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Changing behaviour

Search date September 2003

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QUESTIONS

What are the effects of interventions aimed at changing people's behaviour? 2

INTERVENTIONS

CHANGING BEHAVIOUR

Beneficial

Advice from physicians and trained counsellors to quit smoking 2

Advice on cholesterol lowering diet 9

Advice on reducing sodium intake to reduce blood pressure 10

Antidepressants (bupropion or nortriptyline) as part of a smoking cessation programme (but no evidence of benefit for selective serotonin reuptake inhibitors or moclobemide) 4

Antismoking interventions for pregnant women 5

Antismoking interventions in people at high risk of disease (evidence that counselling or bupropion are effective in this group) 6

Exercise advice to women over 80 years of age 8

Lifestyle interventions for sustained weight loss . . . 10

Nicotine replacement for smoking cessation 3

Likely to be beneficial

Advice from nurses to quit smoking 2

Counselling sedentary people to increase physical activity 7

Lifestyle interventions to maintain weight loss 11

Self help materials for people who want to stop smoking 2

Telephone advice to quit smoking 2

Unknown effectiveness

Lifestyle advice to prevent weight gain 12

Physical exercise to aid smoking cessation 4

Training health professionals in promoting weight loss 12

Training health professionals to give advice on smoking cessation (increases frequency of antismoking interventions, but may not improve effectiveness) 7

Likely to be ineffective or harmful

Acupuncture for smoking cessation 4

Anxiolytics for smoking cessation 4

Key points

- Individual change in behaviour has the potential to decrease the burden of chronic disease due to smoking, diet and low physical activity.
- Smoking quit rates can be increased by simple **advice** from a physician or trained counsellor, overall and in **people at high risk** of smoking related disease, with low intensity advice as effective as high intensity advice.
 - Advice from a nurse, telephone counselling, individualised self help materials and **taking exercise** may also be beneficial.
 - Training health professionals** increases the frequency of offering antismoking interventions but may not increase their effectiveness.
 - Nicotine replacement therapy, bupropion and nortriptyline** may improve short term quit rates as part of smoking cessation strategies.
 - Moclobemide, selective serotonin reuptake inhibitors, anxiolytics and **acupuncture** have not been shown to be beneficial.
 - Smoking cessation programmes increase quit rates in **pregnant women**, but nicotine patches may not be beneficial compared with placebo.
- Physical activity in sedentary people may be increased by **counselling**, with input from exercise specialists possibly being more effective than physicians, in **women over 80 years** and in younger adults.
- **Advice on eating a low cholesterol diet** leads to a mean 0.2 to 0.3 mmol/L decrease in blood cholesterol concentration in the long term, but no consistent effect of this on morbidity or mortality has been shown.
 - Intensive interventions to **reduce sodium** intake lead to small decreases in blood pressure, but may not reduce morbidity or mortality.
 - Advice to lose weight** leads to greater weight loss than no advice, and cognitive behavioural therapy may be more effective than dietary advice.

Maintenance strategies involving personal or family contact, walking training or multifactorial approaches may be more effective at maintaining weight loss compared with no strategies, but have resource implications.

We don't know whether lifestyle advice, with or without financial incentives, can prevent weight gain, or whether training health professionals leads to greater weight loss in people in their care.

DEFINITION	Cigarette smoking, diet, and level of physical activity are important in the aetiology of many chronic diseases. Individual change in behaviour has the potential to decrease the burden of chronic disease, particularly cardiovascular disease. This chapter focuses on the evidence that specific interventions lead to changed behaviour.
INCIDENCE/ PREVALENCE	In the developed world, the decline in smoking has slowed and the prevalence of regular smoking is increasing in young people. A sedentary lifestyle is becoming increasingly common and the prevalence of obesity is increasing rapidly.
AIMS OF INTERVENTION	To encourage individuals to reduce or abandon unhealthy behaviours and to take up healthy behaviours; to support the maintenance of these changes in the long term.
OUTCOMES	Ideal outcomes are clinical, and relate to the underlying conditions (longevity, quality of life, and rate of stroke or myocardial infarction). However, the focus of this chapter, and the outcomes reported by most studies, are proxy outcomes, such as the proportion of people changing behaviour (e.g. stopping smoking) in a specified period.
METHODS	<i>Clinical Evidence</i> search and appraisal September 2003.

QUESTION What are the effects of interventions aimed at changing people's behaviour?

OPTION **ADVICE TO QUIT SMOKING**

Systematic reviews have found that simple, one off advice from a physician during a routine consultation increased the proportion of smokers quitting smoking and not relapsing for 1 year. One systematic review found that advice from trained counsellors also increases quit rates compared with minimal intervention. One systematic review found limited evidence that advice to quit smoking from nurses increased quitting at 1 year compared with no advice. One systematic review provided limited evidence that telephone counselling improved quit rates compared with interventions with no personal contact. One systematic review found that self help materials slightly improved smoking cessation compared with no intervention. It found that individually tailored materials were more effective than standard or stage based materials. One subsequent RCT found no significant difference in abstinence rates at 6 months between self help materials based on the stages of change model and standard self help literature.

Benefits: We found five systematic reviews ^{[1] [2] [3] [4] [5]} and two subsequent RCTs. ^{[6] [7]}

Physicians:

The first review (search date 2000, 34 RCTs, 28 000 smokers) considered advice given by physicians, most often in the primary care setting, but also in hospitals and other clinics. ^[1] It found that brief advice improved quit rates compared with no advice (16 trials, 12 with follow up for at least 1 year; 451/7705 [5.9%] with brief advice v 241/5870 [4.1%] with no advice; meta-analysis OR 1.69, 95% CI 1.45 to 1.98). Intensive advice slightly improved quit rates compared with minimal advice among smokers not at high risk of disease (10 trials, 7 with follow up for at least 1 year; OR with intensive v minimal advice 1.23, 95% CI 1.02 to 1.49). The first subsequent RCT tested a brief (10 minute) intervention given by general practitioners who had received 2 hours of training. ^[6] The intervention increased the abstinence rate at 12 months (7.3% with control v 13.4% with intervention; P < 0.05).

Counsellors:

The second systematic review (search date 2002, 15 RCTs) examined individual counselling of at least 10 minutes by professionals trained in smoking cessation (social work, psychology, psychiatry, health education, and nursing). ^[2] Follow up was at 6–12 months. The review found that counselling increased the rate of quitting (340/2590 [13%] with counselling v 232/2592 [9%] with control; OR of quitting 1.64, 95% CI 1.33 to 2.01). ^[2] The authors did not find a greater effect of intensive counselling compared with brief counselling (3 RCTs; OR 0.98, 95% CI 0.61 to 1.56).

Nurses:

The third review (search date 2001, 22 RCTs, 5 with follow up for < 1 year) considered the effectiveness of smoking interventions delivered by a nurse. It found that advice from a nurse increased

the rate of quitting by the end of follow up (meta-analysis of 18 studies: 646/4836 [13.4%] with advice v 405/3356 [12.1%] with control; OR 1.50, 95% CI 1.29 to 1.73).^[3] However, this review did have methodological weaknesses (see comment below).

Telephone advice:

The fourth systematic review (search date 2000, 23 RCTs) considered counselling delivered by telephone.^[4] Ten of the included trials (9 with follow up for at least 12 months) compared proactive telephone counselling versus minimum intervention (involving no person to person contact). Pooled analysis was not possible because of statistical heterogeneity among trials. However, three trials found that telephone counselling was significantly more effective than minimum intervention, four trials found a non-significant benefit, and none of the trials found significant harms of telephone counselling.

