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Behavioural Interventions for Type 2 Diabetes

An Evidence-Based Analysis

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About the Medical Advisory Secretariat

The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

The Medical Advisory Secretariat conducts systematic reviews of scientific evidence and consultations with experts in the health care services community to produce the *Ontario Health Technology Assessment Series*.

About the Ontario Health Technology Assessment Series

To conduct its comprehensive analyses, the Medical Advisory Secretariat systematically reviews available scientific literature, collaborates with partners across relevant government branches, and consults with clinical and other external experts and manufacturers, and solicits any necessary advice to gather information. The Medical Advisory Secretariat makes every effort to ensure that all relevant research, nationally and internationally, is included in the systematic literature reviews conducted.

The information gathered is the foundation of the evidence to determine if a technology is effective and safe for use in a particular clinical population or setting. Information is collected to understand how a new technology fits within current practice and treatment alternatives. Details of the technology's diffusion into current practice and input from practising medical experts and industry add important information to the review of the provision and delivery of the health technology in Ontario. Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to optimize patient outcomes.

If you are aware of any current additional evidence to inform an existing evidence-based analysis, please contact the Medical Advisory Secretariat: MASinfo.moh@ontario.ca. The public consultation process is also available to individuals wishing to comment on an analysis prior to publication. For more information, please visit http://www.health.gov.on.ca/english/providers/program/ohtac/public_engage_overview.html.

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Abbreviations

BMI	Body mass index
HbA1c	Glycosylated hemoglobin
ITT	Intention to treat analysis
MAS	Medical Advisory Secretariat
ODEM	Ontario diabetes economic model
QI	Quality improvement
RCT	Randomized controlled trial
RD	Registered dietician
RE-AIM	Reach, efficacy, adoption, implementation, maintenance
RN	Registered nurse
SD	Standard deviation
UKPDS	United Kingdom prospective diabetes study

Executive Summary

In June 2008, the Medical Advisory Secretariat began work on the Diabetes Strategy Evidence Project, an evidence-based review of the literature surrounding strategies for successful management and treatment of diabetes. This project came about when the Health System Strategy Division at the Ministry of Health and Long-Term Care subsequently asked the secretariat to provide an evidentiary platform for the Ministry's newly released Diabetes Strategy.

After an initial review of the strategy and consultation with experts, the secretariat identified five key areas in which evidence was needed. Evidence-based analyses have been prepared for each of these five areas: insulin pumps, behavioural interventions, bariatric surgery, home telemonitoring, and community based care. For each area, an economic analysis was completed where appropriate and is described in a separate report.

To review these titles within the Diabetes Strategy Evidence series, please visit the Medical Advisory Secretariat Web site, http://www.health.gov.on.ca/english/providers/program/mas/mas_about.html,

1. Diabetes Strategy Evidence Platform: Summary of Evidence-Based Analyses
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6. Home Telemonitoring for Type 2 Diabetes: An Evidence-Based Analysis
7. Application of the Ontario Diabetes Economic Model (ODEM) to Determine the Cost-effectiveness and Budget Impact of Selected Type 2 Diabetes Interventions in Ontario

Objective

The objective of this report is to determine whether behavioural interventions[1] are effective in improving glycemic control in adults with type 2 diabetes.

Background

Diabetes is a serious chronic condition affecting millions of people worldwide and is the sixth leading cause of death in Canada. In 2005, an estimated 8.8% of Ontario's population had diabetes, representing more than 816,000 Ontarians. The direct health care cost of diabetes was $1.76 billion in the year 2000 and is projected to rise to a total cost of $3.14 billion by 2016. Much of this cost arises from the serious long-term complications associated with the disease including: coronary heart disease, stroke, adult blindness, limb amputations and kidney disease.

[1] Referred to in the diabetes literature as self-management support interventions

Type 2 diabetes accounts for 90–95% of diabetes and while type 2 diabetes is more prevalent in people aged 40 years and older, prevalence in younger populations is increasing due to a rise in obesity and physical inactivity in children.

Data from the United Kingdom Prospective Diabetes Study (UKPDS) has shown that tight glycemic control can significantly reduce the risk of developing serious complications in type 2 diabetics. Despite physicians' and patients' knowledge of the importance of glycemic control, Canadian data has shown that only 38% of patients with diabetes have HbA1C levels in the optimal range of 7% or less. This statistic highlights the complexities involved in the management of diabetes, which is characterized by extensive patient involvement in addition to the support provided by physicians. An enormous demand is, therefore, placed on patients to self-manage the physical, emotional and psychological aspects of living with a chronic illness.

Despite differences in individual needs to cope with diabetes, there is general agreement for the necessity of supportive programs for patient self-management. While traditional programs were didactic models with the goal of improving patients' knowledge of their disease, current models focus on behavioural approaches aimed at providing patients with the skills and strategies required to promote and change their behaviour.

Several meta-analyses and systematic reviews have demonstrated improved health outcomes with self-management support programs in type 2 diabetics. They have all, however, either looked at a specific component of self-management support programs (i.e. self-management education) or have been conducted in specific populations. Most reviews are also qualitative and do not clearly define the interventions of interest, making findings difficult to interpret. Moreover, heterogeneity in the interventions has led to conflicting evidence on the components of effective programs. There is thus much uncertainty regarding the optimal design and delivery of these programs by policymakers.

Evidence-Based Analysis of Effectiveness

Research Questions

1. Are behavioural interventions effective in improving glycemic control in adults with type 2 diabetes?

2. Is the effectiveness of the intervention impacted by intervention characteristics (e.g. delivery of intervention, length of intervention, mode of instruction, interventionist etc.)?

Inclusion Criteria

- English Language
- Published between January 1996 to August 2008
- Type 2 diabetic adult population (>18 years)
- Randomized controlled trials (RCTs)
- Systematic reviews, or meta-analyses
- Describing a multi-faceted self-management support intervention as defined by the 2007 Self-Management Mapping Guide (1)
- Reporting outcomes of glycemic control (HbA1c) with extractable data
- Studies with a minimum of 6-month follow up

Exclusion Criteria

- Studies with a control group other than usual care
- Studies with a sample size <30
- Studies without a clearly defined intervention

Outcomes of Interest

- Primary outcome: glycemic control (HbA1c)
- Secondary outcomes: systolic blood pressure (SBP) control, lipid control, change in smoking status, weight change, quality of life, knowledge, self-efficacy, managing psychosocial aspects of diabetes, assessing dissatisfaction and readiness to change, and setting and achieving diabetes goals.

Search Strategy

A search was performed in OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, the Cumulative Index to Nursing & Allied Health Literature (CINAHL), The Cochrane Library, and the International Agency for Health Technology Assessment (INAHTA) for studies published between January 1996 and August 2008. Abstracts were reviewed by a single author and studies meeting the inclusion criteria outlined above were obtained. Data on population characteristics, glycemic control outcomes, and study design were extracted. Reference lists were also checked for relevant studies. The quality of the evidence was assessed as being either high, moderate, low, or very low according to the GRADE methodology.

Summary of Findings

The search identified 638 citations published between 1996 and August 2008, of which 12 met the inclusion criteria and one was a meta-analysis (Gary et al. 2003). The remaining 11 studies were RCTs (9 were used in the meta-analysis) and only one was defined as small (total sample size N=47).

Summary of Participant Demographics across studies

A total of 2,549 participants were included in the 11 identified studies. The mean age of participants reported was approximately 58 years and the mean duration of diabetes was approximately 6 years. Most studies reported gender with a mean percentage of females of approximately 67%. Of the eleven studies, two focused only on women and four included only Hispanic individuals. All studies evaluated type 2 diabetes patients exclusively.

Study Characteristics

The studies were conducted between 2002 and 2008. Approximately six of 11 studies were carried out within the USA, with the remaining studies conducted in the UK, Sweden, and Israel (sample size ranged from 47 to 824 participants).The quality of the studies ranged from moderate to low with four of the studies being of moderate quality and the remaining seven of low quality (based on the Consort Checklist). Differences in quality were mainly due to methodological issues such as inadequate description of randomization, sample size calculation allocation concealment, blinding and uncertainty of the use of intention-to-treat (ITT) analysis. Patients were recruited from several settings: six studies from primary or general medical practices, three studies from the community (e.g. via advertisements), and two from outpatient diabetes clinics. A usual care control group was reported in nine of 11 of the studies and two studies reported some type of minimal diabetes care in addition to usual care for the control group.

Intervention Characteristics

All of the interventions examined in the studies were mapped to the 2007 Self-management Mapping Guide. The interventions most often focused on problem solving, goal setting and encouraging participants to engage in activities that protect and promote health (e.g. modifying behaviour, change in diet, and increase physical activity). All of the studies examined comprehensive interventions targeted at least two self-care topics (e.g. diet, physical activity, blood glucose monitoring, foot care, etc.). Despite the homogeneity in the aims of the interventions, there was substantial clinical heterogeneity in other intervention characteristics such as duration, intensity, setting, mode of delivery (group vs. individual), interventionist, and outcomes of interest (discussed below).

Duration, Intensity and Mode of Delivery

Intervention durations ranged from 2 days to 1 year, with many falling into the range of 6 to 10 weeks. The rest of the interventions fell into categories of ≤ 2 weeks (2 studies), 6 months (2 studies), or 1 year (3 studies). Intensity of the interventions varied widely from 6 hours over 2 days, to 52 hours over 1 year; however, the majority consisted of interventions of 6 to 15 hours. Both individual and group sessions were used to deliver interventions. Group counselling was used in five studies as a mode of instruction, three studies used both individual and group sessions, and one study used individual sessions as its sole mode of instruction. Three studies also incorporated the use of telephone support as part of the intervention.

Interventionists and Setting

The following interventionists were reported (highest to lowest percentage, categories not mutually exclusive): nurse (36%), dietician (18%), physician (9%), pharmacist (9%), peer leader/community worker (18%), and other (36%). The 'other' category included interventionists such as consultants and facilitators with unspecified professional backgrounds. The setting of most interventions was community-based (seven studies), followed by primary care practices (three studies). One study described an intervention conducted in a pharmacy setting.

Outcomes

Duration of follow up of the studies ranged from 6 months to 8 years with a median follow-up duration of 12 months. Nine studies followed up patients at a minimum of two time points. Despite clear reporting of outcomes at follow up time points, there was poor reporting on whether the follow up was measured from participant entry into study or from end of intervention. All studies reported measures of glycemic control, specifically HbA_{1c} levels. BMI was measured in five studies, while body weight was reported in two studies. Cholesterol was examined in three studies and blood pressure reduction in two. Smoking status was only examined in one of the studies. Additional outcomes examined in the trials included patient satisfaction, quality of life, diabetes knowledge, diabetes medication reduction, and behaviour modification (i.e. daily consumption of fruits/vegetables, exercise etc). Meta-analysis of the studies identified a moderate but significant reduction in HbA_{1c} levels -0.44% 95%CI: -0.60, -0.29) for behavioural interventions in comparison to usual care for adults with type 2 diabetes. Subgroup analyses suggested the largest effects in interventions which were of at least duration and interventions in diabetics with higher baseline HbA_{1c} (≥9.0). The quality of the evidence according to GRADE for the overall estimate was moderate and the quality of evidence for the subgroup analyses was identified as low.

ES Table 1: Summary of Meta-Analysis of Studies Investigating the Effectiveness of Behavioural Interventions on HbA_{1c} in Patients with Type 2 Diabetes.

Group	Estimate of effect [95% Confidence Interval]
Overall	-0.44 [-0.60, -0.29]
High Quality	-0.50 [-0.75, -0.26]
Low Quality	-0.37 [-0.62, -0.13]
Intervention length < 6 weeks	-0.42 [-0.68, -0.15]
Intervention length 6 weeks x < 1 year	-0.43 [-0.74, -0.12]
Intervention length =1 year	-0.68 [-1.22, -0.14]
Community-based setting	-0.48 [-0.70, -0.26]
Primary Care setting	-0.42 [-0.68, -0.15]
Interventionist < 2 disciplines	-0.44 [-0.66, -0.22]
Interventionist ≥ 2 disciplines	-0.51 [-0.84, -0.17]
Baseline HbA1c <9.0	-0.40 [-0.55, -0.24]
Baseline HbA1c ≥9.0	-0.79 [-1.23, -0.34]
Group sessions	-0.47 [-0.66, -0.28]
Individual sessions*	-0.80 [-1.35, -0.25]
Combined Group/Individual sessions	-0.30 [-0.57, -0.02]
Hispanic Population	-0.42 [-0.71, -0.13]
Non-Hispanic Population	-0.46 [-0.66, -0.25]

* Based on one study

Conclusions

- Based on moderate quality evidence, behavioural interventions as defined by the 2007 Self-management mapping guide (Government of Victoria, Australia) produce a moderate reduction in HbA1c levels in patients with type 2 diabetes compared with usual care.
- Based on low quality evidence, the interventions with the largest effects are those:
  - in diabetics with higher baseline HbA_{1c} ($\geq$9.0)
  - in which the interventions were of at least 1 year in duration

Background

In June 2008, the Medical Advisory Secretariat began work on the Diabetes Strategy Evidence Project, an evidence-based review of the literature surrounding strategies for successful management and treatment of diabetes. This project came about when the Health System Strategy Division at the Ministry of Health and Long-Term Care subsequently asked the secretariat to provide an evidentiary platform for the Ministry's newly released Diabetes Strategy.

