EVIDENCE SUMMARY TABLE 3a: INTERVENTIONS TO PREVENT WEIGHT GAIN, IMPROVE BEHAVIOURS ASSOCIATED WITH THE MAINTENANCE OF A HEALTHY WEIGHT, IMPROVE DIET AND INCREASE ACTIVITY LEVELS IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (MENOPAUSE)

SUMMARY

One systematic review of 18 RCTs assessed the effect of exercise (walking, other aerobic training, resistance training, strength training with weights machines or combinations) in postmenopausal women. One RCT was included that aimed to prevent excessive weight gain during the menopause, with the full anthropometric results at 54 months published in 2003. The study was conducted in Pittsburgh and followed women from pre-menopause for 54 months when 35% of the women had become postmenopausal. The aim of the intervention was to provide modest weight loss to keep the women at their baseline weight by the end of the study. The study reported changes in weight, BMI, % body fat, % fat-free mass, PA and energy intake. The intervention included 1300 kcal (5.44 MJ)/day (25% of energy from total fat, 7% of energy from saturated fat and 100 mg cholesterol), PA expenditure of 1000–1500 kcal (4.19–6.28 MJ)/week (mainly through increasing walking and lifestyle activities) other lipid-lowering dietary strategies, i.e. increasing soya protein, fruits and vegetables and fibre if necessary; provided in a cognitive-behavioural programme and compared with an assessment-only control.

In the study, women were predominantly White, college-educated and employed full-time. 53.6% were of normal weight at baseline and all women were healthy with average risk factor levels. Mean age was 47 years and mean BMI was 25 kg/m^2. Women ($n = 535$) were randomised and the study was adequately powered to detect statistically significant differences in outcomes, with only 5% dropout and an ITT analysis.

Evidence of efficacy for weight management/reduction

In the systematic review, weight and body fat were studied in 18 studies with 1804 subjects. Body composition was improved in nine studies and most studies showed a small loss of body weight and fat. The effect seemed to be optimal when combining exercise with a weight-reducing diet. The most effective results were accomplished in three studies with overweight participants who used weight-reducing diets in combination with exercise training. The mean weight loss ranged was 2–10 kg in 12 weeks to 1 year.

At 54 months 55% of the intervention women were at or below their baseline weight compared with 26% in the control.

Mean weight change (kg) at 54 months was also significant between groups (–0.1 [SD 5.2] intervention vs. +2.4 [SD 4.9] control. There was a significant reduction in waist circumference (cm) at 54 months compared with control (–2.9 [SD 5.3] vs. –0.5 [SD 5.6], $p < 0.001$). There was a significant reduction in BMI (kg/m^2) in intervention women compared with control at 54 months (0.05 [SD 2.0] vs. 0.96 [SD 1.8], $p < 0.001$). Change in % body fat was also significantly reduced in the intervention group compared with control at 54 months (–0.5 [SD 4.1] vs. 1.1 [SD 3.9], $p < 0.01$). Fat-free mass (kg) was also significantly reduced in the intervention group compared with control at 54 months (0.0 [SD 1.9] vs. 0.5 [SD 2.1], $p < 0.05$).

Evidence of efficacy for diet/physical activity outcomes

In the systematic review the most effective exercise prescription for losing body fat was 30–60 min of walking or other aerobic training at 45–75% VO_{2max} on 3–5 days per week for 15 weeks to 1 year, or strength training with weight machines, five exercises with 80% of one repetition maximum with eight repetitions and three sets twice a week for 1 year.

Energy intake (kcal/day) was significantly reduced in the intervention group compared with control at 54 months (–160 [SD 465] vs. –25 [SD 560] [–0.67 {SD 1.95} vs. –0.10 {SD 2.34} MJ/day], $p < 0.01$). The intervention group reported eating significantly less dietary fat and cholesterol than controls.

There was a significant increase in the amount of energy expended through physical exercise (kcal/day) in the intervention group compared with controls at 54 months (275 [SD 1173] vs. –113 [SD 1261] [1.15 {SD 4.91} vs. –0.447 {SD 5.28} MJ/day], $p < 0.001$) (blocks walked (*no further details reported)* (kcal/ 188 [SD 615] vs. –83 [SD 611] kcal/day [0.79 {SD 2.57} vs. –0.35 {SD 2.56} MJ/day], $p < 0.001$). There was no significant difference between the groups in terms of energy expended through sport and recreational activity (kcal/day) (intervention vs. control): 57 (SD 1023) vs. –47 (SD 1104) (0.24 [SD 4.28] vs. –0.20 [SD 4.62] MJ/day). There was a significant increase in the intervention group (counts/hour of activity) when measured with the activity monitor at 54 months compared with control (2.3 [SD 9.1] vs. –0.26 [SD 7.8], $p < 0.01$).

Evidence of corroboration in the UK
Evidence of corroboration was limited. Although none of the identified RCTs focussing on pregnancy, menopause or smoking cessation were UK-based, it is likely that the findings are applicable to the UK population.

Cost-effectiveness data
No cost-effectiveness data were reported.