Self help materials:

We found one systematic review (search date 2002, 51 RCTs)^[5] that examined effects of providing materials giving advice and information to smokers attempting to give up on their own and one subsequent RCT.^[7] The review found that self help materials without face to face contact slightly improved smoking cessation compared with no intervention (11 RCTs, including 8 RCTs with at least 12 months' follow up; OR 1.24, 95% CI 1.07 to 1.49). Individually tailored materials were more effective than standard or stage based materials (10 RCTs; OR for cessation 1.36, 95% CI 1.13 to 1.64). The subsequent RCT (2471 smokers) found no significant difference in abstinence rates at 6 months between self help materials based on the stages of change model and standard self help literature (abstinence: OR for stage of change materials v standard self help material 1.53, 95% CI 0.76 to 3.10).^[7]

Harms: We found no evidence of harm.

Comment: The effects of advice may seem small, but a year on year reduction of 2% in the proportion of smokers would represent a significant public health gain. In the systematic review of advice provided by nurses,^[3] there was significant heterogeneity of the study results and many studies may not have been adequately randomised (7/18 [39%] studies did not specify the randomisation method and 3/18 [17%] used an inadequate form of randomisation).

OPTION NICOTINE REPLACEMENT FOR SMOKING CESSATION

One systematic review found that nicotine replacement is an effective additional component of cessation strategies. We found no evidence of any particular method of nicotine delivery having superior efficacy. We found limited evidence from five RCTs (follow up 2–8 years) that the benefit of nicotine replacement treatment on quit rates decreased with time.

Benefits: Abstinence at 12 months:

We found one systematic review (search date 2002)^[8] that identified 51 trials of nicotine chewing gum, 34 of nicotine transdermal patches, four of nicotine intranasal spray, four of inhaled nicotine, and three of sublingual tablets. All forms of nicotine replacement were more effective than placebo. When the abstinence rates for all trials were pooled according to the longest duration of follow up available, nicotine replacement increased the odds of abstinence compared with placebo (3335/19 783 [16.8%] with nicotine replacement v 1835/17 977 [10.2%] with placebo; OR 1.74, 95% CI 1.64 to 1.86). The review found no significant difference in abstinence with different forms of nicotine replacement in indirect comparisons (OR 1.66 for nicotine chewing gum v 2.27 for nicotine nasal spray) or direct comparisons (1 RCT, inhaler v patch; OR 0.57, 95% CI 0.19 to 1.65). In trials that directly compared 4 mg with 2 mg nicotine chewing gum, the higher dose improved abstinence in highly dependent smokers (OR 2.18, 95% CI 1.49 to 3.17). High dose patches slightly increased abstinence compared with standard dose patches (6 RCTs; OR 1.21, 95% CI 1.03 to 1.42). The review found no significant difference in effectiveness for 16 hour compared with 24 hour patches, and no difference in effect in trials where the dose was tapered compared with those where the patches were withdrawn abruptly. Use of the patch for 12 weeks was as effective as longer use and there was limited evidence that repeated use of nicotine replacement treatment in people who have relapsed after an initial course may produce further quitters, though the absolute effect was small. One included RCT (3585 people) found that abstinence at 1 week was a strong predictor of 12 month abstinence (25% of those abstinent at 1 week were abstinent at 12 months v 2.7% of those not abstinent at 1 week).^[9] One meta-analysis of relapse rates in nicotine replacement trials found that nicotine replacement increased abstinence at 12 months, but that continued nicotine replacement did not significantly affect relapse rates between 6 weeks and 12 months.^[10]

Longer term abstinence:

We found five RCTs^{[11] [12] [13] [14] [15]} that found nicotine replacement did not affect long term abstinence. In one RCT that compared nicotine spray with placebo, 47 people abstinent at 1 year

were followed for up to a further 2 years and 5 months, after which there was still a significant, although smaller, difference in abstinence (abstinence in the longer term 15.4% with nicotine spray v 9.3% with placebo; NNT [for 1 extra person to abstain] 7 at 1 year v 11 at 3.5 years).^[11] The second RCT compared 5 months of nicotine patches plus nicotine spray versus the same patches plus a placebo spray. It found no significant difference between treatments after 6 years (16.2% abstinent with nicotine spray v 8.5% with placebo spray; P = 0.08).^[12] The third RCT compared patches delivering different nicotine doses versus placebo patches. The trial followed everyone that quit at 6 weeks for a further 4–5 years and found no significant difference in relapse between the groups. Overall, 73% of people who quit at 6 weeks relapsed.^[13] The fourth RCT followed up 840 of 1686 people, 8 years after they participated in a trial of nicotine replacement therapy.^[14] It found similar rates of relapse in the active and placebo groups, with no significant difference between the groups in 8 year continuous abstinence rates (OR 1.39, 95% CI 0.89 to 2.17).^[14] The fifth RCT followed 107 of 311 health care workers 5 years after they participated in a trial comparing nicotine replacement therapy versus placebo patch.^[15] It found no significant difference in abstinence rates at 5 years (18% with nicotine v 14% with placebo; P = 0.797).

Harms: Nicotine chewing gum has been associated with hiccups, gastrointestinal disturbances, jaw pain, and orodental problems. Nicotine transdermal patches have been associated with skin sensitivity and irritation. Nicotine inhalers and nasal spray have been associated with local irritation at the site of administration. Nicotine sublingual tablets have been reported to cause hiccups, burning, smarting sensations in the mouth, sore throat, coughing, dry lips, and mouth ulcers.^[16]

Comment: Nicotine replacement may not represent an “easy cure” for nicotine addiction, but it does improve the cessation rate. The evidence suggests that the most of smokers attempting cessation fail at any one attempt or relapse over the next 5 years. Multiple attempts may be needed.

OPTION ACUPUNCTURE FOR SMOKING CESSATION

One systematic review found no significant difference between acupuncture and control in smoking cessation rates at 1 year.

Benefits: We found one systematic review (search date 2002, 22 RCTs, 4158 adults, 330 young people aged 12–18 years) comparing acupuncture with sham acupuncture, other treatment, or no treatment.^[17] Seven RCTs (2701 people) reported abstinence after at least 12 months. The review found no significant difference in smoking cessation with acupuncture compared with control at 12 months (OR 1.08, 95% CI 0.77 to 1.52).

Harms: None reported.

Comment: None.

OPTION PHYSICAL EXERCISE FOR SMOKING CESSATION

One systematic review found limited evidence that physical exercise may increase smoking cessation.

Benefits: We found one systematic review (search date 2002, 8 RCTs)^[18] comparing exercise versus control interventions. Only one of the eight trials found evidence for exercise aiding smoking cessation. However, the trials which did not show a significant effect of exercise on smoking abstinence were too small to exclude reliably an effect of intervention and had numerous methodological limitations. One RCT (281 women) found that three exercise sessions a week for 12 weeks plus a [cognitive behavioural programme](#) improved continuous abstinence from smoking at 12 months compared with the cognitive behavioural programme alone (11.9% with programme plus exercise v 5.4% with programme alone; OR 2.36, 95% CI 0.97 to 5.70).^[19]

Harms: None reported.

Comment: None.

