidence of T2DM, where possible all individuals allocated to the intervention (or control) group contributed to the number of person-years, even if they withdrew or were lost

to follow-up. If it was not clear when a participant withdrew or was lost to follow up it was assumed that they contributed person-time for exactly half of the follow-up period for which incidence was reported. Study arms that reported zero new cases of T2DM at end of study follow-up were excluded from before and after analysis. However, for intervention and control comparisons 0.5 was added to the T2DM incidence of each arm to maintain ratios and allow inclusion. At point of extraction all values reported in imperial units were converted into metric units. Capillary blood glucose values were converted to plasma equivalent values.<sup>26</sup> If studies did not directly report the mean and standard deviation (SD), for change from baseline to 12-18 months for the outcomes of interest, they were calculated from reported standard errors (SE), p-values or confidence interval (CI), as recommended by the Cochrane Collaboration.<sup>27</sup> The mean change was calculated by subtracting the baseline mean value from the mean at 12-18 months. Where data was insufficient to allow calculation of the SD, values for each outcome were imputed based on the correlation estimates from those studies that were reported in sufficient detail; for weight the correlation which was used in these imputations was 0.95.<sup>28-32</sup> For HbA1c, fasting and 2-hour glucose outcomes these correlation estimates were 0.71, 0.43 and 0.27 respectively, calculated from the Let's Prevent study.<sup>33</sup>

Initial meta-analyses for all endpoints were performed across intervention arms only in order to assess overall incidence of T2DM and weight, HbA1c, fasting and 2-hour glucose changes attributed to intervention. However, further meta-analyses was carried out in RCTs only, comparing the incidence of T2DM and weight, fasting and 2-hour glucose changes in intervention arms with usual care arms, in order to assess improvements in outcomes beyond that seen in control arms. For weight, fasting and 2-hour glucose changes analyses were also carried out for follow-up periods of greater than 18 months, where data permitted. Subgroup analyses and meta-regression analyses were conducted in RCTs only (comparing intervention to usual care) for T2DM incidence, weight, and fasting and 2-hour glucose outcomes. As less than ten RCTs reported HbA1c no subgroup analyses were performed for this outcome. The confounding effects of study level variables (overall % of males, % of non-white ethnicity, mean age and mean BMI at baseline) on all outcomes were evaluated via meta-regression and subgroup analyses. Subgroup analyses for age and BMI variables focused on the effect of study inclusion criteria. Meta-regression was conducted assessing the effect of adherence to NICE and IMAGE guidelines on progression to diabetes, weight loss and glucose outcomes. Further subgroup analyses using categorised NICE and IMAGE scores were conducted to identify the range of scores which corresponded to the greatest reduction in incidence, maximised weight and glucose reductions. Additional details of interventions were extracted covering programme content, various aspects of contact frequency, use of behaviour change techniques, the setting and delivery, use of particular PA and diet components, how individuals were identified as high risk and the evidence base for the intervention. For each of these areas, subgroup analyses were conducted for all categorical variables as well as meta-regression for continuous variables. For each subgroup analysis effect sizes were reported from meta-analyses, with

p-values calculated by running meta-regression models with the subgroup variable included as a categorical covariate.

### Assessment of heterogeneity

Heterogeneity was assessed using the  $I^2$  statistic. Due to high levels of heterogeneity reported in the previous systematic-review, random effects models were used throughout to calculate pooled effect sizes. All analyses were performed in Stata version 13.1 (StatCorp, College Station, Texas, US).

# Results

## Original literature search

The original literature search identified 3872 unique titles or abstracts, of which 114 potentially relevant papers were retrieved (Figure 1). A further 20 papers were identified from reference lists. Clarification of eligibility criteria and/or additional data was requested from authors for 13 studies. Replies were received for 12, with ten included in the final review consisting of 25 studies<sup>28-32,34-53</sup> (35 papers<sup>28-32,34-63</sup>).

## Updated literature search

When the search was extended beyond July 2012, a further 1372 unique titles were identified; 53 of these titles were eligible for full text retrieval. Further eligibility information and/or outcome data was sought and received from the authors of one paper. Search of Open Grey identified two possible theses for inclusion.<sup>64,65</sup> Further data for ten unpublished studies was sourced directly from authors working in the prevention area via emailing lists, with eligibility criteria confirmed/data requested and received for two of these studies. An additional two recently completed studies were identified as relevant. The new search yielded a further 11 studies<sup>33,66-75</sup> (nine papers<sup>66,68,69,73,75-78</sup>) for inclusion in the review, bringing the total number of studies eligible for inclusion in the systematic review to 36<sup>28-53,66-75</sup> (44 papers<sup>28-32,34-63,66-69,73,75-78</sup>). See Figure 1.

## Summary of included studies

Details of the 36 studies<sup>28-53,66-75</sup> included in the review are given in Table 1, with details of outcomes presented in Table 2. Interventions across studies ranged from diet only, PA only or both. There were no studies assessing diet only. Diet or PA advice given in brief was treated as standard care unless informing a core part of the intervention. Thirty four studies implemented a combination intervention of diet and PA, whilst two studies evaluated the impact of a standalone PA intervention.<sup>52,74</sup> Eight studies offered supervised PA sessions as part of the intervention, with one study offering them on an optional basis.<sup>28</sup> Four studies included substantial amounts of supervised PA in conjunction with dietary advice.<sup>57,68-70</sup> The majority of studies were RCTs (n=18), 15 had a before and after study design and the remaining included matched cohort, prospective cohort and non-randomised controlled trial designs.

Studies were conducted in Europe (n=17), the US (n=15), Australia (n=3) and Japan (n=1), however ethnicity was poorly reported. Of those conducted in Europe, eight were from the UK. Numbers of participants recruited to intervention arms ranged from 8 to 2798 individuals across studies, with 33 studies consisting of a minimum of 50 participants. A wide range of

methods were utilised to identify individuals at high risk of developing T2DM. The criteria used, alone or in combination, included: elevated BMI; elevated diabetes risk score (FINDRISC,<sup>79</sup> ADA,<sup>80</sup> ADA,<sup>80</sup> AUSRISK,<sup>81</sup> Leicester Risk Assessment tool<sup>82</sup>); raised random, fasting or two-hour glucose (finger prick or venous sample); advanced age; ethnicity; family history of diabetes; previous medical history of cardiovascular disease, polycystic ovary syndrome, gestational diabetes or metabolic syndrome; elevated BP or lipids. Total follow-up ranged from 12 months to approximately four years. The mean age of participants (across all arms) ranged from 38 to 65 years, with the percentage of males in the studies spanning zero to 66%. Mean BMI across studies fell between 25-37kg/m<sup>2</sup>. Overall, changes in PA and diet were poorly reported. Substantial heterogeneity was evident between studies in terms of setting, population, criteria used to identify diabetes risk, interventions and follow-up.

A total of 16 studies (18 intervention arms) reported incidence of T2DM. Of these 18 arms, 13 were RCT intervention arms. One study arm, reporting zero cases of T2DM (Ma et al - self-directed intervention arm<sup>68</sup>), was excluded from the analysis including intervention arms only, but was included in the analysis between intervention and control arms. Weight change data at 12 to 18 months follow up was available for 35/36 studies (38 study arms), with one study (Costa et al<sup>38</sup>) not reporting on weight outcome at all. Of these 38 arms, 20 were RCT intervention arms. Fasting glucose was reported across 24 studies (27 intervention arms), of which 14 studies (16 intervention arms) were RCTs. A total of 14 studies (15 intervention arms) reported changes in 2-hour glucose outcomes at 12-18 months follow-up. Ten of the 15 intervention arms were from RCTs. HbA1c glucose levels were available for ten studies (11 intervention arms), of which nine were RCT intervention arms.

Detailed evidence tables for each study are given in Appendix 3.

## Study quality

A detailed assessment of study quality is presented in Appendix 4. External validity evaluated the characteristics of study participants, whilst internal validity of studies was assessed over the following three areas; definition, and allocation to, intervention and control conditions, outcomes assessed over different time periods and methods of analyses. Ratings were specific to study design, in that scores were based on only those elements which applied to the study to be evaluated.

Most studies (34/36) achieved a high quality rating for internal validity. All 18 RCTs received high quality ratings for internal validity, whilst 16/18 non-RCTs achieved the same rating. However, ratings were not consistent across allocation, outcome and analysis subsections. Of the 18 RCT studies, ten maximised minimisation of bias across six or more of the ten criteria for definition of and allocation to intervention. One non-RCT (Kramer 2010), which consisted of randomisation to one of two intervention arms with no control comparison, also

scored high ratings across six allocation criteria. For the other 17 non-RCTs, predominately before and after designs, only four to five elements were directly relevant to the study design. For these studies, 13 received a high rating for three or more elements of allocation.

Information on outcome measures was well reported and generally scored high ratings for objectivity and relevance across all study types. Twenty-six studies minimised bias for five or more elements relating to outcomes; 16 RCTs and ten non-RCTs. Methods of analysis were not always appropriate to minimise bias. Only 11 studies met five or more of the criteria to achieve a high quality rating, of which eight were RCTs and three non-RCTs. Of all 36 studies, 11 RCTs and seven non-RCTs minimised introduction of bias by conducting an intention-to-treat analysis. Across the three sections, bias was most prevalent due to the inappropriate allocation to intervention, including lack of (concealment of) randomisation, and failure to compare to a control as close to usual care as possible. Analysis of effect introduced bias for many studies, with several studies analysing on a complete case basis, likely inflating intervention effect estimates.

Inconsistent reporting of the source/eligible population and area and selected participants meant that only 13 studies were given a high quality rating for external validity, eight of which were RCTs. A further 21 studies (10 RCTs, 11 non-RCTs) achieved a moderate rating for external validity, meaning that some bias was introduced due to inappropriate selection of participants.

### Scoring of intervention content

A detailed breakdown of coding scores for each study intervention arm is given in Appendices 5 and 6. Nineteen study intervention arms achieved a NICE score of  $\geq 9$  out of a possible 12, whilst 31 studies scored  $\geq 7$ . As for the IMAGE guidelines, 15 studies achieved a score of  $\geq 5$  out of a possible 6.

A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice

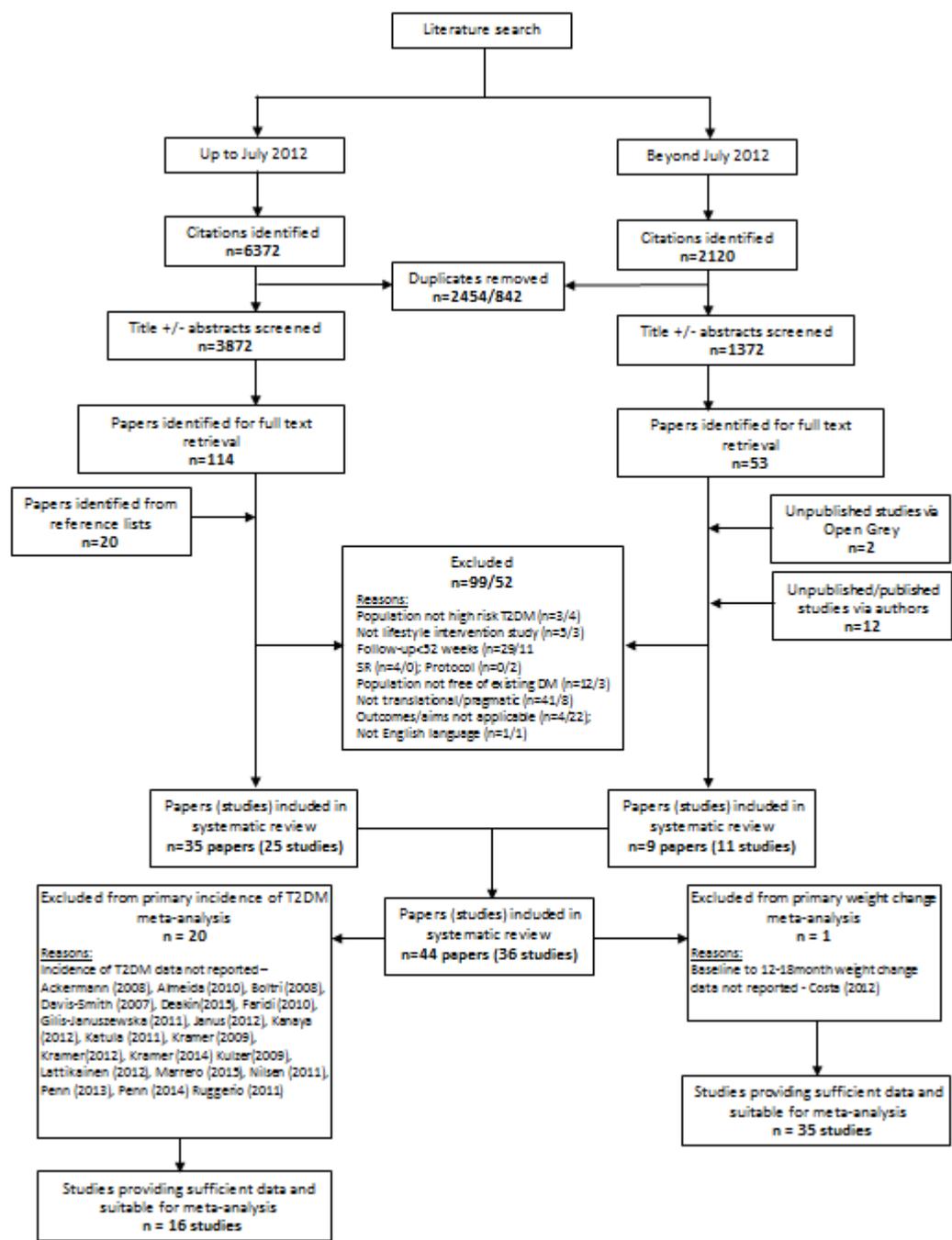


Figure 1: Flow chart of selection of studies from search to final inclusion

Table 1 Characteristics of studies included in the systematic review

Author & Year	Study design	Study/ intervention name	Definition of high risk of T2DM	Focus of Intervention(s)	No recruited overall (& by group)	No study groups	Follow-up (months)	Setting	Country	Ethnicity %	Age (mean)	Male (%)	BMI (mean kg/m <sup>2</sup> )
Absetz 2007 (& 2009)	Before & after	GOAL	Aged 50-65 years; Any risk factor from obesity, ↑BP, ↑plasma glucose, ↑lipids; FINDRISC score ≥12	Lifestyle (Diet & exercise)	352	1	12 & 36	Primary care	Finland	N/R	58 (F); 59 (M)	25	33 (F); 32 (M)
Ackermann 2008 (& 2011)	RCT	DEPLOY	BMI ≥24 & ADA diabetes risk score ≥10; CBG random (110 – 199mg/dl) or fasting (100 – 199mg/dl)	Lifestyle (Diet & exercise)	92	2	12	Community (YMCA)	US	82% White, 3% Hisp, 12% Af-Am, 5% other	58	45	31
Almeida 2010	Matched cohort	KPCO	Existing IFG (110 – 125mg/dl) identified from medical records	Lifestyle (Diet & exercise)	1640 (1520 data available)	2	12	Integrated healthcare organisation	US	N/R	55	47	30
Bhopal 2014	RCT	PODOSA	Aged ≥35 Indian/Pakistani origin Waist circumference (≥90cm men, ≥80cm women) IFG/IGT according to WHO criteria	Lifestyle (Diet & exercise)	171 (85+86)	2	12, 24 & 36	Home based, voluntary organisations, NHS, workplace settings	UK	33% Indian, 67% Pakistani	53	46	30.6

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Author & Year	Study design	Study/ intervention name	Definition of high risk of T2DM	Focus of Intervention(s)	No recruited overall (& by group)	No study groups	Follow-up (months)	Setting	Country	Ethnicity %	Age (mean)	Male (%)	BMI (mean kg/m <sup>2</sup> )
Boltri 2008	Before & after	DPP in faith based setting	ADA diabetes risk score $\geq 10$ ; CBG fasting (100 – 125mg/dl)	Lifestyle (Diet & exercise)	8	1	12	Community (Church)	US	Af-Am community	52*	42*	32
Costa 2012	Prospective cohort	DE-PLAN Spain	FINDRISC score $\geq 14$ or 2hr OGTT ( $\geq 7.8$ and $< 11.1$ mmol/l)	Lifestyle (Diet & exercise)	552 (219+333)	2	Median 4.2yrs	Primary care	Spain	White-European	62	32	31
Davies 2015	RCT	Let's Prevent	Leicester Risk Assessment tool, modified for use at practice level; Aged 40 to 75 years if English speaking European or 25–75 years if South Asian; IFG identified (75g OGTT FPG $\geq 6.1$ and $\leq 6.9$ ), IGT (2-hour blood glucose $\geq 7.8$ and $\leq 11$ ) before Jan 2013, HbA1c % $\geq 6.5$ (regardless of OGTT results) after Jan 2013	Lifestyle (Diet & exercise)	880 (433 + 447)	2	12, 24 & 36	Outpatient Setting	UK	84% White European, 16% ethnic minority groups	64	64	32.5
Davis-Smith 2007	Before & after	DPP in rural church based setting	ADA diabetes risk score $\geq 10$ ; CBG fasting (100 – 125mg/dl)	Lifestyle (Diet & exercise)	11	1	12	Community (Church)	US	Af-Am community	N/R	27	36†

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Deakin 2015	Before & after	X-POD	High diabetes risk score, family history of diabetes, HbA1c ( $\geq 42$ & $\leq 27$ mmol/mol), Fasting ( $\geq 5.5$ & $\leq 6.9$ ), OGTT ( $\geq 7.8$ & $\leq 11.0$ ), overweight/obese, hypertension, history of gestational diabetes	Lifestyle (Diet & exercise)	54	1	12	Various (community and outpatient settings)	UK	51% White, 30% Black, 13% other, 3% Asian and 3% mixed	N/R	N/R	N/R
Faridi 2010	Non-randomised controlled trial	PREDICT	1 or more risk factor from BMI $\geq 25$ , FH diabetes, gestational diabetes	Lifestyle (Diet & exercise)	146	2	12	Community (Church)	US	100% Af-Am	N/R	32	33
Gilis-Januszezka 2011	Before & after	DE-PLAN Poland	FINDRISC score $\geq 14$	Lifestyle (Diet & exercise, optional supervised sessions)	175	1	12	Primary care	Poland	NR	NR	22	32
Janus 2012	RCT	pMDPS	Aged 50–75 years; AUSDRISK score $\geq 15$ ,	Lifestyle (Diet & exercise)	92 (49 + 43)	2	12	Community / primary care	Australia	100% non-Aboriginal/Torres Strait Islander	~65	34	~31
Kanaya 2012	RCT	Live Well, Be Well	Moderate/high diabetes risk score & CBG fasting (106 - 160mg/dl)	Lifestyle (Diet & exercise)	238 (119 + 119)	2	12	Community	US	20% Af-Am, 20% non-Hispanic White, 32% Latino, 14% Asian, 14% other	~56	36	~30

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Katula 2011 (& 2013)	RCT	HELP PD	BMI ≥25 <40 & CBG random; FPG (95 - 125mg/dl)	Lifestyle (Diet & exercise)	301 (151 + 150)	2	12, 18, & 24	Community various venues	US	74% White, 25% Af-Am, 1% other	58	43	33
Kramer 2009	Before & after	GLB 2005 – 2008	BMI ≥25 & metabolic syndrome or CBG fasting (100 – 125mg/dl)	Lifestyle (Diet & exercise)	42	1	12	Primary care & university based support centre	US	White 100%	57	21	35
Kramer 2012	Before & after	GLB 2009	Fasting glucose 100 – 125mg/dl	Lifestyle (Diet & exercise)	60 (31+29)	2	12	Community (YMCA) and university	US	90% Caucasian	55	35	~36
Kramer 2014	Before & after	GLB 2008	Aged ≥25 years & BMI≥25 & fasting glucose 100 – 125mg/dl and/or metabolic syndrome	Lifestyle (Diet & exercise)	81	1	12	University medical centres	US	96% Caucasian	53	12	37.2†
Kulzer 2009	RCT	PREDIAS	FINDRISC score ≥10 or assessed as ↑risk diabetes by primary care physician	Lifestyle (Diet & exercise)	182 (91 + 91)	2	12	Outpatient setting	Germany	N/R	56	57	32
Laatikainen 2007 (& 2012)	Before & after	GGT study	FINDRISC score ≥12	Lifestyle (Diet & exercise)	311	1	12	Primary care	Australia	N/R	57	28	34
Ma 2013 (Ma 2009 & Xiao 2013)	RCT	E-LITE	BMI ≥25 & fasting plasma glucose 100 – 125mg/dl or metabolic syndrome	Lifestyle (Diet & exercise, supervised exercise for 1 group) ‡	241 (79 + 81 + 81)	3	15 & 24	Primary care	US	78% non-Hispanic White, 17% Asian/Pacific Islander	53	53	32

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Makrilakis 2010	Before & after	DE-PLAN Greece	FINDRISC score $\geq 15$	Lifestyle (Diet & exercise)	191	1	12	Primary care, workplace	Greece	NR	56	40	32
Marrero 2015	RCT	Weight Watchers	ADA risk score $\geq 5$ , HbA1c % > 5.7 and < 6.4 and CCBG of 110–199 mg/dl (100–109 if fasting $\geq 8$ hours)	Lifestyle (Diet & exercise)	225 (113 + 112)	2	6, 12	Private	US	64% Caucasian, 25% Af-Am, 7% Asian Pacific Islander, 2% Multiracial, 2% Other	52	15	36.8
Mensink 2003 (& 2003) (Roumen 2008 & 2011)	RCT	SLIM study	Aged >40 years & FH diabetes or BMI $\geq 25$ ; IGT (OGTT 2hrG $\geq 7.8$ & <12.5) & FPG <7.8	Lifestyle (Diet & supervised exercise)	114 (55 + 59)	2	12, 24, 36, 48 (Roumen)	unclear	Netherlands	White Caucasian	57	56	30
Nilsen 2011	RCT	APHRODITE study	FINDRISC score $\geq 9$	Lifestyle (Diet & exercise, minimal supervised exercise)	213 (104+109)	2	18	Primary care	Norway	NR	47	50	37
Ockene 2012	RCT	Lawrence Latino DPP	BMI $\geq 24$ , >30% increased likelihood of diabetes over next 7.5 from validated risk algorithm	Lifestyle (Diet & exercise, supervised exercise)	312 (150+162)	2	12	Community, family health centre	US	60% Dominican; 40% Puerto Rican	52	26	34
Parikh 2010	RCT	Project HEED	BMI $\geq 25$ & pre-diabetes; CBG fasting <126mg/dl & 2hr CBG following 75g	Lifestyle (Diet & exercise)	99 (50 + 49)	2	12	Community various venues	US	89% Hisp, 9% Af-Am	48	15	32

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			glucose										
Payne 2008	Before & after	Ballarat Diabetes Prevention Pilot Initiative (BDPPI)	Aged ≥45 years or aged ≥35 Aboriginal, Torres Strait Islanders, Pacific Islanders, Indian, Chinese) & BMI ≥30 &/or ↑BP; Existing CVD, PCOS, gestational diabetes; 1st degree FH diabetes; IGT or IFG	Lifestyle (Diet & exercise, supervised exercise program)	122 (62 + 60)	2	12	Outpatient facility	Australia	N/R	53	22	35
Penn 2009	RCT	European Diabetes Prevention Study (EDIPS) -Newcastle	BMI >25 & aged >40 years; IGT (OGTT 2hrG ≥7.8 & <11.1)	Lifestyle (Diet & exercise)	102 (51 + 51)	2	12 & 3.1 yrs mean	Outpatient setting	UK	N/R	57	40	34
Penn 2013	Before & after	New Life, New You (NLNY)	Aged 45-65 years, & FINDRISC score 11-20 or >20 if GP confirms no DM	Lifestyle (Diet & supervised exercise)	218	1	12	Community & leisure centres	UK	N/R	54	31	34
Penn 2014	Before & after	New Life, New You (NLNY)	Age>25 years, non-white ethnicity & FINDRISC score ≥ 11	Lifestyle (Diet & supervised exercise)	188	1	8 weeks, 6, 12	Community & leisure centres	UK	70% Pakistani, 13% Black-African, 8% Other Asian, 5% Arabic, 4% Other	39	0	30.5

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Author & Year	Study design	Study/ intervention name	Definition of high risk of T2DM	Focus of Intervention(s)	No recruited overall (& by group)	No study groups	Follow-up (months)	Setting	Country	Ethnicity %	Age (mean)	Male (%)	BMI (mean kg/m <sup>2</sup> )
Ruggiero 2011	Before & after	DPP in Latino population	BMI≥24.9	Lifestyle (Diet & exercise)	69	1	12	Community various venues	US	Hispanic	38	7	31
Saaristo 2010, (Rautio 2011 & 2012)	Before & after	FIN-D2D	FINDRISC score ≥15 or IFG or IGT or CVD event or gestational diabetes	Lifestyle (Diet & exercise)	2798	1	12	Primary care	Finland	NR	54	49	~31
Sakane 2011	RCT	N/R	IGT identified as follows: IFG ≥5.6 & <7.0; Random PG (≥7.8 <11.1 within 2 hrs of meal) or (≥6.1 & <7.8, ≥2 hrs after meal); IGT	Lifestyle (Diet & exercise)	296 (146 + 150)	2	12 & 36	Various: primary care, workplace, collaborative centre	Japan	N/R	51	51	25
Vermunt 2012 (& 2011)	RCT	APHRODITE study	FINDRISC score ≥13	Lifestyle (Diet & exercise)	925 (479+446)	2	18, 30	Primary care	Netherlands	NR	NR	NR	~29
Yates 2009 (& 2011)	RCT	PREPARE	BMI ≥25 (23 for SAs); Screened detected IGT	Lifestyle (Exercise)	98 (33+31+34)	3	12, 24	Outpatient setting	UK	75% † White, 24% SA, 1% Black	65†	66†	29.2†
Yates 2015	RCT	Walking Away	Leicester Risk Assessment tool identifying those in 90th risk percentile in each practice;	Lifestyle (Exercise)	808 (385 + 423)	2	12, 24, 36	Hospital, primary care, community settings	UK	89% White-European, 11% other ethnic minority groups	63	64	32.4

\*Boltri estimated from larger cohort (n = 26) who were screened with CBG; ‡Ma 1 study group received intervention face-to-face and 1 group mainly via self-directed DVD; † given for completers. Payne randomly allocated to 2 exercise groups but most results presented overall. Abbreviations: ADA, American Diabetes Association; Af-Am, African

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American; AUSDRISK, Australian Diabetes Risk Assessment Tool; BP, blood pressure; BMI, body mass index; CBG, capillary blood glucose; CI, confidence interval; CVD, cardiovascular disease; F, female; FH, family history; FINDRISC, Finnish Diabetes Risk Score; FPG, fasting plasma glucose; HbA1c, glycated haemoglobin; HDL, high density lipoprotein; Hisp, Hispanic; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; LDL, low density lipoprotein; M, male; N/R, not reported; OGTT, oral glucose tolerance test; PCOS, polycystic ovary syndrome; PG, plasma glucose; SA, South Asian; T2DM, type 2 diabetes

Table 2: Incidence of T2DM, mean change (baseline - 12 to 18 months) in weight, HbA1c, fasting and 2-hour glucose outcomes

Author	Year	Study design	Arm	T2DM N/1000 person-years	Weight (kg)			HbA1c (%)			Fasting glucose (mmol/l)			2 hour glucose (mmol/l)		
					n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Absetz	2009	B&A	Int	34.6	312	-0.8	4.5	-	-	-	312	0.1	0.6	312	0.1	1.7
Ackerman	2008	RCT	Int	-	29	-5.7	5.2	29	-0.1	0.4	-	-	-	-	-	-
Ackerman	2008	RCT	UC	-	33	-1.6	5.2	33	0	0.4	-	-	-	-	-	-
Almeida	2010	M cohort	Int	-	760	-1.4	3.5	-	-	-	-	-	-	-	-	-
Bhopal	2014	RCT	Int	144.6	85	-1.0	5.1	-	-	-	-	-	-	-	-	-
Bhopal	2014	RCT	UC	202.4	83	-0.3	4.7	-	-	-	-	-	-	-	-	-
Boltri	2008	B&A	Int	-	8	-0.5	4.9	-	-	-	8	-0.4	0.2	-	-	-
Costa	2012	P cohort	Int	183.2	-	-	-	-	-	-	-	-	-	-	-	-
Davies	2015	RCT	Int	149.9	447	-0.3	6.1	447	-0.03	0.3	447	-0.02	0.3	447	-1.3	2.5
Davies	2015	RCT	UC	171.1	433	-0.03	7.2	433	0.02	0.5	433	-0.02	0.7	433	-1.3	1.8
Davis-Smith	2007	B&A	Int	-	10	-4.8	11.5	-	-	-	10	-0.6	0.5	-	-	-
Deakin	2015	B&A	Int	-	54	-9.0	49.3	-	-	-	54	-0.4	3.4	-	-	-
Faridi	2010	B&A	Int	-	83	0.1	11.8	-	-	-	-	-	-	-	-	-
Gilis-Januszewska	2011	B&A	Int	-	175	-1.9	5.0	-	-	-	175	0.1	0.7	175	0.3	2.4
Janus	2012	RCT	Int	-	38	-2.7	4.4	37	0.1	0.4	37	-0.03	0.4	36	-0.1	1.8
Kanaya	2012	RCT	Int	-	113	-0.6	3.4	-	-	-	113	-0.9	10.8	-	-	-
Katula	2011	RCT	Int	-	135	-7.0	4.5	-	-	-	135	-0.3	0.6	-	-	-
Kramer	2009	B&A	Int	-	42	-4.2	5.7	-	-	-	-	-	-	-	-	-
Kramer (CPC)	2012	B&A	Int	-	29	4.0	5.0	27	-0.2	0.3	27	-0.3	0.6	-	-	-
Kramer (TPC)	2012	B&A	Int	-	31	-2.6	6.4	31	-0.1	0.2	31	-0.1	0.5	-	-	-
Kramer	2014	B&A	Int	-	52	-5.6	2.5	-	-	-	50	-0.3	0.8	-	-	-
Kulzer	2009	RCT	Int	-	91	-3.6	5.1	91	0	0.3	91	-0.3	0.7	91	-0.5	1.9
Laatikainen	2012	B&A	Int	-	221	-2.6	5.2	-	-	-	221	-0.1	0.5	232	-0.6	1.7
Ma	2013	RCT	Int (Self-directed)	0	81	-4.5	8.1	-	-	-	81	-0.2	0.8	-	-	-
Ma	2013	RCT	Int (Coached)	12.7	79	-6.3	8.0	-	-	-	79	-4.0	6.9	-	-	-

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Author	Year	Study design	Arm	T2DM N/1000 person-years	Weight (kg)			HbA1c (%)			Fasting glucose (mmol/l)			2 hour glucose (mmol/l)		
					n	Mean	SD	n	Mean	SD	n	Mean	SD	n	Mean	SD
Ma	2013	RCT	UC	12.3	81	-2.4	8.1	-	-	-	81	0.01	0.9	-	-	-
Makrilakis	2010	B&A	Int	44.3	125	-1.0	4.7	-	-	-	125	-0.2	0.7	125	0.03	1.9
Marrero	2015	RCT	Int	-	112	-5.6	6.4	-	-	-	-	-	-	-	-	-
Marrero	2015	RCT	UC	-	113	-0.1	8.5	-	-	-	-	-	-	-	-	-
Mensink	2003	RCT	Int	161.6	47	-2.7	3.8	47	-0.2	0.7	47	-0.1	0.7	47	-0.8	0.3
Mensink	2003	RCT	UC	339.6	45	-0.2	3.4	55	-0.2	0.3	55	0.02	0.6	55	0.4	2.2
Nilsen	2011	RCT	Int	-	93	-2.5	7.3	93	0	0.4	93	0.2	1.1	-	-	-
Nilsen	2011	RCT	UC	-	89	-3.0	7.2	89	0	0.4	89	0.1	0.8	-	-	-
Ockene	2012	RCT	Int	12.9	147	-1.1	4.6	149	-0.1	0.3	147	0.03	0.7	-	-	-
Ockene	2012	RCT	UC	34.2	142	0.3	4.2	142	-0.04	0.2	142	-0.1	0.9	-	-	-
Parikh	2010	RCT	Int	360.0	35	-3.3	3.3	35	-0.3	0.2	35	0.6	0.8	35	0.2	2.1
Parikh	2010	RCT	UC	330.0	37	-1.1	3.7	37	-0.3	0.2	37	0.6	0.6	37	0.6	2.1
Payne	2008	B&A	Int	8.2	122	-4.1	5.2	-	-	-	122	-0.2	0.5	118	-0.3	1.4
Penn	2009	RCT	Int	32.7	39	-2.3	5.1	-	-	-	-	-	-	-	-	-
Penn	2009	RCT	UC	67.1	43	0.01	4.0	-	-	-	-	-	-	-	-	-
Penn	2013	B&A	Int	-	134	-3.7	6.7	-	-	-	-	-	-	-	-	-
Penn	2014	B&A	Int	-	121	-2.5	6.7	-	-	-	-	-	-	-	-	-
Ruggerio	2011	B&A	Int	-	57	-1.3	5.1	-	-	-	-	-	-	-	-	-
Saaristo	2010	B&A	Int	61.3	2798	-1.1	5.6	-	-	-	-	-	-	-	-	-
Sakane	2011	RCT	Int	72.3	146	-1.4	4.1	-	-	-	123	-0.1	0.6	123	-1.2	1.8
Sakane	2011	RCT	UC	138.5	131	-0.8	3.7	-	-	-	131	-0.2	0.6	131	-0.7	1.7
Vermunt	2012	RCT	Int	96.8	393	-0.6	5.1	-	-	-	302	-0.1	0.4	302	0.1	1.5
Vermunt	2012	RCT	UC	115.1	371	-0.3	4.5	-	-	-	302	-0.1	0.5	302	0.2	1.6
Yates	2009	RCT	Int (PREPARE + pedometer)	70.8	29	0.5	3.8	-	-	-	29	-0.2	0.5	29	-1.8	2.2
Yates	2009	RCT	Int (PREPARE)	139.1	29	-0.5	3.8	-	-	-	29	-0.03	0.4	29	0.2	1.7
Yates	2009	RCT	UC	198.3	29	-0.7	3.5	-	-	-	29	0.1	0.7	29	-0.3	2.1
Yates	2015	RCT	Int	110.8	423	-0.5	5.2	423	0.1	0.5	423	-0.02	0.6	423	-0.2	2.7
Yates	2015	RCT	UC	79.6	385	-0.9	10.0	385	-0.1	1.0	385	0.1	0.9	385	-0.4	2.7

RCT Randomised Controlled Trial; M Matched; P Prospective; Int Intervention; UC Usual Care

# Research question 1: What is the effectiveness of diabetes prevention programmes on delaying the onset and reducing the incidence of type 2 diabetes, weight and glucose in high risk populations in practice?

The incidence of T2DM and weight, fasting, 2-hour glucose and HbA1c changes at 12-18 months were pooled across intervention arms in order to assess the overall effectiveness of diabetes prevention programmes. For weight, fasting and 2-hour glucose endpoints, the long term effectiveness (follow-up data at time points greater than 18 months) of the intervention were also evaluated, in comparison with reductions at 12-18 months. The impact of intervention on outcomes relative to no or reduced intervention (control/usual care) was also assessed, in order to better understand the residual effect of pragmatic diabetes prevention programmes.

## Incidence of T2DM

Figure 2 shows the incidence rate (per 1 person-year) of T2DM by study type (RCT, other). The overall incidence of T2DM was 75 cases per 1000 person years. The incidence rate was higher in the RCTs (n=12) at 84 cases per 1000 person-years, whilst the pooled incidence rate of T2DM was 55 cases per 1000 person-years across five non-RCTs. This difference was not statistically significant ( $p=0.41$ ). Twelve RCTs reported incidence of T2DM in a diabetes prevention programme compared with usual care. Figure 3 displays incidence rate ratios for T2DM. The pooled incidence rate ratio of T2DM was 26% lower in those receiving a diabetes prevention programme compared with usual care (95% CI 7%, 42%).