After an initial review of the strategy and consultation with experts, the secretariat identified 5 key areas in which evidence was needed. Evidence-based analyses have been prepared for each of these 5 areas: insulin pumps, behavioural interventions, bariatric surgery, and community based care. For each area, an economic analysis was completed where appropriate and is described in a separate report.

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Objective

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Clinical Need and Target Population

Diabetes is a serious chronic condition affecting millions of people worldwide and is the sixth leading cause of death in Canada. In 2005, an estimated 8.8% of Ontario's population had diabetes, representing more than 816,000 Ontarians. (2) The direct health care cost of diabetes was $1.76 billion in the year 2000 and is projected to rise to a total cost of $3.14 billion by 2016. (3) Much of this cost arises from the serious long-term complications associated with the disease including: coronary heart disease, stroke, adult blindness, limb amputations and kidney disease. In terms of population, type 2 diabetes accounts for 90% to 95% of all diabetes cases and is more prevalent in those aged 40 years and older. In recent years, there has been an increased prevalence in younger populations due to the concomitant rise of obesity and physical inactivity in children.

Data from the United Kingdom Prospective Diabetes study (UKPDS) has shown that tight glycemic control in type 2 diabetics significantly reduces their risk of developing serious complications. Every 1.0% absolute decrease in HbA_{1c} (a measure of averaged blood glucose levels) leads to a 21% relative

decrease in any end-point related to diabetes, a 14% relative decrease in all-cause mortality, a 14% relative decrease in myocardial infarction, and a 37% relative decrease in micro-vascular endpoints. (4;5) Additional risk factors that can be modified to lower the risk of developing complications are blood pressure control, lipid control, and regular foot and eye care. Other risk factors linked to improved outcomes for diabetics include physical activity and smoking cessation. However, despite physicians' and patients' knowledge of the importance of glycemic control, Canadian data has shown that only 38% of patients with diabetes have HbA_{1C} levels in the optimal range of 7% or less. (1)

Diabetes Management

Like other chronic illnesses, the management of diabetes is characterized by extensive patient involvement in addition to physician support. Specifically, there is an enormous demand on patients to manage the physical, emotional and psychological aspects of living. They are expected to follow an intense process of behavioural self-regulation through diet, exercise, self-monitoring of blood glucose, foot care, and medical appointments. Patients' ability to manage their disease is influenced by a range of factors including social, environmental and individual variables as illustrated in Figure 1.

Despite differences in individuals' needs for coping with diabetes, there is general agreement for the necessity of supportive programs for patients managing their disease. (7) While traditional programs were didactic models with the goal of improving patients' knowledge of their disease, current models focus on behavioural approaches aimed at providing patients with the skills and strategies required to promote and change their behaviour. (8)

As noted previously, behavioural interventions are referred to in the diabetes literature as self-management support interventions. The term 'self-management', however, is often confusing as there is no universally accepted definition and it's used interchangeably with other concepts such as self-care, self-management training, patient empowerment, and self-management education. (9) In simplest terms, self-management can be described as what the patient does and self-management support can be defined as what the health professional, the practice, and system provide. (10) In 2003, the Institute of Medicine used the following definition for self-management support:

"…the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support."

The above definition is used for this analysis to describe the interventions of interest.

Several meta-analyses and systematic reviews have demonstrated improved health outcomes with self-management support programs in type 2 diabetics. (11) But these have all either looked at a specific component of self-management support programs (e.g. self-management education) or have been conducted in specific populations. Most reviews are also qualitative and do not clearly define the interventions of interest making findings difficult to interpret. Furthermore, heterogeneity in the interventions has led to conflicting evidence on the components of effective programs. (12) Thus, there is much uncertainty regarding the optimal design and delivery of these programs by policymakers. (13;14)

Outcomes associated with interventions that promote behaviour change

Clinical outcomes that may be evaluated in studies of behavioural intervention include measures of blood glucose control (HbA_{1c}, fasting blood glucose), blood pressure, lipids, weight loss, and body mass index (BMI). Changes in diet, exercise, and smoking may also be examined. Psychosocial outcomes frequently reported in studies include quality of life, depression, health beliefs, self-efficacy, satisfaction with daily life, empowerment, and diabetes knowledge. Despite this range, the success of diabetes interventions is most widely measured by HbA_{1c}, blood pressure and blood glucose levels. (15)

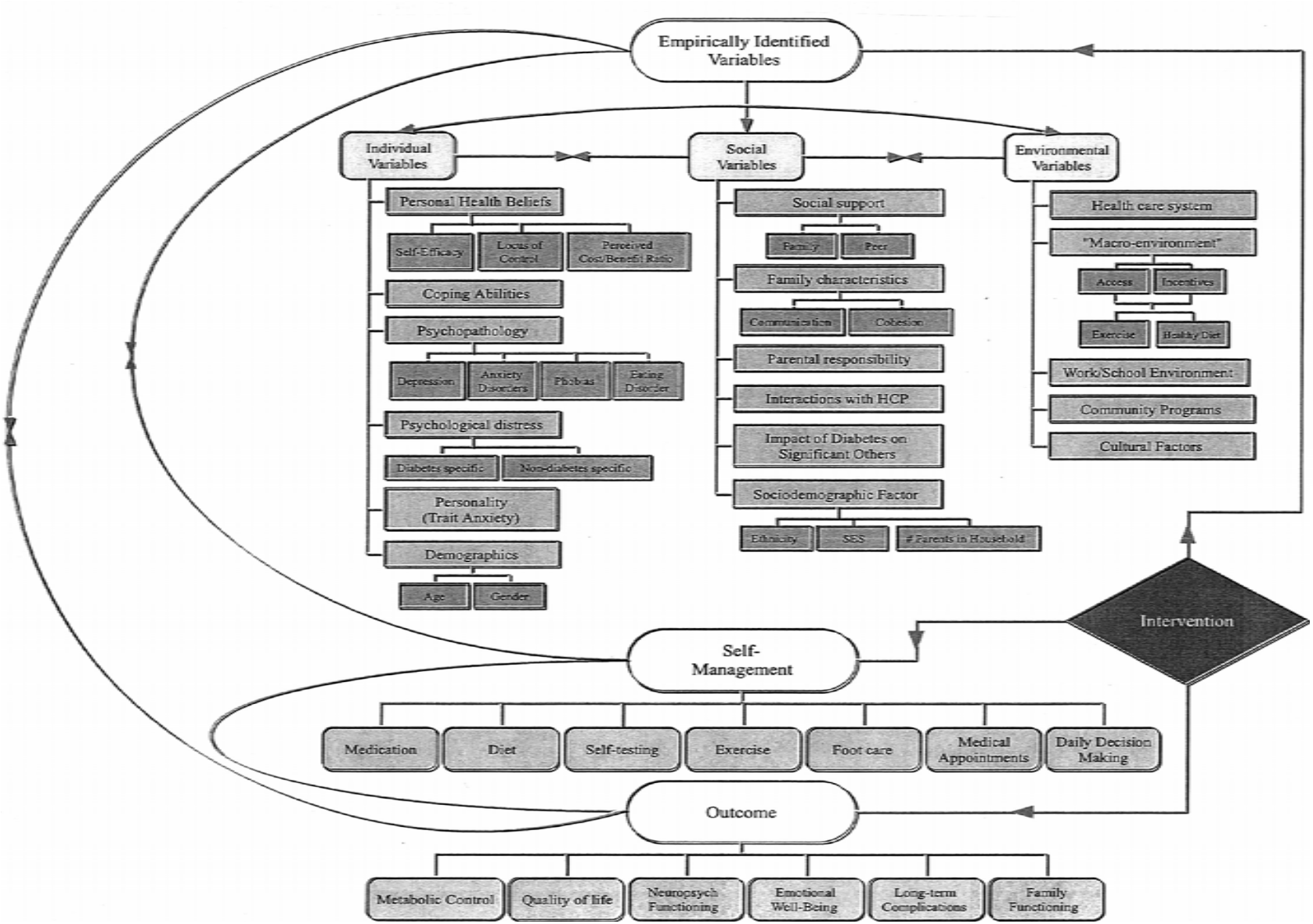


Figure 1: Psychobehavioural model of variables influencing self-management and clinical outcome in diabetes

Source: Goder-Frederick, 2002 (6)

Evidence-Based Analysis of Effectiveness

Research Questions

1. Are behavioural interventions effective in improving glycemic control in adults with type 2 diabetes?

2. Is the effectiveness of the intervention impacted by intervention characteristics (e.g. delivery of intervention, length of intervention, mode of instruction, interventionist etc.)?

Methods

Inclusion Criteria

- English language
- Published between 1996 and August 2008
- Adults >18 years of age
- Type 2 diabetes
- Randomized controlled trials (RCTs), systematic reviews, or meta-analyses
- Studies must describe a multi-faceted behavioural intervention as defined by the 2007 Self Management Mapping Guide (1)
- Reporting outcomes of glycemic control (HbA1c) with extractable data;
- Studies with a minimum of 6 months of follow up

Exclusion Criteria

- Studies with a control group other than usual care[2]
- Studies with a sample size <30
- Studies without a clearly defined intervention

Outcomes of Interest

- Primary outcome: glycemic control (HbA1c)
- Secondary outcomes: systolic blood pressure control, lipid control, change in smoking status, weight change, quality of life, knowledge, self-efficacy, managing psychosocial aspects of diabetes, assessing dissatisfaction and readiness to change, and achieving diabetes goals.

Method of Review

A search was performed in OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, the Cumulative Index to Nursing & Allied Health Literature (CINAHL), The Cochrane Library, and the International Agency for Health Technology Assessment (INAHTA) for studies published between 1996 and August 2008. The search strategy is detailed in Appendix 1. Abstracts were reviewed, and studies meeting the inclusion criteria outlined above were obtained. Reference lists were also checked for relevant studies. Results for HbA_{1c} outcomes from individual studies were meta-analyzed using a random-effects model.

[2] usual care is defined as routine care or routine care + minimal diabetes care

Mapping Interventions to a Set Criteria

As noted previously, there is much disparity in the literature as to the definition of self management support and the components of these programs. In order to reduce the heterogeneity across studies included in this review, we aimed to standardize the content of the interventions using the Government of Victoria self-management mapping guide. (1) In order for a study to be included in this review, the study interventions had to meet the criteria outlined in the mapping guide (Figure 2).

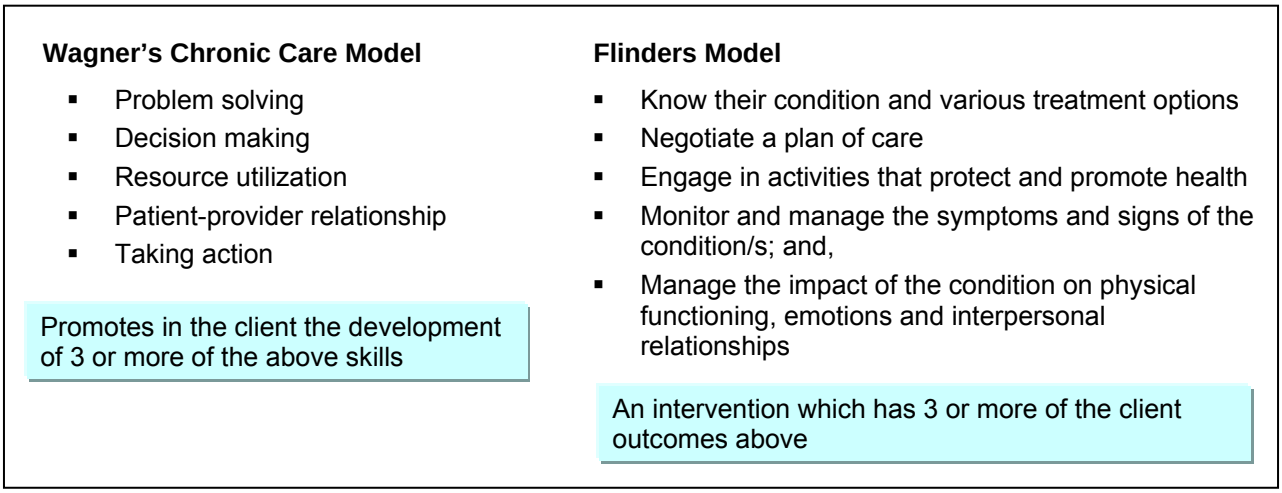


Figure 2: Criteria for self-management support intervention

Statistical Challenges – Meta-analysis

Meta-analyzing pre-post continuous measurements such as HbA_{1c} values presents statistical challenges as studies quite often report only baseline (pre) and final values (post) for intervention and control groups, without reporting change-from-baseline values. While the absolute difference between pre and post can be easily calculated (final value minus baseline value), the standard deviation of this intra-group difference, necessary for meta-analysis, is often lacking. To clarify the statistical challenges relevant to this report, it is important to define some terms:

- *The intra-group change from baseline to final* refers to the mean difference between baseline and final values within intervention or within control groups (i.e. the difference in pre and post measurements within groups).
- *The inter-group difference* refers to the mean difference in intra-group change from baseline to final (as defined above) between intervention and control (i.e. the difference in change-from-baseline values between groups).