OPTION ANTIDEPRESSANT AND ANXIOLYTIC TREATMENT FOR SMOKING CESSATION

Systematic reviews have found that quit rates are increased by bupropion and nortriptyline given as part of a smoking cessation programme, but not by moclobemide, selective serotonin reuptake inhibitors, or anxiolytics.

Benefits:**Antidepressants:**

We found one systematic review of antidepressants given as part of a smoking cessation programme (search date 2002, 30 RCTs).^[20] Sixteen of the RCTs (7397 people) reported 12 month cessation rates. The review found that bupropion significantly increased quit rates compared with placebo at 6–12 months (data from 10 RCTs with 12 months' follow up plus 6 RCTs with 6 months' follow up; OR of quitting 1.97, 95% CI 1.67 to 2.34).^[20] Two RCTs identified by the review compared bupropion plus a nicotine patch versus patch alone and found different results. One RCT (893 people) found that combined treatment improved cessation compared with patch alone (OR 2.65, 95% CI 1.58 to 4.45). The second RCT (244 people) found no significant difference (OR 0.75, 95% CI 0.59 to 3.00). Five other included RCTs (3 with 6 months' and 2 with 12 months' follow up) found that nortriptyline improved long term (6–12 month) abstinence rates compared with placebo (OR 2.80, 95% CI 1.81 to 4.32). One RCT of moclobemide found no significant difference in abstinence at 12 months. Four included RCTs of selective serotonin reuptake inhibitors found no significant effect (OR 0.97, 95% CI 0.71 to 1.32).

Anxiolytics:

We found one systematic review of anxiolytics (search date 2000, 6 RCTs).^[21] Four of the RCTs (626 people) reporting 12 month cessation rates found no significant increase in abstinence between anxiolytics and control treatment.^[21]

Harms:**Antidepressants:**

Headache, insomnia, and dry mouth were reported in people using bupropion.^[21] Nortriptyline can cause sedation and urinary retention, and can be dangerous in overdose. One large RCT found that discontinuation rates caused by adverse events were 3.8% with placebo, 6.6% for nicotine replacement treatment, 11.9% for bupropion, and 11.4% for bupropion plus nicotine replacement treatment.^[22] Allergic reactions to bupropion have been reported in about 1/1000 people.

Anxiolytics:

Anxiolytics may cause dependence and withdrawal problems, tolerance, paradoxical effects, and impair driving ability.

Comment:

None.

OPTION**ANTISMOKING INTERVENTIONS FOR PREGNANT WOMEN**

Two systematic reviews found that antismoking interventions in pregnant women increased abstinence rates during pregnancy. One RCT found that nicotine patches did not significantly increase quit rates in pregnant women compared with placebo.

Benefits:

We found two systematic reviews^{[23] [24]} and three additional RCTs.^{[25] [26] [27]} The most recent review (search date 1998, 44 RCTs) assessed smoking cessation interventions in pregnancy. It found that smoking cessation programmes improved abstinence (OR of continued smoking in late pregnancy with antismoking programmes v no programmes 0.53, 95% CI 0.47 to 0.60).^[23] The findings were similar if the analysis was restricted to trials in which abstinence was confirmed by means other than self reporting. The review calculated that of 100 smokers attending a first antenatal visit, 10 stopped spontaneously and a further six or seven stopped as the result of a smoking cessation programme. Five included trials examined the effects of interventions to prevent relapse in 800 women who had quit smoking. Collectively, these trials found no evidence that the interventions reduced relapse rate.^[23] One earlier systematic review (search date not reported, 10 RCTs, 4815 pregnant women)^[24] of antismoking interventions included one trial of physician advice, one trial of advice by a health educator, one trial of group sessions, and seven trials of behavioural therapy based on self help manuals. Cessation rates among trials ranged from 1.9–16.7% in the control groups and from 7.1–36.1% in the intervention groups. The review found that antismoking interventions significantly increased the rate of quitting (ARI with intervention v no intervention 7.6%, 95% CI 4.3% to 10.8%).^[24] One additional RCT found that nicotine patches did not significantly alter quit rates in pregnant women compared with placebo.^[25] The second additional RCT (1120 pregnant women) compared a brief (10–15 minute) smoking intervention delivered by trained midwives at booking interviews versus usual care.^[26] It found no significant difference in smoking behaviour between women receiving intervention compared with usual care (abstinence in final 12 weeks of pregnancy until birth 17% in each group; abstinence for 6 months after birth 7% with intervention v 8% with control). The intervention was difficult to implement (see comment below). The third additional RCT compared [motivational interviewing](#) with usual care in 269 women in their 28th week of pregnancy who had smoked in the past month.^[27] It found no significant differences in cessation rate between intervention and control group at 34th week or at 6 months post partum.

Harms:

None reported.

Comment: The recent review found that some women quit smoking before their first antenatal visit, and most of these will remain abstinent.^[23] Recruitment to the RCT comparing midwife delivered intervention versus usual care was slow. Midwives reported that the intervention was difficult to implement because of a lack of time to deliver the intervention at the booking appointment.^[26]

OPTION ANTISMOKING INTERVENTIONS FOR PEOPLE AT HIGH RISK OF DISEASE

Systematic reviews and four subsequent RCTs have found that antismoking advice improves smoking cessation in people at high risk of smoking related disease. We found no evidence that high intensity advice is more effective than low intensity advice in high risk people. One RCT found that bupropion increased cessation rates in smokers with cardiovascular disease.

Benefits: We found no trials in which the same intervention was used in high and low risk people. We found one systematic review (search date not reported, 4 RCTs, 13 208 healthy men at high risk of heart disease),^[24] one systematic review among people admitted to hospital (search date 2002, 17 RCTs),^[28] one systematic review among people with chronic obstructive pulmonary disease (search date 2002, 5 RCTs),^[29] and five subsequent RCTs.^{[30] [31] [32] [33] [34]} The first review found that antismoking advice improved smoking cessation rates compared with control interventions among healthy men at high risk of heart disease (ARI of smoking cessation 21%, 95% CI 10% to 31%; NNT 5, 95% CI 4 to 10).^[24] One early trial (223 men) that was included in the review used non-random allocation after myocardial infarction. The intervention group was given intensive advice by the therapeutic team while in the coronary care unit. The trial found that the self reported cessation rate at 1 year or more was higher in the intervention group than the control group (63% quit in the intervention group v 28% in the control group; ARI of quitting 36%, 95% CI 23% to 48%).^[35] The second review included seven trials (6 of them with at least 12 months' duration) of high intensity behavioural interventions (defined as contact in hospital plus active follow up for at least 1 month) among smokers admitted to hospital. The review found that active intervention increased quit rates compared with usual care (OR 1.82, 95% CI 1.49 to 2.22).^[28] The third review (search date 2002, 2 RCTs reporting cessation rate at greater-than or equal to 12 months) concentrated on smoking cessation among people with chronic obstructive pulmonary disease.^[29] It found that psychosocial interventions plus nicotine replacement therapy plus a bronchodilator significantly increased cessation rates at 5 years compared with no treatment (RR 4.00, 95% CI 3.25 to 4.93). The first subsequent RCT compared postal advice on smoking cessation versus no intervention in men aged 30–45 years with either a history of asbestos exposure, or forced expiratory volume in 1 second in the lowest quartile for their age. Postal advice increased the self reported sustained cessation rate at 1 year compared with no intervention (5.6% with postal advice v 3.5% with no intervention; $P < 0.05$).^[30] The second subsequent RCT (254 smokers admitted to hospital with coronary artery disease) compared a stepped care approach where people who did not quit by the end of each stage received successively more intense interventions (consisting of counselling plus nicotine patch) versus a brief cessation intervention.^[31] It found no significant difference in cessation rates at 1 year (39% with more intensive intervention v 36% with brief intervention; $P = 0.36$). The third subsequent RCT (223 smokers admitted to hospital) compared intensive counselling plus outpatient follow up plus nicotine patches versus minimal counselling plus nicotine patches.^[32] It found no significant difference in cessation rate between intensive and minimal intervention at 12 months (16% with intensive counselling v 9% with minimal counselling; $P = 0.21$). The fourth subsequent RCT (432 people with cancer) compared a brief structured intervention from a physician versus usual care.^[33] It found no significant difference between interventions in cessation rates at 1 year (13.3% with intervention v 13.6% with usual care; $P = 0.52$). The fifth subsequent RCT (629 people with cardiovascular disease) compared sustained release bupropion (150 mg/day increasing to 150 mg twice daily) therapy versus placebo for 7 weeks.^[34] It found that bupropion significantly increased cessation rates at 12 months compared with placebo (22% with bupropion v 9% with placebo; $P < 0.001$).