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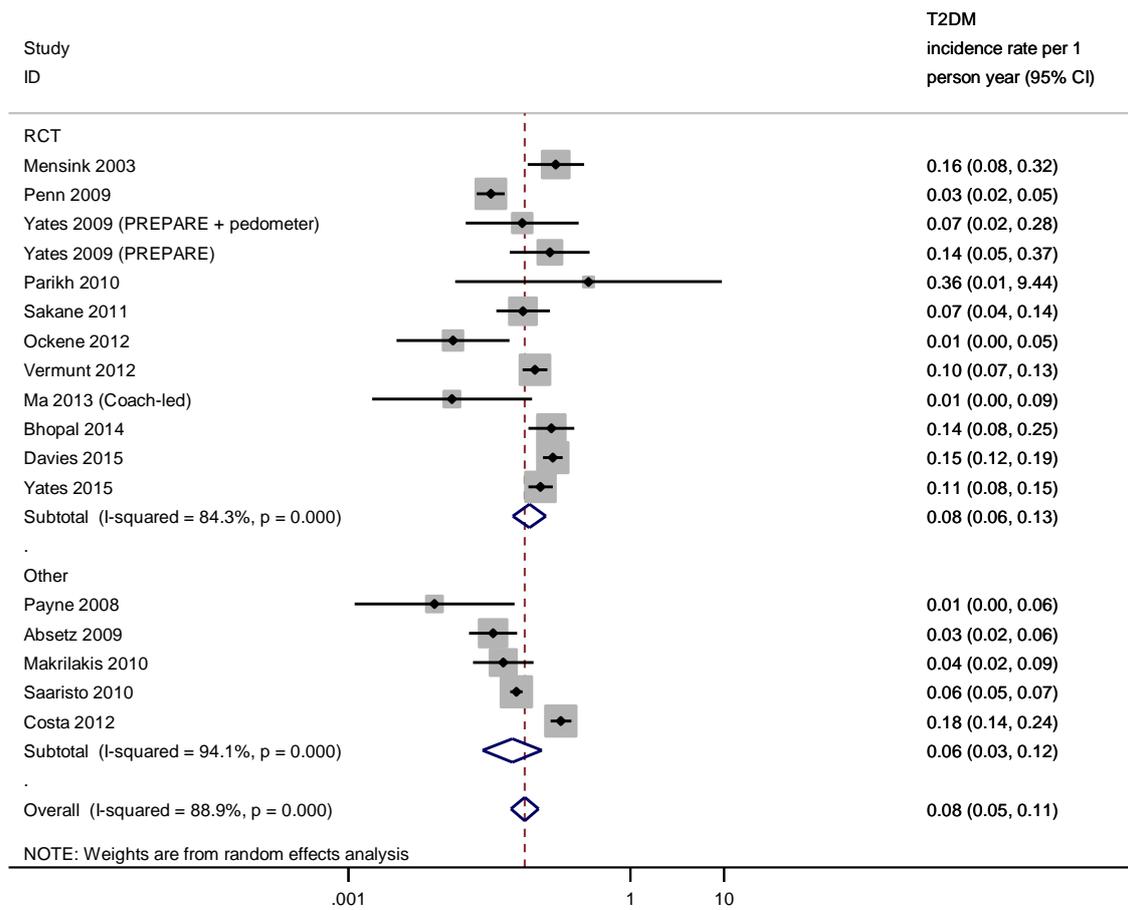


Figure 2: Forest plot showing T2DM incidence rate per 1 person-year across intervention arms

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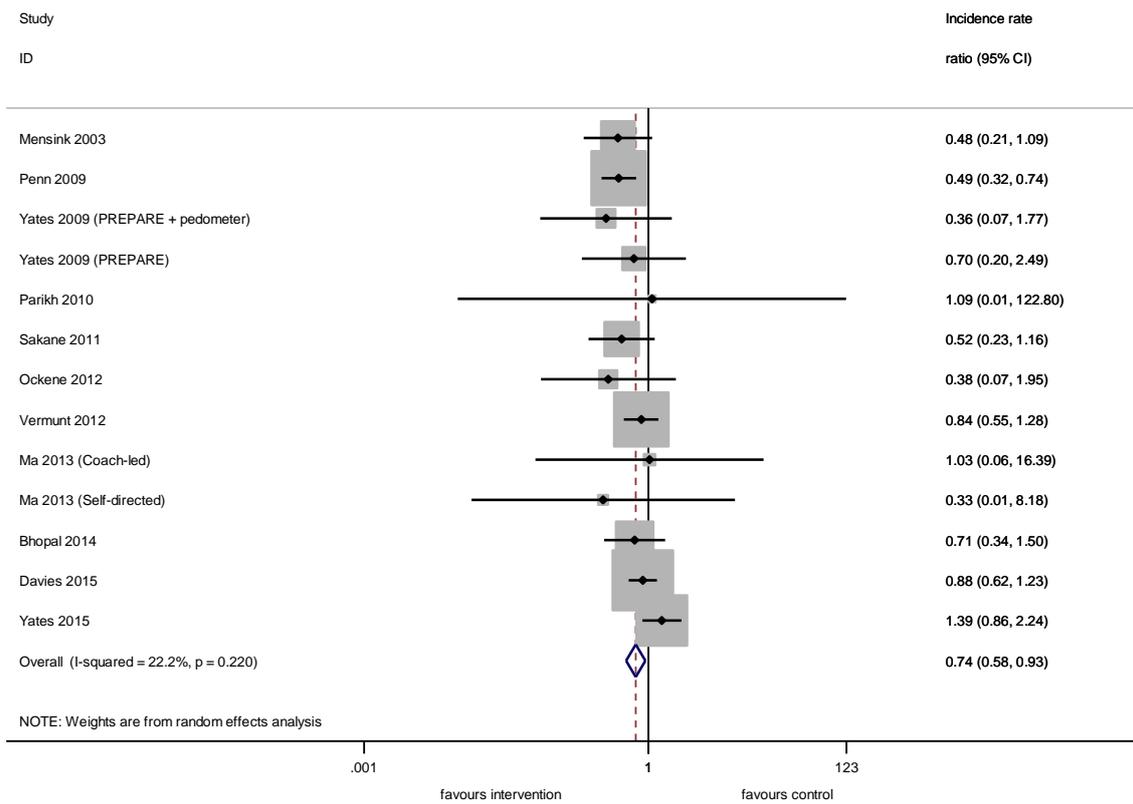


Figure 3: Intervention vs. Control forest plot showing incidence rate ratios of T2DM in RCTs only

## Weight

Attending a diabetes prevention programme corresponded to an overall 2.46kg mean weight loss at 12 to 18 months follow-up, as shown in Figure 4. There was no difference in weight loss by study type ( $p=0.92$ ). Twenty RCTs were included in the meta-analysis for weight change which compared attending a diabetes prevention programme with usual care. When compared with usual care the pooled mean weight loss was 1.57kg higher (95% CI -2.28, -0.86) in those receiving the intervention, as presented in Figure 5.

The majority of studies reporting longer term follow up data for weight change did so at two ( $n=5$ ) or three years follow up ( $n=5$ ). One study reported weight change at 28 months, whilst another study reported this data at 30 months. All studies were RCTs with the exception of one (Absetz et al). In those studies reporting weight change after the first year, attending a diabetes prevention programme corresponded to a pooled weight loss of 2.13kg; however heterogeneity was high ( $I^2=93\%$ ). In particular mean weight loss for intervention arms reporting at two years follow up was 3.27kg (95% CI -5.54, -1.01), whilst pooled results from those studies reporting at three years corresponded to a smaller weight loss of 0.88kg (95% CI -1.24, -0.52). However, weight loss reported at 28 months ( $p=0.44$ ), 30 months ( $p=0.22$ ) or three years ( $p=0.07$ ) was not significantly different than at two years follow-up. Weight loss at more than 18 months follow-up was not significantly lower than the pooled 2.46kg weight loss observed at 12-18 months follow up ( $p=0.61$ ).

Figure 7 shows the pooled weight loss difference between the intervention and control groups in the 11 RCTs reporting weight at greater than 18 months. Overall, the intervention was associated with 1.26kg more weight loss than usual care over long term follow-up (95% CI -2.35, -0.18). Compared to 24 months there was no difference in the weight loss seen at 28, 30 or 36 months. The 1.26kg weight loss seen at more than 18 months follow-up was not significantly different from the 1.57kg observed at 12-18 months ( $p=0.64$ ).

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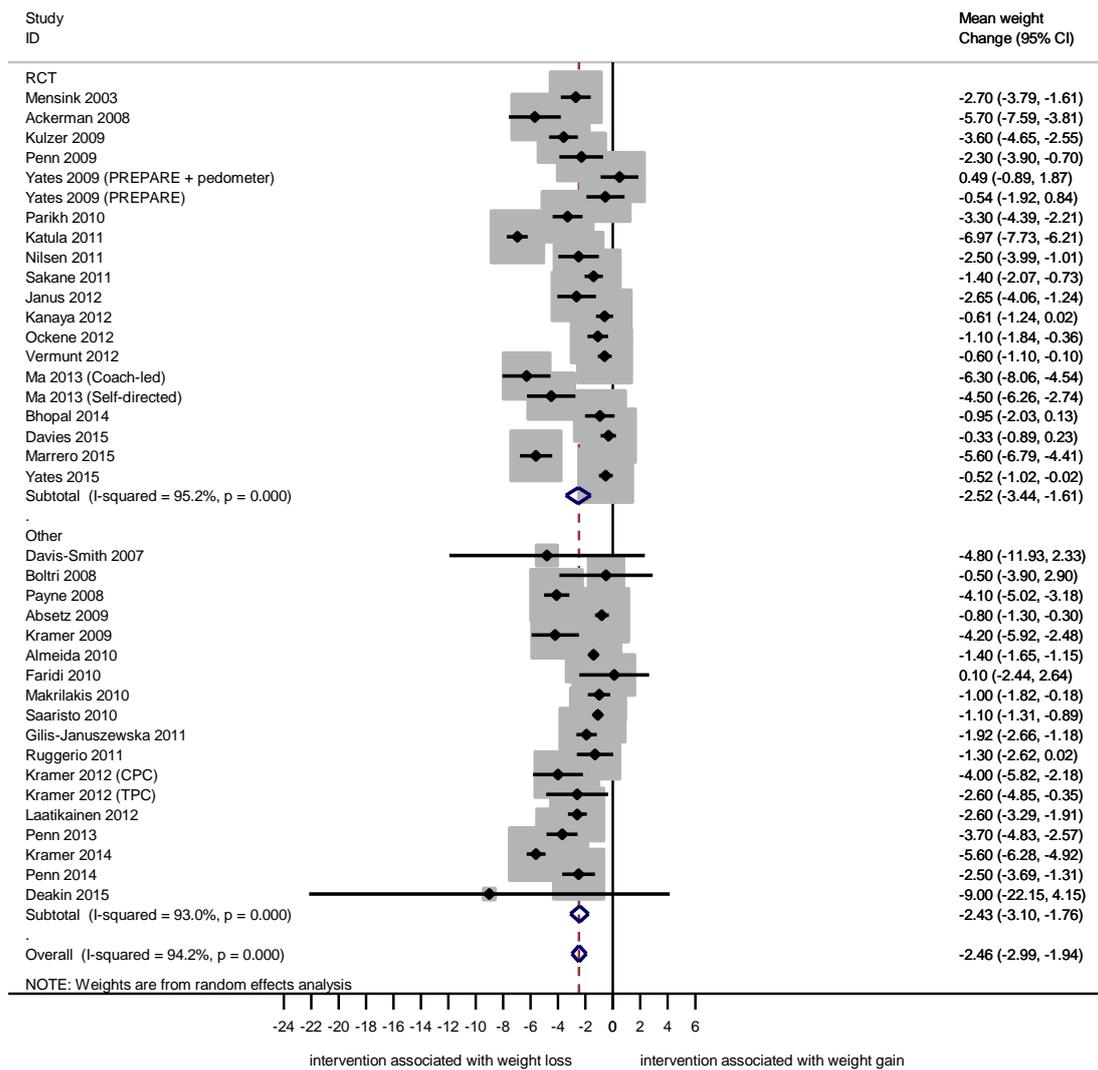


Figure 4: Before and after forest plot showing weight change at 12-18 months across intervention arms

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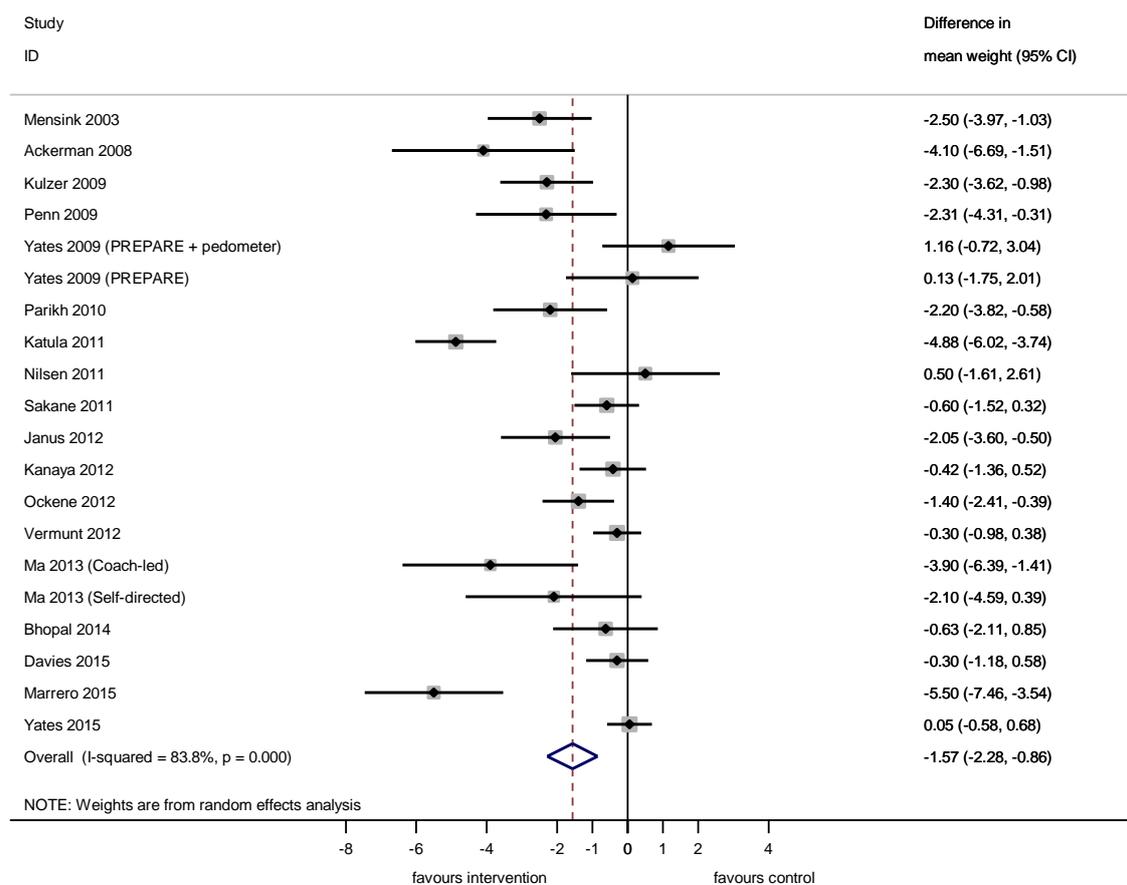


Figure 5: Intervention vs. control forest plot showing difference in mean weight at 12-18 months in RCTs only

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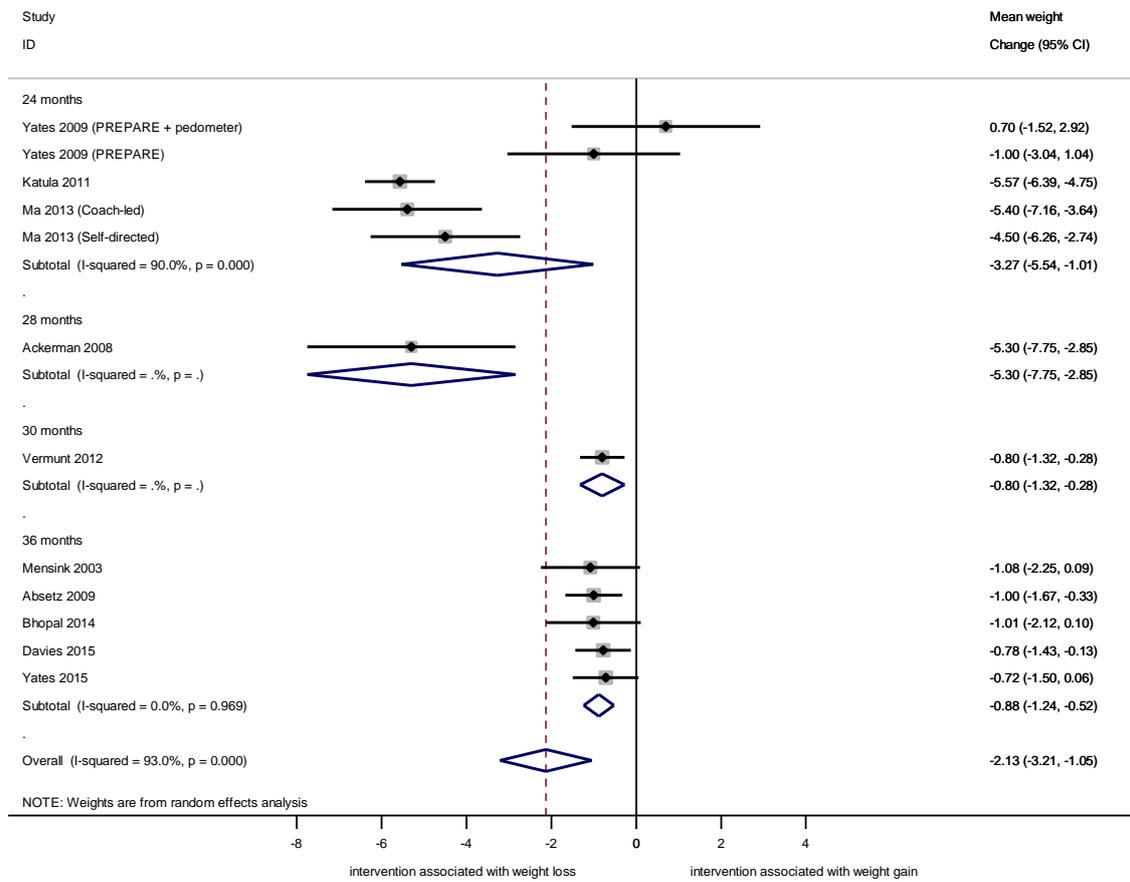


Figure 6: Before and after forest plot showing weight change at greater than 18 months across intervention arms

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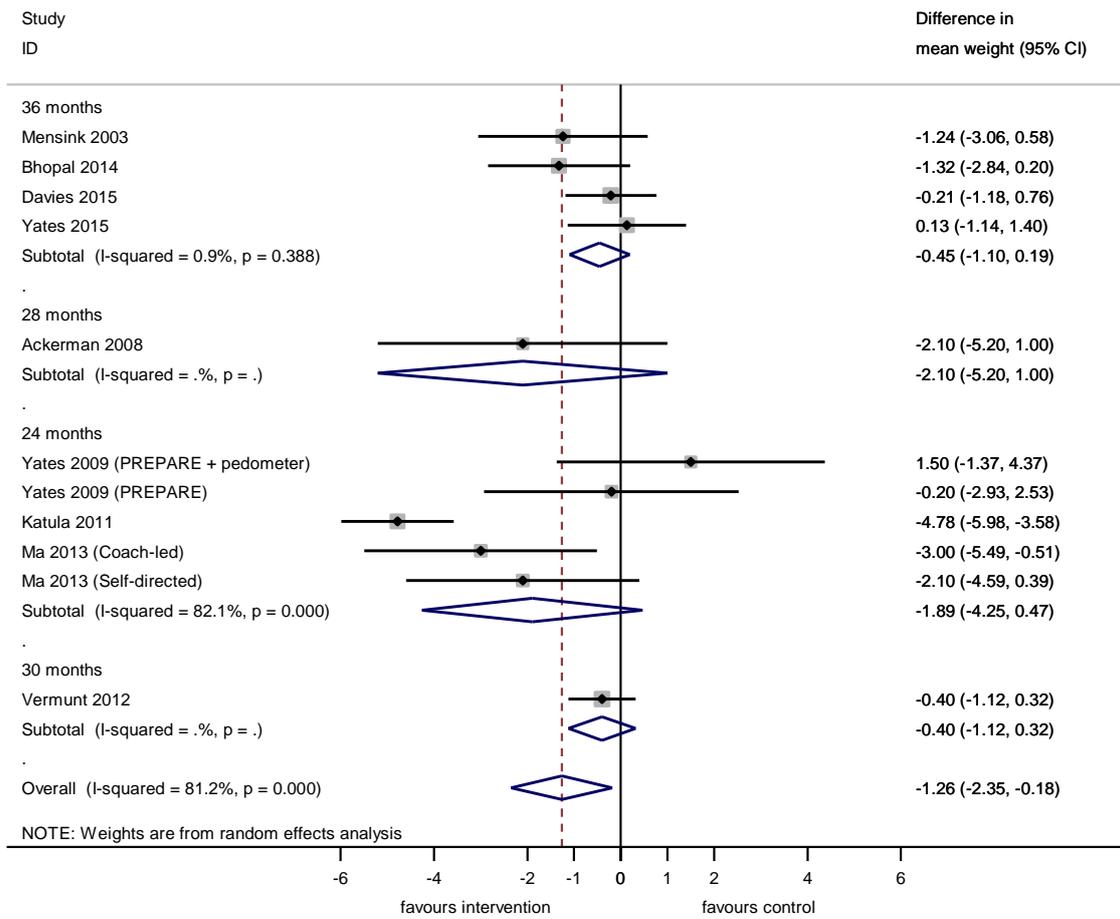


Figure 7: Intervention vs. Control forest plot showing difference in mean weight at greater than 18 months in RCTs only

## Fasting glucose

Twenty-seven studies reported fasting glucose outcomes, of which 16 were from RCTs. The pooled change from baseline in fasting glucose was 0.09mmol/l (95% CI -0.14, -0.04). A larger reduction of 0.15mmol/l was seen across non-RCTs compared to 0.06 mmol/l in the RCT arms, this difference was not statistically significant ( $p=0.14$ ). When compared with usual care there was a 0.06mmol/l (95% CI -0.11, 0) greater reduction in fasting glucose at 12-18 months follow-up as seen in Figure 9. This was not statistically significant.

Nine studies, eight RCTs and one non-RCT, reported fasting glucose post 18 months. The pooled change from baseline in fasting glucose was a non-significant increase of 0.01mmol/l, Figure 10. The pooled increase in fasting glucose at over 18 months follow-up was not significantly higher than the decrease seen at 12-18 months follow-up ( $p=0.16$ ).

When comparing those attending a diabetes prevention programme with usual care at greater than 18 months follow-up a significantly higher reduction in fasting glucose of 0.07mmol/l was observed. This was not significantly different to the reduction observed at 12-18 months follow up ( $p=0.56$ ).

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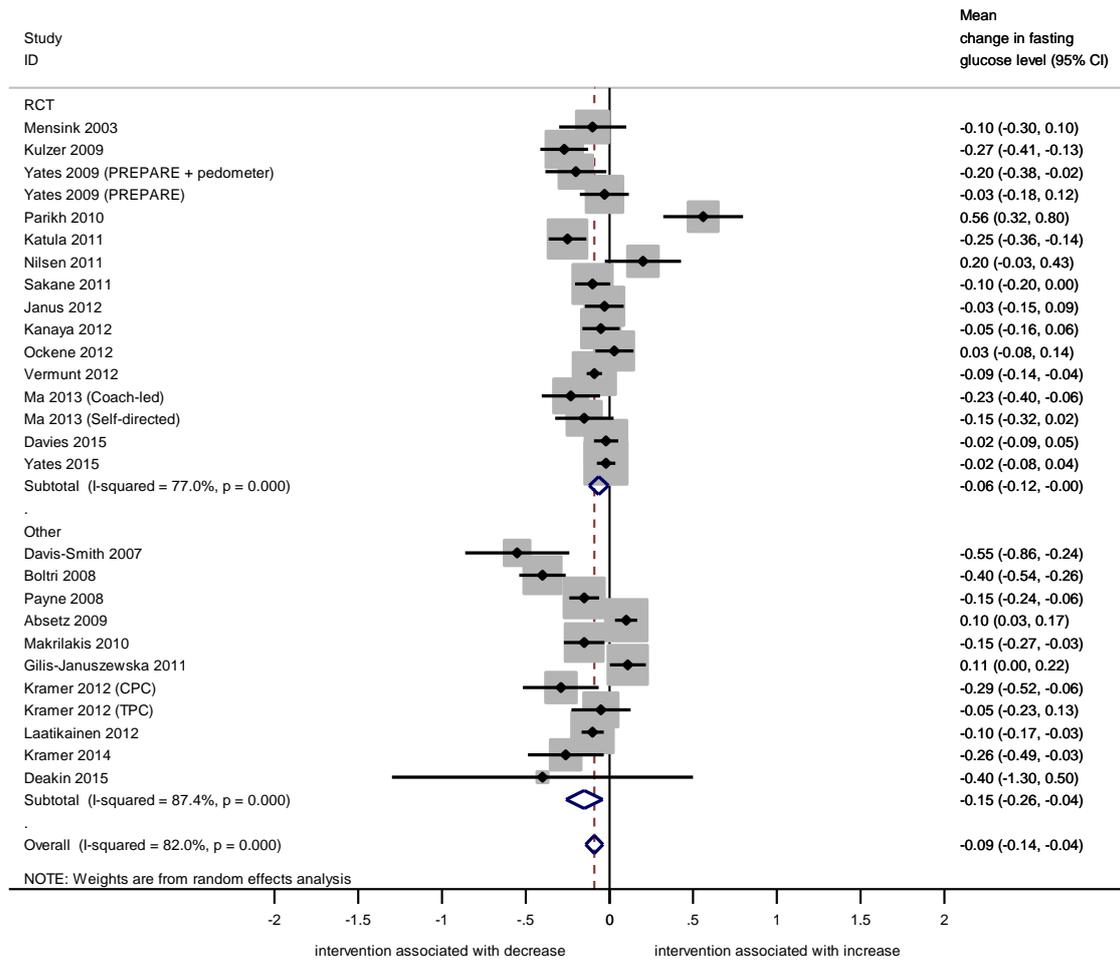


Figure 8: Before and after forest plot showing fasting glucose change at 12-18 months across intervention arms

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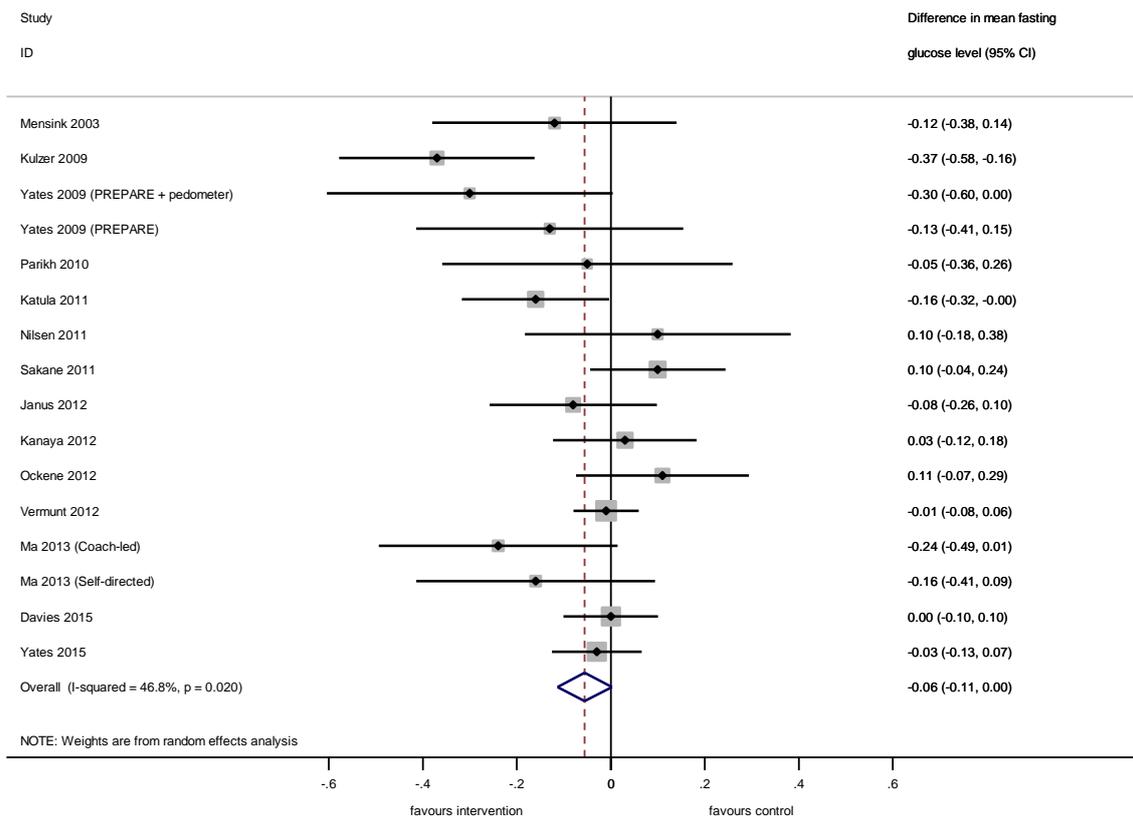


Figure 9: Intervention vs. Control forest plot showing difference in mean fasting glucose at 12-18 months in RCTs only

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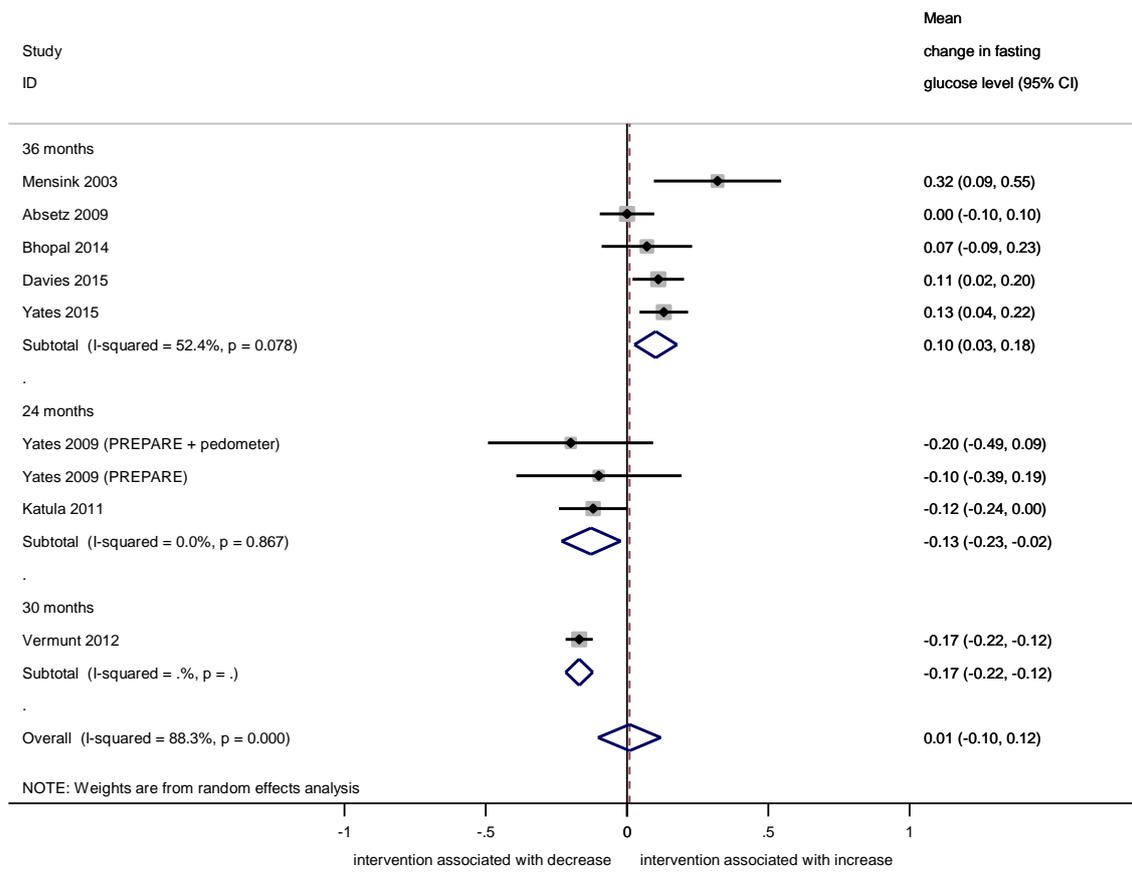


Figure 10: Before and after forest plot showing fasting glucose change at greater than 18 months across intervention arms

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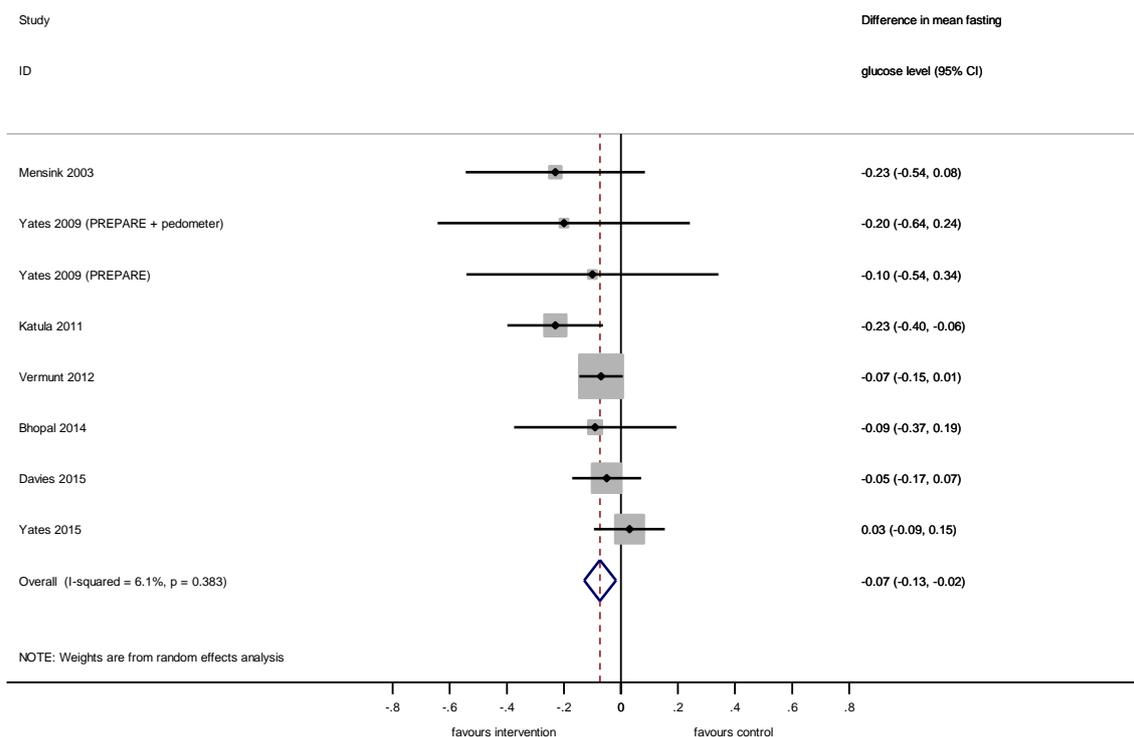


Figure 11: Intervention vs. Control forest plot showing difference in mean fasting glucose at greater than 18 months in RCTs only

## 2-hour glucose

Fifteen intervention arms reported 2-hour glucose change from baseline at 12-18 months follow-up. Ten of these were RCTs, with five being non-RCTs. The pooled reduction in 2-hour glucose was 0.38mmol/l (95% CI -0.66, -0.10). There was no difference between study types ( $p=0.20$ ). Pooled reduction in 2-hour glucose was 0.28mmol/l in those who received the intervention compared with usual care, this was not significant.

Eight studies reported change in 2-hour glucose at follow-up times greater than 18 months. All but one of these were RCTs. The pooled decrease in 2-hour glucose from baseline was 0.28mmol/l across intervention arms, with variation between time points. This was not significantly different to the reduction seen at 12-18months follow-up. A higher pooled reduction in 2-hour glucose of 0.52mmol/l was seen in intervention arms when compared with usual care, across RCTs. This was not a significant reduction and was not significantly different to the reduction observed at 12-18 months follow-up ( $p=0.52$ ).