To solve the problem of missing standard deviations, the Cochrane Handbook for Systematic Reviews has identified two solutions (http://www.cochrane-handbook.org/), both of which should be explored in any meta-analysis:

1. Meta-analyze only the inter-group difference in mean final values between intervention and control. This approach assumes that the inter-group difference in mean final values will be similar to the inter-group difference of the intra-group change from baseline to final if baseline values do not significantly differ between intervention and control. One can test for significant differences at baseline — if they do not differ, this approach is valid.

2. Use statistical calculations to derive the standard deviations for the intra-group change from baseline to final, then meta-analyze these data. Repeated (pre and post) measurements made on the same participants tend to be correlated, thus lowering standard errors and creating tighter confidence intervals in comparison to single measurements. A correlation coefficient quantifies this correlation between repeated measurements. This lowering of standard errors explains why meta-analyzing the change-from-baseline values is favourable to meta-analyzing final values only, particularly if there are significant differences between intervention and control at baseline. There are two ways to derive the standard deviations for the intra-group change from baseline to final when information is lacking:

a. Derive the standard deviation of the intra-group change from baseline to final using P-values, confidence intervals, or standard errors reported from a t-test of the intra-group change from baseline to final. A study which does not report standard deviations for the intra-group change from baseline to final, however, is unlikely to report relevant t-test values. This approach is, therefore, rare.

b. Calculate the standard deviation of the intra-group change from baseline to final by imputing a correlation coefficient. Correlation coefficients can be calculated from studies that report all relevant data (baseline ±SD, final ±SD, intra-group difference ±SD). These correlation coefficients can then be applied to studies lacking relevant information to derive appropriate standard deviations. Alternatively, one can impute varying correlation coefficients and run multiple sensitivity meta-analyses to observe any changes in effect. It is of importance, however, to note that imputation of various values has been historically shown to have little effect on the summary estimates and conclusions of a meta-analysis. (16;17)

For this particular paper, both final values and change–from-baseline values were meta-analyzed. Standard deviations for change-from-baseline values were generated by imputing varying correlation coefficients of 0.25, 0.5, and 0.75 and observing the effect on summary estimates and statistical heterogeneity. This range (0.25–0.75) was chosen to cover a wide range of possible correlation coefficients It should be noted that decreasing the correlation coefficient will result in a more conservative summary estimate, as this will increase trial standard deviations, subsequently resulting in a widening of confidence intervals around individual trial effect sizes and yielding a slight decrease in the overall summary effect size. Choosing a smaller correlation coefficient will also decrease overall statistical heterogeneity by widening confidence intervals.

Studies Included for Meta-Analysis

Most studies reported sufficient information around the primary outcome of HbA_{1c} to allow for inclusion in meta-analysis. Contact with the authors of the trial by Sarkadi et al. 2004 was necessary to obtain relevant standard deviations for trial inclusion. Two trials were excluded from the meta-analysis as relevant standard deviations were not reported and authors could not be contacted. One trial was excluded from meta-analysis post-hoc — the trial by Gallegos et al. 2006 for several reasons:

1. Including the trial in meta-analysis introduced excessive statistical heterogeneity (see Figure A1, Appendix 4);

2. The trial was an extreme outlier (confidence intervals did not even span the summary estimate; Figure A1, Appendix 4);

Figure A2, Appendix 4 presents a meta-analysis with the trial by Gallegos et al. 2006 excluded and shows a marked decrease in the statistical heterogeneity (I^2 = 8% as compared to I^2= 69% in Figure A1, Appendix 4) .

Assessment of Quality of Evidence

The quality assigned to individual studies was determined using MAS' adaptation of the levels-of-evidence hierarchy proposed by Goodman. (18) The overall quality of the evidence was examined according to the GRADE Working Group criteria (see Table 1). (19)

- Quality refers to criteria such as the adequacy of allocation concealment, blinding, and follow-up.
- Consistency refers to the similarity of estimates of effect across studies. If there is important unexplained inconsistency in the results, our confidence in the estimate of effect for that outcome decreases. Differences in the direction of effect, the size of the differences in effect, and the significance of the differences guide the decision about whether important inconsistency exists.
- Directness refers to the extent to which the interventions and outcome measures are similar to those of interest.

As stated by the GRADE Working Group, the following definitions were used in grading the quality of the evidence.

High: Further research is very unlikely to change confidence in the estimate of effect.

Moderate: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.

Very low: Any estimate of effect is very uncertain.

Table 1: Summary of GRADE Quality Assessment for Behavioural Interventions

Intervention	# of Studies	Quality Assessment					Summary of Findings	
		Design	Quality	Consistency	Directness	Other	Effect (HbA1c) Mean Difference [95% CI]	Quality
Behavioural interventions (all studies)	8	RCT	Serious limitations†	Consistent	Direct	None	-0.44 [-0.60, -0.29]	Moderate
		High	Moderate	Moderate	Moderate			
Behavioural interventions: where intervention duration = 1 year	2	RCT	Serious limitations‡	Consistent	Some uncertainty about directness§	None	-0.68 [-1.22, -0.14]	Low
		High	Moderate	Moderate	Low			
Behavioural interventions: in patients with high baseline HbA1c (≥9.0)	2	RCT	Serious limitations¥	Consistent	Some uncertainty about directness§	None	-0.79 [-1.23, -0.34]	Low
		High	Moderate	Moderate	Low			

*RCT refers to randomized controlled trial; CI, confidence interval; Int, intervention

† Unclear allocation concealment, unclear if outcome assessors were blinded in 4 studies. Although 4 studies represented 50 % of body of evidence the sample size represented only 25% of the overall population therefore it was not downgraded any further.

‡ Unclear allocation concealment, unclear if outcome assessors were blinded, unclear whether analysis was completed with Intention-to-treat (ITT)

§ One RCT (Brown et al.) contributes to the majority of the sample size and is based on a Hispanic population

¥ Unclear allocation concealment in both RCTs, unclear whether ITT was used in one RCT, possible bias in one RCT due to enhanced follow-up of participants (outcome measured at 8 years)

Results of Evidence-Based Analysis

The database search identified 638 relevant citations published between January 1996 and August 2008. Of the 638 abstracts identified, 12 studies met the inclusion criteria as described above (see Appendix 2). Of these, one article was a meta-analysis and the remaining 11 studies were RCTs. Only one RCT was defined as small (total sample size N=55) (see Table 2).

Table 2: Quality of Evidence of Included Studies*

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT, systematic review of RCTs	1	11
Large RCT unpublished but reported to an international scientific meeting	1(g)	0
Small RCT	2	1
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	0
Non-RCT with historical controls	3b	0
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	0
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

†For each included study, levels of evidence were assigned according to a ranking system based on a hierarchy proposed by Goodman. (18) An additional designation "g" was added for preliminary reports of studies that have been presented at international scientific meetings. Non-RCT, clinical trial that is not randomized, e.g., a cohort study; RCT refers to a randomized controlled trial.
Adapted from the Oxford Centre for Evidence (18)

Summary of Existing Evidence

Ten reviews were identified through our literature search focusing on self-management in type 2 diabetics. The majority of these, however, were not directly applicable to our analysis as they focused on a specific aspect of self-management (e.g. self-management education), examined very specific populations, or did not have clearly defined inclusion criteria of the interventions being reviewed. Furthermore, one review did not report on outcomes of glycemic control and another study had a systems focus. The only review with direct relevance to our analysis, was Gary et al. 2003. (20) This meta-analysis included 18 studies from the years 1966-1999, which evaluated the effects of an intervention aimed at behaviour change on glycemic control in type 2 diabetics. The authors concluded that educational and behavioural interventions produced a moderate decline in HbA_{1C} of 0.43% (95% CI, -0.71, -0.14). Studies with physicians as interventionists produced larger effects and those with nurses (RNs) or registered dieticians (RDs) produced similar results with respect to effectiveness. Interventions with group or individual counselling produced similar effects.

Table 3: Summary of Evidence on Self-Management Support Interventions in Type 2 Diabetes

Study (type)	# of trials Search years	Focus of Review	Applicability to MAS analysis
Eakin E. 2002 (SR*)	10 1987-2001	Self-management interventions in disadvantaged populations	Broad: Evaluating overall public health impact using RE-AIM † framework; no clearly defined interventions
Steed L. 2003 (SR)	36 1980-2001	Education, self management and psychological interventions	Narrow: Search term self-care not used; focused on psychosocial outcomes only; type 1&2
Norris S. 2002 (MA)	31 1980-1999	Self-management education for Adults	Narrow focus: self-management education
Norris S. 2001 (SR)	72 1980-1999	Self-Management training	Narrow focus: self-management education
Gary T. 2003 (MA)	18 1966-1999	Educational and Behavioural Interventions	Directly applicable to MAS analysis
Sarkisian C. 2003 (SR)	12 1985-2000	Self-care interventions for older African American, or Latino adults	Narrow Focus: Specific to older African American, or Latino adults
Shojania K. 2006 (MR)	66 1966-2006	Quality improvement strategies (including case-management and team changes)	Broad Focus: QI strategies – system focus; not all included studies focused on self-management support
Van Dam H. 2003 (SR)	8 1980-2001	Provider-patient interaction and provider consulting style	Broad Focus: provider-patient interaction; not all included studies focused on self-management support; search did not include self-care
Whittemore R. 2007 (SR)	11 1990-2006	Culturally Competent Interventions for Hispanic Adults	Narrow focus: Specific to Hispanic adults with Diabetes; not all included studies focused on self-management support
Deakin T. 2008 (MA)	11 1966-2003	Group-based training for self-management strategies	Broad focus: Not all included studies focused on self-management support

*SR; Systematic review, MA; meta-analysis, MR; meta-regression

†Reach, efficacy, adoption, implementation, maintenance

Summary of Literature Review Findings

The database search identified 638 relevant citations, of which 12 met the inclusion criteria described above. One article identified was a meta-analysis (Gary et al. 2003) and has been summarized above. All remaining studies identified were RCTs, of which one was defined as small (total sample size N=47). Of the 11 RCTs, nine were used in the meta-analysis, while two did not report relevant standard deviations in the trials and authors could not be contacted.

A total of 2,549 participants were included in the 11 identified studies. The mean age of participants reported was approximately 58 years and the mean duration of diabetes was approximately 6 years. Most studies reported gender with a mean percentage of females of approximately 67%. Of the 11 studies, two focused only on women and four included only Hispanic individuals. All studies evaluated type 2 diabetes patients exclusively.

Study Characteristics

The studies were conducted between 2002 and 2008 and six were carried out in the USA, with the remaining studies conducted in the UK, Sweden, and Israel (sample sizes ranged from 47 to 824 participants).The quality of the studies ranged from moderate to low, with four of the studies being of moderate quality and the remaining seven of low quality (based on the Consort Checklist). Differences in quality were mainly due to methodological issues such as inadequate description of randomization, sample size calculation allocation concealment, blinding and uncertainty of the use of intention-to-treat (ITT) analysis. Patients were recruited from several settings: six studies from primary or general medical practices, three studies from the community (e.g. via advertisements), and two studies from outpatient diabetes clinics. A usual care control group was reported in nine of eleven of the studies and two studies reported some type of minimal diabetes care in addition to usual care for the control group.

All of the interventions examined in the studies were mapped to the 2007 Self-management Mapping Guide. The interventions most often focused on problem solving, goal setting and encouraging participants to engage in activities that protect and promote health (e.g. modifying behaviour, change in diet, and increase physical activity). All of the studies examined comprehensive interventions targeting at least two self-care topics (e.g. diet, physical activity, blood glucose monitoring, foot care, etc.). Despite the homogeneity in the aims of the interventions, there was substantial clinical heterogeneity in other intervention characteristics such as duration, intensity, setting, mode of delivery (group vs. individual), interventionist, and outcomes of interest (discussed below).