Harms: The fifth subsequent RCT found that bupropion increased insomnia, dry mouth, and cardiovascular events compared with placebo (insomnia: 24% with bupropion v 12% with placebo; dry mouth: 18% with bupropion v 10% with placebo; cardiovascular events: 7.7% with bupropion v 4.5% with placebo; P value not reported).^[34] The systematic reviews and other RCTs did not report harms.

Comment: There was heterogeneity in the four trials included in the review among healthy men at high risk of heart disease, partly because of a less intense intervention in one trial and the recording of a change from cigarettes to other forms of tobacco as success in another.^[24] One of the included trials was weakened by use of self reported smoking cessation as an outcome and non-random allocation to the intervention.^[35]

OPTION

TRAINING HEALTH PROFESSIONALS TO ENCOURAGE SMOKING CESSATION

One systematic review found that training health professionals increases the frequency of antismoking interventions being offered. It found no good evidence that antismoking interventions are more effective if the health professionals delivering the interventions received training. One RCT found that a structured intervention delivered by trained community pharmacists increased smoking cessation rates compared with usual care delivered by untrained community pharmacists.

Benefits: We found one systematic review^[36] and one subsequent RCT.^[37] The review (search date 2000, 9 RCTs) included eight RCTs of training medical practitioners and one RCT of training dental practitioners to give antismoking advice.^[36] All the trials took place in the USA. The training was provided on a group basis, and variously included lectures, videotapes, role play, and discussion. The importance of setting quit dates and offering follow up was emphasised in most of the training programmes. The review found no good evidence that training health professionals leads to higher quit rates in people receiving antismoking interventions from those professionals, although training increased the frequency with which such interventions were offered. Three of the trials used prompts and reminders to practitioners to deploy smoking cessation techniques, and found that prompts increased the frequency of health professional interventions.^[36] The subsequent RCT compared a structured smoking cessation intervention delivered by community pharmacists, who had received 3 hours of training versus no specific training or antismoking intervention.^[37] Intervention delivered by trained pharmacists improved abstinence compared with usual care (AR of abstinence at 12 months: 14.3% with intervention v 2.7% with usual care; RR 5.3; NNT 9; CI values not reported; P < 0.001).

Harms: None reported.

Comment: The results of the systematic review should be interpreted with caution because there were variations in the way the analysis allowed for the unit of randomisation.

OPTION

COUNSELLING FOR INCREASING PHYSICAL ACTIVITY IN SEDENTARY PEOPLE

We found limited evidence from systematic reviews and subsequent RCTs that counselling sedentary people increased physical activity compared with no intervention. Limited evidence from RCTs suggests that consultation with an exercise specialist rather than or in addition to a physician may increase physical activity at 1 year. We found limited evidence that interventions delivered by new media can lead to short term changes in physical activity.

Benefits: We found three systematic reviews that focused on different types of interventions^[38]^[39]^[40] and nine subsequent RCTs.^[41]^[42]^[43]^[44]^[45]^[46]^[47]^[48]^[49] The first review (search date 1996, 11 RCTs based in the USA, 1699 people) assessed the effect of single factor physical activity promotion on exercise behaviour.^[38] Seven trials evaluated advice to undertake exercise from home (mainly walking, but including jogging and swimming), and six evaluated advice to undertake facility based exercise (including jogging and walking on sports tracks, endurance exercise, games, swimming, and exercise to music classes). An increase in activity in the intervention groups was seen in trials in which home based moderate exercise was encouraged and regular brief follow up of participants was provided. In most of the trials, participants were self selected volunteers, so the effects of the interventions may have been exaggerated. The second systematic review (search date not reported, 3 RCTs, 420 people) compared "lifestyle" physical activity interventions with either standard exercise treatment or a control group.^[39] Lifestyle interventions were defined as those concerned with the daily accumulation of moderate or vigorous exercise as part of everyday life. The first RCT in the review (60 adults, 65–85 years old) found significantly more self reported physical activity in the lifestyle group than a standard exercise group. The second RCT in the review (235 people, 35–60 years old) found no significant difference in physical activity between the groups. The third RCT in the review (125 women, 23–54 years old) of encouraging walking found no significant difference in walking levels at 30 months' follow up between people receiving an 8 week behavioural intervention and those receiving a 5 minute telephone call and written information about the benefits of exercise, although both groups increased walking. The third review (search date 2002, 7 RCTs and 1 quasi-randomised trial, 9054 people) examined the efficacy of exercise counselling from a primary care clinician compared with a control or comparison group.^[40] Counselling was delivered using advice only, the promotion of self efficacy, posted educational materials, referral to community resources, and written exercise prescriptions. The review found equivocal results and at least one methodological limitation in most studies. There was limited evidence that the interventions in these studies led to short term (< 3 months) improvements in physical activity. There were insufficient studies to consider the relationship between the components of the interventions and the reported efficacy. Only two RCTs identified by the review^[40] were rated as good quality.^[50]^[51] The first good quality RCT identified by the review (874 people) compared 3 minutes