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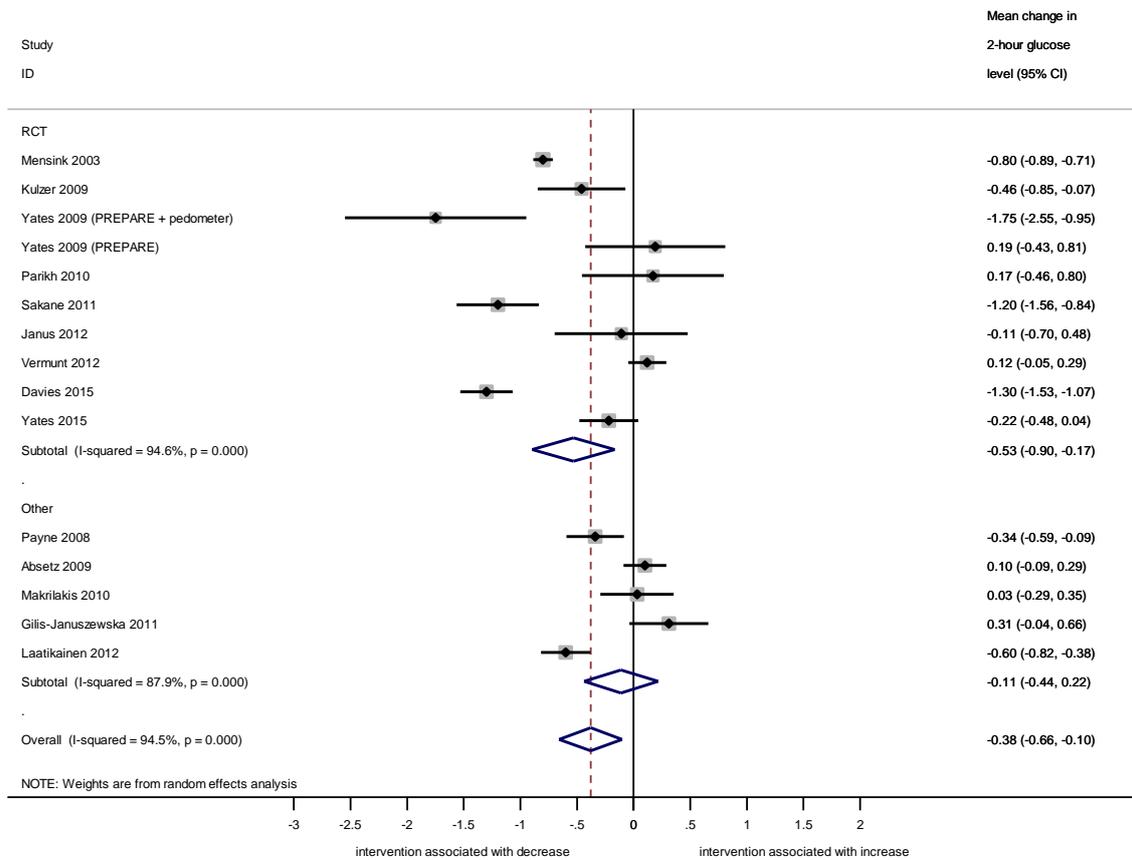


Figure 12: Before and after forest plot showing 2-hour glucose change at 12-18 months across intervention arms

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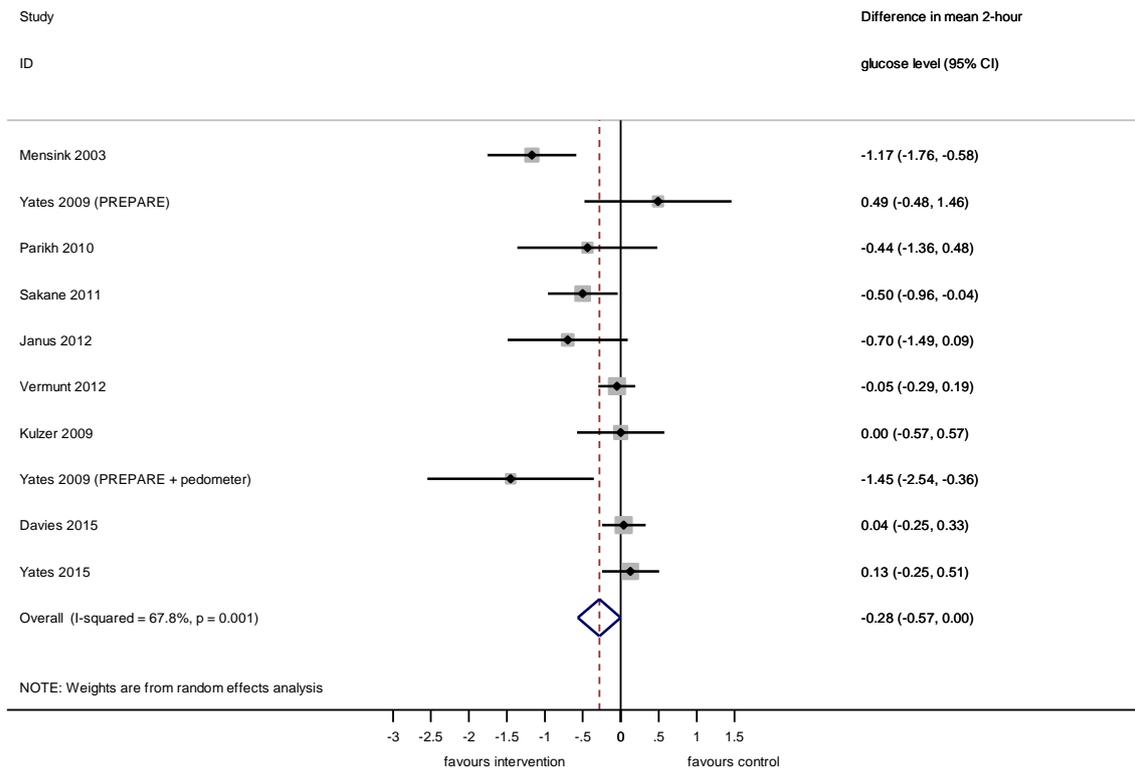


Figure 13: Intervention vs. Control forest plot showing difference in mean 2-hour glucose at 12-18 months in RCTs only

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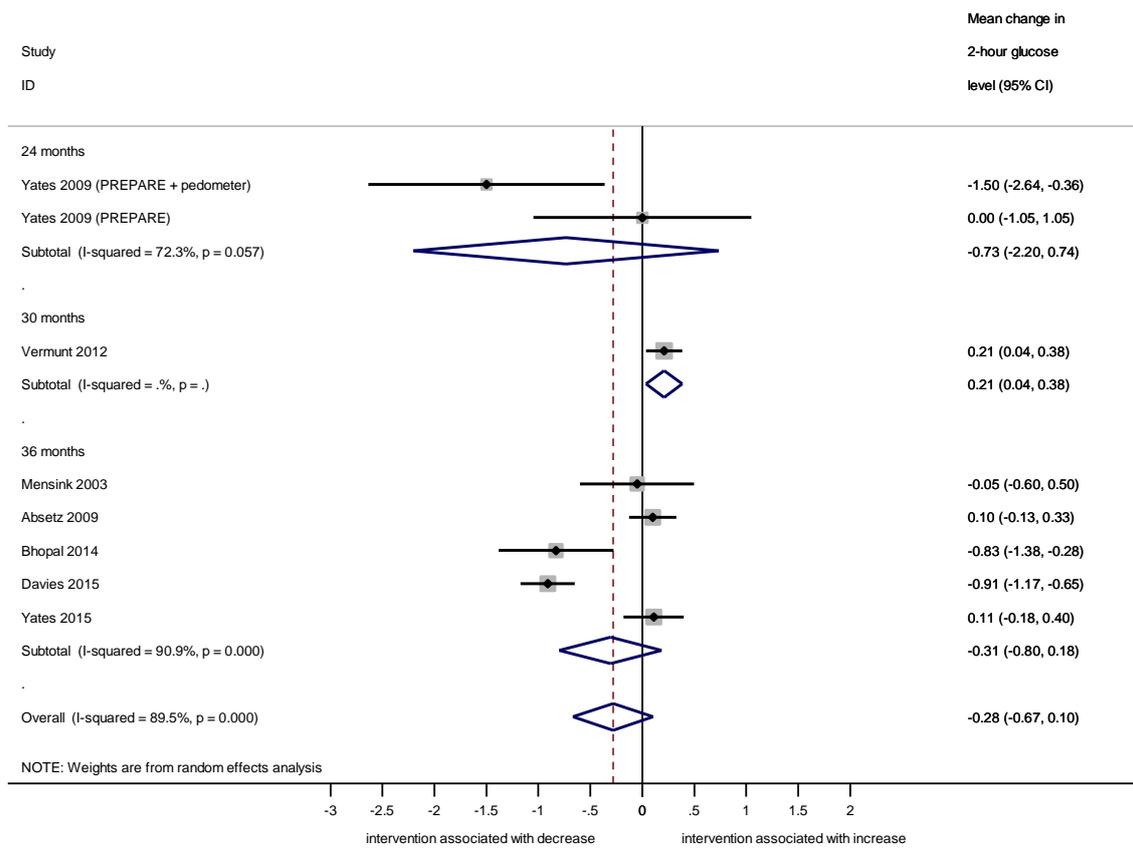


Figure 14: Before and after forest plot showing 2-hour glucose change at greater than 18 months across intervention arms

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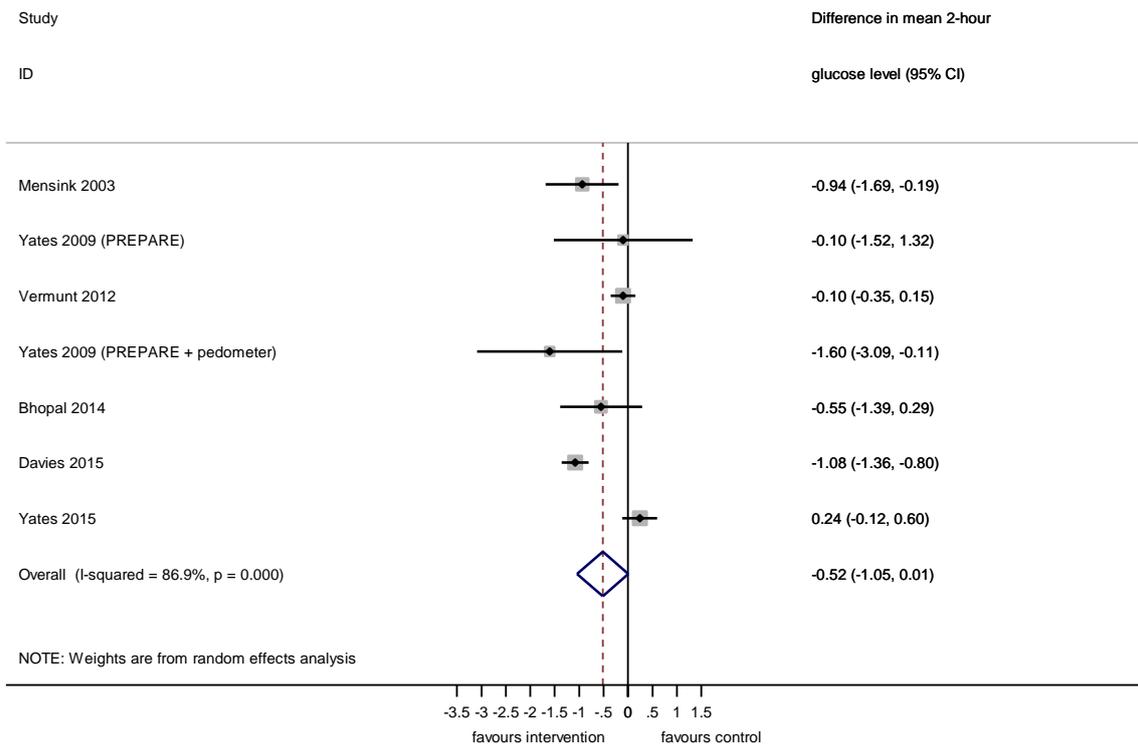


Figure 15: Intervention vs. Control forest plot showing difference in mean 2-hour glucose at greater than 18 months in RCTs only

## HbA1c

Eleven intervention arms reported HbA1c at 12-18 months follow-up. The pooled reduction in HbA1c was 0.07%, with no difference between study types ( $p=0.49$ ). When comparing those who attended a diabetes prevention programme with usual care ( $n=9$ ) an overall significant reduction in HbA1c of 0.04% (95% CI -0.07, -0.01) was seen.

Meta-analyses for change in HbA1c levels at time-points greater than 18 months follow up were not carried out as only three RCTs reported this outcome.

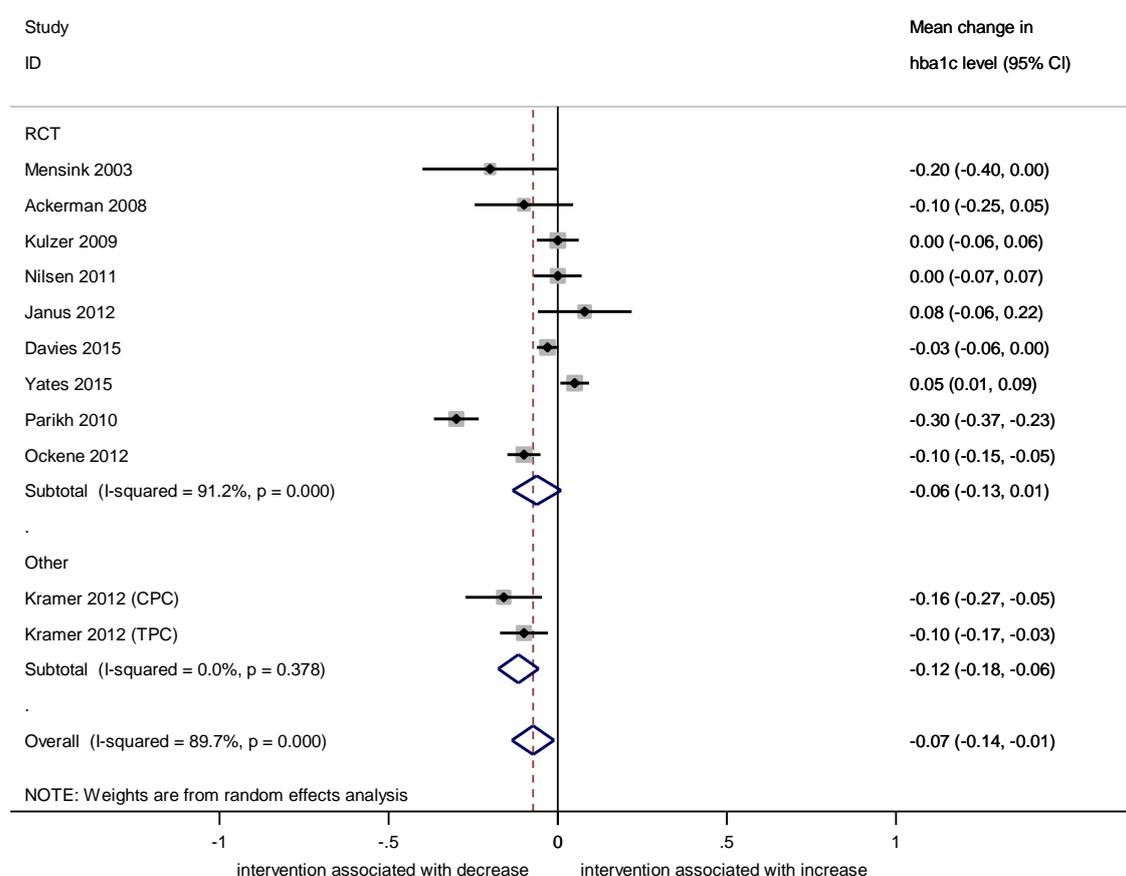


Figure 16: Before and after forest plot showing HbA1c level change at 12-18 months across intervention arms

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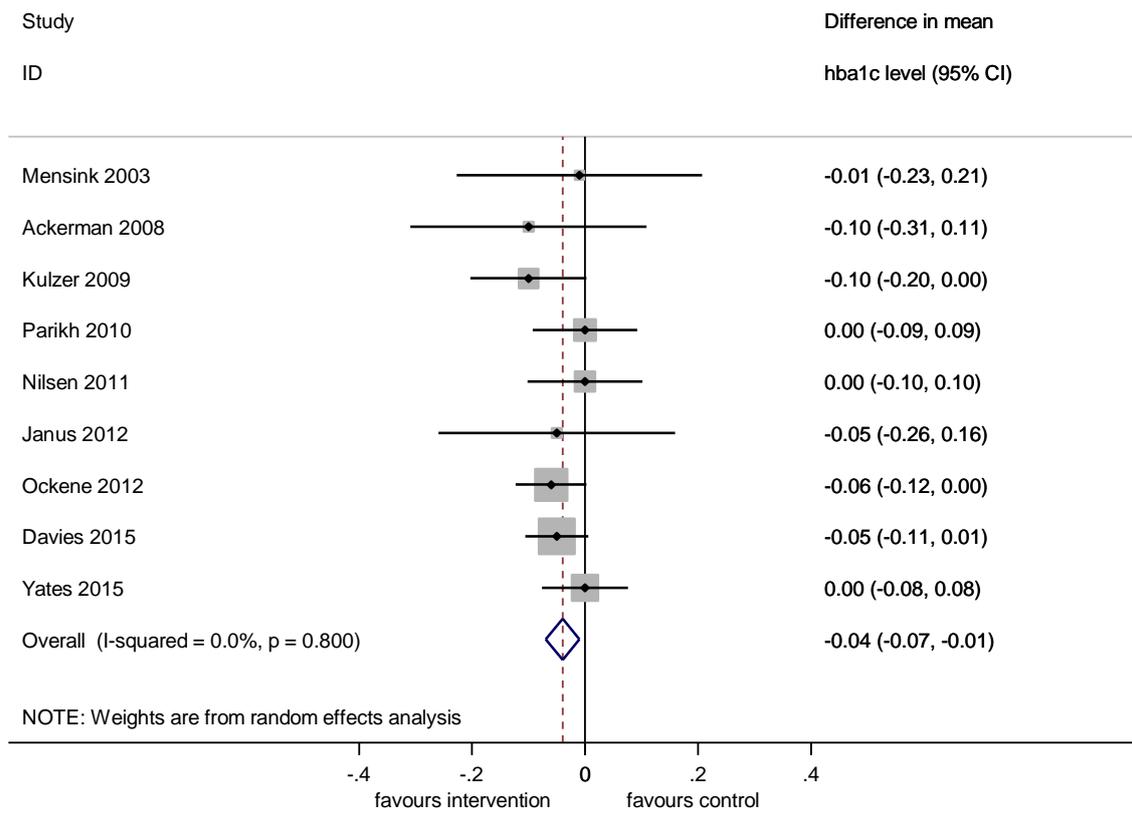


Figure 17: Intervention vs. Control forest plot showing difference in mean HbA1c levels at 12-18 months in RCTs only

## Conclusions

In response to question one, data was pooled in two ways (1) assessing change from baseline in those who received the intervention and (2) assessing the difference between the intervention and usual care arms. Calculating the pooled change from baseline allowed the inclusion of single arm studies, but gives a within group estimate of the intervention effect which has many methodological limitations. This method does not take into account changes over time irrespective of the intervention, the placebo effect or regression to the mean. Therefore within group comparisons should be avoided, with simulation studies showing a type 1 error rate as high as 50% in such analyses compared to 5% for a between group randomised comparison.

Therefore the results from the within group analyses should be viewed with caution. Overall the results presented here show a bigger intervention effect when assessing the change from baseline. Statistically significant reductions in T2DM incidence, weight and HbA1c were seen at 12-18 months for those who received the diabetes prevention programme compared with usual care.

A number of alternative methods have been proposed for combining data from different study designs. Applying these was beyond the scope of this rapid review. Alternative methods of analysis will be assessed in a future project.

As a result of these findings, further analysis will be conducted in RCTs only, in order to provide comparisons against usual care. All secondary endpoints will be assessed at 12-18 months only. As less than ten studies reported HbA1c levels, subgroup analyses were not conducted for this outcome.

## Summary

- diabetes prevention programmes reduce T2DM incidence, weight and HbA1c
- only nine RCTs reported HbA1c levels
- RCT data comparing intervention with control will be used to identify which elements of the interventions were associated with better outcomes and in whom they work best

## Research question 2: In which population groups are the models identified the most effective – age, gender, BMI and ethnicity?

We have conducted a number of analyses to look at the effect of age, gender, BMI and ethnicity on diabetes incidence, weight, fasting and 2-hour glucose change. All of the data presented below is from RCTs only and is based on between group comparisons. These are presented below.

### Age

The mean age of study participants ranged from 46 years up to 66 years. The median mean age was 56, with an inter quartile range of 52 to 63 years. The mean age of participants was not reported in one study. Eleven studies did not restrict inclusion based on age. Seven only recruited those who were middle-aged and two excluded the very elderly.

Table 3 shows the results from the meta-regression analysis which assessed the impact of the study level mean age on the results found for each outcome. No significant changes in outcomes were observed as mean age increased. This shows that there was a consistent effect seen across ages.

Table 4 shows the results from a subgroup analysis by age inclusion criteria for the study and how this affected the outcome seen. Age inclusion criteria were categorised based on how wide the criteria was. If a lower limit of between 18 and 25 years old was utilised with no upper age limit or none was recorded, it was assumed eligibility was not restricted by age. Those criteria including individuals ranging from 30 to 75 years old were loosely categorised as 'middle aged,' whilst those studies with a wider inclusion criteria with a lower limit of 18 to 25 and an upper limit of over 65, were assumed to exclude the elderly.

Comparable results were seen across all outcomes assessed across all age groups. There were high levels of heterogeneity within subgroups for the weight and glucose outcomes which suggested that age did not explain the high levels of study variability seen for these endpoints.

**Table 3: Meta-regression results of the effect of study level mean age on T2DM incidence rate, weight, fasting and 2-hour glucose**

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	12	1.05	0.99, 1.12	0.106
Difference in mean weight, kg	19	0.08	-0.08, 0.24	0.298
Difference in mean fasting glucose, mmol/l	15	-0.01	-0.02, 0.01	0.342
Difference in mean 2-hour glucose, mmol/l	9	0.02	-0.06, 0.10	0.615

**Table 4: Subgroup analysis of effect of age study inclusion criteria on T2DM incidence rate, weight, fasting and 2-hour glucose**

Age inclusion criteria	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Unrestricted	7	1.06	0.71, 1.60	Reference	0.0
Middle aged	6	0.68	0.53, 0.87	0.276	24.3
Very elderly excluded	0	-	-	-	-
Difference in mean weight, kg					
Unrestricted	11	-2.01	-3.29, -0.74	Reference	89.5
Middle aged	6	-0.99	-1.64, -0.34	0.371	54.8
Very elderly excluded	2	-1.03	-3.76, 1.71	0.522	79.5
Difference in mean fasting glucose, mmol/l					
Unrestricted	9	-0.07	-0.15, 0.01	Reference	31.7
Middle aged	5	-0.002	-0.5, 0.05	0.327	0.0
Very elderly excluded	2	-0.15	-0.61, 0.31	0.326	85.5
Difference in mean 2-hour glucose, mmol/l					
Unrestricted	4	-0.23	-0.93, 0.46	Reference	66.7
Middle aged	5	-0.39	-0.78, -0.01	0.327	77.6
Very elderly excluded	1	0.0	-0.57, 0.57	0.326	-

## Gender

Nineteen studies reported data on gender at baseline. The percentage of males included ranged from 15% to 64%. The median percentage of males was 50%, with an inter quartile range of 34% to 57%. There were no single sex studies.

Table 5 and Figure 18 show the results from the meta-regression analysis which assessed the impact of the study level percentage of males on the results found for each outcome. These show that a one unit increase in the percentage of males resulted in a 3% higher incidence of T2DM in those who received the intervention compared with usual care. A one unit increase in the percentage of males was also border-line significantly associated with a very small 0.05kg weight gain compared with usual care (Figure 19). The intervention effect on both fasting and 2-hour glucose outcomes remained consistent as the percentage of males increased.

Additional subgroup analysis was carried out by categorising the mean percentage of males into two groups, <50% males and  $\geq$ 50% males.

Table 6 presents the results for the subgroup analysis for all outcomes. In each case whether the percentage of males was greater than or equal to 50% did not significantly affect T2DM incidence weight or glucose outcomes in intervention arms compared with control arms than if the study level percentage of males was less than 50%. High levels of heterogeneity were observed specifically for the weight outcome, which suggests that these gender categories do not singularly explain the variation in reported weight loss across studies. Additionally categorisations were arbitrary, indicating the possibility that a 50% cut-off may not be appropriate for subgroup analysis.

Table 5: Meta-regression results of the effect of study level percentage of males on T2DM incidence rate, weight, fasting and 2-hour glucose.

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	12	1.03	1.005, 1.05	0.022
Difference in mean weight, kg	19	0.05	-0.001, 0.10	0.054
Difference in mean fasting glucose, mmol/l	15	-0.003	-0.01, 0.002	0.247
Difference in mean 2-hour glucose, mmol/l	9	0.01	-0.02, 0.04	0.455

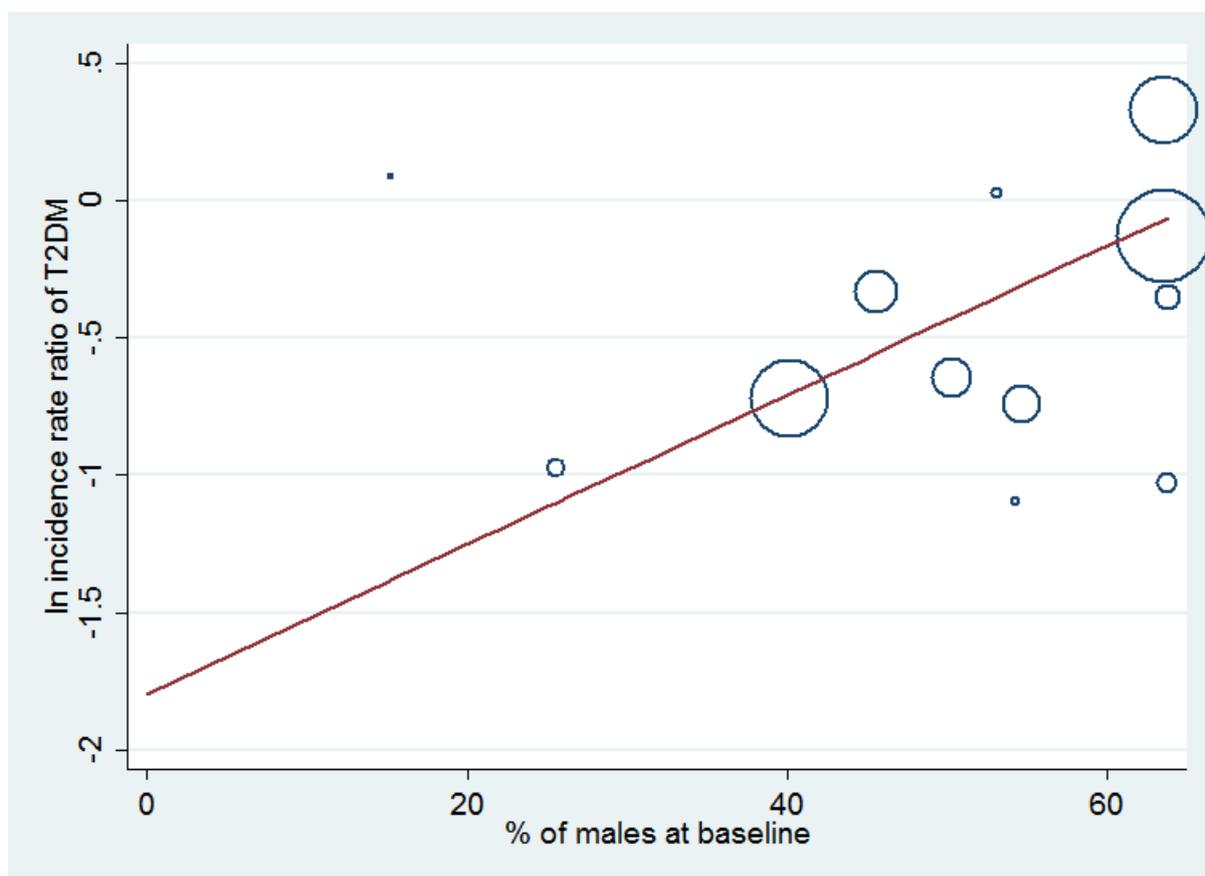


Figure 18: Meta-regression plot of the effect of study level percentage of males on ln T2DM incidence rate ratio comparing incidence rate in intervention arms vs. control arms

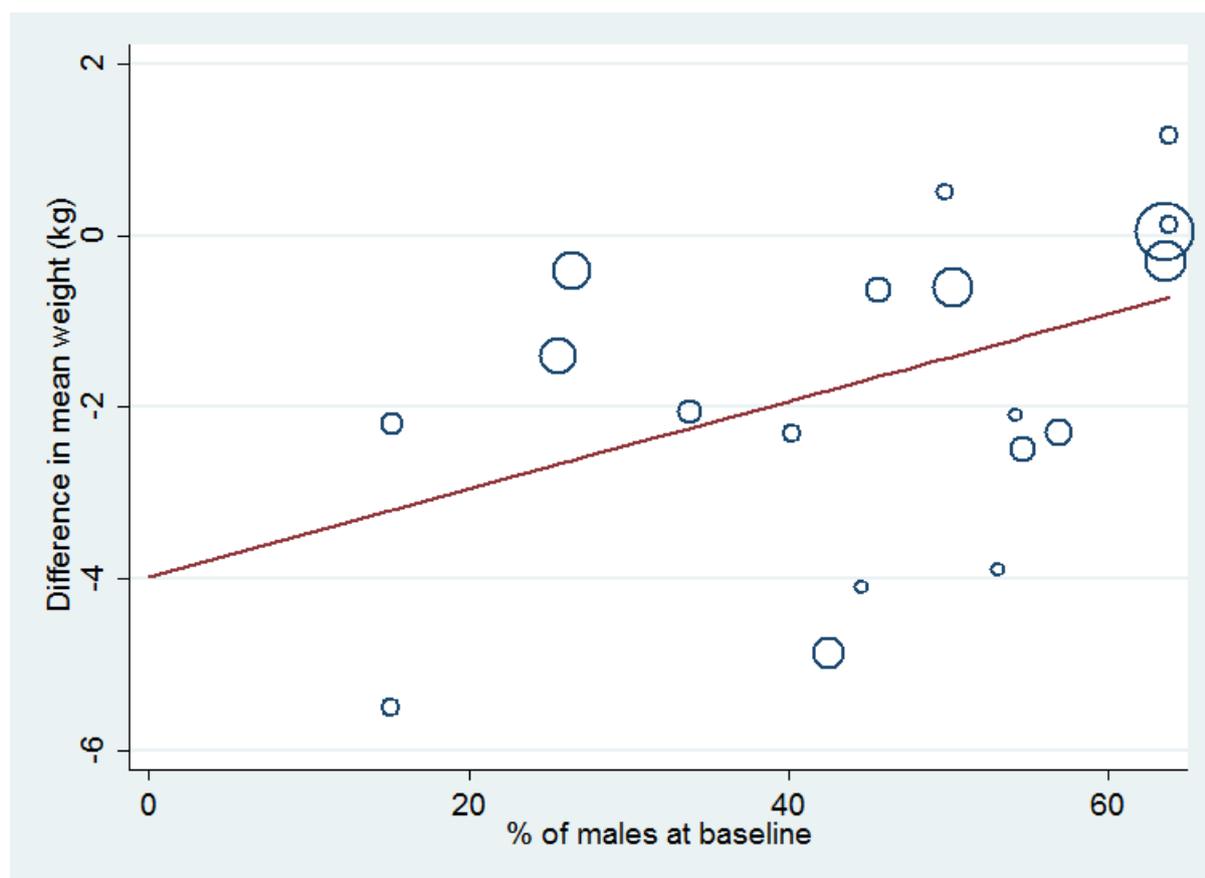


Figure 19: Meta-regression plot of the effect of study level percentage of males on difference in weight change comparing weight change in intervention arms vs. control arms

Table 6: Subgroup analysis of effect of gender ratio on T2DM incidence rate, weight, fasting and 2-hour glucose

% of males	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
< 50% males	4	0.53	0.37, 0.75	Reference	0.0
≥ 50% males	8	0.81	0.59, 1.13	0.254	22.1
Difference in mean weight, kg					
< 50% males	10	-2.25	-3.46, -1.04	Reference	85.0
≥ 50% males	9	-0.97	-1.80, -0.14	0.158	72.7
Difference in mean fasting glucose, mmol/l					
< 50% males	6	-0.02	-0.11, 0.07	Reference	23.8
≥ 50% males	9	-0.11	-0.20, -0.01	0.270	60.7

		Difference in mean 2-hour glucose, mmol/l			
< 50% males	2	-0.59	-1.19, 0.01	Reference	0.0
≥ 50% males	7	-0.30	-0.70, 0.11	0.616	76.0

## BMI

The mean BMI of study participants ranged from 24.6 to 36.8kg/m<sup>2</sup>. The median mean BMI was 31.5kg/m<sup>2</sup>, with an inter quartile range of 29.8 to 32.7kg/m<sup>2</sup>. When assessing the inclusion criteria within the studies, ten did not restrict inclusion based on BMI. Six recruited those with a BMI ≥25, two studies recruited participants with a BMI ≥24 and one study comprised of two intervention arms defined separate criterion for South Asian participants (≥23 for South Asians, ≥25 for other ethnicities).

Table 7 shows the results from the meta-regression analysis. A one kg/m<sup>2</sup> increase in mean BMI did not significantly alter outcomes in intervention groups when compared with control groups. This shows that there was a consistent effect seen on outcomes across BMI.

Table 8 shows the results from a subgroup analysis which assessed the impact of BMI inclusion criteria on the outcomes. The majority of studies did not specify inclusion criteria for BMI. For the incidence of T2DM, those studies which restricted entry criteria to individuals with a BMI ≥25kg/m<sup>2</sup> (i.e. those who were overweight) had a 51% lower incidence rate in the intervention arms compared to the control arms than those studies which did not restrict for BMI, where intervention corresponded to only an 11% reduction in T2DM incidence in comparison with control. This suggests the intervention effect was larger on the incidence of T2DM amongst studies which employed the ≥25kg/m<sup>2</sup> BMI inclusion criteria as opposed to no restrictions.

Similarly studies which included participants with a BMI ≥25kg/m<sup>2</sup> reported a larger weight loss of 3.07kg in intervention arms when compared with control, than studies which did not restrict for BMI, for which the overall weight loss across intervention arms was only 0.98kg greater than control arms. Again the intervention effect was larger for studies which utilised the ≥25kg/m<sup>2</sup> BMI criteria when compared to those studies which did not restrict for BMI.

Subgroup analysis of the effect of BMI inclusion criteria on glucose outcomes showed no significant differences in glucose outcomes in intervention groups compared with control groups. Results should be interpreted with caution due to the low numbers of studies included in each subgroup.

Table 7: Meta-regression results of the effect of study level mean BMI on T2DM incidence rate, weight, fasting and 2-hour glucose

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	13	1.03	0.90, 1.16	0.673
Difference in mean weight, kg	20	-0.23	-0.53, 0.07	0.125
Difference in mean fasting glucose, mmol/l	16	-0.01	-0.03, 0.02	0.694
Difference in mean 2-hour glucose, mmol/l	10	0.07	-0.09, 0.24	0.326

Table 8: Subgroup analysis of effect of BMI inclusion criteria on T2DM

BMI inclusion criteria	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Unrestricted	5	0.89	0.69, 1.16	Reference	27.3
≥25	5	0.49	0.34, 0.71	0.021	0.0
≥24	1	0.38	0.07, 1.95	0.330	-
≥23 (South Asians), ≥25	2	0.54	0.20, 1.46	0.350	0.0
		Difference in mean weight, kg			
Unrestricted	10	-0.98	-1.69, -0.26	Reference	77.5
≥25	6	-3.07	-4.20, -1.95	0.019	59.3
≥24	2	-2.48	-5.07, 0.12	0.280	72.3
≥23 (South Asians), ≥25	2	0.64	-0.68, 1.97	0.186	0.0
		Difference in mean fasting glucose, mmol/l			
Unrestricted	8	-0.02	-0.09, 0.05	Reference	54.4
≥25	5	-0.15	-0.26, -0.05	0.059	0.0
≥24	1	0.11	-0.07, 0.29	0.292	-
≥23 (South Asians), ≥25	2	-0.21	-0.42, -0.002	0.158	0.0
		Difference in mean 2-hour glucose, mmol/l			
Unrestricted	6	-0.09	-0.28, 0.11	Reference	33.5
≥25	2	-0.90	-1.59, -0.20	0.092	41.8
≥24	0	-	-	-	-
≥23 (South Asians), ≥25	2	-0.46	-2.36, 1.44	0.627	85.2

incidence rate, weight, fasting and 2-hour glucose

## Ethnicity

There was variation seen in the ethnicity of the participants in the included studies. We were able to extract a breakdown of ethnicity for thirteen of the twenty RCTs. Seven were conducted in a majority white population (defined as greater than 70% white). Four studies were conducted in a specific ethnic group; these included one study in Hispanic individuals, and one in South-Asians, with two additional studies in which more than 70% of participants came from non-white groups.

The median percentage of non-white participants was 26.2%, which ranged from 11.3% to 100% (Inter quartile range 20.1%, 87.7%). The non-white ethnicities were comprised of Hispanic, South-Asians, Black, mixed ethnic and indigenous Australians (Torres Strait Islander and /or Aboriginal) groups.

The results from the meta-regression using percentage of non-white participants as a measure of ethnicity, showed that as the percentage of non-white individuals increased there was no change in the effect size seen for any of the outcomes (Table 9). Table 10 presents the results of subgroup analysis of ethnic makeup of individuals across studies. No difference in effect was seen between ethnic subgroups for any of the outcomes assessed.

Table 9: Meta-regression results of the effect of study level percentage of individuals of non-white ethnicity on T2DM incidence rate, weight, fasting and 2-hour glucose

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	9	0.99	0.98, 1.01	0.264
Difference in mean weight, kg	13	0.006	-0.03, 0.04	0.762
Difference in mean fasting glucose, mmol/l	10	0.002	-0.001, 0.004	0.170
Difference in mean 2-hour glucose, mmol/l	5	-0.004	-0.04, 0.03	0.723

Table 10: Subgroup analysis of effect of ethnicity ratio on T2DM incidence rate, weight, fasting and 2-hour glucose

Ethnicity	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
>70% Caucasian	5	0.99	0.72, 1.37	Reference	10.3
≤70% Caucasian	1	0.70	0.20, 2.49	0.648	-
>70% BME	3	0.65	0.33, 1.26	0.350	0.0
Difference in mean, kg					
>70% Caucasian	7	-1.90	-3.66, -0.14	Reference	91.9
≤70% Caucasian	3	-2.68	-0.93, -0.08	0.685	93.9
>70% BME	4	-1.05	-1.78, -0.32	0.602	31.8
Difference in mean fasting glucose, mmol/l					
>70% Caucasian	6	-0.09	-0.18, -0.01	Reference	38.9
≤70% Caucasian	1	-0.13	-0.41, 0.15	0.798	-
>70% BME	3	0.05	-0.06, 0.16	0.122	0.0
Difference in mean 2-hour glucose, mmol/l					
>70% Caucasian	3	-0.16	-0.67, 0.36	Reference	72.5
≤70% Caucasian	1	0.49	-0.48, 1.46	0.528	-
>70% BME	1	-0.44	-1.36, 0.48	0.888	-

## Summary

From the data available:

- study level age and ethnicity were not associated with the effectiveness of the intervention
- the mean percentage of males was found to be associated with higher rate of T2DM incidence and weight gain across intervention arms when compared with controls
- studies which utilised BMI inclusion criteria of  $\geq 25\text{kg/m}^2$  were associated with a greater intervention effect on reduction in T2DM incidence rate and weight loss than those which used no BMI inclusion criteria
- all subgroup analyses for weight displayed high levels of heterogeneity.
- some subgroups contained very few studies, so caution in interpretation is advised.

## Research question 3: What are the key identifiable elements across the most efficacious interventions that constitute a successful programme?

We extracted data regarding specific elements of the programmes used in the studies included. We conducted meta-regression analyses and subgroup analyses for T2DM incidence and weight, fasting and 2-hour glucose change from baseline to assess whether these elements led to better outcomes.

### NICE guideline score

Meta-regression was used to assess the effect of total NICE guidance score (Table 11). If a component of an intervention could not be scored it was assumed the component was not used i.e. scored with a zero. As NICE guidance score increases no changes were seen in either the T2DM incidence rate or in 2 hour glucose, suggesting a consistent effect across scores for these outcomes. A one point increase in NICE score was associated with a 0.47kg larger weight loss in intervention arms compared with control arms (Figure 20). Although adherence to NICE guidelines was not significantly associated with a reduction in 2-hour glucose, a per point increase in NICE score corresponded to a 0.03mmol/l greater reduction in fasting glucose in intervention arms compared with control arms (Figure 21). This suggests that as adherence to NICE guidelines increases the reduction seen in fasting glucose.

When scores were not imputed, there remained no significant association between NICE guidance scores and T2DM incidence rate or 2-hour glucose outcomes. However a one-point increase in NICE score resulted in a larger 0.83kg weight loss in intervention arms compared with control arms. When scores were not imputed a significant per point reduction in mean fasting glucose was no longer observed.

Results for subgroup analysis assessing the impact of categorised NICE scores on incidence, weight and glucose endpoints are given in Table 12. The majority of studies scored between 5 to 8 points; therefore this category was used as baseline for comparison between score categories. For the incidence of T2DM and 2-hour glucose, scoring between 9 to 12 points was not significantly associated with improvement in outcomes than those studies scoring 5 to 8 points. However studies scoring 9 to 12 points tended to have a larger weight loss of -3.24kg in intervention

arms compared with control arms than studies scoring 5-8 points for which intervention arms only achieved 0.57kg more weight loss than control arms. A NICE score of between 9 and 12 points also corresponded to a 0.17mmol/l greater fasting glucose reduction in intervention arms compared with control arms, this was significantly higher than the 0.01mmol/l greater reduction seen in studies scoring 5 to 8 points ( $p=0.02$ ). This suggests that the intervention effect on weight loss and fasting glucose was larger for those studies scoring a higher NICE guidance score, specifically between 9 to 12 points, than studies scoring between 5 to 8 points.