Intervention durations ranged from 2 days to 1 year, with many falling into the range of 6 to 10 weeks. The rest of the interventions fell into categories of ≤ 2 weeks (two studies), 6 months (two studies), or 1 year (three studies). Intensity of the interventions varied widely from 6 hours over 2 days, to 52 hours over 1 year; however, the majority consisted of interventions of 6 to 15 hours. Both individual and group sessions were used to deliver interventions. Group counselling was used in five studies as a mode of instruction, three studies used both individual and group sessions, and one used individual sessions as its sole mode of instruction. Three studies also incorporated telephone support as part of the intervention.

The following interventionists were reported (highest to lowest percentage, categories not mutually exclusive): nurse (36%), dietician (18%), physician (9%), pharmacist (9%), peer leader/community worker (18%), and other (36%). The ‘other’ category included interventionists such as consultants and facilitators with unspecified professional backgrounds. The setting of most interventions was community-based (seven studies), followed by primary care practices (three studies).

Outcomes

Duration of follow up of the studies ranged from 6 months to 8 years with a median follow-up duration of 12 months. Nine studies followed up patients at a minimum of two time points. Despite clear reporting of outcomes at follow up time points, there was poor reporting on whether the follow up was measured from participant entry into study or from end of intervention.

All studies reported measures of glycemic control, specifically HbA_{1c} levels. BMI was measured in 5 studies, while body weight was reported in 2 studies. Cholesterol and blood pressure reduction were examined in 3 of 11 and 2 of 11 studies respectively. Smoking status was only examined in one of the studies. Additional outcomes examined in the trials included patient satisfaction, quality of life, diabetes knowledge, diabetes medication reduction, and behaviour modification (i.e. daily consumption of fruits/vegetables, exercise etc). Meta-analysis of the studies identified a moderate but significant reduction in HbA_{1c} levels -0.44% 95%CI: -0.60, -0.29) for behavioural interventions in comparison to usual care for adults with type 2 diabetes (Table 4). Subgroup analyses suggested the largest effects in interventions that were of at least duration and interventions in diabetics with higher baseline HbA_{1c} (≥9.0).

Table 4: Summary of findings of Meta-Analysis of Studies Investigating the Effectiveness of Behavioural Interventions on HbA_{1c} in Patients with Type 2 Diabetes.

Group	Estimate of effect [95% Confidence Interval]
Overall	-0.44 [-0.60, -0.29]
High Quality	-0.50 [-0.75, -0.26]
Low Quality	-0.37 [-0.62, -0.13]
Intervention length < 6 weeks	-0.42 [-0.68, -0.15]
Intervention length 6 weeks x < 1 year	-0.43 [-0.74, -0.12]
Intervention length =1 year	-0.68 [-1.22, -0.14]
Community-based setting	-0.48 [-0.70, -0.26]
Primary Care setting	-0.42 [-0.68, -0.15]
Interventionist < 2 disciplines	-0.44 [-0.66, -0.22]
Interventionist ≥ 2 disciplines	-0.51 [-0.84, -0.17]
Baseline HbA1c <9.0	-0.40 [-0.55, -0.24]
Baseline HbA1c ≥9.0	-0.79 [-1.23, -0.34]
Group sessions	-0.47 [-0.66, -0.28]
Individual sessions*	-0.80 [-1.35, -0.25]
Combined Group/Individual sessions	-0.30 [-0.57, -0.02]
Hispanic Population	-0.42 [-0.71, -0.13]
Non-Hispanic Population	-0.46 [-0.66, -0.25]

*based on one study

Conclusions

- Based on moderate quality evidence, behavioural interventions as defined by the 2007 Self-management mapping guide (Government of Victoria, Australia), produce a moderate reduction in HbA1c levels in patients with type 2 diabetes compared with usual care.

- Based on low quality evidence, the interventions with the largest effects are those:
  - in diabetics with higher baseline HbA_{1c} ($\geq$9.0)
  - in which the interventions were of at least 1 year in duration

Appendices

Appendix 1: Search Strategies

Final Search Strategy – Diabetes Self-Management Interventions

Search date: September 5, 2008
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE, Cochrane Library, CRD/INAHTA
***CINAHL will be searches separately in the new Ebscoe interface and the results provided separately.**

Database: Ovid MEDLINE(R) <1996 to August Week 4 2008>
Search Strategy

1 exp Diabetes Mellitus, Type 2/ (37738)
2 ((ketosis resistant or adult onset or slow onset or maturity onset or non?insulin dependent or stable or type 2 or type II) adj2 (diabet$ or DM)).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (46638)
3 (t2dm or NIDDM).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (4215)
4 or/1-3 (47189)
5 exp Self Care/ or dsme.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (16601)
6 exp Blood Glucose Self-Monitoring/ (1926)
7 exp Patient Participation/ (8185)
8 exp self efficacy/ (5646)
9 (selfmonitor$ or selftest$ or selfcar$ or selfmanage$ or selfmeasure$ or selfregulat$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (61)
10 (self-regulat$ or self-manage$ or self-care or self-monitor$ or self-measure$ or self-test).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (18255)
11 or/5-10 (35506)
12 11 and 4 (1513)
13 limit 12 to (english language and humans and yr="1998 - 2008") (1281)
14 limit 13 to (controlled clinical trial or meta analysis or randomized controlled trial) (237)
15 exp Technology Assessment, Biomedical/ or exp Evidence-based Medicine/ (33791)
16 (health technology adj2 assess$).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (616)
17 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$)).mp. or (published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ab. (63868)
18 exp Random Allocation/ or random$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (364944)
19 exp Double-Blind Method/ (52449)
20 exp Control Groups/ (679)
21 exp Placebos/ (9122)
22 (RCT or placebo? or sham?).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (92654)
23 or/14-22 (469302)
24 13 and 23 (369)

Database: EMBASE <1980 to 2008 Week 36>
Search Strategy

1 exp Non Insulin Dependent Diabetes Mellitus/ (54602)
2 ((ketosis resistant or adult onset or slow onset or maturity onset or non?insulin dependent or stable or type 2 or type II) adj2 (diabet$ or DM)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (38668)

3 (t2dm or NIDDM).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (7247)
4 or/1-3 (62494)
5 exp Self Care/ or dsme.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (13870)
6 exp Self Medication/ or exp Self Control/ or exp Self Monitoring/ (8427)
7 exp Patient Participation/ (2441)
8 exp Empowerment/ (489)
9 (selfmonitor$ or selftest$ or selfcar$ or selfmanage$ or selfmeasure$ or selfregulat$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (163)
10 (self-regulat$ or self-manage$ or self-care or self-monitor$ or self-measure$ or self-test).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (15278)
11 or/5-10 (27068)
12 11 and 4 (1158)
13 limit 12 to (human and english language and yr="1998 - 2008") (881)
14 Randomized Controlled Trial/ (162170)
15 exp Randomization/ (26204)
16 exp RANDOM SAMPLE/ (1229)
17 exp Biomedical Technology Assessment/ or exp Evidence Based Medicine/ (291798)
18 (health technology adj2 assess$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (638)
19 (meta analy$ or metaanaly$ or pooled analysis or (systematic$ adj2 review$) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab. (61496)
20 Double Blind Procedure/ (70398)
21 exp Triple Blind Procedure/ (12)
22 exp Control Group/ (2169)
23 exp PLACEBO/ or placebo$.mp. or sham$.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (206468)
24 (random$ or RCT).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (419146)
25 (control$ adj2 clinical trial$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (279080)
26 or/14-25 (775584)
27 26 and 13 (345)

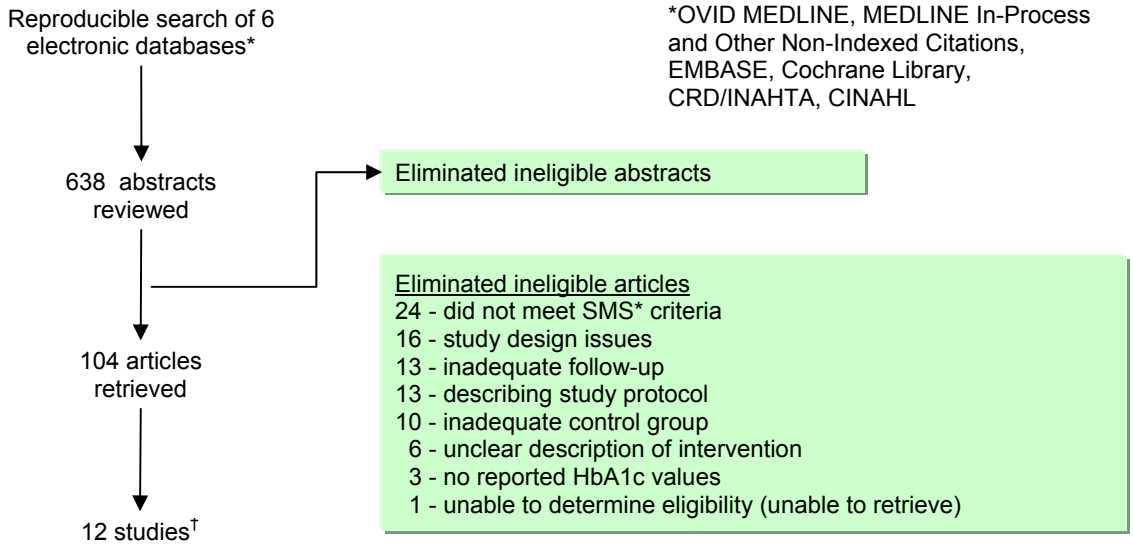
Final Search – Diabetes Self-Care

Database: Cinahl
Saturday, September 06, 2008 10:36:47 PM

#	Query	Limiters/Expanders	Last Run Via	Results
S26	S25 and S17	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	198
S25	S24 or S23 or S22 or S21 or S20 or S19 or S18	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	95914
S24	random*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	77581
S23	systematic* N2 review*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	12648
S22	meta analy* or metaanaly* or pooled analysis or published studies or medline or embase or data synthesis or data extraction or cochrane	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	22217
S21	(MH "Cochrane Library")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	2839
S20	(MH "Meta Analysis")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	6926
S19	(MH "Systematic Review")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	3963
S18	(MH "Random Assignment") or (MH "Random Sample+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	35540
S17	S15 and S6	Limiters - Published Date from: 199801-200812; Language: English Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	965
S16	S15 and S6	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	1117
S15	S14 or S13 or S12 or S11 or S10 or S9 or S8 or S7	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	22618
S14	self-regulat* or self-manage* or self-car* or self-monitor* or self-measure* or self-test*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	16574
S13	self-regulat$ or self-manage$ or self-care or self-monitor$ or self-measure$ or self-test	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL;Pre-CINAHL	13076
S12	(selfmonitor* or selftest* or selfcar* or selfmanage* or selfmeasure* or selfregulat*)	Search modes - Boolean/Phrase	Interface - EBSCOhost	

Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 84
S11 (MH "Blood Glucose Self-Monitoring") Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 1104
S10 (MH "Self Medication") or (MH "Self Administration+") Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 2544
S9 dsme Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 26
S8 (MH "Empowerment") Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 3903
S7 (MH "Self Care+") Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 13506
S6 S5 or S4 or S1 Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 13394
S5 (S3 and S2) Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 8328
S4 t2dm or NIDDM Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 624
S3 diabet* or DM Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 47194
S2 (ketosis resistant or adult onset or slow onset or maturity onset or non?insulin dependent or stable or type 2 or type II) Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 18900
S1 (MH "Diabetes Mellitus, Non-Insulin-Dependent") Search modes - Boolean/Phrase Interface - EBSCOhost
Search Screen - Advanced Search
Database - CINAHL;Pre-CINAHL 11130

Appendix 2: Literature Search Flow Diagram



† 11 RCTs and 1 meta-analysis; 9 RCTs used in meta-analysis

*Self-management support as defined by 2007 Self Management Mapping Guide (Government of Victoria, Australia)

Appendix 3: Study Characteristics

Appendix Table 1: Patient and design characteristics of studies examining behavioural interventions in type 2 diabetics

Study / Country	Population & Setting	Groups (as described by author)	Delivered by/ Mode/ Length of Intervention	Description of Intervention & Follow-up	Results: Glycemic Control	Other outcomes
Sixta et al. 2002 USA	Mexican Americans with type 2 N=63 <u>Subject characteristics</u> - mainly female (71%) - mid 50's - mean duration of DM = 6.8 yrs - mean baseline HbA1c = 7.49 Setting: Community health center	1) usual care[3] 2) culturally sensitive self-care management intervention[4]	Hispanic community worker[5] Group, face-to-face 10 weeks (ten 1.5 – hour sessions weekly)	SMS criteria met: Know their condition and various tx options, negotiate a plan of care, engage in activities that protect and promote health Follow-up: 3 and 6 months from baseline	Control: N = 68 Intervention: N = 63 Negligible changes in HbA1c levels*	Knowledge, Health beliefs
Adolfsson et al. 2007 Sweden	~60 yrs. old Mean duration of diabetes ~6.5 yrs ~40% on oral agents HbA1c value from 6.5-10% Setting: Primary care centres	1) routine diabetes care‡ N = 46 2) empowerment group education N=42 Also had a comparison group for internal validity†	Physicians and diabetes specialist nurses Group Max. 5 sessions of 2.5 hrs each (mean # sessions ~4.7), including 1 follow up session within 7 months	Counselling approach using: problem-solving, identifying feasible changes, supports for and barriers to making changes, goal-setting, making a plan to reach goals Themes: treatment, prevention of complications, blood glucose monitoring, diet, physical activity and daily foot care Follow-up: 1 year from baseline	HbA1c % (SD)¥ Control: Baseline 7.1 (0.8) 1-year 7.4 (1.1) Intervention: Baseline 7.4 (1.0) 1-year 7.3 (1.3) ¥not sig	Diabetes knowledge, self-efficacy, satisfaction with daily life, BMI

[3] Wait-list control; received usual care from a provider at the clinic; included diabetes education provided to patients as part of usual care

[4] Presented in Spanish

[5] Employed by the clinic and supervised by the nurses.