of physician advice plus educational materials, all the above plus behavioural counselling plus interactive mail, and all the above plus telephone counselling plus classes.^[50] It found no significant difference in self reported activity between interventions at 24 months. The second good quality RCT identified by the review (355 sedentary people) compared a brief 5 minute message, a prescription for exercise, and a follow up visit with usual care.^[51] It found no significant difference in the proportion of people meeting the Healthy People 2010 goal after 8 months (28% with advice or prescription v 23% with usual care; difference +5%, 95% CI -6% to +14%). All but two of the subsequent trials^{[47] [49]} involved primary care delivered interventions, although they were not restricted to clinician led interventions.^{[41] [42] [43] [44] [45] [46]} Two of the three trials in which advice was delivered by an exercise specialist rather than a physician found significant improvement in self reported physical activity at long term (> 6 months) follow up compared with controls.^{[43] [44]} A third RCT (1658 people in a primary care setting), which compared a client centred, negotiating style to direct advice and a no intervention control group, did not find any significant difference in changes in physical activity.^[46] One cluster RCT (878 people from 42 rural and urban general practices) compared clinician advice plus a written "green" exercise prescription and up to three 10–20 minute telephone calls from an exercise specialist over 3 months versus usual care.^[48] Clinicians in the intervention practices were offered training in **motivational interviewing** and interviews averaged 7 minutes of general practitioner time or 13 minutes of nurse time. The physical activity goals in the "green" exercise prescription were tailored to the individual but typically involved home based physical activity or walking. It found that the intervention significantly increased physical activity at 12 months compared with usual care (leisure exercise per week: 55 minutes with intervention v 17 minutes with usual care; difference: 33.6 minutes, 95% CI 2.4 minutes to 64.2 minutes). Short term improvement was found in two further trials, but not maintained at 9 months or 1 year.^{[41] [42]} One RCT (298 people) compared physical activity counselling with nutrition counselling, both delivered with automated telephone conversations using digitised human speech.^[47] The system used information about current behaviour and some known determinants to counsel people on either physical activity or nutrition. The percentage of individuals meeting current physical activity recommendations at 3 months' follow up was significantly greater in the physical activity group compared with the nutrition group at 3 months. However, there was no significant difference at 6 months (3 months: 26% with activity counselling v 19.6% with dietary counselling; P = 0.04). One RCT (229 women) of encouraging women to increase walking found significantly increased walking in the intervention group at 10 years' follow up (86% of women available for follow up, median estimated calorie expenditure from self reported amount of walking 1344 kcal/week with encouragement v 924 kcal/week with no encouragement; P = 0.01).^[52] A further RCT (260 people in a primary care setting) compared the additional offer of community walks (led by lay people) versus advice alone.^[45] It found no significant difference in physical activity at 12 months' follow up (ARR for achieving at least 120 minutes of moderate intensity activity a week +6%, 95% CI -5% to +16.4%). One RCT (299 office based civil servants) in a workplace setting compared individual counselling tailored according to the workers' stage of change (7 sessions of 20 minutes each) versus written information on lifestyle.^[49] It found that the intervention significantly increased energy expenditure and cardiorespiratory fitness at 9 months compared with information only (difference in energy expenditure: 176.2 kcal/day, 95% CI 60.6 kcal/day to 291.8 kcal/day; difference in submaximal heart rate: -4.7 beats/minute, 95% CI -7.4 beats/minute to -2.05 beats/minute).^[14] It found no significant difference in the proportion of people meeting criteria for moderate intensity physical activity (OR 1.46, 95% CI 0.76 to 2.79).

Harms: Insufficient detail is available from these studies to judge the potential harm of exercise counselling. In the RCT comparing behavioural counselling with brief advice identified by the third systematic review,^[40] 60% of participants experienced a musculoskeletal event during the 2 years of the study.^[50] About half of these required a visit to the physician. About 5% of all participants were admitted to hospital for a suspected cardiovascular event. The trial lacked a non-intervention control group. We found no evidence that counselling people to increase activity levels increased adverse events compared with no counselling.

Comment: Self reporting of effects by people in a trial, especially where blinding to interventions is not possible (as is the case with advice or encouragement), is a potential source of bias. Few studies conduct intention to treat analyses, which may lead to an exaggeration of the true effect of interventions. Methodological problems in RCTs included in the third review included only moderate follow up rates, highly motivated providers, differences in physical activity levels at baseline between intervention groups, uncertain or low provided adherence, inclusion of some counselling advice in usual care control groups, and inadequate power to detect a clinically important difference.^[40]

OPTION**EXERCISE ADVICE IN WOMEN AGED OVER 80 YEARS**

One RCT found that exercise advice increased physical activity in women aged over 80 years and decreased the risk of falling.

Benefits: We found no systematic review. One RCT (233 women > 80 years old, conducted in New Zealand) compared four visits from a physiotherapist who advised a course of 30 minutes of home based exercises three times a week that was appropriate for the individual versus a similar number of social visits.^[53] After 1 year, women who had received physiotherapist visits were significantly more active than women in the control group, and 42% were still completing the recommended exercise programme at least three times a week. The mean annual rate of falls in the intervention group was 0.87 compared with 1.34 in the control group, a difference of 0.47 falls a year (95% CI 0.04 falls/year to 0.90 falls/year).

Harms: No additional harms in the intervention group were reported.

Comment: None.

OPTION ADVICE ON A CHOLESTEROL LOWERING DIET

Systematic reviews have found that advice on eating a cholesterol lowering diet (i.e. advice to reduce fat intake or increase the polyunsaturated : saturated fatty acid ratio in the diet) leads to a small reduction in blood cholesterol concentrations in the long term (greater-than or equal to 6 months).

Benefits: **Effects on blood cholesterol:** We found three systematic reviews^{[16] [54] [55]} and two subsequent RCTs^{[56] [57]} that reported biochemical rather than clinical end points. None of the reviews included evidence after 1996. One review (search date 1993) identified five trials of cholesterol lowering dietary advice (principally advice from nutritionists or specially trained counsellors) with follow up for 9–18 months.^[54] It found a mean reduction in blood cholesterol concentration in the intervention group of 0.22 mmol/L (95% CI 0.05 mmol/L to 0.39 mmol/L) compared with the control group. There was significant heterogeneity ($P < 0.02$), with two outlying studies — one showing no effect and one showing a larger effect. This review excluded trials in people at high risk of heart disease. Another systematic review (search date 1994) identified 13 trials of more than 6 months' duration and included people at high risk of heart disease.^[16] It found that dietary advice reduced blood cholesterol (mean reduction in blood cholesterol concentration with advice 4.5%, 95% CI 3.9% to 5.1%; given a mean baseline cholesterol of 6.3 mmol/L, mean AR about 0.3 mmol/L). The third systematic review (search date 1996, 1 trial,^[58] 76 people) found no significant difference between brief versus intensive advice from a general practitioner and dietician on blood cholesterol at 1 year.^[55] The first subsequent RCT (186 men and women at high risk of coronary heart disease) compared advice on healthy eating versus no intervention. At 1 year it found no significant differences between groups in total and low density lipoprotein cholesterol concentrations for either sex, even though the reported percentage of energy from fat consumed by both women and men in the advice group decreased significantly compared with that reported by the women and men in the control group.^[56] These results may reflect bias caused by self reporting of dietary intake. The second RCT, in 531 men with hypercholesterolaemia (with and without other hyperlipidaemias) and fat intake of about 35%, compared dietary advice aimed at reducing fat intake to 30% versus 26% versus 22%. All interventions were similarly effective for reducing fat intake (total fat intake after intervention about 26% in all groups).^[57]

Effects on clinical outcomes:

We found two systematic reviews that reported on morbidity and mortality.^{[16] [59]} The first review (search date 1994) compared 13 separate and single dietary interventions.^[16] It found no significant effect of dietary interventions on total mortality or coronary heart disease mortality (total mortality: OR 0.93, 95% CI 0.84 to 1.03; coronary heart disease mortality: OR 0.93, 95% CI 0.82 to 1.06). However, it found a reduction in non-fatal myocardial infarction (OR 0.77, 95% CI 0.67 to 0.90). The second review (search date 1999, 27 studies including 40 intervention arms, 30 901 person years) found dietary advice to reduce or modify dietary fat had no significant effect on total mortality or cardiovascular disease mortality compared with no dietary advice (total mortality: HR 0.98, 95% CI 0.86 to 1.12; cardiovascular disease mortality: HR 0.98, 95% CI 0.77 to 1.07). However, dietary advice significantly reduced cardiovascular disease events (HR 0.84, 95% CI 0.72 to 0.99).^[59] RCTs in which people were followed for more than 2 years showed significant reductions in the rate of cardiovascular disease events. The relative protection from cardiovascular disease events was similar in both high and low risk groups, but was significant only in high risk groups.