Table 11: Meta-regression results of the effect of imputed NICE guidance score on T2DM incidence rate, weight, fasting and 2-hour glucose

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	13	1.06	0.84, 1.33	0.591
Difference in mean weight, kg	20	-0.47	-0.83, -0.11	0.013
Difference in mean fasting glucose, mmol/l	16	-0.03	-0.07, -0.001	0.043
Difference in mean 2-hour glucose, mmol/l	10	0.04	-0.18, 0.25	0.707

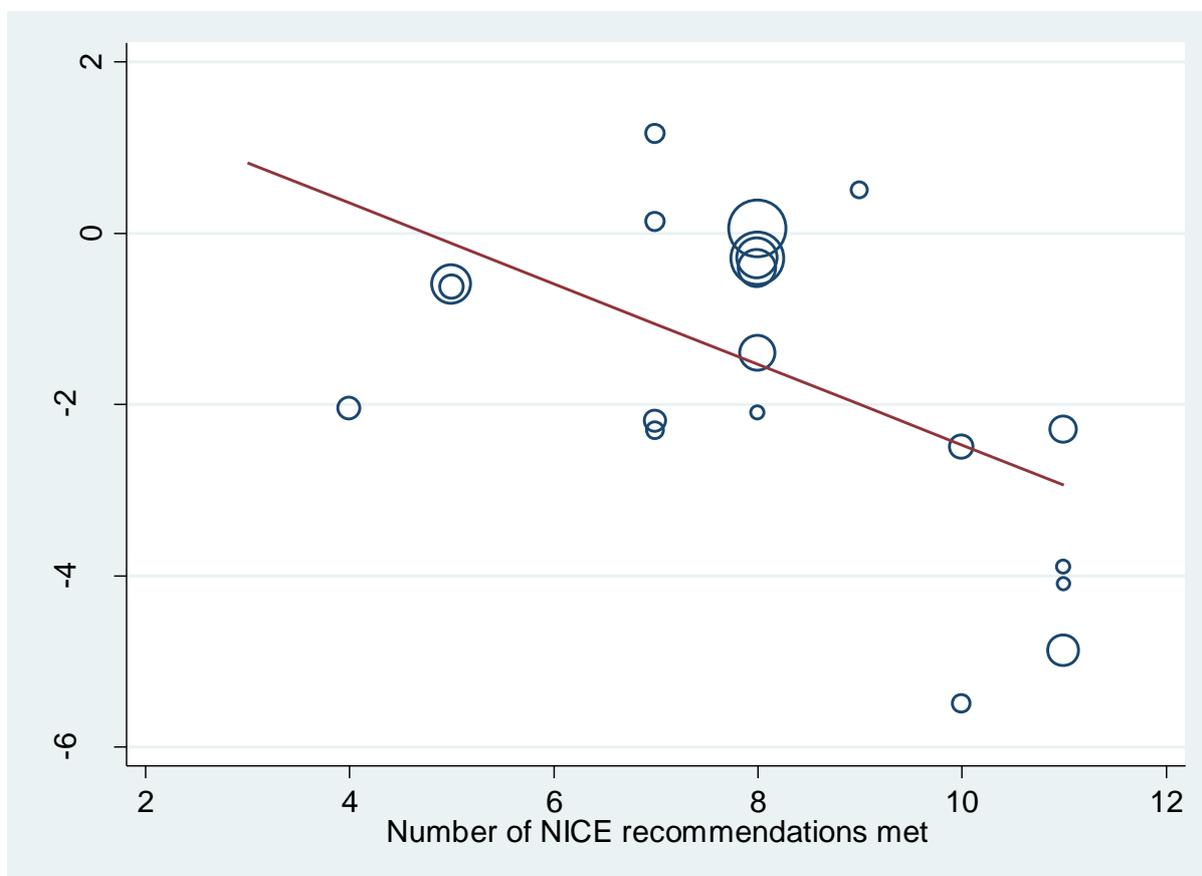


Figure 20: Meta-regression plot of the impact of NICE guidance score on difference in mean weight change between intervention and control arms

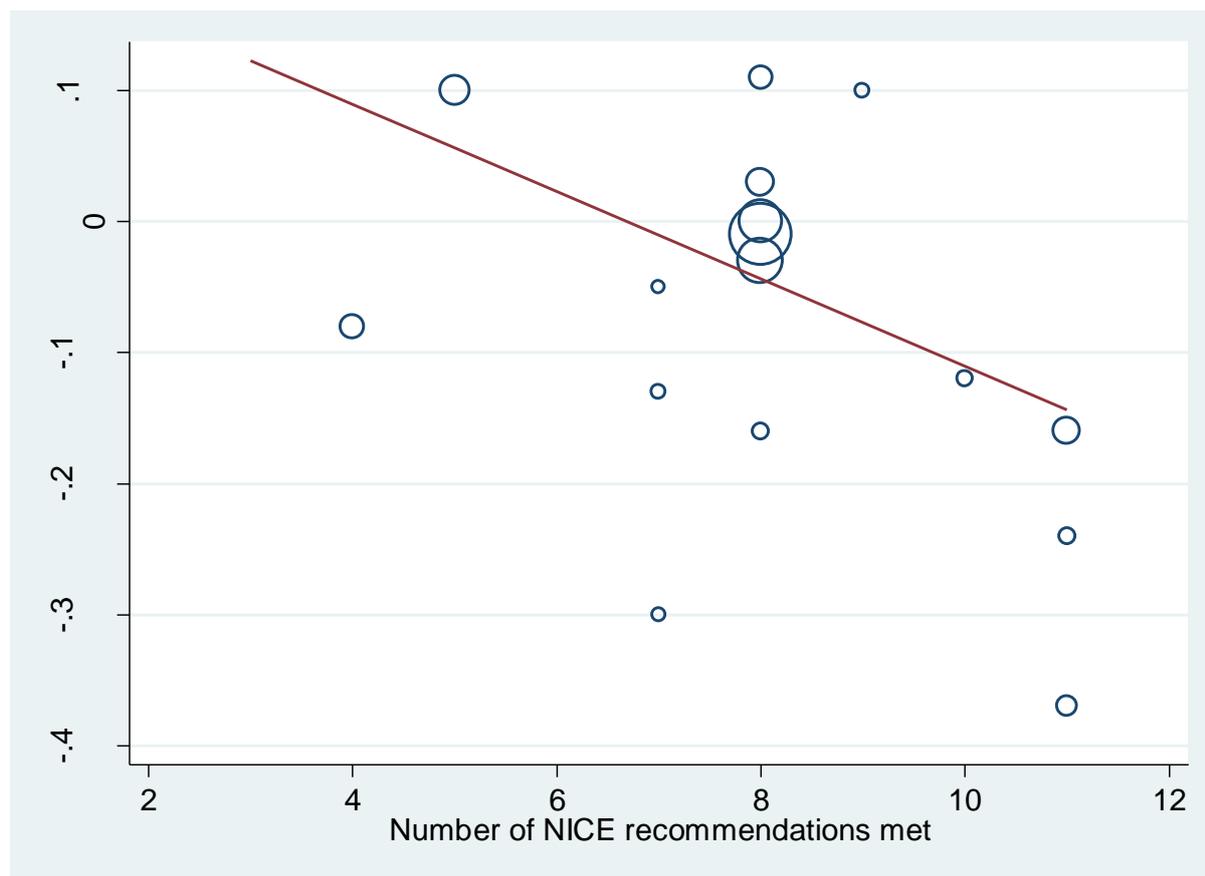


Figure 21: Meta-regression plot of the impact of NICE guidance score on difference in mean fasting glucose change between intervention and control arms

Table 12: Subgroup analysis of effect of categorised NICE scores on T2DM incidence rate, weight, fasting and 2-hour glucose

NICE score	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
0-4	0	-	-	-	-
5-8	11	0.75	0.58, 0.97	Reference	29.2
9-12	2	0.51	0.23, 1.13	0.489	22.2
Difference in mean weight, kg					
0-4	1	-2.05	-3.60, -0.50	0.419	-
5-8	12	-0.57	-1.00, -0.14	Reference	41.8
9-12	7	-3.24	-4.67, -1.81	0.001	78.9
Difference in mean fasting glucose, mmol/l					
0-4	1	-0.08	-0.26,	0.507	-

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		Difference in mean 2-hour glucose, mmol/l			
5-8	10	-0.01	0.10 -0.05, 0.04	Reference	9.1
9-12	5	-0.17	-0.31, -0.04	0.015	46.3
0-4	1	-0.70	-1.49, 0.09	0.456	-
5-8	7	-0.13	-0.39, 0.13	Reference	54.0
9-12	2	-0.58	-1.73, 0.56	0.449	87.2

## IMAGE guideline score

Table 13 presents the results from the meta-regression analyses which assessed the effect of imputed IMAGE guidance score on outcomes. As IMAGE guidance score increases no change was seen in T2DM incidence rate or glucose outcomes, suggesting a consistent effect across scores. A one point increase in IMAGE score was associated with a 1.04kg larger weight loss in intervention arms compared with control arms (Figure 22), resulting in a larger overall weight loss. When IMAGE scores were not imputed the results were comparable.

Subgroup analyses were carried out which assessed the effect of IMAGE score groupings on all endpoints (Table 14). No evidence of a reduction or increase in T2DM incidence rate or glucose outcomes was seen across categories. Achieving an IMAGE score of between 5 to 6 points produced a significantly larger weight loss of 3.36kg in intervention arms when compared with the control arms than scoring between 0 to 2 points which was associated with a 0.06kg weight gain in intervention arms. Therefore the intervention effect on weight was greater as IMAGE score increased, particularly moving from 3 to 4 points to 5 to 6 points.

**Table 13: Meta-regression results of the effect of imputed IMAGE guidance score on T2DM incidence rate weight, fasting and 2-hour glucose**

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	13	0.72	0.45, 1.13	0.139
Difference in mean weight, kg	20	-1.04	-1.50, -0.58	<0.001
Difference in mean fasting glucose, mmol/l	16	-0.03	-0.09, 0.03	0.361
Difference in mean 2-hour glucose, mmol/l	10	-0.09	-0.56, 0.37	0.652

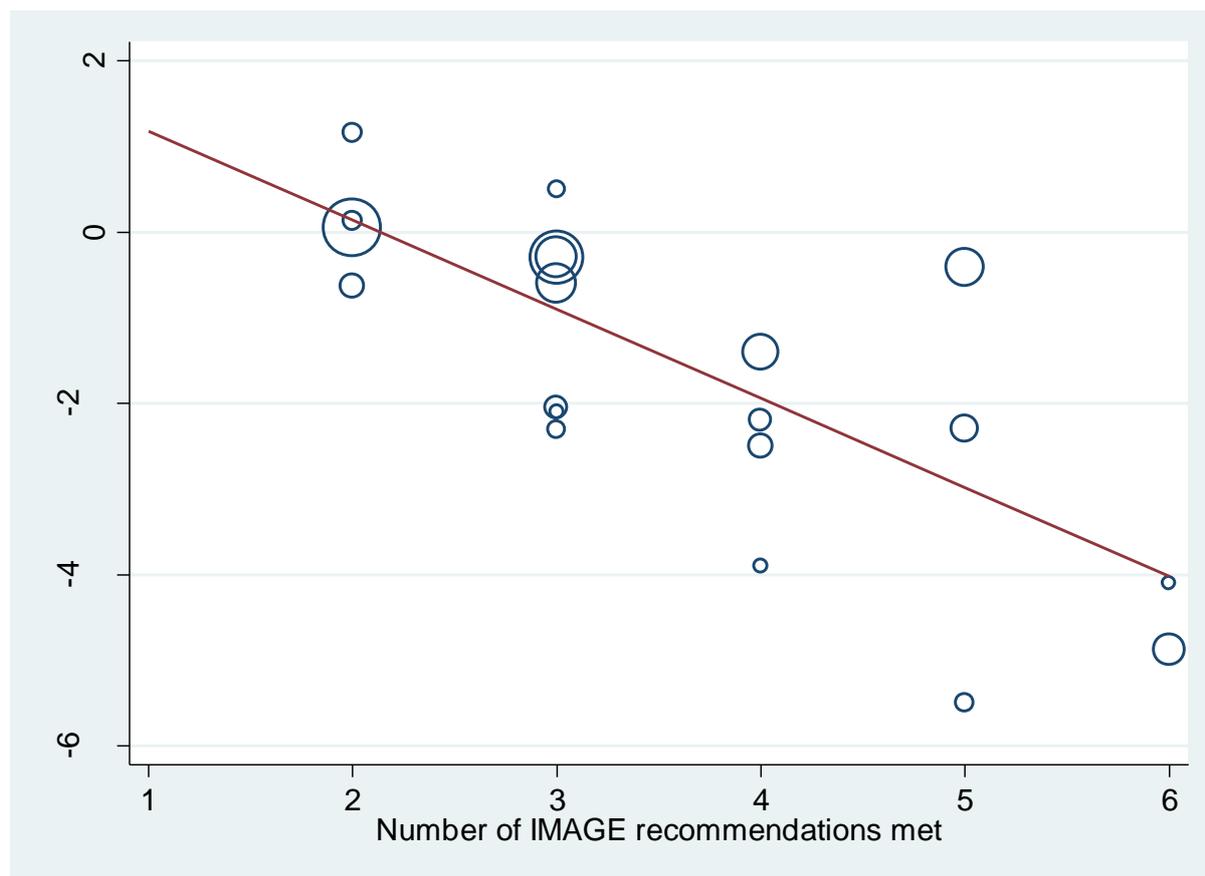


Figure 22: Meta-regression plot of the impact of imputed IMAGE guidance score on difference in mean weight change between intervention and control arms

Table 14: Subgroup analysis of effect of categorised IMAGE scores on T2DM incidence rate, weight, fasting and 2-hour glucose

IMAGE score	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
0-2	4	0.91	0.54, 1.54	Reference	33.6
3-4	9	0.69	0.56, 0.85	0.226	0.0
5-6	0	-	-	-	-
Difference in mean weight, kg					
0-2	4	0.06	-0.47, 0.59	Reference	0.0
3-4	11	-1.31	-1.95, -0.67	0.081	60.3
5-6	5	-3.36	-5.49, -1.22	0.003	91.2
Difference in mean fasting glucose, mmol/l					
0-2	3	-0.17	-0.42, -	Reference	36.9

3-4	10	-0.01	0.09 -0.10, 0.07	0.369	12.6
5-6	3	-0.21	-0.54, 0.08	0.624	75.4
Difference in mean 2-hour glucose, mmol/l					
0-2	3	-0.20	-1.13, 0.73	Reference	75.5
3-4	6	-0.39	-0.75, - 0.04	0.558	72.4
5-6	1	0.0001	-0.57, 0.001	0.838	-

## Programme

Aspects of the intervention programmes across studies were analysed in order to identify components associated with the greatest reduction in T2DM incidence rate as well as those maximising weight loss and reductions in glucose outcomes. The majority of interventions utilised both diet and PA components, with the exception of three RCTs, which used PA as the sole focus of the programme.

Although incidence of T2DM and glucose outcomes were not significantly affected by the type of intervention used, implementing a PA only intervention resulted in a significant 0.16kg weight gain in intervention groups compared with control arms than if a combined diet and PA intervention was utilised, which precipitated an additional weight loss of 1.93kg in intervention arms. This suggests the intervention effect was larger when a combined diet and PA approach was used. It is important to note, however, that the PA subgroup contained only three comparisons, so this result may be an artefact of uneven comparisons between groups.

Heterogeneity was high amongst glucose and weight subgroups, suggesting that the variation in outcomes was not fully explained by the focus of programmes.

**Table 15: Subgroup analysis of effect of intervention contents on T2DM incidence rate, weight, fasting and 2-hour glucose**

Intervention content	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Diet & PA	10	0.69	0.57, 0.84	Reference	0.0
PA only	3	0.94	0.44, 1.98	0.133	38.5
Difference in mean weight, kg					

Diet & PA	17	-1.93	-2.71, -1.15	Reference	83.0
PA only	3	0.16	-0.41, 0.73	0.032	0.0
Difference in mean fasting glucose, mmol/l					
Diet & PA	13	-0.05	-0.12, 0.02	Reference	51.5
PA only	3	-0.10	-0.24, 0.05	0.556	33.4
Difference in mean 2-hour glucose, mmol/l					
Diet & PA	17	-0.33	-0.64, -0.02	Reference	67.7
PA only	3	-0.20	-1.13, 0.73	0.612	75.5

Studies were further grouped depending on what kind of intervention was offered. The most intensive part of an intervention was defined as core, while anything that resembled reduced contact over follow-up time was defined as maintenance.

All RCTs provided either just an intensive core intervention, or paired this with maintenance contact. The results in Table 16 showed that no one type of programme corresponded to significantly better outcomes than another.

**Table 16: Subgroup analysis of effect of type of programme on T2DM incidence rate, weight, fasting and 2-hour glucose**

Programme type	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Core only	8	0.62	0.48, 0.79	Reference	0.0
Core & Maintenance	5	0.93	0.65, 1.33	0.106	23.8
Difference in mean weight, kg					
Core only	9	-1.45	-2.48, -0.41	Reference	79.6
Core & Maintenance	11	-1.69	-2.73, -0.64	0.781	87.2
Difference in mean fasting glucose, mmol/l					
Core only	6	-0.04	-0.12, 0.05	Reference	22.3
Core & Maintenance	10	-0.07	-0.15, 0.01	0.825	57.9
Difference in mean 2-hour glucose, mmol/l					
Core only	5	-0.50	-1.15, 0.15	Reference	79.1

Core & Maintenance	5	-0.12	-0.40, 0.15	0.402	46.7
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The spread of sessions making up an intervention was analysed via subgroup analysis. For studies in which sessions were appropriately spread, a 47% greater reduction in incidence rate of T2DM was seen across intervention arms compared with control arms than just 8% when sessions were not spread over this time frame. Appropriate spread resulted in a smaller additional weight loss in intervention arms of 1.57kg vs. control arms than the 2.32kg weight loss observed for sessions which were not spread over 9 to 18 months. For both glucose endpoints spreading intervention sessions over 9 to 18 months did not result in significant changes in outcomes than spreading sessions over a different time period.

**Table 17: Subgroup analysis of effect of session spread on T2DM incidence rate, weight, fasting and 2-hour glucose**

Sessions spread over 9-18 months	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	6	0.92	0.74, 1.15	Reference	0.0
Yes	7	0.53	0.39, 0.71	0.014	0.0
Difference in mean weight, kg					
No	12	-2.32	-3.43, -1.21	Reference	84.3
Yes	8	-1.57	-1.20, 0.03	0.034	60.7
Difference in mean fasting glucose, mmol/l					
No	8	-0.02	-0.06, 0.02	Reference	0.0
Yes	8	-0.10	-0.22, 0.02	0.414	65.0
Difference in mean 2-hour glucose, mmol/l					
No	7	-0.11	-0.38, 0.16	Reference	50.0
Yes	3	-0.55	-1.17, 0.06	0.310	74.7

The length of the programme was defined as the duration of the most intensive part of the intervention, i.e. the core sessions.

Table 18 presents the results for the subgroup analysis assessing the impact of core programme length on all endpoints. For all outcomes the intervention effect was not significantly affected by the length of programme. However, there was suggestion that T2DM incidence rate decreased by 39% in intervention arms vs. control arms with a programme length of over six months than a shorter programme length of fewer than three months. High levels of heterogeneity were apparent for weight and glucose subgroups suggesting variability was high between RCT study comparisons.

**Table 18: Subgroup analysis of effect of core programme length on T2DM incidence rate, weight, fasting and 2-hour glucose**

Programme length	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Up to 3 months	7	0.97	0.75, 1.27	Reference	0.0
4-6 months	0	-	-	-	-
Longer than 6 months	6	0.61	0.48, 0.78	0.065	0.0
Difference in mean weight, kg					
Up to 3 months	10	-0.98	-1.84, -0.13	Reference	71.1
4-6 months	3	-3.07	-6.42, 0.28	0.112	94.5
Longer than 6 months	7	-1.69	-2.73, -0.65	0.413	80.8
Difference in mean fasting glucose, mmol/l					
Up to 3 months	10	-0.11	-0.19, 0.02	Reference	45.5
4-6 months	2	-0.06	-0.25, 0.12	0.662	65.5
Longer than 6 months	4	0.02	-0.05, 0.10	0.079	23.0
Difference in mean 2-hour glucose, mmol/l					
Up to 3 months	7	-0.14	-0.46, 0.19	Reference	50.1
4-6 months	0	-	-	-	-
Longer than 6 months	3	-0.53	-1.15, 0.09	0.379	84.8

A subgroup analysis for session length was carried out, where session lengths refer to the duration of sessions which were most frequently delivered. If a time range for the sessions was reported, the midpoint was used for categorisation purposes.

Table 19 presents the results of the subgroup analysis. The intervention effect was consistent across session lengths for the incidence of T2DM and glucose outcomes. A significantly greater weight loss in intervention arms compared with control arms of 2.20kg was observed for RCTs with a typical session length of between one to two hours than studies with a session length of less than an hour. This suggested that sessions of between one to two hours duration were associated with a greater intervention effect.

**Table 19: Subgroup analysis of effect of session length on T2DM incidence rate, weight, fasting and 2-hour glucose**

Session length	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
<1 hours	2	0.64	0.37, 1.09	Reference	69.2
1-2 hours	4	0.49	0.24, 0.99	0.606	0.0
>2 hours	5	0.87	0.59, 1.28	0.378	37.8
Difference in mean weight, kg					
<1 hours	2	-1.08	-2.99, 0.84	Reference	71.3
1-2 hours	7	-2.20	-2.79, -1.60	0.004	6.8
>2 hours	6	-0.09	-0.50, 0.33	0.327	0.0
Difference in mean fasting glucose, mmol/l					
<1 hours	1	-0.01	-0.08, 0.06	0.412	-
1-2 hours	6	-0.12	-0.27, 0.03	Reference	60.9
>2 hours	6	-0.01	-0.09, 0.07	0.269	30.5
Difference in mean 2-hour glucose, mmol/l					
<1 hours	1	-0.05	-0.29, 0.19	0.378	-
1-2 hours	4	-0.58	-1.15, -0.01	Reference	62.6
>2 hours	5	-0.16	-0.56, 0.25	0.332	67.7

It was noted whether any attempts had been made to check the feasibility of the proposed intervention, either via pilot implementation, or identifying areas for improvement via focus groups or participant feedback. Half of the studies did carry out some sort of fidelity checking procedure for the intervention.

Table 20 presents the results of the subgroup analysis which was conducted. None of the outcomes were significantly affected by whether fidelity checking procedures were carried out or not.

**Table 20: Subgroup analysis of effect of fidelity checking on T2DM incidence rate, weight, fasting and 2-hour glucose**

Fidelity checking procedures	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	5	0.62	0.48, 0.79	Reference	0.0
Yes	8	0.95	0.73, 1.23	0.102	0.0
Difference in mean weight, kg					
No	10	-1.49	-2.34, -0.64	Reference	77.3
Yes	10	-1.66	-2.89, -0.42	0.907	88.4
Difference in mean fasting glucose, mmol/l					
No	7	-0.04	-0.14, 0.06	Reference	61.9
Yes	9	-0.07	-0.14, 0.004	0.560	31.5
Difference in mean 2-hour glucose, mmol/l					
No	5	-0.44	-0.86, -0.02	Reference	73.7
Yes	5	-0.09	-0.49, 0.31	0.385	56.2

## Frequency and contact time

Meta-regression analysis was conducted to assess the effect of the total number of contacts making up an intervention over the initial 12 to 18 months on outcomes.

The total number of contacts ranged from one to 65, with a median number of contacts of eight (interquartile range 5 to 16). One RCT did not report the number of contacts offered as part of the intervention.

A single unit increase in contact frequency did not significantly impact the incidence rate of T2DM at the 5% level. For the weight outcome, as the number of contacts increased weight loss increased by 0.08kg in intervention arms compared with control arms, resulting in a larger overall weight loss. This suggests that potentially the greater the number of contacts making up an intervention the greater the weight loss, i.e. a larger intervention effect. Unit increases in contact frequency did not correspond to significantly improved fasting and 2-hour glucose outcomes.

Subgroup analyses were carried out in order to identify the optimum number of contacts and are presented in Table 21. Cut points for categories were based on coding for IMAGE guidance scores for maximising frequency of contacts over one year. Where total contacts did not exceed seven, zero was scored (minimum content); for up to 12 contacts one point was scored (moderate contact) and for 13 or more contacts two points were scored (maximised contact).

Studies offering moderate or maximised contact did not significantly reduce incidence of T2DM compared with studies offering minimum contact. Moderate contact was not significantly associated with greater weight loss compared with minimum contact, however 13 or more contacts in a year resulted in a 3.15kg larger weight loss in intervention arms compared with control arms than interventions consisting of up to seven contacts in a year. This suggests maximising contact frequency within an intervention to 13 or more contacts in a 12 month period produced a larger intervention effect on weight outcomes. Large amounts of heterogeneity, however continued to prevail within subgroups for the weight endpoint suggesting that results should be interpreted with caution, as there was continued variability between studies.

**Table 21: Meta-regression results of the effect of contact frequency on T2DM incidence rate, weight, fasting and 2-hour glucose**

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	12	0.91	0.82, 1.01	0.061
Difference in mean weight, kg	19	-0.08	-0.11, -0.04	<0.001
Difference in mean fasting glucose, mmol/l	15	-0.001	-0.01, 0.004	0.641
Difference in mean 2-hour glucose, mmol/l	9	0.01	-0.16, 0.18	0.877

**Table 22: Subgroup analysis of effect of number of contacts on T2DM incidence rate, weight, fasting and 2-hour glucose**

Contact frequency	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
0-7	8	0.80	0.59, 1.08	Reference	23.9
8-12	3	0.50	0.33, 0.75	0.303	0.0
≥13	1	0.38	0.07, 1.95	0.443	
Difference in mean weight, kg					
0-7	8	-0.66	-1.32, -0.01	Reference	58.0
8-12	5	-2.02	-3.18, -0.85	0.176	49.8
≥13	5	-3.15	-5.24, -1.07	0.019	92.0
Difference in mean fasting glucose, mmol/l					
0-7	8	-0.04	-0.15, 0.05	Reference	19.9
8-12	4	-0.16	-0.37, 0.05	0.232	61.8
≥13	3	-0.01	-0.17, 0.14	0.646	63.0
Difference in mean 2-hour glucose, mmol/l					
0-7	7	-0.39	-0.83, 0.04	Reference	77.2
8-12	2	-0.12	-0.61, 0.36	0.691	0.0
≥13	0	-	-	-	-

Meta-regression was carried out to assess the effect of total number of hours of contact in the first 12 to 18 months on all outcomes.

As shown in Table 23, an increase in contact hours did not correspond to a significant change in incidence rate of T2DM or glucose outcomes in intervention arms vs. control arms. However an hour increase in contact in the first 12-18 months resulted in a significant 0.10kg greater weight loss in intervention arms compared with control arms.

The ideal amount of contact time provided over the first 12-18 months was assessed for impact on outcomes, via subgroup analyses. The cut point of 16 hours was based on NICE guideline score criteria.

Although no significant effect of contact time was seen on the incidence rate of T2DM, providing 16 or more hours of contact had a positive effect on weight loss. Providing a contact time of 16 or more hours resulted in a 3.38kg greater weight loss in intervention arms compared with control arms, whereas providing less than 16 hours of contact resulted in only a 0.81kg greater weight loss in intervention arms. This suggests the intervention effect was greater when more contact time was provided, specifically 16 hours or more. Providing 16 or more hours of contact as part of the intervention did not correspond to a significant reduction in 2-hour glucose.

However, there was significant evidence that providing this amount of contact time resulted in a 0.18mmol/l greater fasting glucose reduction for individuals receiving a prevention programme than usual care, when compared with providing less than 16 hours of contact. High levels of heterogeneity were apparent across all but one subgroup, indicating contact time did not explain all of the variation in outcomes between studies (Table 24).

**Table 23: Meta-regression results of the effect of contact hours on T2DM incidence rate, weight, fasting and 2-hour glucose**

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	12	0.98	0.88, 1.08	0.611
Difference in mean weight, kg	19	-0.10	-0.16, -0.04	0.004
Difference in mean fasting glucose, mmol/l	16	-0.001	-0.01, 0.01	0.719
Difference in mean 2-hour glucose, mmol/l	10	0.005	-0.09, 0.10	0.906

**Table 24: Subgroup analysis of effect of number of number of contact hours on T2DM incidence rate, weight, fasting and 2-hour glucose**

Contact time	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
<16 hours	12	0.73	0.57, 0.93	Reference	28.4
≥16 hours	1	1.03	0.06, 1639	0.809	
Difference in mean weight, kg					
<16 hours	14	-0.81	-1.29, -0.33	Reference	55.9
≥16 hours	6	-3.38	-5.07, -1.68	0.002	81.4
<16 hours	12	-0.01	-0.05, 0.03	Reference	1.7
≥16 hours	4	-0.18	-0.35, -0.01	0.016	58.4
<16 hours	9	-0.32	-0.32, -0.01	Reference	71.1
≥16 hours	1	0.0	-0.57, 0.57	0.582	-

Subgroup analyses of contact frequency during the core part of the programme were carried out. Frequency of contact during the intensive phase were categorised according to how often sessions were delivered. If a time period range was reported, for example 12 sessions delivered over 12-14 weeks, the category closest to the average time between contacts was used, in this case weekly.

Table 25 presents the results of the subgroup analysis. Increasing time between contacts did not significantly increase or decrease incidence of T2DM or glucose outcomes in intervention arms compared with control arms. Studies which offered only one-off intervention sessions produced a 0.02kg additional weight gain in intervention arms when compared with control arms than studies which implemented weekly sessions, which were associated with the largest additional 3.08kg weight loss in intervention arms vs. control arms. Having sessions held every two months was associated with a smaller added weight loss of 0.41kg in intervention arms.

There was also indication that contact every other week produced a 1.11kg worth of extra weight loss in intervention arms. Monthly and every other month contact resulted in 0.11 and 0.03mmol/l greater fasting glucose increases in intervention arms compared with control arms than weekly contact. Varied levels of heterogeneity were apparent across subgroups, arising from a combination of few studies in some subgroups and variability between studies. This encourages cautious interpretation.

Table 25: Subgroup analysis of effect of number of contact frequency on T2DM incidence rate, weight, fasting and 2-hour glucose

Contact frequency	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Weekly	3	0.69	0.10, 4.70	Reference	0.0
Fortnightly	0	-	-	-	-
Monthly	1	0.38	0.07, 1.95	0.652	-
Every 2 months	2	0.75	0.51, 1.12	0.941	6.3
Every 3 months	3	0.52	0.38, 0.73	0.793	0.0
One-off	4	0.97	0.66, 1.42	0.734	30.1
Difference in mean weight, kg					
Weekly	8	-3.08	-4.42, -1.74	Reference	76.7
Fortnightly	2	-1.11	-2.69, 0.47	0.081	67.7
Monthly	1	-1.40	-2.41, -0.39	0.222	-
Every 2 months	2	-0.41	-0.95, 0.14	0.017	0.0
Every 3 months	3	-1.76	-3.00, -0.52	0.190	42.6
One-off	4	0.02	-0.46, 0.50	0.002	0.0
Difference in mean fasting glucose, kg					
Weekly	6	-0.17	-0.29, 0.05	Reference	37.0
Fortnightly	2	-0.02	-0.13, 0.10	0.125	0.0
Monthly	1	0.11	-0.07, 0.29	0.050	-
Every 2 months	2	0.03	-0.08, 0.13	0.027	45.0
Every 3 months	1	-0.12	-0.38, 0.14	0.756	-
One-off	4	-0.04	-0.13, 0.04	0.107	21.5
Difference in mean 2-hour glucose, kg					
Weekly	2	-0.12	-0.61, 0.36	Reference	0.0
Fortnightly	1	-0.70	-1.49, 0.09	0.478	-
Monthly	0	-	-	-	-
Every 2 months	2	-0.23	-0.66, 0.20	0.877	65.3
Every 3 months	1	-1.17	-1.76, -	0.165	-

One-off	4	-0.05	0.58 -0.50, 0.40	0.780	63.2
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## Behaviour change

Several subgroup analyses were conducted to assess both the use of certain behaviour change techniques as part of intervention delivery, and also whether use of an optimum number of techniques positively affected outcomes.

The use of self-regulatory techniques, such as self-monitoring of outcomes and relapse prevention methods, did not significantly impact incidence of T2DM, weight or fasting glucose outcomes, as seen in Table 26. There was evidence that for individuals receiving intervention utilising self-regulatory techniques there was a smaller reduction of 0.15mmol/l in 2-hour glucose compared with usual care, than for those interventions not using monitoring for whom the average reduction was 1.17mmol/l. However, only one study was included in the subgroup of interventions not utilising self-regulation methods for the 2-hour glucose outcome, so results should not be over-interpreted.

**Table 26: Subgroup analysis of effect of using self-regulatory techniques on T2DM incidence rate, weight, fasting and 2-hour glucose**

Self-regulatory	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	2	0.60	0.34, 1.04	Reference	0.0
Yes	11	0.76	0.58, 0.99	0.561	29.1
Difference in mean weight, kg					
No	3	-0.99	-2.66, 0.68	Reference	67.0
Yes	17	-1.68	-2.47, -0.89	0.527	85.6
Difference in mean fasting glucose, mmol/l					
No	2	-0.02	-0.23, 0.20	Reference	20.5
Yes	14	-0.06	-0.12, 0.002	0.715	51.7
Difference in mean 2-hour glucose, mmol/l					
No	1	-1.17	-1.76, -0.58	Reference	-
Yes	9	-0.15	-0.38, 0.08	0.048	48.4

Utilising an empathy building approach did not significantly affect incidence of T2DM. However, using this technique resulted in a significantly reduced weight loss of 0.80kg more in intervention arms compared with control arms, than not using this approach, which resulted in a 2.73kg greater weight loss in intervention arms. High levels of heterogeneity were seen for weight subgroups which suggest that there was still a large amount of variability between studies, advocating caution. Although the use of empathy building techniques as part of the intervention did not affect fasting glucose levels, the approach was associated with a negative impact on 2-hour glucose levels. Person-centred intervention corresponded to a 0.03mmol/l decrease in 2-hour glucose in intervention arms compared with control arms, whereas bypassing this approach resulted in a higher 0.77mmol/l reduction in 2-hour glucose levels. This suggests that an empathy building approach detracts from the intervention effect.

**Table 27: Subgroup analysis of effect of using empathy building techniques on T2DM incidence rate, weight, fasting and 2-hour glucose**

Empathy building approach	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	9	0.57	0.36, 0.89	Reference	37.5
Yes	4	0.79	0.58, 1.06	0.315	0.0
Difference in mean weight, kg					
No	8	-2.73	-4.17, -1.29	Reference	85.9
Yes	12	-0.80	-1.40, -0.20	0.021	66.0
Difference in mean fasting glucose, mmol/l					
No	5	-0.07	-0.18, 0.04	Reference	44.0
Yes	11	-0.05	-0.12, 0.02	0.859	51.7
Difference in mean 2-hour glucose, mmol/l					
No	3	-0.77	-1.20, -0.34	Reference	36.1
Yes	7	-0.03	-0.25, 0.19	0.013	35.1

Use of motivational techniques did not significantly impact the incidence rate of T2DM or glucose outcomes as seen in Table 28. However using motivational techniques resulted in a larger 1.90kg additional weight loss in intervention arms in comparison with the smaller reduction of 0.97kg observed when these techniques were not utilised.

**Table 28: Subgroup analysis of effect of using motivational techniques on T2DM incidence rate, weight, fasting and 2-hour glucose**

Motivation	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	7	0.76	0.57, 0.99	Reference	0.0
Yes	6	0.74	0.47, 1.17	0.723	59.3
Difference in mean weight, kg					
No	11	-0.97	-1.68, -0.26	Reference	51.1
Yes	9	-1.90	-2.96, -0.84	0.040	88.3
Difference in mean fasting glucose, mmol/l					
No	8	0.001	-0.07, 0.07	Reference	20.1
Yes	8	-0.11	-0.20, -0.02	0.139	57.4
Difference in mean 2-hour glucose, mmol/l					
No	11	-0.36	-0.79, 0.08	Reference	61.7
Yes	9	-0.23	-0.69, 0.23	0.734	79.4

Use of staggered goals and similar approaches to gradually build confidence had no significant impact on either T2DM incidence, weight or glucose outcomes, compared with not using such techniques, as shown in Table 29.

**Table 29: Subgroup analysis of effect of using gradual confidence building techniques on T2DM incidence rate, weight, fasting and 2-hour glucose**

Gradual building of confidence	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	4	0.74	0.53, 1.03	Reference	0.0
Yes	9	0.72	0.50, 1.03	0.928	43.1
Difference in mean weight, kg					
No	13	-0.73	-1.28, -0.19	Reference	41.7
Yes	7	-2.40	-3.67, -1.13	0.331	89.8
Difference in mean fasting glucose, mmol/l					
No	6	-0.06	-0.18, 0.06	Reference	68.4
Yes	10	-0.05	-0.12, 0.01	0.933	26.3
Difference in mean 2-hour glucose, mmol/l					
No	4	-0.23	-0.53, 0.07	Reference	39.7
Yes	6	-0.34	-0.85, 0.17	0.900	78.2

Subgroup analyses were conducted assessing the impact of the use of three or more behaviour change or 'self-regulatory' techniques as part of the intervention. The cut-point of three was used in line with IMAGE guideline scoring.

Results of the subgroup analyses for all outcomes are shown in Table 30. The effect of intervention was shown to be consistent on T2DM incidence, weight loss and fasting glucose outcomes regardless of whether three or more behaviour change techniques were used or not. However, using three or more techniques was associated with a significantly smaller reduction in 2-hour glucose of 0.15mmol/l for those receiving the intervention compared with usual care, than the reduction of 1.17 mmol/l observed for using fewer than three techniques. Results should be interpreted with caution as only one study used fewer than three of the recommended behaviour change techniques for the 2-hour glucose outcome. In addition large amounts of heterogeneity, particularly for the weight outcome may have impacted results.

**Table 30: Subgroup analysis of effect of using behaviour change techniques on T2DM incidence rate, weight, fasting and 2-hour glucose**

Behaviour change techniques	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
<3 techniques	2	0.60	0.34, 1.04	Reference	0.0
≥3 techniques	11	0.76	0.58, 0.99	0.561	29.1
Difference in mean weight, kg					
<3 techniques	2	-1.57	-2.28, -0.86	Reference	67.5
≥3 techniques	18	-1.58	-2.34, -0.81	0.984	85.0
Difference in mean fasting glucose, mmol/l					
<3 techniques	1	-0.12	-0.38, 0.14	Reference	-
≥3 techniques	15	-0.05	-0.11, 0.01	0.715	49.6
Difference in mean 2-hour glucose, mmol/l					
<3 techniques	1	-1.17	-1.76, -0.58	Reference	-
≥3 techniques	9	-0.15	-0.38, 0.08	0.048	48.4

Techniques advocated by the NICE/IMAGE guidelines were also assessed for their effect on outcomes, via subgroup analysis. Only a minority (n=4) of RCT studies attempted to engage participants with social support outside of the intervention group.

Table 31 presents the results of the analysis. Incidence of T2DM, weight and 2-hour glucose did not change significantly when social support was engaged compared with when it was not engaged. High levels of heterogeneity were apparent for the weight outcome, suggesting that not all variability was explained by the engagement of social support. Also only four RCTS did engage such support, compared with 16 that did not, suggesting that results should not be overemphasised. Adherence to this guideline also resulted in a significant 0.25mmol/l reduction in fasting glucose in intervention arms vs. control arms when compared with lack of social engagement; the latter of which only corresponded to a 0.02mmol/l decrease across intervention arms. Again, it is important to be cautious about these results as only two intervention and control comparisons were coded as engaging social support.

**Table 31: Subgroup analysis of effect of engaging social support on T2DM incidence rate, weight, fasting and 2-hour glucose**

Engage social support	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	12	0.73	0.56, 0.95	Reference	28.5
Yes	1	0.71	0.34, 1.50	0.999	
Difference in mean weight, kg					
No	16	-1.18	-1.81, -0.54	Reference	75.2
Yes	4	-2.94	-4.98, -0.89	0.095	86.3
Difference in mean fasting glucose, mmol/l					
No	13	-0.02	-0.06, 0.03	Reference	12.4
Yes	2	-0.25	-0.46, -0.05	0.010	60.0
Difference in mean 2-hour glucose, mmol/l					
No	9	-0.32	-0.63, -0.01	Reference	71.1
Yes	1	0.0	-0.57, 0.57	0.582	-

## Setting and delivery

Subgroup analyses were conducted to assess the effect of setting and delivery of intervention on outcomes. The majority of RCTs (n=14), were carried out outside of the UK. Of these, eight were US based, four European, one Australian and one Japanese. Only six RCTs were implemented in the UK.