‡ care in accordance with regional diabetes guidelines based on the Swedish National Guidelines

† physicians and diabetes specialist nurses at centers could be responsible for care of patients in both the intervention and control groups

Study / Country	Population	Groups (as described by author)	Delivered by/ Mode/ Length of Intervention	Description of Intervention	Results: Glycemic Control	Other outcomes
Davies et al. 2008 UK	N=824 randomized Newly diagnosed Subject Characteristics - mean age ~60 - % women slightly less than half - Obese BMI ~32 - Mean Baseline HbA1c (%) = 7.9 (control); 8.3 (intervention) Settings: Primary Care Practices, Community, Cluster RCT	1) usual care[6] 2) Structured Group Education Programme	2 health care professional educators Group 6 hours over 1 day or 2 ½ days	Focused on behaviour change -addressed lifestyle factors, food choices, physical activity & CV risk factors - goal setting - non-didactic SMS criteria met: Know their condition and various tx options, negotiate a plan of care, engage in activities that protect and promote health Follow-up: 4, 8, and 12 months from baseline	Treatment difference *between* groups on HbA1c level (95% CI)[7] <u>4 mo.</u> 0.02 (-0.14 to 0.19) p=0.78 8 mo. -0.03 (-0.18 to 0.13) p=0.74 <u>12 mo.</u> 0.05 (-0.10 to 0.20) p=0.52 <u>Overall*</u> 0.01 (-0.12 to 0.14) p=0.88 *not significant *Within* groups 4, 8, 12 mo. Clinically significant ↓ in HbA1c in the intervention group 8 & 12 mo. Clinically significant ↓ in HbA1c in the control grp. Both groups lowered their HbA1c levels to below 7.5.	QOL, Physical activity, Depression Smoking, illness beliefs
Brown et al. 2002 USA	Mexican Americans with type 2 N = 256 <u>Subject characteristics</u> - Mainly female (60-68%) - obese, BMI >30 - Mid 50's - ~8 yrs. duration of diabetes - high baseline HbA1c (~11.80) Setting: Community based sites[8]	usual care[9] 2) culturally competent* diabetes SM intervention[10] *in terms of language, diet, social emphasis, family participation, & cultural health beliefs	nurses[11], dieticians, community workers Group	Instructional sessions: nutrition, self-monitoring of BG, exercise and other self-care topics Support group sessions: promote behaviour changes SMS criteria met: Problem solving, resource utilization, taking action Follow-up: 3, 6, and 12 months from baseline	HbA1c% (SD) Control: N = 128 B: 11.80 (3.02) 3 mo: 11.22 (2.77) 6 mo: 12.20 (2.95) 12 mo: 11.64 (2.85) Intervention: N=128 B: 11.81 (3.00) 3 mo. 10.6 (2.64) 6 mo. 10.80 (2.80) 12 mo. 10.89 (2.56) Statistically significant improvement for INT vs. ctrl	Diabetes-related knowledge, health beliefs, FBG, lipids and BMI

[6] Slightly enhanced; practices provide with resources (i.e. clinical guidelines, pamphlets, resources to enable them to provide contact time = to that of intervention group

[7] Adjusted for baseline and cluster effect

[8] Schools, churches, adult day care centers, health clinics, county agricultural extension offices

Study / Country	Population	Groups (as described by author)	Delivered by/ Mode/ Length of Intervention	Description of Intervention	Results: Glycemic Control	Other outcomes
Gallegos et al. 2006 Mexico	N=47 randomized Mexicans adults Subject characteristics -Mean age ~51 years -HbA1c Intervention 10.36 Control 9.44 -BMI >30 -Years with DM2 = ~9 Poor control of DM2 Setting: Community (nursing school facilities)	1. Comparison group 2. Experimental group	Other Face-to-face, telephone, group & individual sessions 6 educational sessions (90 min/each), and ~20 individual counselling sessions (30-90 min each) over 50 weeks	Counselling sessions – self-care activities at home, goals for specific behaviour were established Follow up at next visit to see if goals were met Follow-up: 3, 6, 9, and 12 months from baseline	Based on a one-way ANOVA for five measurements for Hb1c in experimental and comparison groups, there was a significant difference per group and per time factors (F_4=4.92, p=.003). Differences between the groups were significant in the second, fourth, and fifth measurements. (3, 9 and 12 months)	Self care activities, psychological adaptation, barriers to self-care
Deakin et al. 2006 UK	Adults with type 2 from 16 general medical practices in the UK Subject characteristics - mean age = 61.5 - mean duration of diabetes = 6.7 years -~50/50 ratio of men to women -low level of education Setting: Community venues	1) Individual appointments [12] 2) X-PERT programme	Diabetes research dietician[13] Group (16 per group +4-8 carers) Six weekly 2-hour sessions	Aimed to develop skills and build confidence, to enable patients to make informed decisions regarding their diabetes self-care SMS criteria met: Know their condition and various treatment options, Negotiate a plan of care, Engage in activities that protect and promote health Follow-up: 4, and 14 months from baseline	HbA1c% (SD) Control: N=157[14] B: 7.7 (1.6) 4 mo: 7.8 (1.6) 14 mo: 7.8 (1.6) (ITT n=141) Intervention: N=157 B: 7.7 (1.6) 4 mo. 7.4 (1.3) 14 mo. 7.1 (1.1) (ITT n=150) INT group had a greater reduction in HbA1c (-0.6% vs. +0.1%)* at 14 mos. *Statistically significant	Total cholesterol, body weight, BMI, waist circumference, SBP, DBP, HDL, LDL, total cholesterol to HDL ratio, triglycerides Patient satisfaction, empowerment score, overall QOL Exercise, foot care SM, blood glucose, daily consumption of fruits/veg, diabetes knowledge , DM medication reduction

[9] 1-year wait listed control; provided by physicians or local clinics

[10] Each subject identified a family member who agreed to participate as a support person

[11] All staff was Bilingual Mexican American; community worker's role: provided support (making calls, providing travel, preparing food)

[12] Received diabetes education and review with prearranged ind. Appts. With a dietician (30 min), practice nurse (15 min) and general practitioner (10 min).

Study / Country	Population	Groups (as described by author)	Delivered by/ Mode/ Length of Intervention	Description of Intervention	Results: Glycemic Control	Other outcomes
Sarkadi et al. 2004 Sweden	N=77 Subject characteristics - Mean age ~67 -Mean BMI ~28 - Duration of diabetes Control: 2.6 years Intervention: 5.9 years -Mean Baseline HbA1c% = ~6.5 Setting: Pharmacy	1. control 2. educational program	Specially trained pharmacists, assisted by diabetes nurse specialist (on first 2 occasions) group	Reinforce participants' experiences and use these as a basis for acquisition of practical skills -diaries shared with grp and used to form discussions -problem solving - emotional support SMS criteria met: engage in activities that protect and promote health; monitor and manage the symptoms and signs of the condition and manage the impact of the condition on physical functioning, emotions and interpersonal relationships Follow-up: 6, 12, and 24 months from baseline	HbA1c% (95% CI) Control: B: 6.4 (5.9-6.9) 6 mo: 6.3 (5.7-6.9) 12 mo: 6.4 (5.9-7.0) 24 mo: 6.6 (6.0-7.1) Intervention: B: 6.5 (6.0-7.0) 6 mo. 5.8 (5.4-6.2) 12 mo. 6.2 (5.7-6.7) 24 mo. 6.1 (5.5-6.7) Statistically significant improvement for INT vs. ctrl at 24 months.	items related to personal perceptions about the disease
Rachmani et al. 2005 Israel	n=141 randomized High risk[15] Subject characteristics Mean baseline HbA1c (~9.5) ~50% men Mean duration of diabetes ~6.2 yrs BMI mean ~28 Setting: Primary Care	1) standard consultation[16] 2) patient participation program	Consultants Face to face, individual 2-2h teaching sessions over 2 weeks	Achieving tight control of modifiable RFs - ind. plan of lifestyle modification & a fitness program - measurement of BP weekly - urge their physicians to change or intensify tx if the targets of BP, LDL & HbA1c were not reached. -encouraged to call the consultants for advice. SMS criteria met: Patient-provider relationship, resource utilization, taking action Follow-up: 4 and 8 years from baseline	HbA1c% (SD) Control: N (completed at 4 yrs) = 65 B: 9.6 (1.9) 4 yr: 8.9 (1.2) 8 yr: 9.2 (1.4) Intervention: N (completed at 4 years) =64 B: 9.5 (1.6) 4 yr: 8.2 (1.5) 8 yr: 8.3 (1.6)	BMI, BP, LDL

[13] Took on role of diabetes educator

[14] See patient flow for final sample size in each arm

[15] Had type 2 DM + hypertension & hyperlipidemia and were referred for consultation to a diabetes clinic in an academic hospital

[16] Standard consultations group received 8 consultations over the 8 year follow up, while patient participation program received on average 9 consultations over the same period

Study / Country	Population	Groups (as described by author)	Delivered by/ Mode/ Length of Intervention	Description of Intervention	Results: Glycemic Control	Other outcomes
Lorig et al. 2008 USA	n=533 randomized Spanish speaking adults incl. support person <u>Subject characteristics</u> Mean age =~53 yrs Females (%) Usual care: ~67 SDSMP ~57 Mean HbA1c (%) ~7.4 Setting: Community	1. usual-care wait-list control group† 2. community-based peer-led SDSMP* *Spanish diabetes self-management program	2 Peer Leaders‡ Group classes (10-15 participants), individual telephone follow-up 6 weeks	-problem solving -enhance self-efficacy -make an action plan -decision making -increase diabetes knowledge -Report on successes and problems to grp meal planning SMS criteria met: Problem solving; decision making; taking action Follow-up: 6 and 18 months from baseline	6 month change scores HbA1c (%) Usual care: -0.50 ±1.57 SDSMP: -0.408 ±1.42 P=0.040	Health distress, Self-reported global health, symptoms of hypoglycaemia, symptoms of hyperglycemia, activity limitation, fatigue, Health behaviours, Self-efficacy, Health care utilization
Whittemoreet al. 2004 USA	n=53 randomized Women <u>Subject characteristics</u> Mean age =57.6 yrs Mean baseline HbA1c (~7.7) Mean duration of diabetes 2.7 yrs Setting: Community	1) standard care control condition 2) nurse-coaching intervention	Nurse Face to face, telephone, Group &individual 6 sessions over 6 months (5 of 6 sessions provided in the first 3 months) 2 phone calls provided between 5th and 6th nurse-coaching sessions.	-Present diabetes information in greater depth, -identify personal barriers and facilitators to lifestyle changes -Problem-solve barriers -Negotiate realistic goals -assist in identifying appropriate social support and mental health strategies SMS criteria met: Know their condition and various tx options, negotiate a plan of care, engage in activities that protect and promote health Follow-up: 3 and 6 months from baseline	HbA1c % (SD)¥ Control: Baseline 7.6 (1.0) 3 mo. 7.4 (1.0) 6 mo. 7.5 (1.0) Intervention: Baseline 7.7 (1.0) 3 mo. 7.3 (1.0) 6 mo. 7.5 (1.0) ¥not sig	BMI, Dietary behaviour Diabetes-related stress, Integration of diabetes into daily life

†ranged from community clinics to specialist care and was representative of care received by Spanish speakers in large urban areas
‡spanish-speaking peer leaders came from same communities as the participants. Most had type 2 diabetes and were not health professionals

Appendix Table 2: Summary of studies included in review

						Interventions				
Study	**Country**	**N[1]**	**Special Population**	**Baseline HbA1c %**	**Quality**	**Who†**	**How‡**	**Where**	**Length of Intervention**	**Length of f/u**
Deakin 2006	UK	314	_____	7.7	Moderate	RD	G	Community	6 weeks	4, 14 mo.
Rachmani 2005	Israel	141	High risk[2]	9.5	Moderate	C	I	Primary care	2 weeks	4, 8 years
Lorig 2008	USA	533	Latinos Incl. Support person	7.4	Low	PL	G, I, T	Community	6 weeks	6, 18 mo.
Brown 2002	USA	256	Mexicans Incl. support person	11.8	Low	RN, RD, CW	G	Community	1 year	3, 6, 12 mo.
Sarkadi 2004*	Sweden	77	_____	6.5	Low	P, dRN	G	Pharmacy	1 year	6, 12, 24 mo.
Gallegos 2006	Mexico	47	Mexicans Obese	Ctrl: 9.44 Int: 10.36	Low	O	G, I, F, T	Community	~ 1 yr (50 weeks)	3, 6, 9, 12 mo.
Davies 2008	UK	824	Newly Diagnosed	Ctrl: 7.9 Int: 8.3*	Moderate	O	G	Primary care	1-2 days (6 hrs total)	4, 8, 12 mo.
Holtrop 2002*	USA	132	Women	Ctrl: 7.7 Int: 8.0	Low	O	G, I, T	Community	6 weeks	6 mo.
Sixta 2008	USA	131	Mexicans Primarily female	7.5	Low	CW, RN	G	Community	10 weeks	3, 6 mo.
Whittemore 2004	USA	53	Women	7.7	Low	RN	G, I, F, T	Community	6 months	3, 6 mo.
Adolfsson 2007	Sweden	101	_____	7.3	Moderate	MD, dRN	G	Primary care	5 sessions (12.5 hrs total)	12 mo.