Harms: We found no evidence about harms.

Comment: The finding of a 0.2–0.3 mmol/L reduction in blood cholesterol in the two systematic reviews accords with the findings of a meta-analysis of the plasma lipid response to changes in dietary fat and cholesterol.^[60] The analysis included data from 244 published studies (trial duration 1 day to 6 years), and concluded that adherence to dietary recommendations (30% energy from fat, < 10%

saturated fat, and < 300 mg cholesterol/day) compared with average US dietary intake would reduce blood cholesterol by about 5%.

OPTION ADVICE ON REDUCING SODIUM INTAKE

One systematic review found that, compared with usual care, intensive interventions to reduce sodium intake provided small reductions in blood pressure, however effects on deaths and cardiovascular events are unclear.

Benefits: We found one systematic review (search date not reported).^[61] The review identified three RCTs in 2326 normotensive people, five RCTs in 387 people with untreated hypertension, and three RCTs in 801 people with treated hypertension.^[61] Follow up ranged from 6 months to 7 years. The large, high quality RCTs compared intensive behavioural interventions aimed at reducing salt intake (including comprehensive dietary and behaviour change programmes, group counselling sessions, newsletters, self assessment, goal setting, food tasting, and recipes) versus control interventions that did not promote salt reduction. In the included RCTs, outcomes were inconsistently defined and reported. Overall, the RCTs reported no significant difference in mortality between low salt and usual diet (4 RCTs; AR 8/1151 [0.69%] with low sodium v 9/1242 [0.72%] with control; P = 0.8). The review found no significant difference in cardiovascular events between low sodium diet and usual diet (2 RCTs; AR 42/374 [11.2%] with low sodium v 51/374 [13.6%] with usual diet; P = 0.3). It found that advice to reduce salt intake significantly reduced systolic blood pressure and reduced diastolic blood pressure at 13–60 months compared with control, although the reduction in diastolic pressure was not statistically significant (4 RCTs, 2347 people; reduction in systolic blood pressure: 1.1 mm Hg, 95% CI 1.8 mm Hg to 0.4 mm Hg; reduction in diastolic blood pressure: +0.6 mm Hg, 95% CI +1.5 mm Hg to -0.3 mm Hg). The degree of reduction in sodium intake was not related to change in blood pressure. The review found no significant difference between treatments for systolic or diastolic blood pressure at 7 years but may have lacked power to detect a clinically important difference (1 RCT, 128 normotensive people, change in systolic blood pressure: -1.6 mm Hg with low salt diet v +2.20 mm Hg with usual diet; P = 0.07; change in diastolic blood pressure: -7.5 mm Hg with low salt diet v -5.3 mm Hg with usual diet; P = 0.1). One large RCT identified by the review found that low salt diet advice significantly improved maintenance of blood pressure control after antihypertensive treatment medications were stopped compared with usual diet (1 RCT, 975 people, combined outcome of high blood pressure or restarting treatment or clinical cardiovascular event: RR 0.83, 95% CI 0.75 to 0.92).

Harms: None reported.

Comment: None.

OPTION LIFESTYLE INTERVENTIONS FOR SUSTAINED WEIGHT LOSS

Two large RCTs found that weight loss advice resulted in greater weight loss than no advice. One RCT found that cognitive behavioural therapy was more effective than usual care in promoting weight loss. Systematic reviews found that using behavioural therapy to support advice on diet and exercise is probably more effective in achieving weight loss than diet advice alone. One systematic review found limited evidence that partial meal replacement plans reduced weight loss at 1 year compared with reduced calorie diet in people who completed the treatment.

Benefits: We found four systematic reviews^{[62] [63] [64] [65]} and 21 additional RCTs, p 16.^{[66] [67] [68] [69] [70] [71] [72] [73] [74] [75] [76] [77] [78] [79] [80] [81] [82] [83] [84] [85] [86]} The first systematic review (search date 1995) identified one relevant RCT that found that the combination of diet and exercise in conjunction with behavioural therapy produced significantly greater weight loss than diet alone at 1 year (mean weight loss: 7.9 kg with diet plus exercise plus behavioural therapy v 3.8 kg with diet alone; significance result not reported).^[62] The second systematic review (search date 1997, 3 RCTs) found that diet supported by behavioural therapy was more effective than diet alone at 1 year.^[63] The third systematic review of the detection, prevention, and treatment of obesity (search date 1999) included eight RCTs comparing dietary prescriptions versus exercise, counselling, or behavioural therapy for the treatment of obesity, and three RCTs comparing dietary counselling alone versus no intervention. In both comparisons, initial weight loss was followed by gradual weight regain once treatment had stopped (mean difference in weight change at least 2 years after baseline, 2–6 kg with dietary prescription v 2–4 kg with dietary counselling).^[64] The fourth systematic review (search date 2001, 6 RCTs, 487 people, 75% women, 24% with diabetes) found that **partial meal replacement plans** significantly increased weight loss at 1 year compared with a reduced calorie diet (weight loss for 219 completers, fixed effects model: 7.31 kg with **partial meal** v 2.61 kg with reduced calorie; P = 0.001).^[65] However, results should be interpreted with caution, because of the high rate of withdrawal (47% with partial meal v 64 % with reduced calorie; P for difference = 0.001) and significant heterogeneity among RCTs (P less-than or equal to 0.005).

The additional RCTs are summarised in [table 1, p 16](#). Two large RCTs found that weight loss advice resulted in greater weight loss than no advice. ^[66] ^[79] One RCT found that cognitive behavioural therapy significantly increased weight loss compared with usual care at 1 year. ^[85] The heterogeneity of interventions used in the additional RCTs makes comparison of trials difficult, but no major differences were found among the various weight loss programmes.

Harms: The systematic reviews and RCTs provided no evidence about harms.

Comment: In one RCT (78 obese women), the withdrawal rate for a diet programme was 41% compared with 8% in a non-diet control. ^[73]

OPTION LIFESTYLE INTERVENTIONS FOR MAINTAINING WEIGHT LOSS

One systematic review and additional RCTs found that most types of maintenance strategy result in smaller weight gains or greater weight losses compared with no contact. Strategies that involve personal contact with a therapist, family support, walking training programmes, or multiple interventions, or are weight focused, seem most effective.