Incidence rate of T2DM did not significantly differ in intervention arms compared with control arms for UK and non-UK studies. A significantly larger weight loss was observed in intervention arms for non-UK studies of 2.15kg compared with control arms, than UK studies for which the mean difference in weight loss between arms was only 0.21kg greater in intervention arms. High heterogeneity was apparent for non-UK studies, particularly for the weight endpoint. This and the greater number of non-UK studies available for comparison, suggests that inherent variability between studies should lead to cautious emphasis on results. The country in which studies were conducted did not, however, significantly affect glucose outcomes.

**Table 32: Subgroup analysis of effect of country on T2DM incidence rate, weight, fasting and 2-hour glucose**

Country	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
UK	6	0.77	0.52, 1.13	Reference	58.2
Other	7	0.68	0.49, 0.95	0.488	0.0
Difference in mean weight, kg					
UK	6	-0.21	-0.83, 0.40	Reference	31.9
Other	14	-2.15	-3.07, -1.24	0.029	84.8
Difference in mean fasting glucose, mmol/l					
UK	4	-0.04	-0.13, 0.04	Reference	21.5
Other	12	-0.06	-0.14, 0.02	0.906	54.8
Difference in mean 2-hour glucose, mmol/l					
UK	4	-0.05	-0.50, 0.40	Reference	63.2
Other	6	-0.44	-0.81, -0.06	0.307	67.3

Further subgroup analyses were conducted to assess whether the setting of the intervention affected incidence rate of T2DM or other endpoints. Interventions grouped under community included those implemented in settings that were publicly accessible such as the church or YMCA, whereas ‘private’ referred to interventions delivered through private companies. Studies, for which several venues were utilised to deliver the intervention, were grouped under the ‘various’ heading.

The results in Table 33 suggest that the effect of place of delivery on incidence rate of T2DM was consistent across settings. However, private delivery resulted in a 5.50kg greater weight loss in intervention compared with control arms than delivery in primary care, where weight loss was 1.17kg higher in intervention arms. However, only one study which delivered an intervention in a private setting was included in the subgroup analysis so results must be interpreted with caution. High heterogeneity was displayed for all outcomes. Some subgroups also contained fewer than three studies, which indicate that less emphasis should be placed on these results. The intervention setting did not correspond to a reduction or increase in fasting or 2-hour glucose levels in intervention arms vs. control arms.

**Table 33: Subgroup analysis of effect of intervention setting on T2DM incidence rate, weight, fasting and 2-hour glucose**

Intervention setting	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Primary Care	4	0.79	0.53, 1.18	Reference	0.0
Outpatient	5	0.77	0.49, 1.23	0.863	66.4
Community	1	1.09	0.01, 122.80	0.872	-
Various	2	0.62	0.36, 1.06	0.754	0.0
Difference in mean weight, kg					
Primary Care	5	-1.17	-2.31, -0.02	Reference	66.2
Outpatient	6	-0.56	-1.49, 0.36	0.489	69.5
Community	4	-2.84	-5.28, -0.39	0.175	91.8
Various	3	-0.95	-1.79, -0.11	0.866	24.4
Private	1	-5.50	-7.46, -3.54	0.034	-
Difference in mean fasting glucose, mmol/l					
Primary Care	5	-0.02	-0.13, 0.08	Reference	40.2
Outpatient	5	-0.13	-0.26, 0.003	0.311	69.0
Community	3	-0.06	-0.19, 0.07	0.762	31.2
Various	2	0.02	-0.16, 0.19	0.707	57.9
Difference in mean 2-hour glucose, mmol/l					

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Primary Care	1	-0.05	-0.29, 0.19	0.720	-
Outpatient	5	-0.02	-0.36, 0.33	Reference	51.1
Community	1	-0.44	-1.36, 0.48	0.485	-
Various	2	-0.55	-0.95, -0.15	0.106	0.0

The mode of delivery – face to face or remote contact – was assessed across the whole intervention period, both core and maintenance parts, via subgroup analysis.

Table 34 presents the results of the analysis for all outcomes. The intervention effect remained consistent across modes of deliveries for all outcomes. Variability between studies was high, particularly for weight and glucose outcomes.

**Table 34: Subgroup analysis of effect of mode of delivery on T2DM incidence rate, weight, fasting and 2-hour glucose**

Mode of delivery	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Face to face	8	0.62	0.48, 0.79	Reference	0.0
Remote	1	0.33	0.01, 8.18	0.724	-
Face to face & remote	4	0.94	0.63, 1.39	0.101	38.0
Difference in mean weight, kg					
Face to face	13	-1.58	-2.43, -0.74	Reference	76.2
Remote	1	-2.10	-4.59, 0.39	0.825	-
Face to face & remote	6	-1.57	-2.95, -0.09	0.927	92.2
Difference in mean fasting glucose, mmol/l					
Face to face	9	-0.08	-0.18, 0.02	Reference	54.6
Remote	1	-0.16	-0.41, 0.09	0.646	-
Face to face & remote	6	-0.03	-0.10, 0.05	0.519	45.8
Difference in mean 2-hour glucose, mmol/l					
Face to face	7	-0.43	-0.89, 0.02	Reference	71.5
Remote	0	-	-	-	-
Face to face & remote	3	-0.08	-0.41, 0.26	0.386	59.4

Table 35 presents the subgroup analyses looking at the effect of HCP/non-HCP delivery of the intervention on outcomes. There was no evidence to suggest that an intervention was more or less effective depending on who delivered it.

**Table 35: Subgroup analysis of effect of HCP delivery on T2DM incidence rate, weight, fasting and 2-hour glucose**

HCP delivery	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	6	0.95	0.57, 1.58	Reference	8.5
Yes	7	0.69	0.55, 0.86	0.292	10.2
Difference in mean weight, kg					
No	9	-2.05	-3.59, -0.50	Reference	90.9
Yes	11	-1.13	-1.74, -0.51	0.364	62.0
No	7	-0.07	-0.16, 0.01	Reference	29.0
Yes	9	-0.05	-0.13, 0.03	0.626	57.4
No	4	-0.23	-0.93, 0.46	Reference	66.7
Yes	6	-0.33	-0.66, 0.01	0.722	72.6

As seen in Table 36, outcomes remained consistent across individual, group or combined modes of intervention delivery.

**Table 36: Subgroup analysis of effect of delivery on T2DM incidence rate, weight, fasting and 2-hour glucose**

Delivery	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Individual	2	0.47	0.21, 1.04	0.151	0.0
Group	5	0.98	0.73, 1.32	Reference	6.9
Group & individual	6	0.63	0.49, 0.81	0.096	0.0
		Difference in mean weight, kg			
Individual	2	-2.40	-3.66, -1.13	0.623	0.0
Group	9	-1.54	-2.69, -0.39	Reference	84.6
Group & individual	9	-1.48	-2.56, -0.39	0.941	86.5
		Difference in mean fasting glucose, mmol/l			
Individual	2	-0.14	-0.32, 0.04	0.770	0.0
Group	7	-0.11	-0.21, -0.01	Reference	53.6
Group & individual	7	-0.004	-0.09, 0.08	0.162	47.1
		Difference in mean 2-hour glucose, mmol/l			
Individual	1	-1.17	-1.76, -0.58	0.075	-
Group	7	-0.14	-0.46, 0.19	Reference	50.1
Group & individual	2	-0.23	-0.66, 0.20	0.748	65.3

The majority of studies employed group, or group and individual intervention sessions; therefore identification of the optimum group size was carried out via subgroup analysis for all outcomes. Where a range for the group size was reported, the midpoint was taken for categorisation purposes. If a range crossed widely over two categories, e.g. 10-20, the study was allocated to the larger group size category as a conservative categorisation. If intervention was delivered individually then the group size was categorised as less than ten. If no group size was reported, which

was the case for five RCTs, it was assumed that a group size of up to 15 was not used (NICE guideline), i.e. that more than 15 individuals made up a group.

Table 37 displays the results of the subgroup analysis. The effect of intervention on the incidence rate of T2DM remained consistent across group size categories. For the weight outcome a group size of 10 to 15 individuals resulted in a larger additional 3.80kg weight loss in intervention arms vs. control arms than using a group size of fewer than ten individuals, which was associated with a smaller 0.71kg additional weight loss in intervention arms. The optimum group size to elicit the greatest intervention effect appeared to be 10-15 participants, which was in line with NICE/IMAGE guidelines. The intervention effect remained consistent across group size categories for all outcomes. However, it is important to note that the majority of studies which reported fasting and/or 2-hour glucose changes implemented intervention group sizes of fewer than ten, resulting in very uneven subgroup analyses.

**Table 37: Subgroup analysis of effect of group size on T2DM incidence rate, weight, fasting and 2-hour glucose**

Group size	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
<10	9	0.75	0.57, 1.00	Reference	41.8
10-15	2	1.04	0.10, 11.38	0.797	0.0
>15	2	0.49	0.24, 1.01	0.359	0.0
Difference in mean weight, kg					
<10	11	-0.71	-1.34, -0.07	Reference	62.6
10-15	4	-3.80	-5.21, -2.38	0.003	57.4
>15	5	-1.78	-3.07, -0.48	0.202	83.3
Difference in mean fasting glucose, mmol/l					
<10	9	-0.08	-0.23, -0.002	Reference	51.2
10-15	3	-0.16	-0.41, -0.06	0.323	0.0
>15	4	0.04	-0.04, 0.13	0.104	0.0
Difference in mean 2-hour glucose, mmol/l					
<10	7	-0.20	-0.54, 0.14	Reference	73.5
10-15	1	-0.44	-1.36, 0.48	0.772	-
>15	2	-0.55	-0.95, -0.15	0.468	0.0

## Physical activity component

All interventions utilised a PA component, however some RCTs implemented more rigorous supervised PA sessions, as opposed to others which encouraged or recommended a level of PA. Subgroup analyses looked at whether type of PA components offered had an impact on outcomes.

Results of the analysis can be seen in Table 38. The (optional) supervised category covers both interventions which offered optional or compulsory PA sessions and encompasses those studies which had a very large component of this type of PA in conjunction with minimal or no recommendations for level of activity.

The vast majority of studies only offered recommendations for PA levels; the subgroup analyses showed that the intervention effect on incidence of T2DM and weight loss remained consistent across PA components. Use of supervised PA sessions did not significantly impact fasting glucose outcomes. However, there was some evidence that use of supervised PA sessions improved 2-hour glucose outcomes by 1.17mmol/l in arms receiving the prevention programme, compared with those receiving usual care. However, only one study was included in this subgroup so results should not be over interpreted.

**Table 38: Subgroup analysis of effect of PA component type on T2DM incidence rate, weight, fasting and 2-hour glucose**

Type of PA component	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
Recommended	10	0.76	0.59, 0.99	Reference	32.7
(Optional)	1	0.48	0.21, 1.09	0.403	-
Supervised					
Both	2	0.49	0.12, 2.01	0.595	0.0
Difference in mean weight, kg					
Recommended	16	-1.53	-2.35, -0.72	Reference	85.8
(Optional)	1	-2.50	-3.97, -1.03	0.629	-
Supervised					
Both	3	-1.49	-3.47, 0.49	0.971	71.3
Difference in mean fasting glucose, mmol/l					
Recommended	12	-0.06	-0.13, 0.001	Reference	50.0
(Optional)	1	-0.12	-0.38, 0.14	0.771	-
Supervised					
Both	3	-0.004	-0.23, 0.22	0.488	61.8

		0.22			
		Difference in mean 2-hour glucose, mmol/l			
Recommended	9	-0.15	-0.38, 0.08	Reference	48.4
(Optional) Supervised	1	-1.17	-1.76, -0.58	0.048	-
Both	0	-	-	-	-

Pedometers were given to individuals across 12 RCTs. Table 39 presents the results detailing the effect of pedometer use on outcomes. No significant changes in T2DM incidence rate, weight or glucose outcomes were detected between studies that provided pedometers and those that did not.

**Table 39: Subgroup analysis of pedometer use on T2DM incidence rate, weight, fasting and 2-hour glucose**

Pedometer given	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	6	0.61	0.47, 0.79	Reference	0.0
Yes	7	0.92	0.70, 1.22	0.119	4.7
		Difference in mean weight, kg			
No	12	-1.95	-3.02, -0.88	Reference	86.9
Yes	8	-0.96	-1.81, -0.12	0.290	71.7
		Difference in mean fasting glucose, mmol/l			
No	9	-0.02	-0.07, 0.03	Reference	6.2
Yes	7	-0.11	-0.23, 0.005	0.300	67.6
		Difference in mean 2-hour glucose, mmol/l			
No	6	-0.42	-0.85, 0.01	Reference	70.3
Yes	4	-0.08	-0.46, 0.30	0.436	58.7

## Diet component

Subgroup analyses assessing the effect of set calories, fat, and fibre targets on outcomes were carried out. Use of a particular target was only categorised positively if a specific target was mentioned.

Results for target calorie intakes are presented in Table 40. The intervention effect did not significantly differ by use of target calorie intakes for T2DM incidence. A significantly larger additional weight loss of 3.92kg was observed in intervention arms, when a set calorie intake was utilised, which was more than triple the 1.18 kg additional weight loss observed when no restrictions were imposed. Subgroup analyses were only carried out for fasting glucose, as no studies reporting 2-hour glucose utilised set calorie intake targets. No significant changes in fasting glucose were seen whether calorie restrictions were used or not.

The use of total fat intake targets did not significantly reduce or decrease T2DM incidence rate, weight or glucose outcomes, as seen in Table 41. Use of set fibre intakes did not significantly increase or decrease the intervention effect on T2DM incidence rate or weight loss. Similarly the intervention effect was not significantly impacted by use of dietary fibre targets for glucose outcomes.

All results should be interpreted with caution, as few studies explicitly stated targets. In fact a number of studies did use targets, but did not mention specifics.

**Table 40: Subgroup analysis of effect of set calorie intake targets on T2DM incidence rate, weight, fasting and 2-hour glucose**

Set calorie intake	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
No	11	0.73	0.57, 0.94	Reference	33.8
Yes	2	0.63	0.08, 5.15	0.907	0.0
Difference in mean weight, kg					
No	17	-1.18	-1.79, -0.58	Reference	75.3
Yes	3	-3.92	-5.55, -2.29	0.024	50.9
Difference in mean fasting glucose, mmol/l					
No	13	-0.03	-0.09, 0.03	Reference	44.8
Yes	3	-0.18	-0.30, -0.06	0.085	0.0
Difference in mean					

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		2-hour glucose, mmol/l			
No	10	-0.28	-0.57, 0.001	-	67.8
Yes	0	-	-	-	-

**Table 41: Subgroup analysis of effect of set fat intake targets on T2DM incidence rate, weight, fasting and 2-hour glucose**

	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
<b>Set total fat intake</b>					
No	8	0.86	0.65, 1.13	Reference	11.2
Yes	5	0.62	0.47, 0.82	0.280	0.0
<b>Difference in mean weight, kg</b>					
No	13	-1.06	-1.79, -0.33	Reference	77.2
Yes	7	-2.54	-4.12, -0.95	0.096	88.1
<b>Difference in mean fasting glucose, mmol/l</b>					
No	10	-0.03	-0.12, 0.05	Reference	56.4
Yes	6	-0.08	-0.16, -0.01	0.286	21.0
<b>Difference in mean 2-hour glucose, mmol/l</b>					
No	7	-0.14	-0.45, 0.17	Reference	54.1
Yes	3	-0.60	-1.38, 0.17	0.314	85.0

**Table 42: Subgroup analysis of effect of set fibre intake targets on T2DM incidence rate, weight, fasting and 2-hour glucose**

	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
<b>Set fibre intake</b>					
No	11	0.73	0.55, 0.98	Reference	28.5
Yes	2	0.71	0.43, 1.18	0.917	30.0
<b>Difference in mean weight, kg</b>					
No	17	-1.59	-2.43, -0.75	Reference	85.1
Yes	3	-1.50	-3.04, 0.04	0.964	79.2
<b>Difference in mean fasting glucose, mmol/l</b>					
No	13	-0.06	-0.14, 0.01	Reference	55.5

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Yes	3	-0.03	-0.09, 0.04	0.899	0.0
Difference in mean 2-hour glucose, mmol/l					
No	7	-0.14	-0.45, 0.17	Reference	54.1
Yes	3	-0.60	-1.38, 0.17	0.314	81.8

## Risk identification

The RCTs used a variety of methods to identify individuals at high risk of T2DM. These were wide ranging, however they have been categorised into three broad groups. If some sort of risk score was used, whether validated or not, then the study was assumed to have used one. A glucose test was assumed to be used, regardless of what type and whether fasting, 2-hour or HbA1c levels were used to diagnose high risk.

Use of a particular method of risk identification did not significantly alter the intervention effect on weight or glucose outcomes, as seen in Table 43. However use of only a risk score to identify high risk individuals yielded a 39% higher incidence rate of T2DM for prevention programme arms compared with usual care than using just a glucose test, which corresponded to a reduction in incidence of 47%. Minimal weight should be placed on this result as this analysis included only one study using a standalone risk score to identify high risk individuals.

Meta-regression was carried out to assess the effectiveness of intervention depending on baseline risk of participants. A quantifiable measure of risk was used in the form of baseline levels of mean fasting and 2-hour glucose.

Mean baseline fasting glucose of study participants ranged from 5.17 to 6.05mmol/l, whilst mean baseline 2-hour glucose levels ranged from 5.83 to 9.1mmol/l. The median mean fasting glucose level was 5.65mmol/l, with an inter-quartile range of 5.55 to 5.87mmol/l. For 2-hour glucose the median mean levels was 8.25 mmol/l with interquartile range of 6.34 to 8.77mmol/l. Six RCTs did not report baseline 2-hour glucose, and one RCT reported neither fasting or 2-hour glucose levels at baseline.

No change in intervention effect was seen on weight or glucose outcomes as baseline fasting glucose increased. However, a 1.0mmol/l increase in fasting glucose at baseline corresponded to a 79% higher reduction in incidence rate of T2DM in prevention programme arms in comparison with usual care arms. This suggests that even a smaller 0.1 mmol/l increase in fasting glucose at baseline could result in a substantial 7.9% greater reduction in T2DM incidence in intervention arms. As baseline levels of 2-hour glucose increased, no increased intervention effect was seen on any endpoints. This suggests the effect of intervention was consistent across baseline levels of 2-hour glucose.

**Table 43: Subgroup analysis of effect of methods used to identify high risk individuals on T2DM incidence rate, weight, fasting and 2-hour glucose**

Risk identification	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
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Risk score	1	1.39	0.86, 2.24	0.007	-
Glucose test	9	0.53	0.40, 0.71	Reference	0.0
Both	3	0.84	0.65, 1.10	0.041	0.0
Difference in mean weight, kg					
Risk score	5	-1.81	-3.68, 0.06	0.990	89.4
Glucose test	10	-1.77	-3.01, -0.54	Reference	83.5
Both	5	-0.81	-1.55, -0.07	0.510	62.6
Difference in mean fasting glucose, mmol/l					
Risk score	4	-0.10	-0.26, 0.06	0.869	70.2
Glucose test	8	-0.11	-0.21, -0.01	Reference	37.0
Both	4	0.01	-0.04, 0.06	0.093	0.0
Difference in mean 2-hour glucose, mmol/l					
Risk score	3	-0.08	-0.50, 0.34	0.173	42.1
Glucose test	5	-0.63	-1.18, -0.07	Reference	63.7
Both	2	-0.01	-0.20, 0.17	0.115	0.0

Table 44: Meta-regression results of the effect of baseline fasting glucose levels on T2DM incidence rate, weight, fasting and 2-hour glucose

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	13	0.21	0.07, 0.59	0.007
Difference in mean weight, kg	19	-2.66	-5.85, 0.54	0.097
Difference in mean fasting glucose, mmol/l	16	-0.03	-0.32, 0.25	0.795
Difference in mean 2-hour glucose, mmol/l	10	-0.49	-2.08, 1.11	0.503

Table 45: Meta-regression results of the effect of baseline 2-hour glucose levels on T2DM incidence rate, weight, fasting and 2-hour glucose

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	10	0.83	0.65, 1.05	0.109

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Difference in mean weight, kg	12	0.07	-0.56, 0.70	0.809
Difference in mean fasting glucose, mmol/l	10	0.001	-0.08, 0.08	0.981
Difference in mean 2-hour glucose, mmol/l	10	-0.11	-0.43, 0.21	0.456

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## Evidence base

All interventions were based on an existing evidence base, whether this was one of the major diabetes prevention programmes or another adaptation. Subgroup analyses looking at the evidence base used were carried out.

Table 46 presents results of the analyses. In most cases, the intervention was wholly or partly based on either the US DPP or Finnish DPS. The effect of the intervention on incidence of T2DM was shown to be consistent across evidence bases. However, it was also shown that utilising knowledge from interventions other than all or part of the DPP or DPS lead to a significantly smaller 0.24kg weight loss in intervention groups vs. control groups. This was using the DPP evidence base as a baseline which corresponds to a much higher 3.10kg weight loss in intervention arms compared to control arms. Therefore the intervention effect was reduced for studies using other types of evidence bases. For glucose outcomes no significant differences in intervention effect were seen across intervention evidence bases.

Meta-regression was also utilised to see whether using an increasing number of goals from either the DPP or DPS affected the size of the intervention effect. Where it was reported that all DPP and DPS goals were used the maximum number of goals for that prevention programme was recorded. Otherwise only the goals mentioned were recorded.

As the number of goals used increases there was no significant change in incidence of T2DM, weight or glucose outcomes, as shown in Table 47. This suggests that the effect of intervention was consistent across the number of goals used.

Table 46: Subgroup analysis of effect of evidence base used on T2DM incidence rate, weight, fasting and 2-hour glucose

Evidence base	Number of comparisons	Incidence rate ratio	95% CI	P value	I <sup>2</sup> (%)
DPP	3	0.46	0.13, 1.67	Reference	0.0
DPS	2	0.53	0.37, 0.77	0.814	0.0
DPP & DPS	1	0.48	0.21, 1.09	0.400	-
DPP, DPS & Other	1	0.88	0.62, 1.23	0.971	-
Other	5	0.98	0.70, 1.37	0.322	9.0
Difference in mean weight, kg					
DPP	7	-3.10	-4.78, -1.42	Reference	88.3
DPS	3	-1.55	-2.60, -0.50	0.230	17.7
DPP & DPS	2	-2.39	-3.37, -1.41	0.627	0.0
DPP, DPS & Other	1	-0.30	-1.18, 0.58	0.102	-
Other	6	-0.24	-0.98, 0.50	0.010	53.9
Difference in mean fasting glucose, mmol/l					
DPP	5	-0.07	-0.20, 0.06	Reference	54.1
DPS	1	-0.08	-0.26, 0.10	0.906	-
DPP & DPS	2	-0.26	-0.50, -0.01	0.119	53.8
DPP, DPS & Other	1	0.0001	-0.10, 0.10	0.573	-
Other	5	-0.03	-0.08, 0.02	0.939	0.0
Difference in mean 2-hour glucose, mmol/l					
DPP	0	-	-	-	-
DPS	1	-0.70	-1.49, 0.09	0.510	-
DPP & DPS	2	-0.58	-1.73, 0.56	0.541	87.2
DPP, DPS & Other	1	0.04	-0.25, 0.33	0.759	-
Other	5	-0.12	-0.50, 0.27	Reference	55.7

Table 47: Meta-regression results of the effect of number of goals used from major prevention programmes on T2DM incidence rate, weight, fasting and 2-hour glucose

	Number of comparisons	Effect size	95% CI	P value
Incidence rate ratio of T2DM	8	1.11	0.93, 1.33	0.183
Difference in mean weight, kg	15	0.19	-0.50, 0.89	0.561
Difference in mean fasting glucose, mmol/l	11	0.0004	-0.06, 0.06	0.989
Difference in mean 2-hour glucose, mmol/l	6	-0.06	-0.43, 0.32	0.704

## Summary

- a point increase in NICE or IMAGE score resulted in a larger intervention effect on weight loss and decrease in fasting glucose levels. Specifically, adhering to 9 to 12 NICE guidelines resulted in a larger weight loss and reduction in fasting glucose than adhering to 5 to 8 guidelines. Scoring an IMAGE score of 5 to 6 also maximised weight loss compared to a score of up to 2 points
- utilising a combined diet and PA intervention was associated with greater weight loss than using a PA only intervention
- to maximise reduction in T2DM incidence rate and intervention sessions should be spread across 9-18 months, although weight loss was maximised when the session spread is different to 9-18 months
- the optimum session length to aid greater weight loss was between 1 to 2 hours long
- the total number of sessions over the first 18 months should match or exceed 13 in order to maximise weight loss
- sixteen or more hours of contact should be provided during the first 18 months to maximise weight loss and fasting glucose reductions
- minimum contact, such as one-off or contact every other month, was associated with much smaller weight loss or weight gain compared with weekly contact, whilst monthly and every other month contact was associated with increases in fasting glucose compared to weekly contact
- incorporating three or more behaviour change techniques into the prevention programme resulted in smaller reductions in 2-hour glucose than using fewer than three techniques
- use of self-regulatory – monitoring own progress – techniques was associated with a smaller reduction in 2-hour glucose than not using such methods
- use of empathy building approaches was associated with a smaller weight loss and 2-hour glucose reduction than not using these techniques

- using motivational techniques was associated with a greater weight loss than not using such techniques
- encouraging engagement of social support outside of intervention groups was important to maximise reductions in fasting glucose
- using calorie intake restrictions resulted in maximum weight loss
- studies conducted outside of the UK reported greater weight loss than those conducted in the UK
- intervention delivery in a private setting was associated with greater weight loss
- for group delivered interventions the ideal group size was between 10 to 15 individuals in order to maximise weight loss
- use of a risk score to identify individuals at high risk of T2DM was associated with an increased incidence rate of T2DM. A one mmol/l increase in participant baseline fasting glucose resulted in a substantial decrease in T2DM incidence rate in intervention arms when compared to control arms
- using an evidence base different to the major prevention programmes (DPS or DPP) resulted in smaller weight loss, when compared to using the DPP as the sole evidence base

## Discussion

We have synthesised the results from 36 studies assessing diabetes prevention programmes in a real-world setting. The evidence collated shows that diabetes prevention programmes that aim to translate the findings from large scale efficacy trials into routine care significantly reduce progression to T2DM compared to usual care by 26%. This was complimented by small but statistically significant reductions in weight (-1.57kg) and HbA1c (-0.04%) at 12-18 months post intervention compared with usual care. Although not reaching statistical significance 0.06mmol/l and 0.28mmol/l reductions in fasting and 2 hour glucose respectively were also observed. When assessing the change from baseline in the intervention arms only for the secondary outcomes, greater effects were seen for weight (-2.46kg) and 2-hour glucose (-0.38mmol/l).

Both the Finnish DPS and US DPP showed a 58% reduction in T2DM in those receiving the intervention compared to the usual care group.<sup>7,22</sup> The findings seen here (26%) may reflect the less intensive nature of these interventions, which attempted to replicate the efficacy seen in these studies in a pragmatic lower resource real-world setting.

Although the reduction in the progression of T2DM was substantial, reductions seen in the secondary outcomes were small. The Finnish DPS reported a weight reduction of 4.5kg at 12 months in the intervention arm, which was around 3.5kg larger than that seen in the control group.<sup>83</sup> When assessing those receiving the intervention in the US DPP study, it was found that diabetes incidence can be reduced by around 16% for each kilogram of weight lost.<sup>5</sup> Given the weight loss seen here compared with the usual care group, we would expect around a 25% reduction in T2DM in the intervention group attributable to weight loss, which is in line with the results seen here. Only 50% of those who received the DPP met the weight loss target, in this group a 44% lower incidence of T2DM was seen in those who met the PA target,<sup>5</sup> which suggests a multi-faceted approach to lifestyle change targeting multiple goals should be used. The PREPARE study also showed that an intervention focused on increasing step count through pedometer use found significant improvements in glucose and reduced T2DM incidence,<sup>52</sup> independent of weight loss. Others have suggested that reducing sedentary time may also play a significant role.<sup>84</sup> In fact, a recent analysis of changes in sedentary time for DPP participants reported the impact of intervention on hours spent in sedentary activities. Rockette-Wagner et al reported significantly larger reductions in time spent watching television in the DPP lifestyle intervention arm (-22 minutes/day) when compared with the metformin and placebo arms.<sup>85</sup> Unfortunately the studies assessed did not consistently report data on levels of PA so this outcome could not be assessed, although the majority of programmes included focused on both diet and PA.

Despite the small reductions observed in fasting and 2-hour glucose observed, in the high risk population which was the subject of this review, even small or no adverse changes in glucose outcomes suggests progression to diabetes might be halted. Fasting and 2-hour glucose reflect different physiological aspects which are pertinent in the context of this review. Fasting glucose is more likely to reflect hepatic physiology, with higher levels indicating greater hepatic insulin resistance. In contrast, 2-hour glucose is more likely to reflect peripheral physiology, with higher levels indicating greater peripheral insulin resistance. Worsening peripheral insulin resistance is considered the first step and major site of impairment for the majority of individuals with pre-diabetes, thus 2-hour glucose is more sensitive to change in the underlying pathophysiology of T2DM.<sup>86</sup> In addition, 2-hour glucose also reflects the impact of lifestyle change which strongly promotes peripheral insulin sensitivity. Whilst the degree of change is important, it is also important to consider the natural progression in glucose levels and body weight over time. In those with pre-diabetes, the natural history is for steadily increasing glucose levels over time with as many as 70% of these individuals developing diabetes in their life time.<sup>86</sup> Therefore, interventions that halt this upwards trajectory whilst showing no overall change or a slight reduction in glucose could represent considerable clinical success compared to the background population. The same is also true of weight.

Having established that diabetes prevention programmes such as these work overall, we assessed whether participant characteristics, such as age, sex, BMI and ethnicity, were associated with the outcomes seen, i.e. in whom do the programmes work best? Progression to T2DM and weight and glucose change appeared to be independent of the age and ethnicity of the participants. As the percentage of male participants increased the T2DM incidence relative to the control group increased along with reductions in the observed level of weight loss. This suggests that improved outcomes are seen in studies testing interventions in a predominantly female cohort. This result is in line with the results of the Public Health England rapid review focussing on multi-component weight management programmes. Studies which targeted overweight participants saw bigger gains in terms of the reduction of T2DM, weight and fasting glucose. Those who are overweight represent a high risk group for T2DM; it is intuitive that bigger intervention effects are seen in those at highest risk.

A thorough interrogation of the interventions was undertaken to identify key elements across the most efficacious interventions that constitute a successful programme in order to inform the intervention specification for a National Diabetes Prevention Programme. Although increasing adherence to NICE/IMAGE guidelines did not correspond to a reduction in T2DM incidence, meeting more guideline requirements resulted in increased weight loss and reductions in fasting glucose.

When looking at individual elements of the guidelines there was very little evidence that any particular component assessed affected progression to T2DM; the only significant association was that the intervention sessions spread across 9-18 months lowered T2DM incidence. More elements were associated with increased weight loss, though significance was not reached for all individual components. This inability to identify particular NICE/IMAGE guidelines as optimal for an efficacious intervention, reflects the nature of building complex interventions and emphasises the need for a multi-stranded approach to evaluate effectiveness. A component on its own may not necessarily impact T2DM incidence or weight and glucose outcomes, however when an increasing number are harmoniously utilised together, an interactive effect may be seen, resulting in improved outcomes.

When assessing other elements which could improve outcomes, some of the findings agree with those found in a review of systematic reviews of interventions targeting diet and/or PA in adults at risk of developing T2DM from 1998 to 2008.<sup>87</sup> This review found that intervention effectiveness was increased by engaging social support, targeting both diet and PA, and using well-defined/established behaviour change techniques. Increased effectiveness was also associated with increased contact frequency and using a specific cluster of "self-regulatory" behaviour change techniques (e.g. goal-setting, self-monitoring). This adds weight to the findings shown here.

NICE currently recommend identifying those at risk of diabetes using a two stage process. The first phase should utilise a non-invasive risk score, those at high risk are then offered a glucose blood test.<sup>23</sup> Here we have attempted to compare the outcomes in terms of the identification method used. Given the vast array of identification methods we compared studies grouped into three broad categories: (1) those using a blood test only for identification; (2) those using a risk score only for identification; (3) those using a risk score and a blood test for identification. These results suggested that the use of just a risk score to identify individuals at high risk of T2DM was associated with a higher incidence rate of T2DM, compared to using a glucose test. We believe these results should be viewed with caution as there was only one study in this subgroup. In addition there was much variation in methodologies between the studies, for example some studies used a validated risk score, such as the FINDRISC while others used a non-validated risk factor approach. Also the choice of blood test varied between the studies.

When using baseline fasting glucose as a measure of risk at study outset, a clearer picture emerged. As baseline fasting glucose increased, incidence of T2DM in intervention arms decreased substantially in comparison with usual care. This suggests that the size of risk that individuals carry at the beginning of the study may affect how much benefit they receive from interventions. Specifically, this indicates that individuals at the higher end of the risk spectrum may see more of an effect than

those at the lower end. This suggests that selection of participants should be tightly controlled in order to fully adhere to high risk definitions.

As national and regional health care services have pronounced differences in funding, organisation and infrastructure, it cannot be assumed that the findings from diabetes prevention programmes conducted in a specific population can be generalised across different contexts. Consequently, there may be a need to tailor and evaluate prevention programmes within the health care system in which they are intended to operate. This review identified five RCTs conducted in the UK, of which four quantified effectiveness at reducing progression rates to T2DM; however, only one study was specifically designed to quantify this outcome.<sup>33</sup> The other three studies from the UK were observational in design and are therefore considerably more open to bias than the gold standard RCT design for assessing the efficacy of an intervention. Interestingly the RCTs conducted outside of the UK tended to report greater weight loss than those conducted in the UK.

## Strengths and limitations

For this meta-analysis, an extensive literature search was performed for both published and unpublished studies using comprehensive search criteria and focusing on 'real-world' implementations of diabetes prevention programmes, in order to assess the value of such intervention at routine practice level. As well as searches of Open Grey, authors known to have been or currently involved in studies aiming to prevent diabetes were contacted directly for possible unpublished or newly published data for inclusion. As a result, this meta-analysis includes a wide range of studies that met inclusion criteria and although an exhaustive search cannot be claimed for certainty, every effort was made to retrieve all relevant material.

A quality assessment was carried out for each study using the UK's National Institute for Health and Clinical Excellence (NICE) quality appraisal checklist for quantitative intervention studies.<sup>24</sup> However, assessment is a subjective measure dependant on the person carrying out the assessment. In order to account for this subjectivity and minimise bias, the quality appraisal was conducted by two individuals, and any differences in opinion mediated through discussion. Even so, the checklist used is primarily aimed at RCTs, meaning that the number of criteria contributing to a final rating may differ for different study designs, and so ratings are not typically comparable between study types.

The studies included a range of designs, including both RCTs and observational studies. Therefore data was pooled in two ways (1) assessing the incidence rates of T2DM and/or changes from baseline for weight and glucose in those receiving the prevention programme only, and (2) comparing the incidence rates, weight and glucose in those randomised to receiving the prevention programme to those

receiving usual care. The latter, by design, therefore only included data from RCTs. RCTs are the gold standard for assessing an intervention, with non-randomised studies having a greater potential for bias. Additionally, assessing change in a single arm can over-emphasise the intervention effect as demonstrated by the weight loss data. Therefore, our analyses focussed on the data from the RCTs.

High levels of heterogeneity were found across all of the outcomes assessed. Heterogeneity is a statistical measure of how much variability there is between studies and whether this is more than one would expect by chance. Heterogeneity can be caused by a number of factors such as varying interventions across studies and differences in design and participants. If there are high levels of heterogeneity, especially if there are inconsistencies in the direction of the intervention effect, it might not be sensible to pool studies using meta-analyses. If studies are combined, efforts should be made to try and explain the heterogeneity seen through subgroup analyses and meta regression, which was done here. We assessed many specific factors regarding the intervention and participant population to give a thorough overview of which factors and in whom prevention interventions are most efficacious. This rigorous assessment of the data may give rise to spurious significant findings by chance due to multiple testing. Additionally many subgroups contained data from a limited number of studies. Therefore weight is given to elements on which multiple outcomes showed a positive effect and those subgroups which have more than ten studies included.

The diabetes prevention interventions assessed are complex interventions and therefore it might not be possible to elucidate what constitutes an effective programme through the use of subgroup analyses alone. The subgroup analyses conducted assessed each factor in isolation, it may be that combinations of factors are important and that we cannot assume independence of factors on the outcome. For example, the number of contacts cannot fully be assessed for its role in intervention efficacy if not adjusted for contact time, as length of an individual contact in one programme may be drastically shorter than another. Extending the meta-regression analysis to incorporate multiple factors, which was beyond the scope of this work, may be able to more fully explain the heterogeneity seen.

Very few studies reported outcomes beyond 12 months. Therefore, it is difficult to place the findings of this review into the context of long-term therapeutic benefits of pragmatic lifestyle interventions, especially the sustainability of weight loss (or of changes in dietary behaviour or PA) across an extended period.<sup>88</sup>

## Ongoing research

Several UK-based ongoing studies were identified in the process of the search for which 12-month follow-up data are not currently available. These studies all have the

potential to add to the current evidence base of the effectiveness of translational interventions in primary prevention of diabetes, particularly the larger scale trials.

The Health Technology Assessment (HTA) funded PROPELS trial is evaluating whether the PREPARE model of promoting PA through structured education can be enhanced through highly tailored follow-on text messaging support designed to facilitate and promote continued pedometer use and PA behaviour change [ISRCTN83465245]. The programme has successfully recruited over 1300 participants with pre-diabetes from primary care across the East Midlands and Cambridgeshire and will follow participants over a four year period making it the one of the most extensive pragmatic diabetes prevention trials ever undertaken.