*excluded from meta-analysis

†RN=nurse, dRN= diabetes specialist nurse, MD=physician, RD=registered dietician, C=consultant, P=pharmacist, PL = peer leader; CW=community worker; O=other

‡T =telephone, I=individual counselling, G=group counselling, , CE=clinical education, O=other

[1] Number of participants randomized, [2] type 2+ hypertension + hyperlipidemia,

Appendix 4: Forest Plots

Figure A1: Difference in change-from-baseline HbA_{1c} values between behavioural interventions and usual care control for all studies

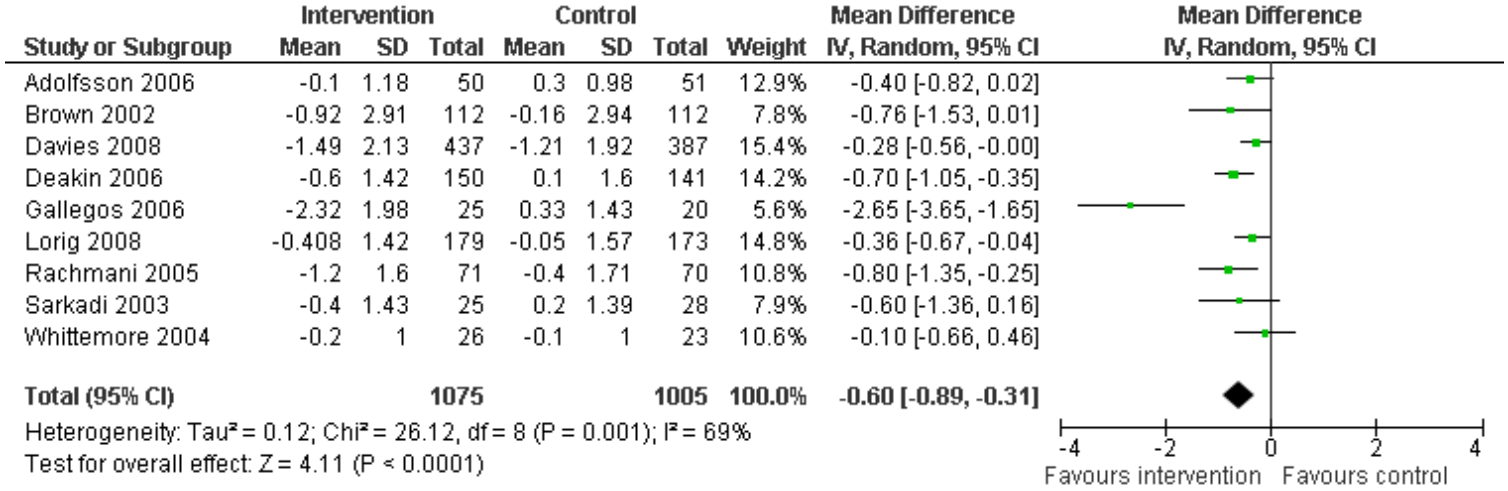


Figure A2: Difference in change-from-baseline HbA_{1c} values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006)

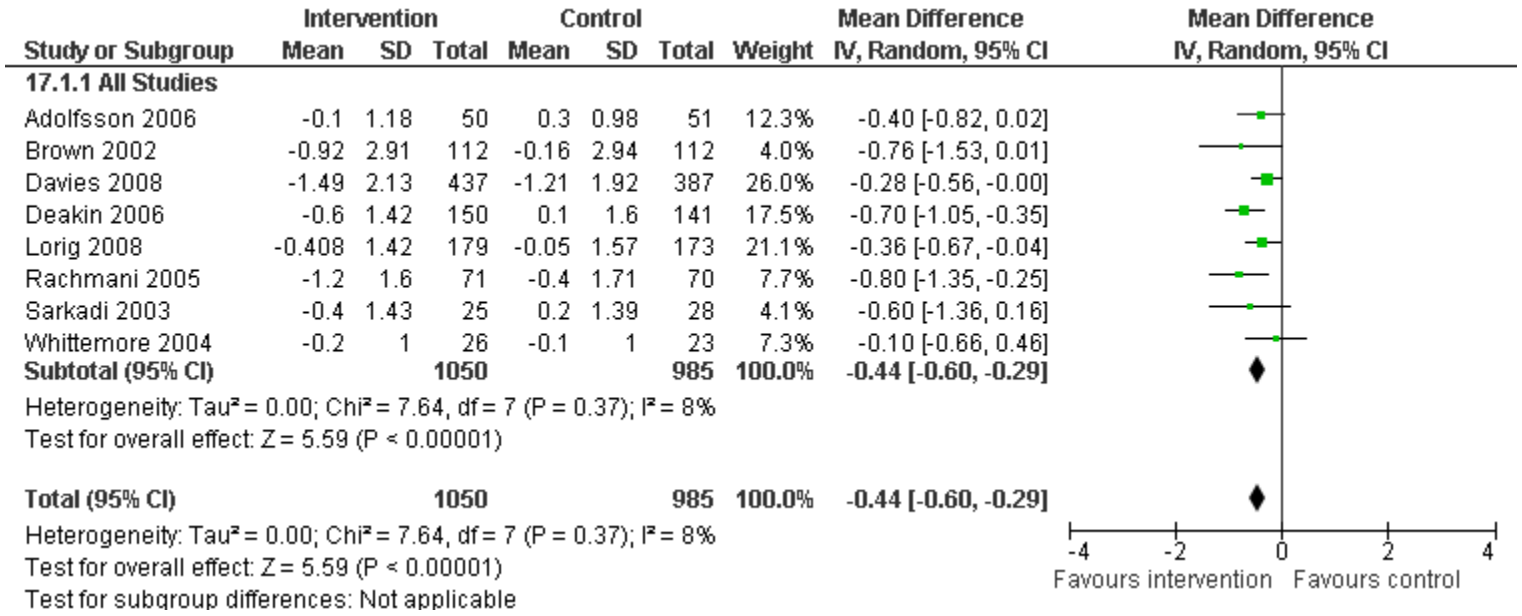


Figure A3: Difference in change-from-baseline HbA1c values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006) subgrouped by study quality

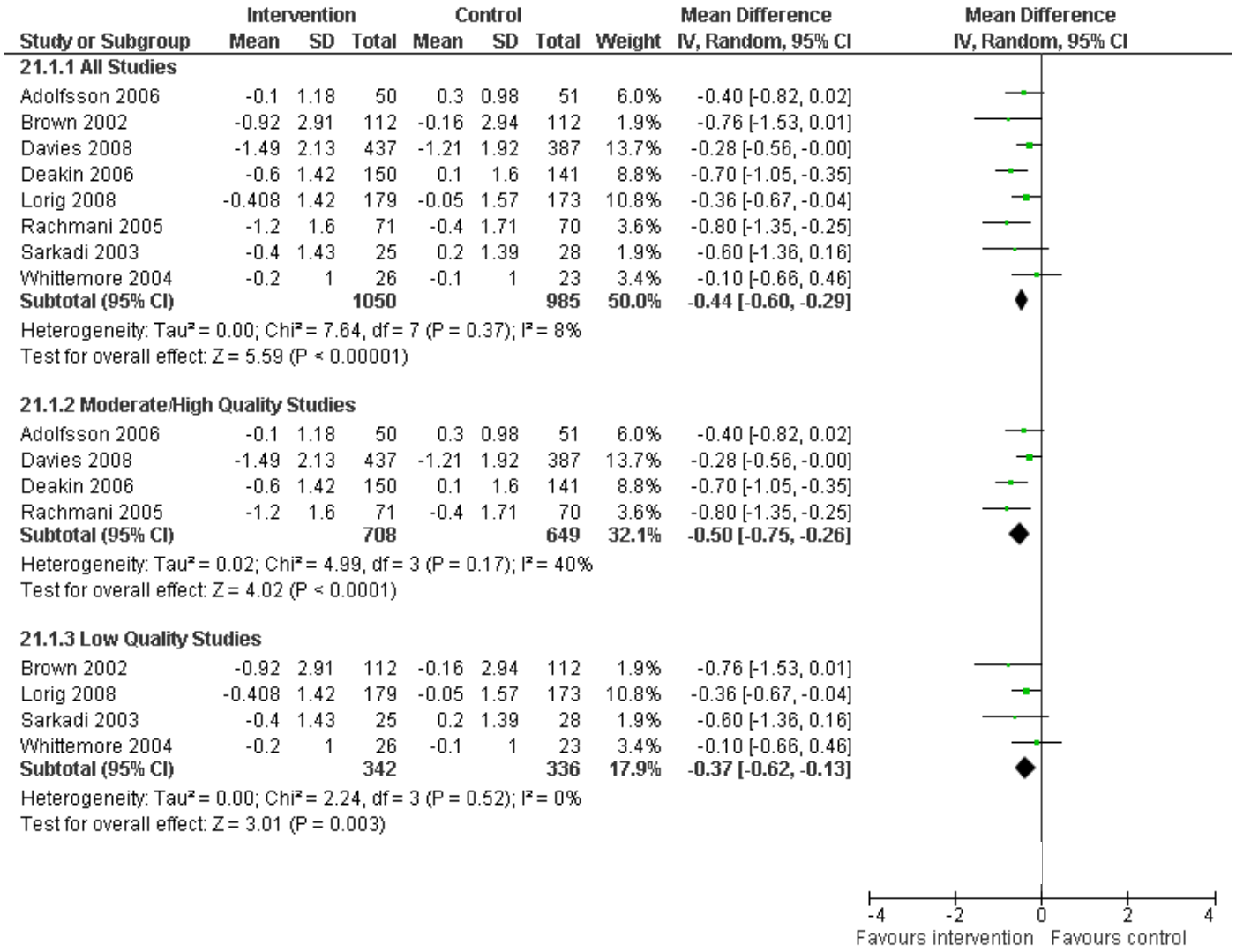


Figure A4: Difference in change-from-baseline HbA1c values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006) subgrouped by study quality