Benefits: We found one systematic review ^[63] and nine additional RCTs. ^[87] ^[88] ^[89] ^[90] ^[91] ^[92] ^[93] ^[94] ^[95] The systematic review (search date 1995, 21 studies) compared different types and combinations of interventions. It found that increased contact with a therapist in the long term produced smaller weight gain or greater weight loss, and that additional self help peer groups, self management techniques, or involvement of the family or spouse may increase weight loss. The largest weight loss was seen in programmes using multiple strategies. Two additional small RCTs (102 people ^[87] and 100 people in two trials ^[91]) assessed simple strategies without face to face contact with a therapist. Frequent telephone contacts, optional food provision, continued self monitoring, urge control, or relapse prevention did not reduce the rate of weight regain. One small RCT (117 people) found that telephone contacts plus house visits did reduce the rate of weight regain compared with no intervention (3.65 kg with telephone contacts plus house visits v 6.42 kg with no intervention; $P = 0.048$). ^[88] One further small RCT (80 obese women) found no difference in weight change at 1 year between participants offered relapse prevention training or problem solving compared with no further contact. ^[93] One RCT (82 women) compared two walking programmes (4.2 or 8.4 MJ/week) plus diet counselling versus diet counselling alone after a 12 week intensive weight reduction programme. ^[92] Both walking programmes reduced weight regain at 1 year (reduction in weight gain compared with dietary counselling alone 2.7 kg, 95% CI 0.2 kg to 5.2 kg with low intensity programme and 2.6 kg, 95% CI 0 kg to 5.1 kg with high intensity programme). At 2 years, weight regain was not significantly different between high intensity programme and control, but was reduced in the low intensity group (reduction in weight gain 3.5 kg, 95% CI 0.2 kg to 6.8 kg with low intensity programme and +0.2 kg, 95% CI -3.1 kg to +3.6 kg with high intensity programme). One additional small RCT (67 people) found that people on a weight focused programme maintained weight loss better than those on an exercise focused programme (weight gain 0.8 kg with weight focused programme v 4.4 kg with exercise focused programme; $P < 0.01$). ^[89] One 5 year RCT (489 menopausal women) compared behavioural intervention in two phases aimed at lifestyle changes in diet and physical activity with lifestyle assessment. People in the intervention group were encouraged to lose weight during the first 6 months (phase I), and thereafter maintain this weight loss for a further 12 months (phase II). The intervention resulted in weight loss compared with control during the first 6 months (-8.9 lb [-4.0 kg] with intervention v -0.8 lb [-0.4 kg] with control; $P < 0.05$), most of which was sustained over phase II (-6.7 lb [-3.0 kg] with intervention v -0.6 lb [-0.3 kg] with control; $P < 0.05$). ^[90] One RCT (90 obese men) compared the effects of walking, resistance training of moderate dose at 6 months, and no increase in exercise control after a 2 month weight loss programme with a very low energy diet. ^[95] It found no significant difference in long term weight maintenance between walking and resistance training programmes and control at 23 months (adjusted mean difference in weight compared with control: +0.8 kg with walking, 95% CI -4.0 kg to +5.6 kg v -0.5 kg with resistance, 95% CI -5.0 kg to +4.0 kg; P between interventions = 0.8). There was poor adherence to prescribed exercise (82% with walking v 66% with resistance). ^[95] One RCT (122 overweight men and women, 101 analyzed) compared the effects of a weight maintenance programme conducted in person (frequent support or minimal support) or over the Internet for 1 year, after a 6 month weight loss programme. ^[94] It found significantly less weight loss with Internet support compared with in person support (weight loss: -5.7 kg with Internet support v -10.4 kg with minimal in person support v -10.4 kg with frequent in person support; $P < 0.05$). ^[94]

Harms: We found no direct evidence that interventions designed to maintain weight loss are harmful.

Comment: Weight regain is common. The resource implication of providing long term maintenance of any weight loss may be a barrier to the routine implementation of maintenance programmes. One RCT

(122 obese people) comparing in person and Internet support for weight maintenance, found attrition rates of 18% after 6 months and 24% after 18 months.^[94]

OPTION LIFESTYLE ADVICE TO PREVENT WEIGHT GAIN

One small RCT found that low intensity education plus a financial incentive increased weight loss compared with no treatment. A second RCT found no significant effect on prevention of weight gain from a postal newsletter with or without a linked financial incentive compared with no contact. One RCT found that a lifestyle advice prevented weight gain in perimenopausal women compared with assessment alone. One small RCT comparing a nutrition course for female students with no nutrition course found no significant increase in weight from baseline in either group at 1 year.

Benefits: We found three systematic reviews (search dates 1995,^[62] 1999,^[63] and not reported^[96]) that included the same two RCTs^[97] ^[98] and two subsequent RCTs.^[99] ^[100] The first RCT (219 people) compared low intensity education with a financial incentive to maintain weight versus an untreated control group. It found significantly greater average weight loss in the intervention group than in the control group (−0.95 kg with intervention v −0.14 kg with control; P = 0.03).^[97] The second RCT (228 men and 998 women) compared a monthly newsletter versus the newsletter plus a lottery incentive versus no contact. There was no significant difference in weight gain after 3 years between the groups (1.6 kg with newsletter v 1.5 kg with newsletter plus lottery incentive v 1.8 kg with no contact).^[98] The first subsequent RCT (535 perimenopausal women) found that lifestyle advice reduced weight gain over 2 years compared with assessment alone (weight gain 0.5 kg with advice v 11.5 kg with assessment alone).^[99] The second small subsequent RCT (40 female students, 33 analyzed) compared the effects of a one semester nutrition course (4 months) with no such course.^[100] It found no significant change from mean baseline weight in either group 1 year after the end of intervention (66.7 kg at baseline to 67.7 kg at 1 year with course v 65.7 kg at baseline to 68.9 kg at 1 year with no course).

Harms: None reported.

Comment: None.

OPTION TRAINING HEALTH PROFESSIONALS IN PROMOTING WEIGHT LOSS

One systematic review of poor quality RCTs provided insufficient evidence on the sustained effect of interventions to improve health professionals' management of obesity. One subsequent cluster RCT found limited evidence that training for primary care doctors in nutrition counselling plus a support programme reduced body weight of the people in their care over 1 year compared with usual care.

Benefits: We found one systematic review (search date 2000, 18 RCTs, 8 with follow up > 1 year)^[101] and one subsequent cluster RCT.^[102] The studies in the review were heterogeneous and poor quality.^[101] The subsequent cluster RCT (1162 people registered with 45 primary care doctors) compared nutrition counselling training plus a support programme for primary care doctors versus usual care (see comment below).^[102] The nutrition supported intervention compared with usual care increased weight loss at 1 year (additional weight loss 2.3 kg; P < 0.001).

Harms: None reported.

Comment: In the subsequent RCT, the doctors were randomly allocated to training but the analysis of results was based on the people in the care of those doctors.^[102] No allowance was made for cluster bias. This increases the likelihood that the additional weight loss could have occurred by chance.

GLOSSARY

Cognitive behavioural programme Traditional cognitive behavioural topics (e.g. self monitoring, stimulus control, coping with cravings and high risk situations, stress management, and relaxation techniques) along with topics of particular importance to women (e.g. healthy eating, weight management, mood management, and managing work and family).

Motivational interviewing A goal directed counselling style that helps participants to understand and resolve areas of ambivalence that impede behavioural change.

Partial meal replacement plan A programme that prescribes a low energy (between 800–1600 kcal/day) diet, where one or two daily meals are replaced by commercially available, energy reduced products that are fortified with vitamins and minerals, and remaining meals consist of normal food.

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TABLE 1 RCTs examining lifestyle interventions to achieve sustained weight loss.