The NIHR-funded Norfolk Diabetes Prevention Study is currently implementing an intervention comprising of up to 21 (six core and 15 optional for maintenance) sessions of group-based education designed to promote weight loss (through changes in diet and PA) in overweight or obese people with pre-diabetes (IFG, IGT, HbA1c-based). Emphasis is on delivery in community settings by trained NHS based lifestyle coaches following identification (and referral) of participants from primary care and via existing screening programmes (health checks and retinal screening). The evaluation study is a full-scale (n=900) RCT with 36-month follow-up, which started in 2011 and will report in 2018 (with possible interim reports at 12-months follow-up).<sup>89</sup>

The Living Well Taking Control diabetes prevention programme in Devon, Birmingham and Newcastle delivers 4-6 weekly 2-hour group sessions with an additional individual session (30 minutes), access to at least five hours of one-to-one or group activities and support through existing services and five 30-minute follow-up support contacts over a total of 12 months (total contact time 16-20 hours). The intervention is specifically designed to adhere to the recommendations on intervention content from the NICE guidance on diabetes prevention. The target population is people with pre-diabetes (IFG, IGT, HbA1c-based). The intervention is delivered by trained lifestyle coaches working in voluntary sector organisations in community settings (e.g. church halls, community centres) following identification (and referral) of participants from primary care/GPs. The NIHR-funded evaluation study is a full-scale (n=320) wait-list controlled two-site RCT (entitled ComPoD), which started in 2014 and will report in August 2016.<sup>90</sup>

The Pre-diabetes and CHD Collaborative in North-East Lincolnshire is currently at the 6-month interim stage, which prevented inclusion in the current meta-analysis. Time to Measure Up education sessions focussing on weight management were offered to those individuals at high risk of developing diabetes (diagnosed via Diabetes UK Risk Assessment form) and CHD. Sessions were offered on a weekly basis in a 4-week rolling format, delivered by diabetes nurse educators at GP practices between April

and November 2014. The follow-up process is currently being refined to allow before and after analysis.<sup>91</sup>

Though pilot data for 108 individuals on the Waste the Waist intervention (designed for people with high cardiovascular risk or pre-diabetes) has been recently published, the study was not included in the meta-analysis, due to the low proportion of people with pre-diabetes in the pilot sample. The lifestyle intervention comprising of nine sessions of 90-120 minutes of group-based intervention with groups of 8-12 people, spread over nine months (total contact time 13.5 hours) aims to achieve weight loss through changes in diet and PA. Delivery was by trained non-NHS based lifestyle coaches in community settings following identification (and referral) of participants from primary care. A full scale RCT is planned to assess effectiveness of the programme, after modification of the intervention based on pilot data.<sup>92</sup>

Finally, Health Guardian is a weight loss and weight loss maintenance intervention targeting dietary and PA behaviour in adults with IGT which is a scalable and commissionable lifestyle service platform co-designed with patients and care teams. Designed for implementation, this service platform consists of CPD approved (RCGP) professional e-Learning programmes, e-Health (web) and m-Health (mobile) tools for implementing best practice behaviour change techniques. Health Guardian also links users with commercially available products and services, tailored programmes and personal coaching. Supported by the NIHR and MRC, the programme is undergoing Phase III trials in at risk groups for diabetes, scalable demonstration in local CCGs and evaluation as a pharmacy enhanced lifestyle service pathway (funded by the MRC and in partnership with Boots). Cluster based controlled trial data demonstrating fidelity of the professional education programmes will be available in 2015 and clinical trials data available in 2016.

## Future research

Our review identified a lack of meaningful literature examining the long-term effect of intervention on maintenance of weight loss and reduced diabetes risk. It is therefore important that any programmes implemented are assessed for their benefits over extended follow-up (ideally for two years or more). Diabetes prevention remains in its infancy in the UK and there is scope for the development and evaluation of innovative approaches as well as a need to identify aspects of PA and diet intervention which are the most greatly associated with decreasing T2DM risk. This will allow the development of prevention programmes that produces optimal effects whilst keeping costs to a minimum.

In terms of the methodology employed to assess the studies completed so far, future work could look at assessing multiple intervention aspects within a single analysis to account for the inter-dependency between factors. Utilising more sophisticated

methodology may help to untangle which combinations of elements lead to success. One possible methodology which may help to achieve this is mixed treatment comparison meta-analysis.

We have focussed here on the quantitative data arising from these studies. Future work could appraise and synthesise data from qualitative studies and process evaluations of the studies included. This would give a more in depth portrayal of issues around acceptability and which intervention elements participants feel promoted success.

## Conclusion

Our review supports previous research, demonstrating that diabetes prevention programmes can significantly reduce the progression to T2DM and lead to reductions in weight and glucose compared with usual care. Those developing prevention programmes should adhere to the NICE and/or IMAGE guidelines to increase efficacy.

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A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice

## Appendix 1: Example search strategy, MEDLINE

1. Aerobic train\$.tw.
2. Behav\$ Modif\$.tw.
3. Behav\$ therap\$.tw.
4. Cognitive\$ therap\$.tw.
5. counsel\$.ti.
6. Health\$ Educ\$.tw.
7. Health\$ Promot\$.tw.
8. Health\$ behav\$.tw.
9. Educat\$ program\$.tw.
10. Patient Educ\$.tw.
11. (Diet\$ adj2 Intervention\$).tw.
12. (Diet\$ adj2 Modif\$).tw.
13. Food habit\$.tw.
14. (Health\$ adj2 Eating).tw.
15. (Nutrition\$ adj2 Counselling).tw.
16. (Nutrition\$ adj2 Therap\$).tw.
17. (Exercis\$ adj2 intervention\$).tw.
18. Physical Exercise.tw.
19. (Exercis\$ adj2 therap\$).tw.
20. Physical endurance.tw.
21. Physical education.tw.
22. Physical Fitness.tw.
23. Physical Activit\$.tw.
24. Physical Train\$.tw.
25. Resistance Train\$.tw.
26. Strength Train\$.tw.
27. (Lifestyle adj2 advice).tw.
28. (Lifestyle adj2 Guid\$).tw.
29. (Lifestyle adj2 Modif\$).tw.
30. Lifestyle Program\$.tw.
31. Weight control\$.tw.
32. Weight Train\$.tw.
33. Weight reduc\$.tw.

34. Weight loss program\$.tw.
35. weight loss.tw.
36. (Weight adj loss adj program\$).tw.
37. (lifestyle adj2 intervention).tw.
38. Sport\$.tw.
39. walk\$.tw.
40. jog\$.tw.
41. swim\$.tw.
42. cycle\$.tw.
43. Bicycle\$.tw.
44. exp Health Promotion/
45. exp Program Evaluation/
46. exp Patient Education as Topic/
47. exp Diet Therapy/
48. exp Nutrition Therapy/
49. exp Exercise Therapy/
50. exp Diet, Reducing/
51. (diabet\$ adj4 lessen\$).tw.
52. (diabet\$ adj5 (reduc\$ adj4 risk\$)).ti,ab.
53. (diabet\$ adj4 (lower\$ adj5 incidence\$)).ti,ab.
54. (diabet\$ adj4 (decreas\$ adj5 risk\$)).ti,ab.
55. (diabet\$ adj4 (reduc\$ adj5 incidence\$)).ti,ab.
56. (diabet\$ adj4 (decreas\$ adj5 incidence\$)).ti,ab.
57. (diabet\$ adj4 (lower\$ adj5 risk\$)).ti,ab.
58. (diabet\$ adj4 (delay\$ adj5 onset\$)).ti,ab.
59. (diabet\$ adj4 (reduc\$ adj5 onset\$)).ti,ab.
60. (diabet\$ adj4 (reduc\$ adj5 progress\$)).ti,ab.
61. (diabet\$ adj4 (decreas\$ adj5 onset\$)).ti,ab.
62. (risk\$ adj4 develop\$ adj4 diabet\$).ti.
63. (reduc\$ adj4 develop\$ adj4 diabet\$).ti,ab.
64. (decreas\$ adj4 develop\$ adj4 diabet\$).ti,ab.
65. (diabet\$ adj4 prevent\$).tw.
66. (diabet\$ adj4 reduc\$).tw.
67. (diabet\$ adj4 decreas\$).tw.
68. (diabet\$ adj4 lower\$).tw.
69. (diabet\$ adj4 lessen\$).tw.
70. (diabet\$ adj4 (reduc\$ adj5 prevalence)).ti,ab.
71. (Diabet\$ adj4 (decreas\$ adj5 progress\$)).ti,ab.

72. (diabet\$ adj4 (lessen\$ adj5 prevalence)).ti,ab.
73. (diabet\$ adj4 (decreas\$ adj5 prevalence)).ti,ab.
74. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50
75. 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73
76. Diabetes Mellitus, Type 2/pc [Prevention & Control]
77. exp Exercise/
78. exp Diet/
79. 77 or 78
80. 76 and 79
81. 74 and 75
82. OBSERVATIONAL.ti,ab.
83. RCT.ti,ab.
84. (RANDOMIS\$4 adj CONTROL adj TRIAL\$).ti,ab.
85. Experimental studies.ti,ab.
86. (QUASI adj EXPERIMENTAL).ti,ab.
87. TRIAL\$.ti,ab.
88. Time-series.ti,ab.
89. Cross-sectional.ti,ab.
90. Cross-sectional studies.ti,ab.
91. longitudinal study.ti,ab.
92. Clinical trial.ti,ab.
93. randomized.ab.
94. placebo.ab.
95. dt.fs.
96. randomly.ab.
97. trial.ab.
98. groups.ab.
99. (Before adj2 after).ab.
100. Cohort analy\$.ab.
101. exp cohort studies/
102. (cohort adj (study or studies)).ab.
103. (follow up adj (study or studies)).ab.
104. Retrospective.ab.
105. 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104

106.80 or 81

107.105 and 106

108.animal/ not (animal/ and human/)

109.107 not 108

110.limit 109 to english language

111.limit 110 to yr=2012-current

## Appendix 2: Example search strategy of Open Grey

1. prevent\*
2. diabet\*
3. (exercise\* OR aerobic\* OR diet\* OR lifestyle\* OR activ\* OR walk\* OR counsel\* OR cognitiv\* OR educat\*)
4. limited to English language documents

## Appendix 3: Evidence tables

The details of the redacted study have been removed

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Absetz et al  <b>Year:</b> 2007 (12m follow up), &amp;2009 (36m follow up)  <b>Citation:</b>                      Absetz P, Valve R, Oldenberg B, Heinonen H, Nissinen A, Fogelholm M, Ilvesmaki V, Talja M, Uutela A. 2007. Type 2 diabetes prevention in the “real world”: one-year results of the GOAL implementation trial. <i>Diabetes Care</i>, 30, 2465-2470.                      Absetz P, Oldenburg B, Hankonen N, Valve R, Heinonen H, Nissinen A, Fogelholm M, Talja M, Uutela A. 2009. Type 2 diabetes prevention in the real world: three-year results of the GOAL lifestyle implementation trial. <i>Diabetes Care</i>, 32 (8) 1418-1420.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after  <b>Quality score:</b>  <b>External validity score:</b></p>	<p><b>Source population/s:</b> Finland;  <i>Across whole study:</i> mean age 58 years old female and 59 years old male, male 25%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i>                      Baseline weight (kg):                      86 (13.2) female, 100.0 (18.1) male                      Baseline BMI (kg/m<sup>2</sup>):                      32.5 (4.6) female, 31.5 (5.2) male                      Baseline waist circumference (cm):                      102.8 (10.7) female, 110.6 (12.6) male</p> <p><b>Eligible population:</b> Recruited from health care centres in Päijät-Häme Province</p> <p><b>Selected population:</b> Age 50-65 year old, with already-identified risk factors (obesity, hypertension, elevated blood glucose, or lipids), with risk score of <math>\geq 12</math> (17% 10-year risk)</p> <p><b>Excluded population/s:</b> Mental health problems or substance abuse likely to interfere with participation, acute cancer, type 2 diabetes requiring pharmacological treatment,</p>	<p><b>Intervention (1) description:</b>  <input type="checkbox"/> GOAL  <input type="checkbox"/> Content and design of intervention underpinned by 5 key lifestyle change objectives:</p> <ol style="list-style-type: none"> <li>1. Less than 30% total energy intake from fat</li> <li>2. Less than 10% total energy intake from saturated fat</li> <li>3. At least 15g fibre/1,000 kcal</li> <li>4. At least 4h/week moderate level physical activity</li> <li>5. More than 5% weight reduction</li> </ol> <p><input type="checkbox"/> 6 2h group-based, task-orientated counselling sessions delivered by trained public health nurses  <input type="checkbox"/> Included information provision, group discussions, self-monitoring of behaviour, goal setting, and planning  <input type="checkbox"/> Printed materials available on existing health education leaflets, materials adapted from earlier studies, materials developed for intervention.  <input type="checkbox"/> Monitoring by nurses of questionnaire data, food diary and physical activity</p>	<p><b>Published data only</b></p> <p><b>Follow up periods:</b> 12, 36 months</p>	<p><b>Source of funding:</b>                      Academy of Finland and the Finnish Ministry of Health (Absetz et al 2007)                      Academy of Finland, the Social Insurance Agency, and the Finnish Ministry of Social Affairs and Health (Absetz et al 2009)</p> <p><b>Other notes:</b>                      Intervention described in more detail at <a href="http://www.palmenia.helsinki.fi/ikihyva/InEnglish.html">http://www.palmenia.helsinki.fi/ikihyva/InEnglish.html</a></p>

	myocardial infarction during past 6m  <b>Setting:</b> Primary care	<b>Sample sizes (baseline):</b> Total n = 352 Intervention female = 270 Intervention male = 91 <b>At 12 months</b> Total n = 303 Intervention female = 226 Intervention male = 77		
<b>Study details</b>	<b>Population and setting</b>	<b>Method of allocation to intervention/control</b>	<b>Outcomes and method of analysis</b>	<b>Notes</b>
<b>Authors:</b> Ackerman et al <b>Year:</b> 2008 (12m follow up), & 2011 (28m follow up) <b>Citation:</b> Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. 2008. Translating the diabetes prevention program into the community: the DEPLOY pilot study. <i>Am J Prev Med</i> , 35 (4) 357-363. Ackermann RT, Finch EA, Caffrey HM, Lipscomb ER, Hays LM, Saha C. 2011. Long-term effects of a community-based lifestyle intervention to prevent type 2 diabetes: the DEPLOY extension pilot study. <i>Chronic Illness</i> , 7 (4) 279-290. <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT	<b>Source population/s:</b> USA; <i>Across whole study:</i> mean age 58 years old, male 45%, ethnicity 82% white 3% Hispanic 12% African-American 5% other.  <i>For each arm (mean, SD):</i> Baseline weight (kg): intervention 94.5 (16.4), control 90.9 (17.3) Baseline BMI (kg/m2): Intervention 32.0 (4.8), control 30.8 (5.1)  <b>Eligible population:</b> People of households within ~5 miles of each YMCA facility who were affected by one or more of the prediabetes risk factors  <b>Selected population:</b> ****  <b>Excluded population/s:</b> Comorbidities expected to limit lifespan to <3 years or to contraindicate the gradual adoption of light/moderate physical activity (e.g. recent cardiovascular event, severe chronic obstructive pulmonary disease, advanced arthritis, poorly controlled hypertension)	<b>Method of allocation:</b> Depending on location of YMCA at which they attended a screening event  <b>Intervention (1) description:</b> <input type="checkbox"/> <i>Diabetes Education &amp; Prevention with a Lifestyle Intervention Offered at the YMCA (DEPLOY)</i> <input type="checkbox"/> Participants assembled into groups of 8-12 people who could meet at a mutually agreeable time <input type="checkbox"/> Involved 16 weekly 60-90 min classroom-style meetings delivered by trained YMCA staff - focussed on building knowledge and skills for goal setting, self-monitoring, problem-solving <input type="checkbox"/> Delivered over 16-20 weeks <input type="checkbox"/> Goals upon completion included 5-7% reduction in baseline body weight, 150 mins/week of moderate-level physical activity similar to brisk walking <input type="checkbox"/> Monthly visits following the first 16 meetings up to 12-14m  <input type="checkbox"/> <i>DEPLOY Extension Study (ES)</i> <input type="checkbox"/> At 16-24m, 5 weekly visits, followed by 8 monthly visits – included topics such as eating to	<b>Published data only</b>  <b>Outcome calculation method:</b> Change in weight was calculated from reported % changes from baseline. SDs were calculated from reported CIs.  <b>Follow up periods:</b> 12 months	<b>Source of funding:</b> National Institute of Diabetes and Digestive and Kidney Diseases, and the Indiana University School of Medicine  <b>Other notes:</b>

	<p><b>Setting:</b> Community (YMCA) in greater Indianapolis</p>	<p>prevent diabetes, menu plans, lifestyle exercise, places to walk in your neighbourhood, handling holidays, vacations, and special events.</p> <p><b>Control description:</b> (2)  <input type="checkbox"/> Brief counselling alone</p> <p><b>Sample sizes (baseline):</b>                  Total n = 92                  Intervention = 46                  Control = 46  <b>At 12 months</b>                  Total n = 62                  Intervention = 29                  Control = 33  <b>At 24 months</b>                  Total n =                  Control =  <b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Almeida et al  <b>Year:</b> 2010  <b>Citation:</b>                  Almeida FA, Shetterly S, Smith-Ray RL, Estabrooks PA. 2010. Reach and effectiveness of a weight loss intervention in patients with prediabetes in Colorado. <i>Prev Chronic Dis</i> 7(5):A103.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Matched cohort</p>	<p><b>Source population/s:</b> USA;  <i>Across whole study:</i> mean age 55 years old, male 47%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i>                  Baseline weight (kg):                  Intervention 85.4 (16.4)                  Control 85.1 (16.7)                  Baseline BMI (kg/m<sup>2</sup>):                  Intervention 29.8 (4.8)                  Control 29.8 (4.8)</p> <p><b>Eligible population:</b> Members of Kaiser Permanente Colorado (KPCO) health care organisation</p> <p><b>Selected population:</b> IFG measurement of 100-125mg/dL,</p>	<p><b>Method of allocation:</b>  <b>Intervention (1) description:</b>  <input type="checkbox"/> Classes of 10-20 participants  <input type="checkbox"/> 4-6 90 min classes offered monthly for 12m  <input type="checkbox"/> Each class began with presentation by dietician or weight loss specialist – included information about prediabetes and diabetes, recommendations for healthful diet and regular physical activity, information on how diet, physical activity and weight loss delay onset of diabetes  <input type="checkbox"/> Each class designed to incorporate social cognitive factors – increasing self-efficacy, reducing barriers to physical</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>                  Weight in lbs changed to kgs                  Final analysis based on n= 1,520 (760 matched pairs)</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b>                  Department of Preventative Medicine at KPCO</p>

	<p>aged 18 years or older, member of KPCO for at least 6m before study start date of Feb 2004</p> <p><b>Excluded population/s:</b> IFG measurement of 126mg/dL or higher, diabetes diagnosis in first 30 days after IFG measurement, a dietitian contact in the 6m before study period</p> <p><b>Setting:</b> Integrated healthcare organisation</p>	<p>activity, identifying rewards for healthful lifestyle</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Each class involved question and answer period and small-group problem solving</li> <li><input type="checkbox"/> At conclusion of each session, participants created personal action plan for preventing diabetes</li> </ul> <p><b>Control description:</b> (2)</p> <p><b>Sample sizes (baseline):</b> Total n = 1640 Intervention = 820 Control = 820 <b>At 12 months</b> Total n = 1520 Intervention = 760 Control = 760 <b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Bhopal et al <b>Year:</b> 2014 <b>Citation:</b> Bhopal RS, Douglas A, Wallia S, Forbes JF, Lean MEJ, Gill JMR, Mcknight JA, Sattar N, Sheikh A, Wild SH, Tuomilehto J, Sharma A, Bhopal R, Smith JBE, Butcher I, Murray GD Effect of a lifestyle intervention on weight change in South-Asian individuals in the UK at high risk of type 2 diabetes: a family-cluster randomised controlled trial. <i>Lancet Diabetes Endocrinol</i>, 2: 218-227 <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> UK; <i>Across whole study:</i> mean age 53 years old, male 46%, ethnicity 33% Indian 67% Pakistani</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): Intervention 79.8(16.2) Control 80.7(15)</p> <p><b>Eligible population:</b> South-Asians in NHS Lothian and NHS Greater Glasgow and Clyde Health Board regions (Scotland, UK).</p> <p><b>Selected population:</b> Aged ≥35 Indian/Pakistani origin Waist circumference (≥90cm men, ≥80cm women)</p>	<p><b>Method of allocation:</b> <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> PODOSA</li> <li><input type="checkbox"/> 15 visits from a dietician over 3 years (baseline, monthly for the first 3 months, then every 3 months)</li> <li><input type="checkbox"/> Dieticians delivered information/advise on achieving weight loss through a calorie-deficit diet and physical activity of at least 30 min daily brisk walking, using culturally adapted and translated resources, including the Counterweight Programme</li> <li><input type="checkbox"/> Annual group sessions including a food shopping tour and brisk walking</li> <li><input type="checkbox"/> Received pedometers</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs were imputed using correlation estimates from studies which reported full outcome data, where necessary Incidence of T2DM at 12m calculated from 3-year incidence rate</p> <p><b>Follow up periods:</b> 12, 24, 36 months</p>	<p><b>Source of funding:</b> Supported by the National Prevention Research Initiative (grant number G0501310), a funding consortium comprising the British Heart Foundation; Cancer Research UK; Department of Health; Diabetes UK; Economic and Social Research Council; Medical Research Council; Health and Social Care Research and Development Office for Northern Ireland; Chief Scientist Office, Scottish Government Health Directorate; the Welsh Assembly Government; and World Cancer Research</p>

	<p>IFG/IGT according to WHO criteria</p> <p><b>Excluded population/s:</b> Taking long-term oral corticosteroids, or weight loss medication health disorders making adherence unlikely, pregnant, or unlikely to remain in the UK for 3 years</p> <p><b>Setting:</b> Home based, voluntary organisations, NHS, workplace settings</p>	<p><b>Control description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Reduced intervention</li> <li><input type="checkbox"/> 4 visits from dietician over 3 years (baseline, then annually)</li> <li><input type="checkbox"/> Given standardised written and verbal advice on healthy eating, diabetes prevention, physical activity, and accessing other weight control and physical activity services</li> <li><input type="checkbox"/> Aimed to halt weight increase</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 171 Intervention = 85 Control = 86</p>		<p>Fund. Additional financial support was provided from NHS Lothian and NHS Greater Glasgow and Clyde Research and Development, Chief Scientist Office, NHS Health Scotland, and NHS National Services Scotland.</p>
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Boltri et al <b>Year:</b> 2008 <b>Citation:</b> Boltri JM, Davis-Smith YM, Seale JP, Shellenberger S, Okosun IS, Cornelius ME. 2008. Diabetes prevention in a faith-based setting: results of translational research. J Public Health Management Practice, 14 (1) 29-32 <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> Before and after</p>	<p><b>Source population/s:</b> USA; <i>Across whole study:</i> mean age 52 years old, male 42%, ethnicity 100% African-American</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): baseline BMO (kg/m<sup>2</sup>): 32</p> <p><b>Eligible population:</b> Church attendees aged 18 years or older</p> <p><b>Selected population:</b> Individuals at high risk for type 2 diabetes mellitus (score &gt;= 10) – risk assessment survey developed by the Centers for Disease Control and Prevention – and those with a FG in the prediabetes 100-125mg/dL range</p> <p><b>Excluded population/s:</b> Diabetes</p>	<p><b>Method of allocation:</b> <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> DPP in faith based</li> <li><input type="checkbox"/> 16-session individualised lifestyle programme conducted over 4 months and delivered by trained volunteer medical personnel with diabetes prevention experience</li> <li><input type="checkbox"/> Goals of a 7% weight loss and 150 mins exercise per week</li> <li><input type="checkbox"/> Designed to teach subjects how to improve their diet, lower fat intake, increase exercise, change behaviour to establish a lifelong healthy lifestyle</li> <li><input type="checkbox"/> Group interactive process, including prayer</li> <li><input type="checkbox"/></li> <li><input type="checkbox"/></li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 8</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> Weight in lbs changed to kgs Fasting glucose in mg/dl converted to mmol/l</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b> Hatcher Foundation, Macon, Georgia; the US Department of Health and Human Services, Health Resources and Services Administration</p> <p><b>Other notes:</b></p>

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Costa et al  <b>Year:</b> 2012  <b>Citation:</b>                      Costa B, Barrio F, Cabre JJ, Pinol JL, Cos X, Sole C, Bolibar B, Basora J, Castell C, Sola-Morales O, Slas-Salvado J, Lindstrom J, Tuomilehto J, 2012. Delaying progression to type 2 diabetes among high-risk Spanish individuals is feasible in real-life primary healthcare settings using intensive lifestyle intervention. <i>Diabetologia</i>, 55, 1319-1328.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Prospective cohort</p>	<p><b>Setting:</b> Community (Church)</p> <p><b>Source population/s:</b> Spain;  <i>Across whole study:</i> mean age 62 years old, male 32%, ethnicity 100% White-European</p> <p><i>For each arm (mean, SD):</i>                      baseline weight (kg):                      baseline BMI (kg/m<sup>2</sup>):                      31.2</p> <p><b>Eligible population:</b> Participants consecutively recruited from random list from computerised public healthcare system to obtain representative sample of population assigned to each of 18 primary healthcare centres</p> <p><b>Selected population:</b> OGTT, did not have diabetes, had either or both of a FINDRISC score &gt;14 or prediabetes defined using WHO criteria for fasting or 2h glucose</p> <p><b>Excluded population/s:</b> Severe psychiatric disease, chronic kidney and liver disease, blood disorders</p> <p><b>Setting:</b> Primary care</p>	<p><b>Method of allocation:</b>  <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <i>DE-PLAN Spain</i></li> <li><input type="checkbox"/> <i>Intensive intervention</i></li> <li><input type="checkbox"/> 6h educational programme scheduled in 2-4 sessions in groups of 5-15 participants or individually</li> <li><input type="checkbox"/> Specific training materials</li> <li><input type="checkbox"/> Cornerstones of contents were: what type 2 diabetes is and what it means to be at risk, the Mediterranean diet and nutritional advice based on the Prevencion con Dieta Mediterranea-Mediterranean Diet Adherence Screener (PREDIMED MED AS) questionnaire, physical activity and its beneficial health effects, tobacco advice.</li> <li><input type="checkbox"/> Regular contact by phone or text message at least once every 6-8 weeks.</li> </ul> <p><b>Intervention (2) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <i>Standard care intervention</i></li> <li><input type="checkbox"/> General information on diet, cardiovascular health, risk of type 2 diabetes</li> <li><input type="checkbox"/> No individualised programme</li> </ul> <p><b>Sample sizes (baseline):</b>                      Total n = 552                      Intensive intervention group = 333 (individual = 103, group = 230)                      Standard care intervention group = 219  <b>At 4 years</b>                      Total n = 324                      Intensive intervention = 207</p>	<p><b>Published data only</b></p> <p><b>Follow up periods:</b> median 4.2 years</p>	<p><b>Source of funding:</b>                      Commission of the European Communities</p> <p><b>Other notes:</b></p>

		Standard care intervention = 117 <b>Baseline comparisons:</b> Groups similar at study outset		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Davies et al  <b>Year:</b> 2015  <b>Citation:</b> Unpublished  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Cluster RCT</p>	<p><b>Source population/s:</b> UK;  <i>Across whole study:</i> mean age 64 years old, male 64%, ethnicity 84% White European, 16% ethnic minority groups</p> <p><i>For each arm (mean, SD):</i>  baseline weight (kg): Intervention 89.9(16.6), control 94.4(18.9)  baseline BMI (kg/m<sup>2</sup>): Intervention 32(5.2)  control 33.1(5.8)</p> <p><b>Eligible population:</b> Aged 40 to 75 years if English speaking European or 25–75 years if South Asian</p> <p><b>Selected population:</b>  Leicester Risk Assessment tool, modified for use at practice level; IFG identified (75g OGTT FPG <math>\geq 6.1</math> and <math>\leq 6.9</math>), IGT (2-hour blood glucose <math>\geq 7.8</math> and <math>\leq 11</math>) before Jan 2013, HbA1c % <math>\geq 6.5</math> (regardless of OGTT results) after Jan 2013</p> <p><b>Excluded population/s:</b>  Unable to give informed consent, diabetes at baseline, pregnant or lactating, terminal illness, require interpreter for language other than South-Asian</p> <p><b>Setting:</b> Outpatient setting</p>	<p><b>Method of allocation:</b>  <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Let's Prevent</li> <li><input type="checkbox"/> Six one-hour structured group education sessions, over three years</li> <li><input type="checkbox"/> Led by Health care professionals</li> <li><input type="checkbox"/> Optional annual three-hour refresher sessions to revise goals, re-examine risk profiles</li> <li><input type="checkbox"/> Regular phone contact (every 3 months) to increase motivation and support goal attainment.</li> <li><input type="checkbox"/> Standard written information (booklet), as received by control group</li> </ul> <p><b>Control description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Information booklet and standard lifestyle advice given by GP</li> <li><input type="checkbox"/> Booklet discussed risk factors for T2DM, and how changes in diet and physical activity levels could prevent progression to T2DM</li> <li><input type="checkbox"/> Information given in accordance with Leventhal's Common Sense Model, addressing Causes, Consequences, Identity, Control/Treatment and Timeline for participants with pre-diabetes</li> </ul> <p><b>Sample sizes (baseline):</b>  Total n = 880  Intervention = 447</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>  Calculated directly from dataset, adjusted for clustering</p> <p><b>Follow up periods:</b> 12, 24, 36</p>	<p><b>Source of funding:</b> NIHR Programme Grant and supported by NIHR CLAHRC – LNR and the NIHR Leicester-Loughborough biomedical Research Unit, a partnership between University Hospitals of Leicester NHS Trust, Loughborough university and University of Leicester</p>

		<p>Control = 433  <b>At 12 months</b>                  Total n = 768                  Intervention = 378                  Control = 390  <b>At 24 months</b>                  Total n = 731                  Intervention = 366                  Control = 365  <b>At 36 months</b>                  Total n = 673                  Intervention = 333                  Control = 340  <b>Baseline comparisons:</b> Groups similar at study outset, but significantly differed in weight, BMI, waist circumference, deprivation score and smoking status</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Davis-Smith  <b>Year:</b> 2007  <b>Citation:</b>                  Davis-Smith M. 2007. Implementing a diabetes prevention program in a rural African-American church. Journal of the National Medical Association, 99 (4) 440-446.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after</p>	<p><b>Source population/s:</b> USA; <i>Across whole study:</i> mean age NR, male 27%, ethnicity 100% African-American</p> <p><i>For each arm (mean, SD):</i>                  baseline weight (kg):                  baseline BMI (kg/m<sup>2</sup>):                  36+</p> <p><b>Eligible population:</b> Attendees of African-American church in a rural Georgia town with a high interest in the project, existence of a health ministry in the church, and an existing relationship with the pastor.</p> <p><b>Selected population:</b> Risk assessment score of <math>\geq 10</math> and a fasting finger-sick glucose (FSG)</p>	<p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 6 session programme designed from the 16 session intensive lifestyle arm of the DPP.</li> <li><input type="checkbox"/> 2 sessions from each theme: nutrition, physical activity, behaviour change</li> <li><input type="checkbox"/> Presented over a 7 week period</li> <li><input type="checkbox"/> Each session led by volunteer healthcare professionals</li> <li><input type="checkbox"/> Diet and physical activity logs reviewed by the group and the leader</li> <li><input type="checkbox"/> After presentation and discussion in each session, individuals set goals for diet, exercise and behaviour change for the subsequent week.</li> <li><input type="checkbox"/> No additional support following 6 sessions</li> <li><input type="checkbox"/> 6 and 12 month follow up</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>                  Weight in lbs changed to kgs                  Fasting glucose in mg/dl converted to mmol/l</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b></p> <p><b>Other notes:</b>                  Description of DPP: Knowler WC, Barrett-Connor E, Fowler SE, et al. 2002. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 346(6)393-403.</p>

	<p>in the range of 100-125mg/dL</p> <p><b>Excluded population/s:</b> Participants with FSG &lt;100mg/dL (given healthy lifestyles hand-out) and FSG &gt;=126mg/dL (advised to follow up with their primary care physician for further evaluation for type 2 diabetes) <b>Setting:</b> Community (Church)</p>	<p>sessions to take measurements, discuss maintaining lifestyle intervention, establish group goals</p> <p><b>Sample sizes (baseline):</b> Total n = 11 <b>At 12 months</b> Total n = 9</p>		
<b>Study details</b>	<b>Population and setting</b>	<b>Method of allocation to intervention/control</b>	<b>Outcomes and method of analysis</b>	<b>Notes</b>
<p><b>Authors:</b> Deakin et al <b>Year:</b> 2015 <b>Citation:</b> Unpublished <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> Before and after</p>	<p><b>Source population/s:</b> UK; <i>Across whole study:</i> mean age NR, male NR, ethnicity 51% white 30% black 13% other 3% asian 3% mixed</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg):</p> <p><b>Eligible population:</b> IGR, obesity, hypertension, gestational diabetes, strong family history, high risk score.</p> <p><b>Excluded population/s:</b> <b>Setting:</b> Various (community and outpatient settings)</p>	<p><b>Method of allocation:</b> <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> X-POD</li> <li><input type="checkbox"/> Programme delivered over 6 weeks (15 hours)</li> <li><input type="checkbox"/> Each week there are 9 learning outcomes – what is prediabetes/diabetes, weight management to include healthy eating and physical activity, carbohydrate and saturated fat awareness, reading and understanding food labels, health checks, care planning and goal setting</li> <li><input type="checkbox"/> Follow up 3-6 months plus 1 year (5 hours).</li> <li><input type="checkbox"/> Each session 2.5 hours</li> <li><input type="checkbox"/> 15-18 participants per session</li> <li><input type="checkbox"/> Delivered by trained educators</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 54 <b>Baseline comparisons:</b> Groups similar at study outset</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs were calculated from Cis</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Other notes:</b> More information on X-POD programme: <a href="http://www.xperthealth.org.uk/at-risk-of-diabetes/reduce-your-risk/x-pod-overview">http://www.xperthealth.org.uk/at-risk-of-diabetes/reduce-your-risk/x-pod-overview</a></p>
<b>Study details</b>	<b>Population and setting</b>	<b>Method of allocation to intervention/control</b>	<b>Outcomes and method of analysis</b>	<b>Notes</b>
<b>Authors:</b> Faridi et al	<b>Source population/s:</b> USA;	<b>Method of allocation:</b>	<b>Published data only</b>	<b>Source of funding:</b>

<p><b>Year:</b> 2010  <b>Citation:</b>                  Faridi Z, Shuval K, Njike VJ, Katz JA, Jennings G, Williams M, Katz DL. 2010. Partners reducing effects of diabetes (PREDICT): a diabetes prevention physical activity and dietary intervention through African-American churches. Health Education Research, 25 (2) 306-315.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Non-RCT</p>	<p><i>Across whole study:</i> mean age NR, male 32%, ethnicity 100% African-American</p> <p><i>For each arm (mean, SD):</i>                  baseline weight (kg):                  baseline BMI (kg/m<sup>2</sup>):                  33</p> <p><b>Eligible population:</b> Adult (aged &gt;=18 years) African-American residents in New Haven or Bridgeport who have diabetes or are at risk of diabetes. Nominated church attendees who were seen by the pastors as natural leaders, respected by members of their respective congregation, willing to commit to intervention and be trained as CHAs. at churches. CHAs recruited 10-15 members of their congregation based on inclusion criteria.</p> <p><b>Selected population:</b> One or more of criteria – BMI &gt;25, parent with diabetes, sibling with diabetes and/or gestational diabetes</p> <p><b>Excluded population/s:</b> Inability to read/speak English, not at risk for diabetes, inability to commit to participating and completing programme for any reason.  <b>Setting:</b> Community (Church)</p>	<p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> PREDICT</li> <li><input type="checkbox"/> CHAs used as mode of delivering intervention</li> <li><input type="checkbox"/> 10-week training session with 21 CHAs before intervention</li> <li><input type="checkbox"/> CHA training focussed on diabetes prevention knowledge, awareness of diabetes-related risk factors, based on DPP lifestyle strategies to reduce incidence of diabetes – topics included health enhancing physical activity programmes/healthful diet, reading food labels, portion control, healthful cooking, weight loss programmes, social support, diabetes medications, empowering participants to communicate with physicians</li> <li><input type="checkbox"/> CHAs instrumental in deciding intervention methods, tailored frequency of contact and teaching methods to participants preferences</li> </ul> <p><b>Control description: (2)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 10-week training session with 21 CHAs after intervention</li> </ul> <p><b>Sample sizes (baseline):</b>                  Total n = 246                  Intervention/New Haven = 121                  Control/Bridgeport = 125  <b>At 12 months</b>                  Total n = 161                  Intervention/New Haven = 83                  Control/Bridgeport = 78  <b>Baseline comparisons:</b> Groups similar at study outset</p>	<p><b>Outcome calculation method:</b>                  Weight in lbs changed to kgs</p> <p><b>Follow up periods:</b> 12 months</p>	<p>Connecticut Health Foundation and the Centers for Disease Control and Prevention</p>
<p><b>Study details</b></p>	<p><b>Population and setting</b></p>	<p><b>Method of allocation to intervention/control</b></p>	<p><b>Outcomes and method of analysis</b></p>	<p><b>Notes</b></p>
<p><b>Authors:</b> Gilis-Januszewska et al</p>	<p><b>Source population/s:</b> Poland;</p>	<p><b>Method of allocation:</b></p>	<p><b>Published data only</b></p>	<p><b>Source of funding:</b></p>

<p><b>Year:</b> 2011  <b>Citation:</b>                  Gilis-Januszewska A, Szybinski Z, Kissimova-Skarbek K, Piwonska-Solska B, Pach D, Topor-Madry R, Tuomilehto J, Lindstrom J, Peltonen M, Schwarz PE, Hubalewska-Dydejczyk A. 2011. Prevention of type 2 diabetes by lifestyle intervention in primary health care setting in Poland: diabetes in Europe prevention using lifestyle, physical activity and nutritional intervention (DE-PLAN) project. The British Journal of Diabetes &amp; Vascular Disease, 11, 198.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after</p>	<p><i>Across whole study:</i> mean age NR, male 22%, ethnicity NR  <i>For each arm (mean, SD):</i> baseline weight (kg): 85.7 (16.1) baseline BMO (kg/m2): 31.8 (5.0)  <b>Eligible population:</b> Patients in the primary health care centres participating in the DE-PLAN project. Advertisements placed alongside self-screening questionnaires In GP's waiting rooms. Patients with known risk factors directly approached by nursing and medical staff.  <b>Selected population:</b> FRS&gt;14  <b>Excluded population/s:</b> Known or OGTT diabetes  <b>Setting:</b> Primary care</p>	<p><b>Intervention (1) description:</b>  <input type="checkbox"/> DE-PLAN Poland  <input type="checkbox"/> Delivered by trained nurses  <input type="checkbox"/> 10 group sessions over 4 months on lifestyle changes, diet and physical activity education  <input type="checkbox"/> Followed by a 6 month continuous part including 6 telephone motivational session and 2 motivational letters  <input type="checkbox"/> Opportunity to participate in once or twice weekly physical activity sessions  <b>Sample sizes (baseline):</b>                  Total n = 175  <b>At 12 months</b>                  Total n = NR</p>	<p><b>Outcome calculation method:</b>                  SDs imputed from correlation estimates from papers reporting full outcome data.  <b>Follow up periods:</b> 12 months</p>	<p><b>Other notes:</b></p>
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Janus et al  <b>Year:</b> 2012  <b>Citation:</b>                  Janus ED, Best JD, Davis-Lameloise N, Philpot B, Hernan A, Bennett CM, O-Reilly S, Carter R, Vartiainen E, Dunbar JA. 2012. Scaling-up from an implementation trial to state-wide coverage: results from the preliminary Melbourne diabetes prevention study. Trials, 13, 152.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> Australia;  <i>Across whole study:</i> mean age ~65 years old, male 34%, ethnicity 100% non-Aboriginal/Torres Strait Islander  <i>For each arm (mean, SD):</i> baseline weight (kg): intervention 87.2 (12.5) control 81.8 (14.4) baseline BMi (kg/m2): intervention 31.4 (4.8) control 30.1 (4.2)  <b>Eligible population:</b> Patients with IGT or IFG identified and contacted, and others were screened opportunistically, from</p>	<p><b>Method of allocation:</b> Individually randomised – generated by random number table and placed in individual sealed opaque envelopes  <b>Intervention (1) description:</b>  <input type="checkbox"/> pMDPS  <input type="checkbox"/> 6 structured 90-min group sessions - 5 fortnightly sessions and final session at 8 months  <input type="checkbox"/> Delivered by trained health professionals  <input type="checkbox"/> Physiotherapist or exercise physiologist and dietician co-facilitated sessions 3 and 4.  <input type="checkbox"/> Finnish Diabetes Prevention Study goals used – no more than</p>	<p><b>Published data only</b>  <b>Outcome calculation method:</b>                  SDs calculated from SEs  <b>Follow up periods:</b> 3 and 12 months</p>	<p><b>Source of funding:</b>                  National Health and Medical Research Council (The Life! Programme funded by the Victorian Government Department of Health)  <b>Other notes:</b></p>