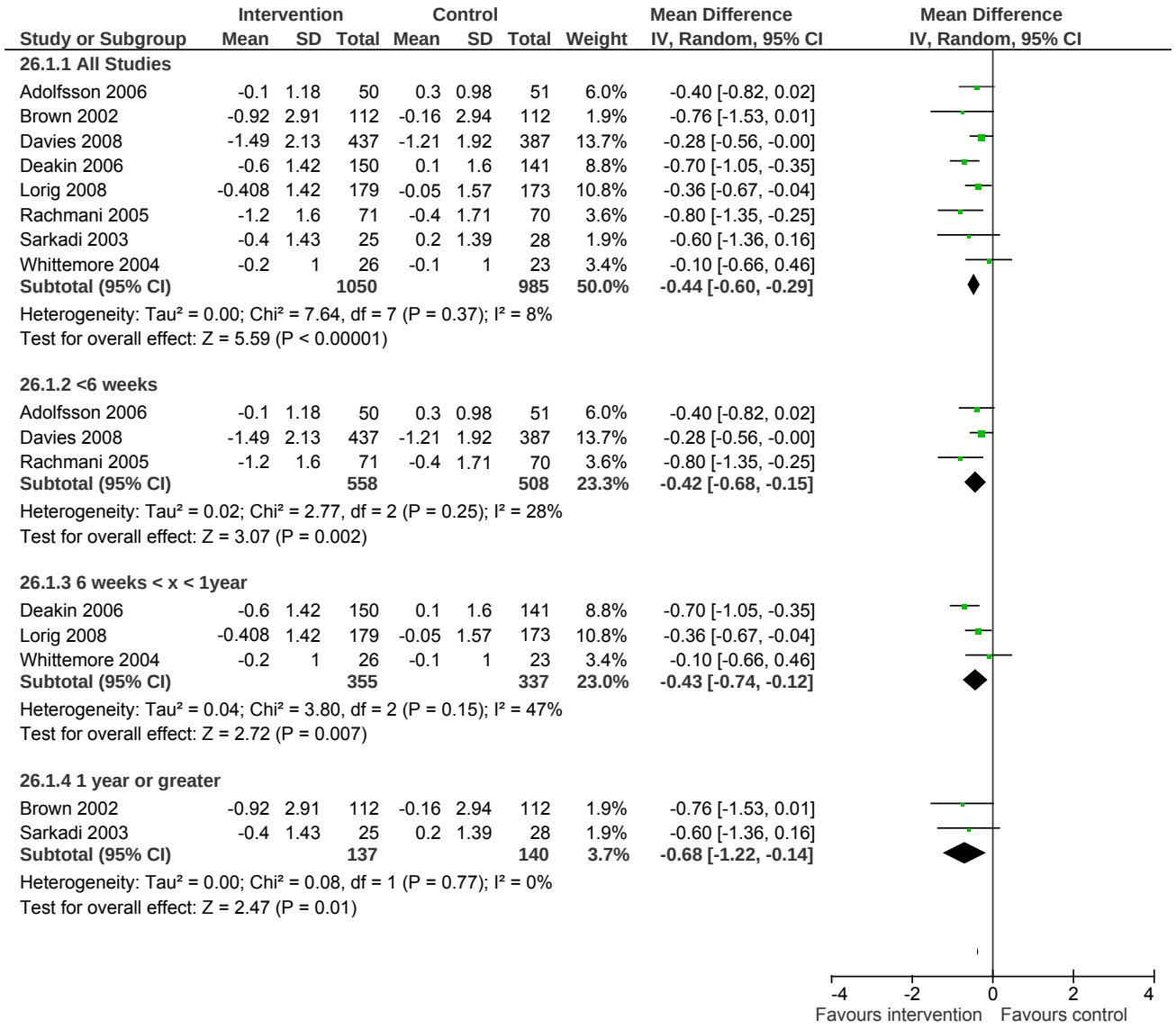


Figure A5: Difference in change-from-baseline HbA_{1c} values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006) subgrouped by study setting

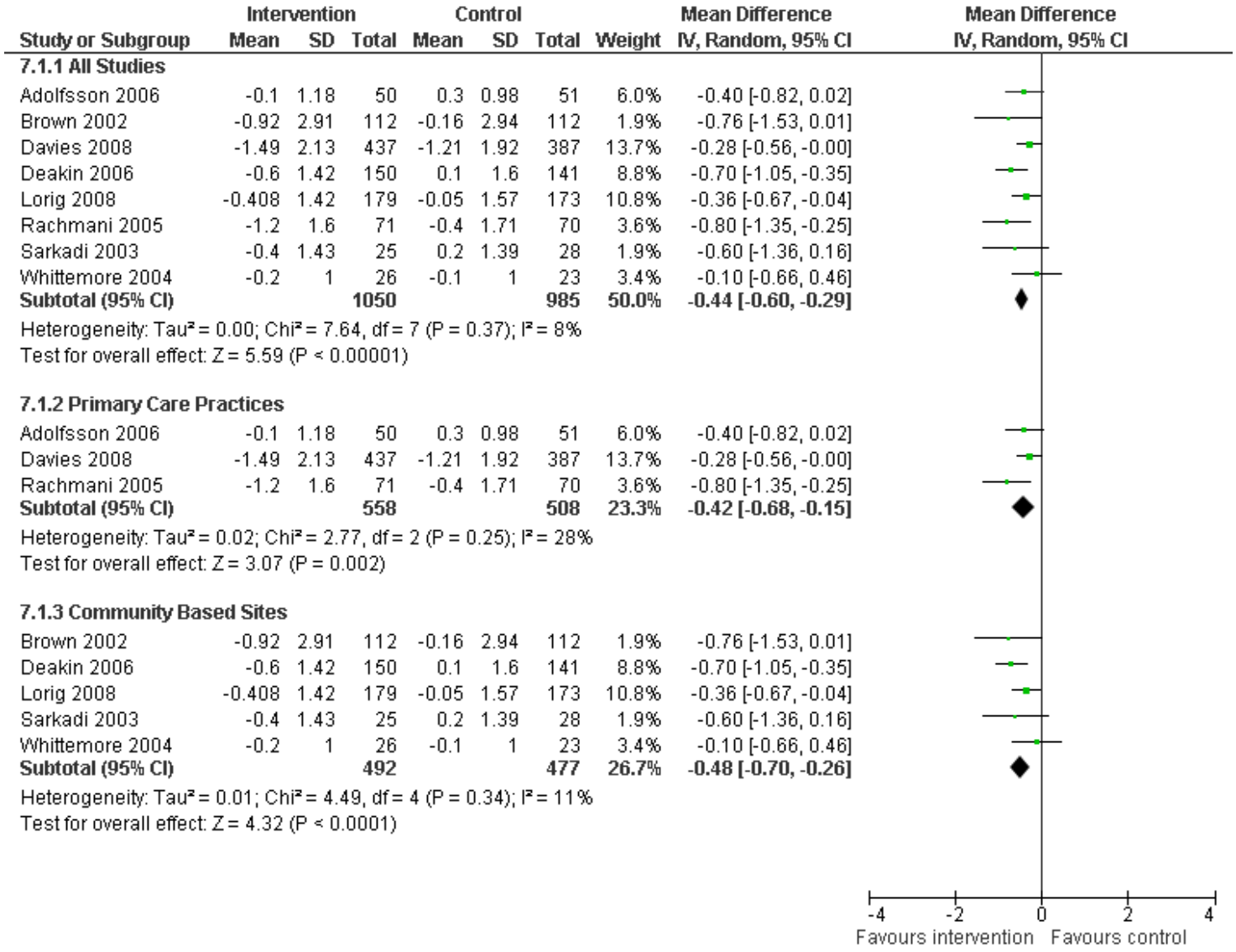


Figure A6: Difference in change-from-baseline HbA1c values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006) subgrouped by interventionist

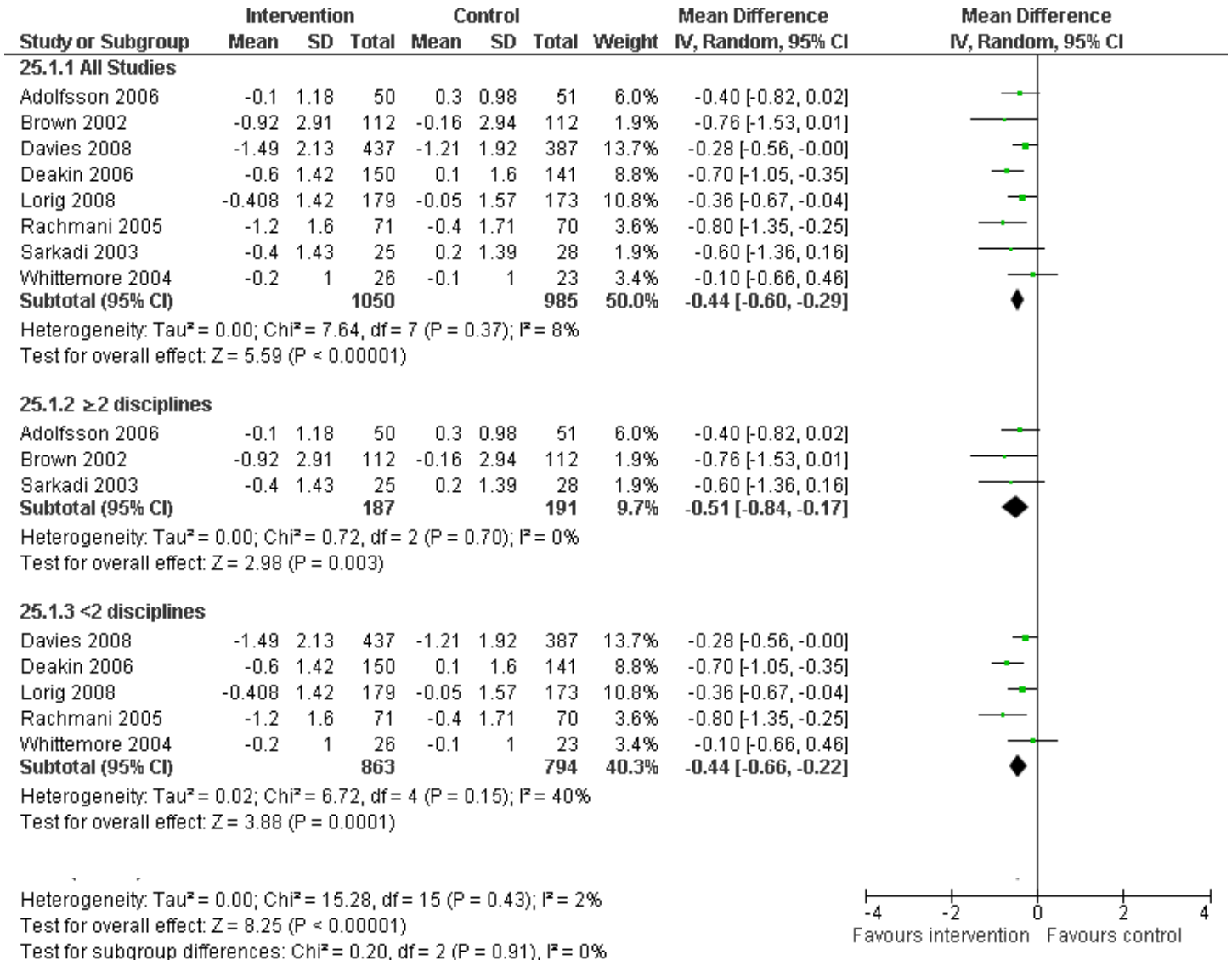


Figure A7: Difference in change-from-baseline HbA_{1c} values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006) subgrouped by mode of delivery

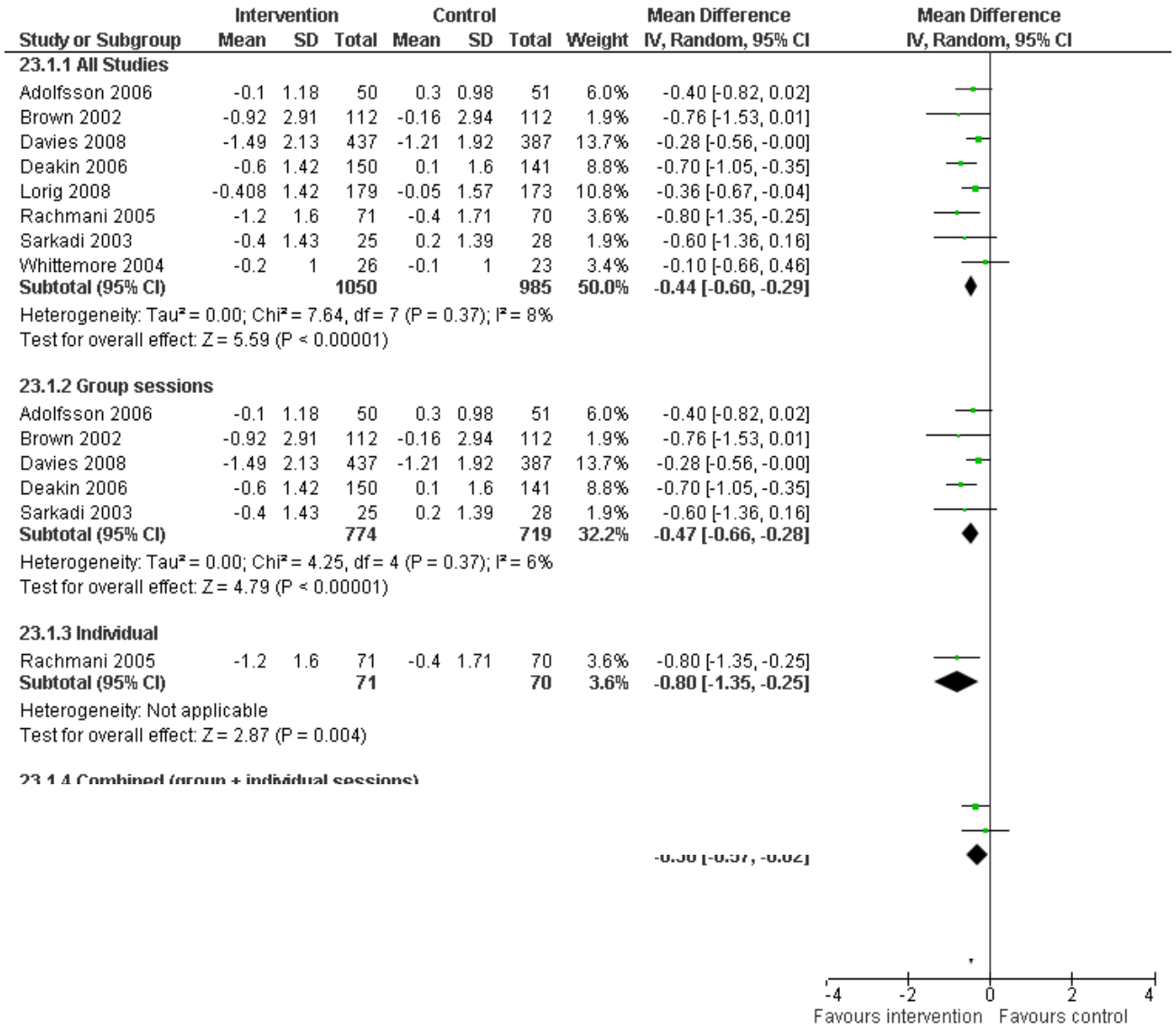


Figure A8: Difference in change-from-baseline HbA_{1c} values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006) subgrouped by baseline HbA_{1c}