Reference	Participants	Interventions	Results
[66]	585 overweight and hypertensive elderly people (subgroup analysis)	Weight loss advice v no weight loss advice	Weight loss advice reduced body weight more than no weight loss advice, but significance not reported (weight change at 30 months: -4.7 kg with weight loss programme v -0.9 kg with no weight loss programme)
[67]	154 non-diabetic people who were 30–100% overweight, with family history of diabetes	Compared 4 treatments for 2 years: diet (reduced calories and fat), exercise, diet + exercise, and no treatment	No significant difference between treatments at 2 years for weight change (-2.1 kg with diet v +1.0 kg with exercise v -2.5 kg with diet + exercise v -0.3 kg with no treatment; P value not reported)
[68]	40 obese women aged 21–60 years, BMI 32.9 kg/m ²	16 week treatment programme: diet + lifestyle advice (advice to increase activity) v diet + aerobics (3 classes/week)	83% completed; no significant difference in weight regain 1 year after treatment (1.6 kg with aerobic v 0.08 kg with lifestyle; P = 0.06)
[69]	148 sedentary overweight women	Compared 3 behavioural weight control programmes: LB exercise, SB exercise, and SBEQ programme	78% completed 18 month programme; SBEQ significantly increased weight loss compared with SB (7.4 kg with SBEQ v 3.7 kg with SB; P < 0.05). No significant difference between weight loss with LB (5.8 kg) and either SB or SBEQ
[70]	24 obese women	Behavioural choice therapy v SBT	Behavioural choice therapy increased weight loss at 12 months compared with OFF (10.1 kg with behavioural choice therapy v 4.3 kg with SBT; P < 0.01)
[71]	80 obese non-smoking people aged 25–45 years, 120–140% ideal body weight	Energy restricted diet v fat restricted diet	Energy restricted diet significantly increased weight loss compared with fat restricted diet at 6 and 18 months (at 6 months: 11.2 kg with energy restricted diet v 6.1 kg with fat restricted diet; P < 0.001; at 18 months: 7.5 kg with energy restricted diet v 1.8 kg with fat restricted diet; P < 0.001)
[72]	166 people	SBT + support from friends v SBT without support	No additional weight loss at 16 months with social support from friends (4.7 kg with behavioural therapy + support v 3.0 kg with behavioural therapy without support; P > 0.05)
[73]	193 obese men and women	5 treatments compared: SBT, SW, SBT + SW, SBT + SW + PT, SBT + SW + PT + I	No significant difference between treatments in weight loss at 18 months (7.6 kg with SBT v 3.8 kg with SW v 2.9 kg with SBT + SW v 4.5 kg with SBT + SW + PT v 5.1 kg with SBT + SW + PT + I)
[74]	42 moderately obese young women, age 18–30 years, 6.8–20.5 kg overweight	3 12 week treatments compared: standard behaviour intervention (weekly meetings + exercise contracting), intensive intervention (weekly meetings + supervised exercise sessions 3 times/week), minimal contact intervention (written lessons with feedback)	38 completers analyzed. Intensive intervention significantly increased weight loss at 1 year compared with standard behaviour intervention or minimal contact (4.6 kg with supervised exercise v 4.3 kg with contracted exercise v 4.2 kg with minimal contact; P < 0.05)
[75]	22 sedentary moderately obese women	Continuous exercise (supervised exercise 30 minutes 3 times/week) v intermittent exercise (advice to walk briskly, twice daily for 15 minutes/session)	Continuous exercise reduced weight at 16 months but the reduction was not significant (from 81.4 kg to 79.7 kg with continuous v from 85.6 kg to 85 kg with intermittent; P value not reported)
[76]	76 women, 58 analyzed	Cognitive behavioural programme (10 weeks) v modified cognitive behavioural programme (10 weeks)	No significant difference between programmes after 1 year follow up (weight loss: 2.1 kg with modified programme v 3.8 kg with standard programme; P value not reported)
[77] (Study 1)	25 people with type 2 diabetes	Diet + moderate exercise for 10 weeks v diet alone	19 people analyzed. No significant difference in weight loss at year (7.8 kg with diet + exercise v 4.0 kg with diet alone; P > 0.10)
[77] (Study 2)	30 people with type 2 diabetes	Diet + more intensive exercise for 10 weeks v diet alone	Diet + intensive exercise significantly increased weight loss compared with diet alone at 1 year (from 104 kg to 96.2 kg with intensive exercise v from 102 kg to 98.2 kg with diet alone; P = 0.01)
[78]	65 obese men and women	Body image treatment + dietician led treatment v dietician led treatment alone	No significant difference in weight loss between treatments at 1 year (4.96% with body image + dietician led v 5.90% with dietician led alone; P value not reported)
[79]	1191 overweight and hypertensive people	Weight loss advice v no weight loss advice	Weight loss advice significantly reduced weight and hypertension more than no weight loss advice at 3 years (weight change at 3 years: -0.2 kg with advice v +1.8 kg with control; RR for hypertension with advice v control 0.81, 95% CI 0.70 to 0.95)

Reference	Participants	Interventions	Results
[79]	588 overweight people	Compared 3 different cognitive behavioural approaches for tailoring lifestyle modification goals to the individual: workbook alone (no tailoring), workbook + computerised tailoring (using computer kiosks with touch screen monitors), workbook + computerised tailoring + personal tailoring (staff consultation)	After 12 months, mean weight loss from baseline was significant in all groups. Combined computerised + personal tailoring significantly improved weight loss compared with workbook alone (mean weight loss: 1 kg with workbook v 2.1 kg with computerised tailoring v 3.3 kg with personal + computerised tailoring; P = 0.02 for workbook v combined group)
[81]	78 obese women, described as "chronic dieters"	24 week "non-diet" wellness programme v traditional "weight loss" programme	Weight loss programme significantly increased weight loss compared with non-diet programme at 1 year (from 101.1 kg to 95.2 kg with diet v from 99.6 kg to 99.9 kg with non-diet; P < 0.001)
[82]	101 obese men and women	Moderate fat (based on the Mediterranean diet), low energy diet v low fat, low energy diet	Moderate fat diet increased weight loss compared with low fat diet after 18 months (mean weight change: -4.1 kg with moderate fat/low energy diet v +2.9 kg with low energy/low fat diet; difference in weight change 7.0 kg, 95% CI 5.3 kg to 8.7 kg)
[83]	120 premenopausal obese women	Advice to eat a low energy Mediterranean style diet v advice on healthy food choices. Both groups advised to increase their levels of physical activity	Low energy Mediterranean style diet advice increased weight loss compared with healthy food choice advice at 2 years (difference -11 kg, 95% CI -14 kg to -8 kg, intention to treat analysis)
[84]	423 moderately overweight people	Commercial weight loss programme v self help group	Commercial weight loss programme significantly reduced weight compared with self help at 2 years (weight change: -2.9 kg with commercial programme v + 0.2 kg with self help; P < 0.001, intention to treat analysis). Withdrawal rate was similar between groups (29% with commercial programme v 25% with self help)
[85]	122 people treated in general practice	CBT (16 sessions of about 90 minutes each) v usual care	CBT group significantly increased weight loss compared with usual care at 1 year (1.8 kg with CBT v 0.2 kg with usual care; P < 0.001). Withdrawal rate was similar with both treatments (23% with CBT v 29% with usual care)
[86]	92 obese people	Internet based weight loss programme + email based behavioural counselling v Internet-based weight loss programme alone	Combined intervention significantly increased weight loss compared with Internet-based programme alone at 1 year (4.4 kg with combined v 2.0 kg with Internet programme alone; P = 0.04, intention to treat analysis)

BMI, body mass index; CBT, cognitive behavioural therapy; I, monetary incentives; LB, long bout; PT, personal trainer; SB, short bout; SBEQ, short bout exercise plus home exercise equipment; SBT, standard behavioural therapy; SW, supervised walks