	<p>primary healthcare practices. Additional recruitment at community events</p> <p><b>Selected population:</b> Aged between 50 and 70 years old, at high risk of type 2 diabetes (scoring <math>\geq 15</math> on AUSDRISK tool)</p> <p><b>Excluded population/s:</b> Diagnosed diabetes, cancer, severe mental illness, substance abuse, recent myocardial infarction, pregnancy, difficulty with spoken and written English, belonging to cultural group for whom AUSDRISK test is not calibrated, other households members involved in study.</p> <p><b>Setting:</b> Community/primary care</p>	<p>30% energy from fat, at least 15g/1,000 kcal fibre, at least 30min/day moderate intensity physical activity, at least 5% body weight reduction</p> <p><input type="checkbox"/> Processes and detailed goals for lifestyle change individually tailored using problem-solving and goal-setting approach.</p> <p><b>Control description:</b> (2)</p> <p><input type="checkbox"/> Usual care provided by GP</p> <p><input type="checkbox"/> Offered the Life! Programme after 12m</p> <p><b>Sample sizes (baseline):</b> Total n = 92 Intervention = 49 Control = 43</p> <p><b>At 12 months</b> Total n = 80 Intervention = 38 Control = 42</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Kanaya et al <b>Year:</b> 2012 <b>Citation:</b> Kanaya AM, Santoyo-Disson J, Gregorich S, Grossman M, Moore T, Stewart AL. 2012. The Live Well, Be Well study: a community-based translational lifestyle program to lower diabetes risk factors in ethnic minority and lower-socioeconomic status adults. <i>Research and Practice</i>, 102 (8) 1551-1558 <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> USA; <i>Across whole study:</i> mean age ~56 years old, male 36%, ethnicity 20% African-American 20% non-Hispanic White 32% Latino 14% Asian 14% other</p> <p><i>For each arm (mean, SD):</i> Baseline weight (kg): Intervention (lb) 177.9 (3.7) Control 176.5 (3.7) baseline BMI (kg/m<sup>2</sup>): intervention 30.1 (5.3) control 29.9 (6.1)</p> <p><b>Eligible population:</b> Community-</p>	<p><b>Method of allocation:</b> Randomly assigned - stratified by self-reported race/ethnicity and age, and generated stratum-specific sequential identification numbers to randomly allocated individuals.</p> <p><b>Intervention (1) description:</b></p> <p><input type="checkbox"/> Live Well, Be Well</p> <p><input type="checkbox"/> 6 month active intervention phase followed by 6 month maintenance phase</p> <p><input type="checkbox"/> Trained health department counsellors provided education and skills training to modify diet and physical activity through</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs calculated from SEs</p> <p><b>Follow up periods:</b> 6 and 12 months</p>	<p><b>Source of funding:</b> National Institute of Diabetes and Digestive and Kidney Diseases, and the Resource Centers for Minority Aging Research program of the National Institute on Aging.</p> <p><b>Other notes:</b></p>

	<p>dwelling adults in 4 distinct low-income neighbourhoods in northern Californian cities. Recruitment with community-based, educational outreach to identify individuals at risk for diabetes</p> <p><b>Selected population:</b> Capillary blood glucose value between 106-160 milligrams/decilitre, moderate to high diabetes risk appraisal score, aged <math>\geq 25</math> years</p> <p><b>Excluded population/s:</b> Diabetes (physician diagnosis, use of insulin or other diabetes medications), diagnosis in past 6 months of myocardial infarction, congestive heart failure, stroke, heart procedure or heart surgery in past 6 months, implanted defibrillator, hip or knee replacement in past 3 months, insufficient cognitive functioning, pregnancy, not conversant in English or Spanish, plans to move out of area within 1 year, spouse or partner already enrolled.</p> <p><b>Setting:</b> Community</p>	<p>primarily telephone-based counselling (12 calls) with 2 in-person sessions and 5 optional group work-shops.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Self-selected and attainable goal-setting and action plans emphasised to enhance self-efficacy.</li> <li><input type="checkbox"/> Motivating interviewing techniques to develop and enhance participants motivation used during telephone calls</li> </ul> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Wait list</li> <li><input type="checkbox"/> Offered lifestyle programme after the trial</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 238 Intervention = 119 Control = 119</p> <p><b>At 12 months</b> Total n = 212 Intervention = 105 Control = 107</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Katula <b>Year:</b> 2011 (&amp;2013) <b>Citation:</b> Katula JA, Vitolins MZ, Rosenberger EL, Blackwell CS, Morgan TM, Lawlor MS, Goff Jr DC. 2011. One-year results of a community-based translation of the diabetes prevention program.:</p>	<p><b>Source population/s:</b> USA; <i>Across whole study:</i> mean age 58 years old, male 43%, ethnicity 74% White 25% African-American 1% other</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): intervention 94.4 (14.7)</p>	<p><b>Method of allocation:</b> <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> HELP PD</li> <li><input type="checkbox"/> LWL intervention administered through a diabetes education programme (DPP) and delivered by community health workers (CHWs)</li> <li><input type="checkbox"/> CHWs were community</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> fasting glucose converted from mg/dl to mmol/l SDs imputed using correlation estimates from studies reporting full outcome data</p>	<p><b>Source of funding:</b> National Institute of Diabetes and Digestive and Kidney Diseases</p>

<p>healthy-living partnerships to prevent diabetes (HELP PD) project. Diabetes Care, 34, 1451-1457.</p> <p><b>Aim of study:</b> Diabetes prevention</p> <p><b>Study design:</b> RCT</p>	<p>control 93.0 (16.2) baseline BMI (kg/m<sup>2</sup>): intervention 32.8 (3.9) control 32.6 (4.1)</p> <p><b>Eligible population:</b> Recruitment primarily through mass mailings to targeted ZIP codes</p> <p><b>Selected population:</b> Evidence of prediabetes on 2 occasions, a confirmatory fasting glucose between 95-125mg/dL, BMI &gt;=25-39.9kg/m<sup>2</sup>.</p> <p><b>Excluded population/s:</b> Comorbid conditions that would make physical activity unsafe or limit participation – recent history of an acute cardiovascular disease event, clinical history of type 2 diabetes, uncontrolled hypertension, cancer or other conditions limiting life expectancy, chronic use of medicines known to influence glucose metabolism, major psychiatric or cognitive problems, participation in a supervised programme for weight loss or another research study that would interfere.</p> <p><b>Setting:</b> Community, various venues</p>	<p>members with type 2 diabetes, well-controlled HbA1c and history of healthy eating and physical activity</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> CHW training consisted of 36 hour programme over 6-9 weeks.</li> <li><input type="checkbox"/> LWL consisted of – decreased caloric intake (goal of 1,200-1,800 kcal/day), increased caloric expenditure through moderate physical activity (&gt;=180 min/week), total weight loss of 5-7% during first 6m</li> <li><input type="checkbox"/> Second 6m, participants encouraged to continue to meet or maintain weight loss goals as long as BMI did not fall below 20kg/m<sup>2</sup></li> <li><input type="checkbox"/> Weekly meetings for first 6m</li> <li><input type="checkbox"/> 8-12 participants/group</li> <li><input type="checkbox"/> 3 personalised consultations with registered dietician (month 1, 3,6)</li> <li><input type="checkbox"/> 2 scheduled contacts with CHW each month, 1 group session, 1 telephone contact (months 7-12)</li> <li><input type="checkbox"/> Supported by DVD series and presentations</li> </ul> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Usual-care</li> <li><input type="checkbox"/> 2 individual sessions with nutritionists during first 3m</li> <li><input type="checkbox"/> Monthly newsletter</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 301 Intervention = 151 Control = 150</p> <p><b>At 12 months</b> Total n = NR Intervention = NR Control = NR</p> <p><b>Baseline comparisons:</b> Groups</p>	<p><b>Follow up periods:</b> 12 months(Katula et al 2011), 18, 24 months (Katula et al 2013)</p>	
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Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Kramer et al  <b>Year:</b> 2009  <b>Citation:</b>                      Kramer MK, Kriska AM, Venditti EM, Miller RG, Brooks MM, Burke LE, Siminerio LM, Solano FX, Orchard TJ. 2009. Translating the diabetes prevention program: a comprehensive model for prevention training and program delivery. <i>Am J Prev Med</i>, 37 (6) 505-511.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after</p>	<p><b>Source population/s:</b> USA;  <i>Across whole study:</i> mean age 57 years old, male 21%, ethnicity 100% White</p> <p><i>For each arm (mean, SD):</i>                      baseline weight (lb): 208.4 (37.2)                      baseline BMI (kg.m2): 34.6 (5.4)</p> <p><b>Eligible population:</b> 2 research practices in Pittsburgh</p> <p><b>Selected population:</b> Aged &gt;=18 years, prediabetes (fasting glucose 100-125mg/dL)</p> <p><b>Excluded population/s:</b> NR</p> <p><b>Setting:</b> Primary care and university based support centre</p>	<p>similar at study outset</p> <p><b>Method of allocation:</b>  <b>Intervention (1) description:</b>  <input type="checkbox"/> GLB 2005-2008  <input type="checkbox"/> 12 weekly 1hour sessions delivered over 12-15 weeks  <input type="checkbox"/> Group classes  <input type="checkbox"/> Primary focus on healthy food choices  <input type="checkbox"/> Initial emphasis on fat intake and calories  <input type="checkbox"/> Pedometer introduced during core session  <input type="checkbox"/> Use of inexpensive food samples and incentives  <input type="checkbox"/> Prevention training conducted by DPSC faculty via 2 day workshop  <input type="checkbox"/> Ongoing support for implementation provided by DPSC  <input type="checkbox"/> Evaluated programme in 2 primary care practices and in subjects referred directly to the Diabetes Prevention Support Center in 2007-2008.</p> <p><b>Sample sizes (baseline):</b>                      Total n = 42  <b>At 12 months</b>                      Total n = NR</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>                      NA</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b>                      Sponsored by funding from the 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</p>
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Kramer  <b>Year:</b> 2012  <b>Citation:</b>                      Kramer KM, Venditti, emler LN, Kriska AM, Miller RG, Orchard TJ. 2012. Long-term strategies for diabetes prevention: evaluation of the group lifestyle balance post-</p>	<p><b>Source population/s:</b> USA;  <i>Across whole study:</i> mean age 55 years old, male 35%, ethnicity 90% Caucasian</p> <p><i>For each arm (mean, SD):</i>                      baseline weight (lb):                      CPC group 225.3 (35.3)</p>	<p><b>Method of allocation:</b>                      Randomly assigned</p> <p><b>Intervention (1) description:</b>  <input type="checkbox"/> GLB 2009  <input type="checkbox"/> Traditional post-core sessions (TPC)  <input type="checkbox"/> Initial 12 core sessions over 12-</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>                      Weight changed from lbs to kgs                      Fasting glucose converted from mg/dl to mmol/l</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b>                      Robert C. and Veronica Atkins Foundation</p>

<p>core sessions focusing on carbohydrate and hunger management. Diabetes and Metabolism, 8 (2)  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after</p>	<p>TPC group 222.7 (44.7) baseline BMI (kg/m2):                  CPC group 37.4 (6.1)                  TPC group 35.7 (5.0)</p> <p><b>Eligible population:</b> Recruitment at the University of Pittsburgh campus faculty, YMCA newsletter to members, flyers with information about GLB programme and study mailed to selected ZIP codes within 4 mile radius of YMCA</p> <p><b>Selected population:</b> Non diabetic individuals, aged &gt;=18 years, BMI &gt;=25/kg2, prediabetes (fasting glucose 100-125mg/dL) and/or metabolic syndrome.</p> <p><b>Excluded population/s:</b>NR</p> <p><b>Setting:</b> Community (YMCA) and university</p>	<p>14 weeks</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 9 monthly support sessions</li> <li><input type="checkbox"/> Delivered by 2 GLB trained health professionals</li> <li><input type="checkbox"/> GLB programme – a group behavioural lifestyle intervention adapted from DPP lifestyle intervention – same goals including weight loss of 7%, increase in activity to 150mins/week.</li> </ul> <p><b>Intervention (2) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> As above but TPC plus a carbohydrate</li> </ul> <p>And hunger management focus (CPC)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> CPC included information on reducing less healthy carbohydrates, choosing healthier carbohydrates, monitoring carbohydrate quality, identifying hunger versus craving, dealing with food cravings, increasing satiety.</li> <li><input type="checkbox"/> Record intake of better foods vs. poor food choices.</li> <li><input type="checkbox"/> Hunger management techniques</li> </ul> <p><b>Sample sizes (baseline):</b>                  Total n = 60                  CPC = 29                  TPC = 31</p> <p><b>At 12 months</b>                  Total n =                  CPC =                  TPC =</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
Authors: Kramer et al	Source population/s: USA;	Method of allocation:	Published data only	Source of funding:

<p><b>Year:</b> 2014  <b>Citation:</b>                  Kramer MK, Miller RG, Siminerio LM. 2014. Evaluation of a community diabetes prevention program delivered by diabetes educators in the United States: one-year follow up. Diabetes Research and Clinical Practice, 106, e49-e52.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after</p>	<p><i>Across whole study:</i> mean age 53 years old, male 12%, ethnicity 96% Caucasian</p> <p><i>For each arm (mean, SD):</i>                  baseline weight (kg):                  baseline BMI (kg/m<sup>2</sup>):                  37.2</p> <p><b>Eligible population:</b> Recruitment completed through existing network of primary care physicians and local endocrinologists who were already referring patients with diabetes for DSME. Also, diabetes educators advertised in local newspapers and flyers at several community sites</p> <p><b>Selected population:</b>                  Overweight/obese adults with prediabetes (fasting glucose 100-125mg/dL) and/or metabolic syndrome with physician referral</p> <p><b>Excluded population/s:</b>  <b>Setting:</b> University medical centres</p>	<p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> GLB 2008</li> <li><input type="checkbox"/> Initial 12 1 hour core sessions over 12-14 weeks</li> <li><input type="checkbox"/> Delivered by 2 GLB trained health professionals</li> <li><input type="checkbox"/> GLB programme – a group behavioural lifestyle intervention adapted from DPP lifestyle intervention – same goals including weight loss of 7%, increase in activity to 150mins/week.</li> <li><input type="checkbox"/> Home assignments including self-monitoring of eating and physical activity</li> <li><input type="checkbox"/> After 12 sessions, monthly meetings for 9 months to collect weight and activity minutes, and for provision of support for healthy lifestyle change</li> </ul> <p><b>Sample sizes (baseline):</b>                  Total n = 81  <b>At 12 months</b>                  Total n = 52</p>	<p><b>Outcome calculation method:</b>                  Fasting glucose converted from mg/dl to mmol/l</p> <p><b>Follow up periods:</b> 12 months</p>	<p>Sanofi-Aventis</p>
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Kulzer et al  <b>Year:</b> 2009  <b>Citation:</b>                  Kulzer B, Hermanns N, Gorges D, Schwarz P, Haak T. 2009. Prevention of diabetes self-management program (PREDIAS): effects of weight, metabolic risk factors, and behavioural outcomes. Diabetes Care, 32 (7), 1143-1146</p>	<p><b>Source population/s:</b> Germany;  <i>Across whole study:</i> mean age 56 years old, male 57%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i>                  baseline weight (kg):                  intervention 92.1 (16.5)                  control 93.6 (19.3)                  baseline BMI (kg.m<sup>2</sup>):                  intervention 31.0 (4.7)                  control 32.0 (5.7)</p>	<p><b>Method of allocation:</b> Block randomisation</p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> PREDIAS</li> <li><input type="checkbox"/> 12 90min lessons</li> <li><input type="checkbox"/> Weeks 1-8 – 8 core lessons given (1/week)</li> <li><input type="checkbox"/> Last 4 lessons bimonthly booster lessons</li> <li><input type="checkbox"/> Conducted in small groups</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>                  Fasting and 2-hour glucose converted from mg/dl to mmol/l</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b>                  Roche Diagnostics</p>

<p><b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT</p>	<p><b>Eligible population:</b></p> <p><b>Selected population:</b> Aged 20-70 years, BMI <math>\geq 26</math> kg/m<sup>2</sup>, IGT, ability to read and understand German, elevated diabetes risk based on a high score (&gt;20) on the diabetes risk score</p> <p><b>Excluded population/s:</b> Manifest diabetes or diagnosis of serious illness (e.g. cancer).</p> <p><b>Setting:</b> Outpatient setting</p>	<p><input type="checkbox"/> Delivered by diabetes educators or psychologists <input type="checkbox"/> Received exercise book – information about diabetes prevention, table of caloric values and worksheets (e.g. eating diaries and logbooks for physical activity)</p> <p><b>Control description:</b> (2) <input type="checkbox"/> Written information about diabetes prevention</p> <p><b>Sample sizes (baseline):</b> Total n = 182 Intervention = NR Control = NR <b>At 12 months</b> Total n = 165 Intervention = NR Control = NR <b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Laatikainen et al <b>Year:</b> 2007 (&amp;2012) <b>Citation:</b> Laatikainen T, Dunbar JA, Chapman A, Kilkkinen A, Vartiainen E, Heistaro S, Philpot B, Absetz P, Bunker S, O'Neil A, Reddy P, Best JD, Janus ED. 2007. Prevention of type 2 diabetes by lifestyle intervention in an Australian primary health care setting: greater green triangle (GGT) diabetes prevention project. BMC Public Health, 7, 249. <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> Before and after</p>	<p><b>Source population/s:</b> Australia; <i>Across whole study:</i> mean age 57 years old, 28% male, ethnicity NR</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): 91.7 (17.7) baseline BMI (kg/m<sup>2</sup>): 33.5 (5.9)</p> <p><b>Eligible population:</b> Patients presenting at local General Practices at high risk of developing type 2 diabetes (screened using The Diabetes Risk Score tool)</p> <p><b>Selected population:</b> Patients</p>	<p><b>Method of allocation:</b> <b>Intervention (1) description:</b> <input type="checkbox"/> GGT study <input type="checkbox"/> 6 90min sessions delivered during 8 month period by trained nurses <input type="checkbox"/> First 5 sessions in first 3 months with 2 week intervals between sessions, last session at 8 months <input type="checkbox"/> Delivered by specially trained nurses, dieticians, physiotherapists <input type="checkbox"/> Goal-setting approach used to motivate <input type="checkbox"/> Regular self-assessment to empower participants to take responsibility for own decisions</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> NA</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b> The Australian Government Department of Health and Ageing.</p>

	<p>with score <math>\geq 12</math> on The Diabetes Risk Score</p> <p><b>Excluded population/s:</b> Cancer, recent myocardial infarction or stroke, cognitive impairment, substance abuse, pregnancy, previous type 2 diabetes diagnoses.</p> <p><b>Setting:</b> Primary care</p>	<p>and make informed choices</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Social support enhanced by group setting – encouraged participants to seek support from own social networks</li> <li><input type="checkbox"/> Targets followed lifestyle targets in the Finnish Diabetes Prevention Study aiming to reduce weight, total and saturated fat intake, and increase fibre intake and physical activity</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 311 <b>At 12 months</b> Total n = 237</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Ma et al <b>Year:</b> 2013 (Ma 2009 and Xiao 2013) <b>Citation:</b> Ma J, Yank V, Xiao L, Lavort PW, Wilson SR, Rosas LG, Stafford RS. 2013. Translating the diabetes prevention program lifestyle intervention for weight loss into primary care. <i>Jama Intern Med</i>, 173 (2) <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT <b>Quality score:</b> <b>External validity score:</b></p>	<p><b>Source population/s:</b> USA; <i>Across whole study:</i> mean age 53%, male 53%, ethnicity 78% non-Hispanic White 17% Asian/Pacific Islander</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): coach-led 95.3 (18.0) DVD 93.6 (17.1) Usual care 92.6 (18.1) baseline BMI (kg/m<sup>2</sup>): 32 Coach-led 31.8 (5.1) DVD 31.7 (4.7) Usual care 32.4 (6.3)</p> <p><b>Eligible population:</b> Recruited from single primary care clinic within Silicon Valley</p> <p><b>Selected population:</b> Aged <math>\geq 18</math> years, BMI <math>\geq 25</math>, presence of prediabetes (fasting glucose 100-125mg/dL) or metabolic syndrome</p>	<p><b>Method of allocation:</b> Randomised allocation using covariate-adaptive Efron's based coin method</p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> E-LITE</li> <li><input type="checkbox"/> Coach-led group</li> <li><input type="checkbox"/> 3 month intensive intervention phase – adapted 12 session DPP lifestyle intervention curriculum delivered face to face in 12 weekly classes by registered dietitian certified to deliver GLB programme</li> <li><input type="checkbox"/> 12 month maintenance phase</li> <li><input type="checkbox"/> Food tastings at end of each weekly class</li> <li><input type="checkbox"/> 30-45 min guided physical activity</li> <li><input type="checkbox"/> Development of individual action plan/goals for next week</li> <li><input type="checkbox"/> Personalised messages on at least monthly basis that provided progress feedback and lifestyle</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs calculated from SEs</p> <p><b>Follow up periods:</b> 15,24</p>	<p><b>Source of funding:</b> National Institute of Diabetes and Digestive and Kidney Diseases, a Scientist Development Grant award from the AHA, and internal funding from the Palo Alto Medical Foundation Research Institute.</p>

	<p><b>Excluded population/s:</b> Serious medical or psychiatric conditions (e.g. stroke, psychotic disorder) or special life circumstances (e.g. pregnancy, planned move)</p> <p><b>Setting:</b> Primary care</p>	<p>coaching absed on self-monitoring records during maintenance phase</p> <p><b>Intervention (2) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Self-directed DVD intervention</li> <li><input type="checkbox"/> 3 month intensive intervention phase followed by 12 month maintenance phase</li> <li><input type="checkbox"/> Lifestyle intervention curriculum delivered via a home-based DVD</li> <li><input type="checkbox"/> No food tastings</li> </ul> <p><b>Control description: (2)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Usual care</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 241 Coach-led = 79 DVD = 81 Control = 81</p> <p><b>At 15 months</b> Total n = 221 Coach-led = 72 DVD = 75 Control = 74</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Makrilakis et al <b>Year:</b> 2010 <b>Citation:</b> Makrilakis K, Liatis S, Grammatikou, Perrea D, Katsilambros N. 2010. Implementation and effectiveness of the first community lifestyle intervention programme to prevent type 2 diabetes in Greece: the DE-PLAN study. <i>Diabetic Medicine</i>, 27, 459-465. <b>Aim of study:</b> Diabetes</p>	<p><b>Source population/s:</b> Greece; <i>Across whole study:</i> mean age 56 years old, male 40%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): primary-care centres 87.6 (14.2) occupational centres 90.4 (14.1) baseline BMI (kg/m<sup>2</sup>): primary-care centres 32.9 (5.7) occupational centres 31.5 (3.7)</p> <p><b>Eligible population:</b> Recruited</p>	<p><b>Method of allocation:</b></p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> DE-PLAN Greece</li> <li><input type="checkbox"/> 1 year intervention consisting of 6 sessions (1 hour each)</li> <li><input type="checkbox"/> Delivered by registered dietician at the area of participants' residence or work</li> <li><input type="checkbox"/> Groups of 6-10 participants</li> <li><input type="checkbox"/> Information on healthy lifestyle, personal discussion, written materials (leaflets, etc) provided in every session</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> NA</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b> Commission of the European Communities, Directorate C-Public Health</p>

<p>prevention <b>Study design:</b> Before and after</p>	<p>using FINDRISC questionnaire to identify high-risk individuals for the development of type 2 diabetes. Questionnaires given to all people without diabetes in 6 primary-care centres for them to return at next visit, and at 6 companies where doctors of the investigators' team visited the company and distributed the questionnaire which were completed on site</p> <p><b>Selected population:</b> FINDRISC score <math>\geq 15</math>, maximum 26</p> <p><b>Excluded population/s:</b> diabetes <b>Setting:</b> Primary care, workplace</p>	<p><input type="checkbox"/> Core intervention goals – 5 prevention goals from the Finnish DPS study <input type="checkbox"/> General counselling to increase physical activity – no formal exercises given</p> <p><b>Sample sizes (baseline):</b> Total n = 191 Primary-care centres = 118 Occupational centres = 73 <b>At 12 months</b> Total n = 125 Primary-care centres = 71 Occupational centres = 54 <b>Baseline comparisons:</b> Groups similar at study outset</p>		
<p><b>Study details</b></p>	<p><b>Population and setting</b></p>	<p><b>Method of allocation to intervention/control</b></p>	<p><b>Outcomes and method of analysis</b></p>	<p><b>Notes</b></p>
<p><b>Authors:</b> Mensink et al <b>Year:</b> 2003 (&amp; 2003) <b>Citation:</b> Mensink M, Corpeleijn E, Feskens EJM, Kruijshoop M, Saris WHM, de Bruin TWA, Blaak EE. 2003. Study on lifestyle-intervention and impaired glucose tolerance Maastricht (SLIM): design and screening results. Diabetes Research and Clinical Practice, 61, 49-58. Mensink M, Feskens EJM, Saris WHM, de Bruin TWA, Blaak EE. 2003. Study on lifestyle intervention and impaired glucose tolerance Maastricht (SLIM): preliminary results after one year <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> Netherlands; <i>Across whole study:</i> mean age 57 years old, male 56%, ethnicity 100% White Caucasian</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): intervention 86.3 (2.1) control 83.5 (1.6) baseline BMI (kg/m<sup>2</sup>): intervention 29.7 (0.5) control 29.2 (0.5)</p> <p><b>Eligible population:</b> A large existing cohort, monitoring health and disease in the general population</p> <p><b>Selected population:</b> age 40-70 years, Caucasian, family history of diabetes or BMI <math>\geq 25</math>kg/m<sup>2</sup>, mean 2-h glucose concentration of both OGTTs carried out <math>\geq 7.8</math></p>	<p><b>Method of allocation:</b> Randomly assigned</p> <p><b>Intervention (1) description:</b> <input type="checkbox"/> SLIM study <input type="checkbox"/> Dietary intervention – based on Dutch guidelines for a healthy diet - encouraged to stop smoking and reduce alcohol intake – advice given at regular intervals by skilled dietician on individual basis after consideration of a 3 day food record <input type="checkbox"/> Goal body weight loss 5-7% <input type="checkbox"/> Exercise intervention – encouraged to increase level of physical activity to at least 30min of moderate physical activity/day for at least 5 days/week – individual advice given on how to increase physical activity and goals are set, encouraged to participate in exercise programme designed for study (participation is</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs calculated from SES/Cis Incidence of T2DM calculated from three-year incidence rate</p> <p><b>Follow up periods:</b> 12 (Mensink et al 2003)</p>	<p><b>Source of funding:</b> Netherlands Organisation for Scientific Research and the Dutch Diabetes Research Foundation</p>

	<p>and <math>\leq 12.5</math> mmol/l, fasting glucose concentration <math>&lt; 7.8</math> mmol/l</p> <p><b>Excluded population/s:</b> diabetes, mean 2-h glucose <math>&gt; 12.5</math> mmol, fasting glucose values <math>&gt; 7.8</math> mmol/l, any chronic illness that makes 5-years survival improbable, or that interferes with glucose tolerance, or that makes participation in a lifestyle-intervention impossible, medication known to interfere with glucose tolerance, participation in regular vigorous exercise and/or diet programme</p> <p><b>Setting:</b> Unclear</p>	<p>recorded)</p> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Oral and written information about beneficial effects of healthy diet, weight loss and increased physical activity</li> <li><input type="checkbox"/> No individual advice or programmes provided</li> <li><input type="checkbox"/> No additional appointments scheduled</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 114 Intervention = NR Control = NR</p> <p><b>At 12 months</b> Total n = 102 Intervention = 47 Control = 55</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Nilsen et al <b>Year:</b> 2011 <b>Citation:</b> Nilsen V, Bakke PS, Gallefoss F Effects of lifestyle intervention in persons at risk of type 2 diabetes mellitus —results from a randomised, controlled trial. BMC Public Health 11:893 <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> Norway; <i>Across whole study:</i> mean age 47 years old, male 50%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): Intervention 110.5 Control 111.7 baseline BMI (kg/m<sup>2</sup>): Intervention 37 Control 35.8</p> <p><b>Eligible population:</b> individuals aged 18-64</p> <p><b>Selected population:</b> FINDRISC score <math>\geq 9</math></p> <p><b>Excluded population/s:</b></p>	<p><b>Method of allocation:</b> <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> APHRODITE study</li> <li><input type="checkbox"/> As control, with addition of participation in group-based programme</li> <li><input type="checkbox"/> <math>\leq 10</math> participants per group</li> <li><input type="checkbox"/> One day a week (five hours per day) for six weeks, with additional gathering after 12-weeks</li> <li><input type="checkbox"/> Additional 30-minute consultation after last group meeting</li> <li><input type="checkbox"/> Increasing knowledge and self-consciousness, how to avoid diabetes and CAD</li> <li><input type="checkbox"/> Factual information provision about nutrition, physical activity, habit change, action plans, risk</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs were imputed using correlation estimates from studies which reported full outcome data</p> <p><b>Follow up periods:</b> 18 months</p>	<p><b>Source of funding:</b> EUROCADET (Key determinants of the future incidence of cancer across Europe: impact of prevention), funded by the 6th Framework programme of the Commission of European Communities (EUROCADET: SP23-CT-2005-006528, Contract Number 006528).</p>

	<p>diagnosis of diabetes mellitus, presence of serious heart, lung, kidney or liver failure, serious psychiatric illness, substance abuse or unable to speak Norwegian language</p> <p><b>Setting:</b> Primary care</p>	<p>situations, coping strategies</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Physical training</li> <li><input type="checkbox"/> Delivered by interdisciplinary team – dietician, physiotherapist, ergonomist, nurse, physician</li> </ul> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Consultations with study physician at 6, 12 and 18 months using motivational interviewing</li> <li><input type="checkbox"/> Standard care from GP</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 213 Intervention n =109 Control =104</p> <p><b>At 18 months</b> Total n = 182 Intervention = 93 Control = 89</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Ockene et al <b>Year:</b> 2012 <b>Citation:</b> Ockene IS, Tellez TL, Rosal MC, Reed GW, Mordes J, Merriam PA, Olendzki BC, Handelman G, Nicolosi R, Ma Y. 2012. Outcomes of a Latino community-based intervention for the prevention of diabetes: the lawrences latino diabetes prevention project. Am J Public Health, 102, 336-342. <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> USA; <i>Across whole study:</i> mean age 52 years old, male 26%, ethnicity 60% Dominican 40% Puerto Rican</p> <p><i>For each arm (mean, SD):</i> baseline weight (lb): intervention 190.2 (31.9) control 191.2 (36.3) baseline BMI (kg/m<sup>2</sup>): intervention 33.6 (5.1) control 34.2 (5.9)</p> <p><b>Eligible population:</b> GLFHC patient panel and additional outreach methods (public service announcements on local radio and television stations, newspaper</p>	<p><b>Method of allocation:</b> <b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Lawrence Latino DPP</li> <li><input type="checkbox"/> 3 individual and 13 group sessions over 12m</li> <li><input type="checkbox"/> Duration of first group session 1.5 hours, remaining group sessions were 1 hour</li> <li><input type="checkbox"/> Duration of first individual visit was 1 hour, last 2 were 30 mins each</li> <li><input type="checkbox"/> Additional individual sessions scheduled when patients missed group sessions</li> <li><input type="checkbox"/> Dietary goals – increasing intake of whole grains and non-starchy vegetables, reducing sodium, total and saturated fat, portion sizes, and intake of refined</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> Weight in lbs change to kgs HbA1c in mmol/mol converted to % Fasting glucose in mg/dl converted to mmol/l SDs calculated from CIs</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b> National Institute of Diabetes and Digestive and Kidney Diseases, NIDDK, National Heart, Lung and Blood Institute</p>

	<p>advertisements, mailings to non-GLFHC physicians)</p> <p><b>Selected population:</b> Self-reported Latino/Hispanic ethnicity, age <math>\geq 25</math> years, BMI <math>\geq 24</math>, 30% or greater likelihood of being diagnosed with diabetes over the succeeding 7.5 years</p> <p><b>Excluded population/s:</b> Inability to walk 5 city blocks, life-limiting medical conditions, taking medication or having medical condition that interfered with assessment of diabetes risk</p> <p><b>Setting:</b> Community, family health centre</p>	<p>carbohydrates and starches</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Physical activity goals – increase walking by 4000 steps/day over baseline, pedometer given to monitor</li> <li><input type="checkbox"/> Goal-setting and self-monitoring worksheets</li> <li><input type="checkbox"/> Activities such as demonstration of healthy cooking methods and portion sizes with real foods, and practice walking with pedometers during sessions</li> <li><input type="checkbox"/> Tailored to population by being culturally and literacy-sensitive</li> </ul> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Usual care</li> </ul> <p><b>Sample sizes (baseline):</b> Total n = 312 Intervention = 162 Control = 150</p> <p><b>At 12 months</b> Total n = 294 Intervention = 151 Control = 143</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Parikh et al <b>Year:</b> 2010 <b>Citation:</b> Parikh P, Simon EP, Fei K, Looker H, Goytia C, Horowitz CR. 2010. Results of a pilot diabetes prevention intervention in East Harlem, New York City: project HEED. Am J Public Health, 100, s232-s239. <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> USA; <i>Across whole study:</i> mean age 48 years old, male 15%, ethnicity 89% Hispanic 9% African-American</p> <p><i>For each arm (mean, SD):</i> baseline weight (lb): intervention 174.0 (39.0) control 162.0 (27.0) baseline BMI (kg/m<sup>2</sup>): intervention 32.0 (4.0) control 31.0 (5.0)</p>	<p><b>Method of allocation:</b> Randomly assigned by blocked randomisation by recruitment site</p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Project HEED</li> <li><input type="checkbox"/> Brief verbal and written information about prediabetes and results of all their screening tests to take home to share with clinicians</li> <li><input type="checkbox"/> Followed self-efficacy theory – contained simple, actionable</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> Weight changed from lbs to kgs Fasting and 2-hour glucose converted from mg/dl to mmol/l</p> <p><b>Follow up periods:</b> 3,6, 12 months</p>	<p><b>Source of funding:</b> National Center on Minority Health and Health Disparities and the New York State Department of Health Diabetes Prevention and Control Program</p>

	<p><b>Eligible population:</b> East Harlem residents</p> <p><b>Selected population:</b> Aged <math>\geq 18</math> years, English or Spanish speaking, BMI <math>\geq 25</math>, able to participate in group session, prediabetes glucose levels</p> <p><b>Excluded population/s:</b> pregnancy, diabetes, glucose-altering medications, normal glucose levels, diabetes level glucose readings</p> <p><b>Setting:</b> Community, various venues</p>	<p>messages, easily taught by lay leaders, focussed on enhancing self-efficacy to make lifestyle changes</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Presented in workshop consisting of 8 1.5 hour sessions over 10 weeks</li> <li><input type="checkbox"/> Topics included diabetes prevention, finding and affording healthy foods, label reading, fun physical activity, planning a healthy plate, making traditional foods healthy, portion control</li> </ul> <p><b>Control description:</b> NR</p> <p><b>Sample sizes (baseline):</b> Total n = 99 Intervention = 50 Control = 49 <b>At 12 months</b> Total n = 72 Intervention = 35 Control = 37 <b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Payne et al <b>Year:</b> 2008 <b>Citation:</b> Payne WR, Walsh KJ, Harvey JT, Livy MF, McKenzie KJ, Donaldson A, Atkinson MG, Keogh JB, Moss RS, Dunstan DW, Hubbard WA. 2008. Effect of a low-resource-intensive lifestyle modification program incorporating gymnasium-based and home-based resistance training on type 2 diabetes risk in Australian adults. <i>Diabetes Care</i>, 31 (12) 2244-2250.</p>	<p><b>Source population/s:</b> Australia; <i>Across whole study:</i> mean age 53 years old, male 22%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): 96.2(21.1) baseline BMI (kg.m<sup>2</sup>): 35.0 (6.8)</p> <p><b>Eligible population:</b> Ballarat residents recruited through media campaign and promotional materials distributed in socioeconomically disadvantaged</p>	<p><b>Method of allocation:</b></p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> BDPPI method</li> <li><input type="checkbox"/> 52-week BDPPI used quasi-experimental two-group repeated-measures design</li> <li><input type="checkbox"/> Goals – weight loss <math>&gt;5\%</math>, <math>\geq 150</math> weighted mins and <math>\geq 5</math> sessions of at least moderate physical activity each week (in addition to resistance training programme), diet with fat content <math>&lt;30\%</math> and saturated fat content <math>&lt;10\%</math> of total energy intake</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs were calculated from CIs</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b> The Australian Government Department of Health and Aging, Canberra</p>

<p><b>Aim of study:</b> Diabetes prevention <b>Study design:</b> Before and after</p>	<p>localities. Primary health care professional encouraged to refer eligible participants.</p> <p><b>Selected population:</b> IGT or IFG, Aboriginal or Torres Strait Islanders aged <math>\geq 35</math> years, individuals from the Pacific Islands or Indian subcontinent or of Chinese origin aged <math>\geq 35</math> years who were either obese (BMI <math>\geq 30</math>) or hypertensive or both, individuals with clinical cardiovascular disease (myocardial infarction, angina, stroke), obese women with polycystic ovary syndrome, women with previous gestational diabetes mellitus, individuals aged <math>\geq 55</math> years, and individuals aged <math>\geq 45</math> years who had a first degree relative with type 2 diabetes</p> <p><b>Excluded population/s:</b> Medically unstable conditions, uncorrected visual or hearing impairment, unable to attend regularly</p> <p><b>Setting:</b> Outpatient facility</p>	<p><input type="checkbox"/> Weeks 1-6 – 6 1.5 hour group education sessions conducted in regional, clinical outpatient facility – used self-management principles to develop problem-solving, decision-making, self-monitoring, goal-setting, thought/emotion management skills, included physical activity and dietary components directed by dietician, psychologist and exercise therapist to groups of 15-20</p> <p><input type="checkbox"/> Weeks 7-18 – a 12 week resistance training programme – participants randomly assigned to either gymnasium-based (n=62) or home-based (n=60)</p> <p><input type="checkbox"/> Weeks 19-52 – maintenance programme where participants were encouraged to continue recommended regimen and attend 3 2hour group reinforcement sessions, sent newsletters containing self-management, healthy eating, and physical activity advice</p> <p><b>Sample sizes (baseline):</b> Total n = 122 <b>At 12 months</b> Total n = 98</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Penn et al <b>Year:</b> 2009 <b>Citation:</b> Penn L, White M, Oldrod J, Walker M, ALberti GMM, Mathers JC. 2009. Prevention of type 2 diabetes in adults with impaired glucose tolerance: the European diabetes prevention RCT in</p>	<p><b>Source population/s:</b> UK; <i>Across whole study:</i> mean age 57 years old, male 40%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): intervention 93.4 (16.0) control 90.6 (12.5) baseline BMI (kg.m2):</p>	<p><b>Method of allocation:</b> Randomly allocated</p> <p><b>Intervention (1) description:</b> <input type="checkbox"/> Behavioural interventions – regular individual advice from dietician and physiotherapist trained in motivational interviewing <input type="checkbox"/> £0 min session following</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs calculated from CIs</p> <p><b>Follow up periods:</b> 12 and 3.1 years mean</p>	<p><b>Source of funding:</b> Wellcome Trust</p>