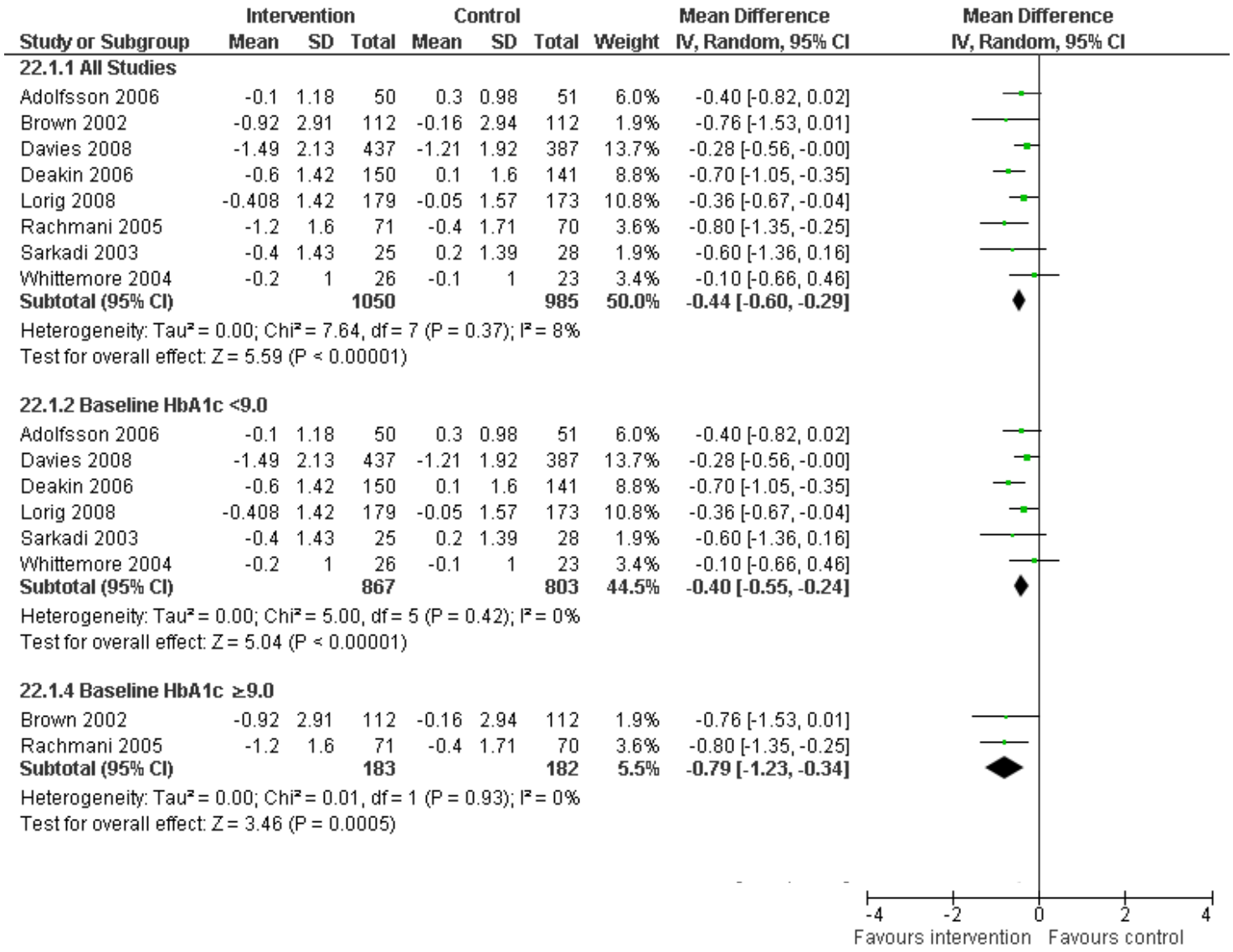
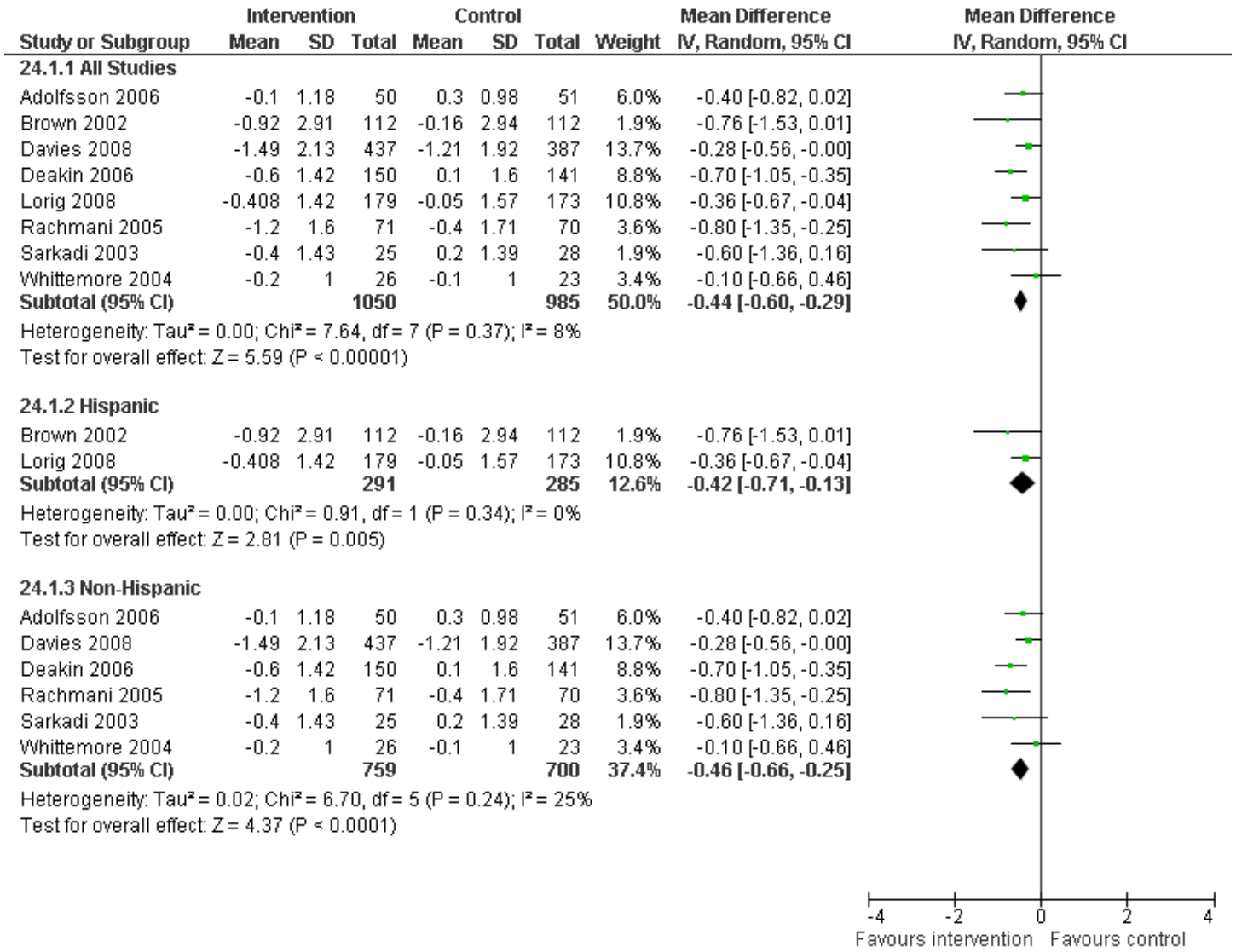


Figure A9: Difference in change-from-baseline HbA_{1c} values between behavioural interventions and usual care control for all studies (excluding Gallegos 2006) subgrouped by minority populations



References

(1) Government of Victoria. 2007 Self-management mapping guide [Internet]. Melbourne, Victoria: Victorian Government, Department of Human Services. 2007 August. [cited: 2009 Jun 1]. 22 p. Available from: http://www.health.vic.gov.au/pcps/downloads/self_management_guide.pdf

(2) Lipscombe LL, Hux JE. Trends in diabetes prevalence, incidence, and mortality in Ontario, Canada 1995-2005: a population-based study. Lancet 2007; 369(9563):750-6.

(3) Ohinmaa A, Jacobs P, Simpson S, Johnson JA. The projection of prevalence and cost of diabetes in Canada: 2000 to 2016. Can J Diabetes 2004; 28(2):116-23.

(4) Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatmtent and risk of complications in patients with type 2 diabetes: UKPDS 33. Lancet 1998; 352:837-53.

(5) Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. UK Prospective Diabetes Study Group. BMJ 1998; 317(7160):703-13.

(6) Gonder-Frederick LA, Cox DJ, Ritterband LM. Diabetes and behavioral medicine: the second decade. J Consult Clin Psychol 2002; 70(3):611-25.

(7) Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2008 clinical practice guidelines for the prevention and management of diabetes in Canada. Can J Diabetes 2008; 32(Suppl 1):S1-S201.

(8) Glasgow RE, Anderson RM. In diabetes care, moving from compliance to adherence is not enough. Something entirely different is needed. Diabetes Care 1999; 22(12):2090-2.

(9) McGowan, P. Self-management: a background paper [Internet]. Victoria, BC: University of Victoria, Centre on Aging. 2005. [cited: 2009 May 25]. 10 p. Available from: http://www.coag.uvic.ca/cdsmp/documents/What_is_Self-Management.pdf

(10) Von KM, Gruman J, Schaefer J, Curry SJ, Wagner EH. Collaborative management of chronic illness. Ann Intern Med 1997; 127(12):1097-102.

(11) Eakin EG, Bull SS, Glasgow RE, Mason M. Reaching those most in need: a review of diabetes self-managementinterventions in disadvantaged populations. Diabetes Metab Res Rev 2002; 18:26-35.

(12) Chodosh J, Morton S, Mojica W, Maglione M, Suttorp M, Hilton L et al. Meta-analysis: chronic disease self-management programs for older adults. Ann Intern Med 2005; 143(6):427-38.

(13) Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Ann Behav Med 2003; 26(1):1-7.

(14) Pearson ML, Mattke S, Shaw R, Ridgely MS, and Wiseman SH. Patient self-management support programs: an evaluation. Final contract report (Prepared by RAND Health under Contract No. 282-00-0005) [Internet]. 2007 November. [cited: 2009 Jan 2]. 43 p. AHRQ Publication No. 08-0011. Available from: http://www.ahrq.gov/qual/ptmgmt/ptmgmt.pdf

(15) Magwood GS, Zapka J, Jenkins C. A review of systematic reviews evaluating diabetes interventions: focus on quality of life and disparities. Diabetes Educ 2008; 34(2):242-65.

(16) Furukawa TA, Barbui C, Cipriani A, Brambilla P, Watanabe N. Imputing missing standard deviations in meta-analyses can provide accurate results. J Clin Epidemiol 2006; 59(1):7-10.

(17) Thiessen PH, Barrowman N, Garg AX. Imputing variance estimates do not alter the conclusions of a meta-analysis with continuous outcomes: a case study of changes in renal function after living kidney donation. J Clin Epidemiol 2007; 60(3):228-40.

(18) Goodman C. Literature searching and evidence interpretation for assessing health care practices. The Swedish council on Technology Assessment in Health Care. 1993.

(19) Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S. Grading quality of evidence and strength of recommendations. BMJ 2004; 328(7454):1490.

(20) Gary TL, Genkinger JM, Guallar E, Peyrot M, Brancati FL. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. Diabetes Educ 2003; 29(3):488-501.