<p>Newcastle upon Tyne, UK. BMC Public Health, 9, 342.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> RCT</p>	<p>intervention 34.1 (5.5)  control 33.5 (4.6)</p> <p><b>Eligible population:</b> Recruitment by referral from primary care physicians who identified eligible participants likely to be at risk of IGR from their primary care databases</p> <p><b>Selected population:</b> Aged <math>\geq 40</math> years, BMI <math>\geq 25</math>, established IGT defined as mean 2h plasma glucose value <math>\geq 7.8</math>mmol/l and <math>&lt; 11.1</math>mmol/l from 2 consecutive standard OGTTs</p> <p><b>Excluded population/s:</b> Previous diagnosis of diabetes, chronic illness that would make participation in moderate physical activity impossible, on special diet for medical reasons</p> <p><b>Setting:</b> Outpatient setting</p>	<p>randomisation, session 2 weeks later, then monthly for first 3 months and every 3 months thereafter up to 5 years</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Invited to group sessions – ‘cook and eat’ events</li> <li><input type="checkbox"/> Regular quarterly newsletter – healthy eating recipes, nutritional information, suggestions for local walks, exercise options</li> <li><input type="checkbox"/> Dietary intervention – advice and counselling to develop individual plan for behaviour change, with aim of achieving <math>&gt; 50\%</math> total dietary intake from carbohydrate, reduced total and saturated fat intake with <math>&lt; 30\%</math> total dietary from fat, increased fibre intake, weigh loss to achieve BMI <math>&lt; 25</math></li> <li><input type="checkbox"/> Physical activity intervention – encourage participation in physical activity equivalent to accumulating 30mins moderate aerobic physical activity/day.</li> <li><input type="checkbox"/> Analysis of 3 day food and activity diaries, collected quarterly, used to tailor individual advice and goals</li> <li><input type="checkbox"/> Information pack detailing facilities and opportunities for physical activity in Newcastle upon Tyne, a city card, and opportunity to meet with trainer at local leisure centre</li> <li><input type="checkbox"/> Offered standard health promotion advice</li> </ul> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Usual care by primary care physician</li> <li><input type="checkbox"/> Offered standard health promotion advice</li> </ul>		
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		<p><b>Sample sizes (baseline):</b> Total n = 102 Intervention = 51 Control = 51</p> <p><b>At 12 months</b> Total n = 83 Intervention = 39 Control = 41</p> <p><b>At 5 years</b> Total n = 42 Intervention = 21 Control = 21</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Penn et al <b>Year:</b> 2013 <b>Citation:</b> Penn L, Ryan V, White M. 2013. Feasibility, acceptability and outcomes at a 12-month follow-up of a novel community-based intervention to prevent type 2 diabetes in adults at high risk: mixed methods pilot study. <i>BMJ Open</i>, 3, e003585. <b>Aim of study:</b> Diabetes prevention <b>Study design:</b> Before and after</p>	<p><b>Source population/s:</b> UK; <i>Across whole study:</i> mean age 54 years old, male 31%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): 92.1 (19.8) baseline BMI (kg/m<sup>2</sup>): 33.4 (5.9)</p> <p><b>Eligible population:</b> Residents of local authority that ranks in the 10 most socioeconomically deprived in England</p> <p><b>Selected population:</b> Aged 45-65 years, living in central Middlesborough UK, elevated risk of type 2 diabetes</p> <p><b>Excluded population/s:</b> <b>Setting:</b> Community and leisure centres</p>	<p><b>Method of allocation:</b> Those with FINDRISC 11-20 allocated to intervention</p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 10-week programme of twice weekly 1.5 hour sessions to groups of 15-20 participants</li> <li><input type="checkbox"/> Each session comprised a supervised PA or, a cookery session, followed by a reflective discussion that covered PA, nutrition, weight management, strategies for behaviour change</li> <li><input type="checkbox"/> Monthly newsletters with information, advice and recipes available, mostly online</li> <li><input type="checkbox"/> Leisure-centre based and included trainer-led walks</li> <li><input type="checkbox"/> At end of 10-week programme - ongoing support with regular mobile phone text message and email reminders, 'drop-in' activity sessions and encouragement to join in local events up to assessment at 12 months.</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> Male and female data combined (Cochrane Handbook) SDs calculated from CIs</p> <p><b>Follow up periods:</b> 10 weeks, 6, 12 months</p>	<p><b>Source of funding:</b> Middlesborough Council, Middlesborough Primary Care Trust, Public Health North East, Sport England, Newcastle University, Institute of Health and Society</p>

Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Penn et al  <b>Year:</b> 2014  <b>Citation:</b> Penn L, Sniehotta F, White M. 2014. Cultural adaptation of the 'New life, New you' behavioural intervention for prevention of type 2 diabetes in Black and minority ethnic communities in Middlesborough: evaluation report June 2014.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after</p>	<p><b>Source population/s:</b> UK;  <i>Across whole study:</i> mean age 39 years old, male 0%, ethnicity 70% Pakistani 13% Black-African 8% other Asian 4% other</p> <p><i>For each arm (mean, SD):</i>  baseline weight (kg): 76.8 (15.0)  baseline BMI (kg/m<sup>2</sup>): 30.6 (5.4)</p> <p><b>Eligible population:</b> Recruitment held in local venues which were advertised and promoted via community workers</p> <p><b>Selected population:</b> Aged &gt;=25 years, ethnic minority heritage, no diagnosis of diabetes, living in Middlesborough local authority area, able to participate in group delivered physical activity, FINDRISC score &gt;=11, (HbA1c &gt;=48 advised to contact GP and only eligible if they returned signed letter from GP confirmed no diabetes diagnosis)</p> <p><b>Excluded population/s:</b> FINDRISC score &lt;11</p> <p><b>Setting:</b> Community and leisure centre</p>	<p><b>Sample sizes (baseline):</b>  Total n = 218  <b>At 12 months</b>  Total n = 134</p> <p><b>Method of allocation:</b></p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 8 week programme of group (15-20 participants) delivered physical activity sessions (1 hour) each followed by behavioural counselling and advice (30mins) to promote increased PA, healthy eating and weight loss with support to 12 months of follow up</li> <li><input type="checkbox"/> Delivered by one community interest company (CIC) founder member, who recruited other local Pakistani women to assist with delivery (trained to qualify as fitness trainers)</li> <li><input type="checkbox"/></li> <li><input type="checkbox"/></li> </ul> <p><b>Sample sizes (baseline):</b>  Total n = 188  <b>At 12 months</b>  Total n = 121</p>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b> SDs calculated from CIs</p> <p><b>Follow up periods:</b> 8 weeks, 6, 12 months</p>	<p><b>Source of funding:</b> Sport England, Middlesborough Council, Middlesborough Primary Care Trust, the North East Strategic Health Authority</p>
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Ruggiero et al</p>	<p><b>Source population/s:</b> USA;</p>	<p><b>Method of allocation:</b></p>	<p><b>Published data only</b></p>	<p><b>Source of funding:</b> The Making</p>

<p><b>Year:</b> 2011  <b>Citation:</b> Ruggiero L, Oros S, Choi YK. 2011. Community-based translation of the diabetes prevention program's lifestyle intervention in an underserved Latino population. <i>The Diabetes Educator</i>, 37 (4) 564-572.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after  <b>Quality score:</b>  <b>External validity score:</b></p>	<p><i>Across whole study:</i> mean age 38 years old, male 7%, ethnicity 100% Hispanic</p> <p><i>For each arm (mean, SD):</i>  baseline weight (lb): 172.2 (26.1)  baseline BMI (kg.m2): 31.2 (4.3)</p> <p><b>Eligible population:</b> Recruitment in 3 neighbourhoods with large Latino populations in south-west Chicago</p> <p><b>Selected population:</b> Aged 18-65 years, glucose levels in the normal to prediabetes range (as determined by the NKFI nurse practitioner using ADA criteria), no current diagnosis of diabetes, BMI &gt;24.9, not pregnant or planning to become pregnant during study period, self-identified as Latino, living in target community, no reported medical restrictions related to the programme dietary and physical activity goals</p> <p><b>Excluded population/s:</b> unknown diabetes</p> <p><b>Setting:</b> Community, various venues</p>	<p><b>Intervention (1)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The Healthy Living Program (HLP) – based on DPP's 1-year intensive lifestyle programme, and was tailored and enhanced for a Latino community</li> <li><input type="checkbox"/> Delivered by community health workers</li> <li><input type="checkbox"/> Core programme with weekly sessions that shifted to monthly sessions for the 'after core' programme</li> <li><input type="checkbox"/> Goals of 7% weight loss and increasing physical activity to 150mins per week of moderate activity</li> <li><input type="checkbox"/> Programme session materials</li> <li><input type="checkbox"/> Supplemental culturally appropriate educational materials (recipe book, National Diabetes Education Program materials), self-monitoring tools (weight chart), pedometer, body weight scale, measuring cups</li> <li><input type="checkbox"/> Delivered in small groups (n=9) by community resident or CHW who served as the Healthy Life Coach (HLC)</li> </ul> <p><b>Sample sizes (baseline):</b>  Total n = 69  <b>At 12 months</b>  Total n = 57</p>	<p><b>Outcome calculation method:</b>  Weight changed from lbs to kgs</p> <p><b>Follow up periods:</b> 6, 12 months</p>	<p>the Connection (MTC) initiative was a part of the Illinois Prevention Research Center supported by Cooperative Agreement No. 1-U48-DP-000048 from the US Centers for Disease Control and Prevention (CDC), including support from the Division of Diabetes Translation.</p>
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Saaristo et al  <b>Year:</b> 2010 (Rautio et al 2011, 2012)  <b>Citation:</b> Saaristo T, Moilanen L, Korpi-Hyovalti E, Vanhala M, Saltevo J, Niskanen L, Jokelainen J,</p>	<p><b>Source population/s:</b> Finland;  <i>Across whole study:</i> mean age 54 years old, male 49%, ethnicity NR</p> <p><i>For each arm (mean, SD):</i>  baseline weight (kg):  baseline BMI (kg/m2):</p>	<p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> FIN-D2D</li> <li><input type="checkbox"/> Either individual counselling visits or group sessions</li> <li><input type="checkbox"/> Focus was on weight, meal frequency, fat intake, quality of fat, use of salt, fibre intake, use of</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>  NA</p> <p><b>Follow up periods:</b> 12 months</p>	<p><b>Source of funding:</b>  Financing from the hospital districts of Pirkanmaa, Southern Ostrobothnia, Northern Ostrobothnia, Central Finland, and Northern Savo, the Finnish National Public Health Institute,</p>

<p>Peltonen M, Oksa H, Tuomilehto J, Uusitupa M, Keinanen-Kiokaanniemi S. 2010. Lifestyle intervention for prevention of type 2 diabetes in primary health care: one-year follow up of the Finnish National Diabetes Prevention Program (FIN-D2D). <i>Diabetes Care</i>, 33, 2146-2151.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> Before and after</p>	<p>~31  <b>Eligible population:</b> Recruited from 400 participating primary health care outpatients clinics using FINDRISC  <b>Selected population:</b> FINDRISC <math>\geq 15</math>, history of IFG or IGT, an ischemic cardiovascular disease event, or gestational diabetes  <b>Excluded population/s:</b>  <b>Setting:</b> Primary care</p>	<p>alcohol, exercise, or smoking  <input type="checkbox"/> Group sessions varied from weight maintenance groups to exercise groups and lectures on diabetes and lifestyle changes  <input type="checkbox"/> Frequency of intervention visits varied among health centres, depending on local circumstances and resources  <b>Sample sizes (baseline):</b>  Total n = 2798  <b>At 12 months</b>  Total n = NR</p>		<p>the Finnish Diabetes Association, the Ministry of Social Affairs and Health in Finland, Finland's Slottery Machine Association, the Commission of the European Communities</p>
Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Sakane et al  <b>Year:</b> 2011  <b>Citation:</b>  Sakane N, Sato J, Tsushita K, Tsujii S, Kotani K, Tsuzaki K, Tominaga M, Kawazu S, Sato Y, Usui T, Kamae I, Yoshida T, Kiyohara Y, Sato S, Kuzuya H. 2011. Prevention of type 2 diabetes in a primary healthcare setting: three-year results of lifestyle intervention in Japanese subjects with impaired glucose tolerance. <i>BMC Public Health</i>, 11, 40.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> Japan;  <i>Across whole study:</i> mean age 51 years old, male 51%, ethnicity NR    <i>For each arm (mean, SD):</i>  baseline weight (kg):  intervention 64.9 (12.9)  control 63.9 (11.7)  baseline BMI (kg/m<sup>2</sup>):  intervention 24.8 (3.6)  control 24.5 (3.2)    <b>Eligible population:</b> Recruited through health check-ups conducted at each collaborative centre    <b>Selected population:</b> aged 30-60 years, one of the following - FPG <math>\geq 5.6</math>mmol/l but <math>&lt; 7.0</math>mmol/l, cCPG <math>\geq 7.8</math>mmol/l but <math>&lt; 11.1</math>mmol/l when blood drawn within 2h after meal, or CPG <math>\geq 6.1</math> mmol/l but <math>&lt; 7.8</math>mmol/l when blood drawn 2h or more after meal, or IGT as indicated by</p>	<p><b>Method of allocation:</b> Randomly assigned    <b>Intervention (1) description:</b>  <input type="checkbox"/> Goals – reduce initial body weight by 5% in overweight/obese subjects, increase energy expenditure due to leisure time physical activity by 700kcal/week  <input type="checkbox"/> Delivered by study nurse to group and individual sessions using guideline, curriculum, and educational materials provided by committee of study group  <input type="checkbox"/> 27-page booklet titled “Change Your Lifestyle to Prevent Diabetes” provided  <input type="checkbox"/> 1-6 months – 4 2-3 hour group sessions using slides, videotapes, booklet  <input type="checkbox"/> Individual session conducted biannually during 3 years – each lasting 20-40mins, where personalised goals were set  <input type="checkbox"/> After first year, telephone</p>	<p><b>Published data only</b>    <b>Outcome calculation method:</b>  SDs were imputed using correlation estimations from studies which reported full outcome data where necessary    <b>Follow up periods:</b> 12, 36 months</p>	<p><b>Source of funding:</b>  The Ministry of Health, Welfare, and Labour of Japan    <b>Other notes:</b></p>

	<p>previous 75g OGTT.</p> <p><b>Excluded population/s:</b> Previous diagnosis of diabetes other than gestational diabetes, history of gastrectomy, physical conditions such as ischemic heart disease, heart failure, exercise-induced asthma, and orthopaedic problems where exercise was not allowed by doctor, definitive liver and kidney diseases, autoimmune diseases, habit of drinking heavily (&gt;=69g of ethanol/day), already taking part in lifestyle modifications</p> <p><b>Setting:</b> Various primary care, workplace, collaborative centre</p>	<p>contact could replace face to face sessions</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Assessment of dietary intake conducted using semi quantitative food frequency questionnaire (FFQ) – advised to take proper amount of calories, decrease mean percent of energy derived from dietary fat to less than 25%, restrict daily alcohol consumption to less than 160kcal, eat 3 meals/day, avoid eating late at night</li> <li><input type="checkbox"/> Aerobic exercise recommended</li> <li><input type="checkbox"/> Between visit contact by fax made monthly during initial 12m</li> </ul> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Only 1 group session on healthy lifestyle and prevention of diabetes at baseline</li> <li><input type="checkbox"/> No individual guidance</li> </ul> <p><b>Sample sizes (baseline):</b>                  Total n = 296                  Intervention = 146                  Control = 150  <b>At 12 months</b>                  Total n = NR                  Intervention = NR                  Control = NR  <b>At 36 months</b>                  Total n = 213                  Intervention = 103                  Control = 110  <b>Baseline comparisons:</b> Groups similar at study outset</p>		
<b>Study details</b>	<b>Population and setting</b>	<b>Method of allocation to intervention/control</b>	<b>Outcomes and method of analysis</b>	<b>Notes</b>
<p><b>Authors:</b> Vermunt et al  <b>Year:</b> 2012 (&amp;2011)  <b>Citation:</b>                  Vermunt PWA, Milder IEJ,</p>	<p><b>Source population/s:</b>                  Netherlands;  <i>Across whole study:</i> mean age NR, male % NR, ethnicity NR</p>	<p><b>Method of allocation:</b></p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Goals – weight reduction 5%,</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>                  NA</p>	<p><b>Source of funding:</b>                  ZonMw ‘the Netherlands Organisation for Health Research and development’</p>

<p>Wielgaard F, de Vries JHM, Baan CA, van Oers JAM, Westert GP. 2012. A lifestyle intervention to reduce type 2 diabetes risk in Dutch primary care: 2.5-year results of a randomised controlled trials. <i>Diabetic Medicine</i>, 29, e223-e231.</p> <p><b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> RCT</p>	<p><i>For each arm</i> (mean, SD):  baseline weight (kg):  intervention 84.3 (15.9)  control 82.1 (14.5)  baseline BMI (kg/m<sup>2</sup>):  intervention 29.0 (4.4)  control 28.5 (4.2)</p> <p><b>Eligible population:</b> Recruited by 48 general practitioners from 14 general practices in Eindhoven and surroundings</p> <p><b>Selected population:</b> Aged &gt;=40 and &lt;=70 years, FINDRISC &gt;=13</p> <p><b>Excluded population/s:</b> NR</p> <p><b>Setting:</b> Primary care</p>	<p>physical exercise of moderate to high intensity for at least 30mins/day for at least 5 days/week, dietary fat intake less than 30%, saturated fat intake less than 10% of total energy intake, dietary fibre of at least 3.4g/MJ</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Behavioural techniques to influence participant motivation, action, and maintenance</li> <li><input type="checkbox"/> 11 consultations of 20min scheduled over 2.5 years alternately with the nurse practitioner and general practitioner</li> <li><input type="checkbox"/> 5 group meetings organised by dietitians and physiotherapists to provide more detailed information on diet and exercise</li> <li><input type="checkbox"/> Invited for 1 hour consultation with dietician, in which a 3 day food record was discussed</li> </ul> <p><b>Control description:</b> (2)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Oral and written information about type 2 diabetes and a healthy lifestyle</li> <li><input type="checkbox"/> Nurse practitioner visited only for measurements</li> </ul> <p><b>Sample sizes (baseline):</b>  Total n = 925  Intervention = 479  Control = 446</p> <p><b>At 12 months</b>  Total n = NR  Intervention = NR  Control = NR</p> <p><b>At 2.5 years</b>  Total n = 709  Intervention = 368  Control = 341</p>	<p><b>Follow up periods:</b> 6, 18, 30 months</p>	
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Study details	Population and setting	Method of allocation to intervention/control	Outcomes and method of analysis	Notes
<p><b>Authors:</b> Yates et al  <b>Year:</b> 2009 (&amp;2011)  <b>Citation:</b>                      Yates T, Davies M, Gorely T, Bull F, Khunti K. 2009. Effectiveness of a pragmatic education program designed to promote walking activity in individuals with impaired glucose tolerance. <i>Diabetes Care</i>, 32, 1404-1410.  <b>Aim of study:</b> Diabetes prevention  <b>Study design:</b> RCT</p>	<p><b>Source population/s:</b> UK;  <i>Across whole study:</i> mean age 65 years old, male 66%, ethnicity 75% White 24% South Asian 1% Black (given for completers)</p> <p><i>For each arm (mean, SD):</i>                      baseline weight (kg):                      PREPARE 81.9 (14.2)                      PREPARE + pedometer 79.4 (16.4)                      Control 81.1 (15.0)                      baseline BMI (kg/m<sup>2</sup>):                      PREPARE 29.5 (4.9)                      PREPARE + pedometer 28.7 (4.8)                      Control 29.8 (4.4)</p> <p><b>Eligible population:</b> Recruited from ongoing population-based diabetes screening programmes in Leicester, contacted by lotter and follow up telephone call by member of screening team</p> <p><b>Selected population:</b> BMI <math>\geq 25</math> or <math>\geq 23</math> for South Asians with screening detected IGT</p> <p><b>Excluded population/s:</b> Diabetes</p> <p><b>Setting:</b> Outpatient setting</p>	<p><b>Baseline comparisons:</b> Groups similar at study outset</p> <p><b>Method of allocation:</b> Randomly assigned using block design</p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> PREPARE</li> <li><input type="checkbox"/> Single-session group-based education programme</li> <li><input type="checkbox"/> 180 min long, 105 min dedicated to addressing the causes, complications, timeline, and identity of IGT and 75 min targeted to addressing perceived effectiveness of exercise as a treatment for IGT, walking self-efficacy beliefs, barriers to walking, self-regulatory strategies</li> <li><input type="checkbox"/> Written curriculum modelled on person-centred philosophy and learning techniques developed for DESMOND programme</li> <li><input type="checkbox"/> Encouraged to set time-based goals designed to match advice given to pedometer group – sedentary individuals to reach at least 30 min moderate-intensity physical activity/day, those already achieving 30min/day to at least maintain current activity levels</li> <li><input type="checkbox"/> Encouraged to set proximal goals, form action plans, record daily activity levels</li> </ul> <p><b>Intervention (2) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> PREPARE + pedometer</li> <li><input type="checkbox"/> As above but with use of pedometer</li> <li><input type="checkbox"/> Encouraged to set personalised steps-per-day goals based on</li> </ul>	<p><b>Published data only</b></p> <p><b>Outcome calculation method:</b>                      SDs calculated from CIs</p> <p><b>Follow up periods:</b> 12, 24 months</p>	<p><b>Source of funding:</b>                      Diabetes UK</p>

		<p>baseline ambulatory activity level</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Sedentary participants to increase levels by at least 3,00 steps/day (30min walking), those achieving &gt;6,000 steps/day to reach at least 9,000 steps/day, those achieving &gt;9,000 steps/day to maintain activity levels</li> <li><input type="checkbox"/> Participants enabled to set action plan detailing where, when, and how their first proximal goal would be reached and encouraged to repeat this process for each new proximal goal</li> <li><input type="checkbox"/> Encouraged to wear pedometer on daily basis and use activity log</li> </ul> <p><b>Control description: (2)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Brief information sheet in the mail, detailing the likely causes, consequences, symptoms, and timeline associated with IGT, along with information about how physical activity can be used to treat/control the condition</li> </ul> <p><b>Sample sizes (baseline):</b>                  Total n = 98                  PREPARE = 31                  PREPARE + pedometer = 33                  Control = 34</p> <p><b>At 12 months</b>                  Total n = 84                  PREPARE = 28                  PREPARE + pedometer = 30                  Control = 26</p> <p><b>Baseline comparisons:</b> Groups similar at study outset</p>		
<b>Study details</b>	<b>Population and setting</b>	<b>Method of allocation to intervention/control</b>	<b>Outcomes and method of analysis</b>	<b>Notes</b>
<b>Authors:</b> Yates et al <b>Year:</b> 2012 (protocol) 2015	<b>Source population/s:</b> UK; <i>Across whole study:</i> mean age 63	<b>Method of allocation:</b> Randomisation conducted at level	<b>Published data only</b>	<b>Source of funding:</b> National Institute for Health Research

<p><b>Citation:</b> Yates T, Davies MJ, Henson J, Troughton J, Edwardson C, Gray LJ, Khunti K. 2012. Walking away from type 2 diabetes: trial protocol of a cluster randomised controlled trial evaluating a structured education programme in those at high risk of developing type 2 diabetes. BMC Family Practice, 13, 46.</p> <p><b>Aim of study:</b> Diabetes prevention</p> <p><b>Study design:</b> RCT</p>	<p>years old, male 64%, ethnicity 89% White-European 11% other ethnic minority groups</p> <p><i>For each arm (mean, SD):</i> baseline weight (kg): baseline BMI (kg/m<sup>2</sup>): 32.4'</p> <p><b>Eligible population:</b> Recruitment from 10 GP practices from the Leicestershire region through letter of invitation</p> <p><b>Selected population:</b> High risk individuals using MIQUEST programme</p> <p><b>Excluded population/s:</b> Existing diagnosis of type 2 diabetes or diagnosed at baseline, taking steroids, unable to speak English</p> <p><b>Setting:</b> Hospital, primary care, community settings</p>	<p>of GP practice by a trained individual who is independent of study team using a blocked design</p> <p><b>Intervention (1) description:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Walking Away</li> <li><input type="checkbox"/> Group-based structured educational programme based on the content and behaviour change techniques of the PREPARE programme</li> <li><input type="checkbox"/> Delivered by trained educators over 3 hours</li> <li><input type="checkbox"/> Designed to promote walking activity by targeting perceptions and knowledge of IGT and physical activity self-efficacy as well as promoting self-regulatory skills such as goal-setting strategies, self-monitoring, and relapse prevention</li> <li><input type="checkbox"/> Self-regulation designed around pedometer use</li> <li><input type="checkbox"/> Sedentary participants to increase levels by at least 3,00 steps/day (30min walking), those achieving &gt;6,000 steps/day to reach at least 9,000 steps/day, those achieving &gt;9,000 steps/day to maintain activity levels</li> <li><input type="checkbox"/> Encouraged to set proximal goals, form action plans, record daily activity levels</li> </ul> <p><b>Control description: (2)</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Booklet detailing information on risk factors for type 2 diabetes and how physical activity and lifestyle change can be used to prevent or delay the disease</li> </ul>	<p><b>Outcome calculation method:</b> Directly from dataset, adjusted for clustering</p> <p><b>Follow up periods:</b> 12, 24, 36 months</p>	<p>Collaboration in Applied Health Research and Care for Leicestershire, Northamptonshire and Rutland</p>
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		<p><b>Sample sizes (baseline):</b> Total n = 808 Intervention = 422 Control = 384 <b>At 12 months</b> Total n = 700 Intervention = 357 Control = 343 <b>At 24 months</b> Total n = 665 Intervention = 337 Control = 328 <b>At 36 months</b> Total n = 550 Intervention = 260 Control = 290 <b>Baseline comparisons:</b> Groups similar at study outset</p>		
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## Appendix 4: Study quality

	Checklist criteria	Absetz 2009	Ackerman 2008	Almeida 2010	Bhopal 2014	Boltri 2008	Costa 2012	Davies 2015	Davis-Smith 2007	Deakin 2015	Faridi 2010	Gilis-Januszewska 2011	Janus 2012	Kanaya 2012	Katula 2011	Kramer 2009	Kramer 2012	Kramer 2014	Kulzer 2009	Laatikainen 2012	Ma 2013	Makrilakis 2010	Mensink 2003	Niilsen 2011	Ockene 2012	Parikh 2010	Payne 2008	Penn 2009	Penn 2013	Penn 2014	Ruggerio 2011	Saariisto 2010	Sakane 2011	Vermunt 2011	Yates 2009	Yates 2015	Redacted			
1.1	Source population or area well described	+	++	+	+	++	+	+	++	+	++	++	+	++	+	++	++	++	+	+	++	++	+	++	++	++	++	+	+	+	++	++	+	+	+	+	+	+	+	
1.2	Eligible population or area representative	++	++	+	++	+	++	++	+	R N	+	+	++	++	++	+	+	+	+	+	+	+	++	+	++	++	++	++	+	+	+	++	++	+	++	++	+	+	+	
1.3	Selected participants or areas representative	++	++	++	+	+	++	+	++	R N	+	+	++	+	++	+	+	+	+	++	+	+	++	+	+	++	+	++	++	+	+	+	+	++	++	+	+	+	+	+
2.1	Allocation: selection bias minimised	NA	+	NR	++	NA	+	+	NA	NA	+	NA	++	++	++	NA	+	NA	++	NA	+	NA	++	++	++	++	N	++	NA	NA	NA	NA	NA	+	+	++	++	++	++	



A systematic review and meta-analysis assessing the effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes mellitus in routine practice

2.8	All participants accounted for at study conclusion	++	+	++	++	++	+	+	++	N R	+	++	+	++	++	+	++	+	+	+	++	+	++	++	+	++	+	+	+	++	N A	++	++	++	+	+		
2.9	Setting reflects usual UK practice	++	++	+	+	++	++	++	++	++	++	++	++	++	++	++	+	+	++	++	++	+	+	++	++	+	+	++	++	++	++	++	++	++	++	+	+	
2.10	Intervention or control reflects usual UK practice	++	++	++	+	++	++	++	++	++	++	++	+	+	++	++	+	++	+	++	+	++	++	++	+	+	+	+	++	++	++	++	++	++	++	++	+	
3.1	Outcome measures reliable	++	+	+	++	+	++	+	+	++	++	++	++	++	++	++	++	++	++	++	+	++	++	++	++	+	++	++	++	++	++	++	++	++	++	++	++	
3.2	Outcome measures complete	++	++	++	++	++	++	++	++	+	+	++	+	+	++	++	++	++	++	++	++	+	++	++	++	+	++	++	++	++	++	++	++	++	++	++	++	
3.3	All important outcomes assessed	++	++	+	++	++	+	++	++	++	+	++	++	+	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	
3.4	Outcomes relevant	++	++	NA	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	
3.5	Similar follow-up times in groups	N A	++	++	++	NA	++	++	NA	N A	++	NA	++	++	++	NA	++	N A	++	NA	++	NA	++	++	++	++	++	N A	++	N A	N A	N A	N A	++	++	++	++	++



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5.1	Study results internally valid (i.e. unbiased)	++	++	+	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++
5.2	Findings generalizable to source population (i.e. externally valid)	++	++	+	+	+	++	+	++	+	+	+	++	++	++	+	+	+	+	+	+	+	++	+	++	++	++	++	+	+	+	++	+	+	++	+	++	+	+	+

## Appendix 5: Coding of intervention content

1. Aim to promote changes in both diet and physical activity.	Yes /No (1,0)
2. Use established, well defined behaviour change techniques (e.g. Specific goal-setting, relapse prevention, self-monitoring, motivational interviewing, prompting self-talk, prompting practice, individual tailoring, time management).	Yes /No (1,0). Yes is scored if, as well as basic information provision, it includes $\geq 3$ techniques from Table 14 in the IMAGE guideline (which provides definitions used by NICE and other reviewers), or from a recognised taxonomy of behaviour change techniques [Michie 2011].
3. Work with participants to engage social support for the planned behaviour change (i.e. engage important others such as family, friends, and colleagues).	Yes /No (1,0). Yes is scored if participants are encouraged to identify and seek social support <i>outside</i> the group (i.e. in their day to day lives). Encouraging social support within the group in a group based intervention is not sufficient to code Yes.
4. Maximize the frequency or number of contacts with participants (within the resources available).	High /Medium /Low (2,1,0), based on median split of <i>total number of contacts</i>  Structured PA (e.g. gym-based exercise) sessions that were offered have not been counted, as they are assumed not to involve a substantial interactive component. Written contacts (newsletters etc) were not counted.
5. Use a coherent set of 'self-regulatory' intervention techniques (Specific goal setting (ideally with coping planning aka 'relapse prevention'); Prompting self-monitoring; Providing feedback on performance; problem-solving; Review of behavioural goals).	Yes /No (1,0). Yes is scored if the intervention includes goal setting, self-monitoring (of outcomes or behaviours) and at least one other self-regulation technique (providing feedback on performance, problem-solving (relapse prevention), revising action plans in the light of performance)
6. Use a group size of 10-15. This recommendation is designed to balance cost and effectiveness, rather than to be an exact specified range, so we coded for "a group size of no more than 15" (the point at which effectiveness is expected to be diminished).	Yes /No (1,0). If a range was reported for group size (e.g. groups of 15-20), the mid-point of the range was used for coding purposes.  If individual (one-to-one) intervention was used, then a Yes is coded (1 case).
7. Provide at least 16 hours of contact time over the first 18 months	Yes /No (1,0). Contact time is assumed to be 1 hour per group session if session-length is not stated (1 case) or 10 mins for a telephone contact (2 cases), 30 mins for an individual counselling session (1 case) and 15 mins for a GP visit (1 case).
8. Ensure programmes adopt a person-centred, empathy-building approach	Yes /No (1,0). Coded as Yes if it is explicitly stated that a person-centred, empathy-building or empowerment theory based approach was used throughout, or if motivational interviewing or other empathy-building techniques are specified
9. Allow time between sessions, spreading them over a period of 9-18 months	Yes /No (1,0)
10. Information provision: to raise awareness of the benefits of and types of lifestyle changes needed	Yes /No (1,0)
11. Exploration and reinforcement of participants' reasons for wanting to change and their confidence about making changes.	Yes /No (1,0)
12. Gradual building of confidence (self-efficacy) by starting with achievable and sustainable short-term goals and setting of graded tasks	Yes /No (1,0)
13. Use a logical sequence of intervention methods (e.g. Motivation, action-planning, maintenance)	Yes /No (1,0)
<b>Total IMAGE guidance score</b>	Possible maximum score of 6 points: 1 point for each Yes for items 1,2,3 and 5. For item 4, score 2 points for a High amount of contact, 1 point for a medium amount..
<b>Total NICE guidance score</b>	Possible maximum score of 12 points: IMAGE score (as above but without item 4, which overlaps with

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	item 7) plus 1 point for each Yes for items 6 to 13
14. Intervention fidelity checking	We also coded whether the developers used specific methods to check intervention fidelity (e.g. monitoring the first 4 sessions and giving formative feedback).

## Appendix 6: Coding scores for study interventions

	Absetz 2009	Ackerman	Almeida 2010	Bhopal 2014	Botri 2008	Costa 2012	Davies 2015	Davis-Smith	Deakin 2015	Faridi 2010	Gliss-	Janus 2012	Kanaya 2012	Katula 2011	Kramer 2009	Kramer 2012	Kramer 2012	Kramer 2014	Kulzer 2009	Laatikainen	Ma 2013	Ma 2013	Makriliakis	Mensink	Nilsen 2011	Ockene 2012	Parikh 2010	Payne 2008	Penn 2009	Penn 2013	Penn 2014	Ruggerio	Saaristo 2010	Sakane 2011	Vermunt	Yates 2009	Yates 2009	Yates 2015	Redacted	
1. Diet & physical activity	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	
2. Established techniques	1	1	1	x	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	x	x	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
3. Engage social support	0	1	0	1	1	1	0	x	x	1	1	0	0	1	1	1	1	x	1	0	0	0	x	x	0	x	0	0	0	0	1	1	1	0	x	0	0	0	0	x
4. Maximised the frequency or number of contacts	0	2	0	0	2	1	0	0	1	x	2	0	2	2	1	2	2	2	1	0	0	1	0	0	1	2	1	2	1	0	0	2	1	0	x	0	0	0	2	
No of contacts in 1yr (total no if different)	6	23	1	7	16	10	6	6	8	x	16	6	19	41	12	21	21	21	12	6	1	12	6	5	11	16	8	13	8	3	8	22	8	6	x	3	3	2	53	
				(15)			(16)						(65)										(13)	(12)			(24)					(10)	(17)			(6)				
No of physical activity sessions in 1yr	0	0	0	0	0	0	0	0	0	0	78	0	0	0	0	0	0	0	0	0	0	0	52	x	0	0	24	1	17	8	0	0	0	0	0	0	0	0	0	
5. Self-regulatory intervention techniques	1	1	0	x	1	1	1	x	1	0	1	1	1	1	1	1	1	1	1	1	1	1	x	x	x	1	1	1	1	1	1	1	0	1	1	1	1	1	1	
6. Group size ≤15	1	1	0	1	1	1	1	1	0	x	1	x	x	1	1	1	1	1	1	1	1	1	1	1	1	x	1	0	1	0	0	1	1	x	1	1	1	1	x	
7. Contact time ≥16 hours	0	1	0	0	1	0	0	0	1	x	0	0	0	1	0	1	1	1	1	0	0	1	0	0	1	0	0	1	0	1	0	1	0	0	0	0	0	0	0	1
8. Person centred, empathy building approach	1	0	0	x	0	1	1	x	1	0	1	0	1	0	0	0	0	0	1	1	x	1	x	x	1	1	1	1	1	0	0	0	0	1	x	1	1	1	1	x
9. Sessions spread	0	1	0	1	0	1	0	0	1	x	1	0	1	1	0	1	1	1	0	1	1	1	1	1	1	x	0	1	1	0	0	1	0	0	1	0	0	0	0	1
10. Information provision	1	1	1	1	1	1	1	x	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
11. Exploration & reinforcement of motivation	1	1	1	x	1	1	0	x	x	0	1	x	0	1	1	1	1	1	1	1	1	1	x	x	1	1	0	1	1	0	0	x	1	x	1	0	0	1	1	
12. Building of confidence (self-efficacy)	1	1	0	x	1	0	1	x	1	0	1	x	1	1	1	1	1	1	0	1	x	1	x	x	x	1	0	1	1	1	1	x	1	x	X	1	1	1	1	
13. Logical sequence of intervention methods	1	1	0	x	1	1	1	x	1	0	1	0	1	1	1	1	1	1	1	1	1	1	x	x	1	x	1	1	1	1	1	1	1	0	0	1	1	1	1	
Total NICE score	9	11	4	5	10	10	8	3	9	4	11	4	8	11	9	11	11	10	11	9	8	11	4	4	9	7	7	10	10	8	7	9	7	5	8	7	7	8	9	

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<b>NICE score without imputation</b>	9	11	4	x	10	10	8	x	x	x	11	x	x	11	9	11	11	10	11	9	x	11	x	x	3	x	7	10	10	8	7	x	7	x	x	7	7	8	x	
<b>Total IMAGE score</b>	3	6	2	2	6	5	3	2	4	3	6	3	5	6	5	6	6	5	5	3	3	4	1	1	x	5	4	5	4	4	4	4	6	3	3	3	2	2	2	5
<b>IMAGE score without imputation</b>	3	6	2	x	6	5	3	x	x	x	6	3	5	6	5	6	6	x	5	3	3	4	x	x	x	x	4	5	4	4	4	6	3	x	x	2	2	2	x	
<b>14. Intervention fidelity checking</b>	0	1	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0	1	1	1	0	0	0	1	1	1	0	