EVIDENCE TABLE 3a: INTERVENTIONS TO PREVENT WEIGHT GAIN IN INDIVIDUALS AT VULNERABLE LIFE-STAGES (MENOPAUSE)

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/ Comments
Asikainen et al. (2004) Systematic Review (RCTs with >25 subjects and <35% attrition) 1++	All the subjects used in the studies were postmenopausal women aged 50–65 years. If a study had younger or older women then it was accepted providing the mean age was in the range of 50–65 years. Subjects had either been selected either on a voluntary basis or from a population-based sample. All subjects were sedentary at baseline or had some leisure PA that was kept constant during the study. Healthy women were accepted as well as subjects with diseases or risk factors such as dyslipidaemia, hypertension, obesity or osteoporosis. Hormone replacement therapy (HRT) and other medications were allowed.	To evaluate data from RCTs on exercise training studies with special reference to improving health in early postmenopausal women. Walking, other aerobic training, resistance training, strength training with weights machines or combinations of these were used. Exercise could be in addition to diet. Minimum 8 weeks. No further details on length of follow-up	Weight and body fat were studied in 18 studies with 1804 subjects. Body composition was improved in nine studies. Most studies showed a small loss of body weight and fat. The effect seems to be optimal when combining exercise with a weight reducing diet. The most effective results were accomplished in three studies with overweight participants who used weight-reducing diets in combination with exercise training. The mean weight loss ranged from 2 to 10 kg in 12 weeks to 1 year. The most effective exercise prescription for losing body fat was 30–60 min of walking or other aerobic training at 45–75% VO_{2max} on 3–5 days per week for 15 weeks to 1 year, or strength training with weight machines, five exercises with 80% of one repetition maximum with eight repetitions and three sets twice per week for 1 year.	Training programmes were relatively short in duration. VO_{2max} and muscular strength also reported in paper but not extracted for this review.
Simkin-Silverman et al.	**Eligibility criteria:** **Inclusion:**	**Intervention:** **Phase 1:** Cognitive-	**Lost to follow-up:** Intervention: n = 14	Some activity self-reported as

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/ Comments
2003 RCT 1++ **Aim:** To test whether an intensive behavioural lifestyle intervention aimed at dietary and PA behaviour could prevent: 1) menopausal-related increases in LDL-cholesterol: and 2) weight gain NB. This is the only one RCT that met the criteria for inclusion.	Women aged 44–50 years who by self-report were pre-menopausal and not taking HRT, BMI 20–34 kg/m^2, fasting total cholesterol 140–260 mg/dl, fasting LDL-cholesterol 80–160 mg/dl, fasting glucose levels >140 mg/dl, diastolic blood pressure >95 mmHg **Exclusion:** Women taking lipid-lowering medication, antihypertensive medication, thyroid medication, psychotropic medication. **Setting:** Health Studies Clinic, University of Pittsburgh, USA. **Sample size:** Intervention: n = 260 Control: n = 275 Predominantly White, married, college educated, employed full-time. **Baseline BMI (kg/m^2):** Normal weight (BMI ≤24.9):	behavioural approach to weight control with strong emphasis on increasing PA and cholesterol lowering. Weeks 1–20 included 15 group meetings (20 women per group), given homework assignments and handouts, given weight loss goal in order to prevent any weight gain above baseline by end of the trial (BMI [kg/m^2] ≤24 asked to lose 2.3 kg, BMI 25–26 asked to lose 4.5 kg, BMI 27–34 asked to lose 6.8 kg). For first month followed daily diet of 1300 kcal (5.44 MJ), 25% energy from fat, 7% energy from saturated fat, 100 mg cholesterol, then could modify to suit their taste preferences; sessions on recipe modification, food labelling, social support, assertiveness training, restaurant eating; calcium supplement plus vitamin D (1200 mg/day) recommended, asked to increase PA expenditure to	Control: n = 12 **Weight outcomes:** Weight change from baseline (mean kg, intervention vs. control): 6 months: –4.9 vs. –0.4 18 months: –3.0 vs. +0.3 54 month: –0.1 (SD 5.2) vs. +2.4 (SD 4.9) At or below baseline weight at 54 months (intervention vs. control): 55 (136/246) vs. 26% (68/261); $p < 0.05$ Waist circumference (cm) at 54 months (intervention vs. control): –2.9 (SD 5.3) vs. –0.5 (SD 5.6), $p < 0.001$ Change in BMI (kg/m^2) (intervention vs. control): 0.05 (SD 2.0) vs. 0.96 (SD 1.8), $p < 0.001$ Change in % body fat (intervention vs. control): –0.5 (SD 4.1) vs. 1.1 (SD 3.9), $p < 0.01$ Fat-free mass (measured with a Hologic QDR 2000 dual-energy X-ray absorptiometer [DEXA]) (kg) (intervention vs. control):	was dietary intake, activity monitor actually measured PA. This study had power to detect an effect size of intervention of 90% or greater for weight and LDL-Cholesterol compared with control, at a significance level of 0.05 (two-tailed comparisons with an alpha level of 0.05)

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/ Comments
	53.6% Overweight (BMI 25–29.9): 35.5% Obese (BMI ≥30.0): 10.8% Mean BMI: 25	1000–1500 kcal [4.19–6.28 MJ]/week (e.g. brisk walking 10–15 miles [16–24 km]) combining moderate aerobic activity with lifestyle activity, women monitored intake and activity and received feedback. **Phase 2:** Months 6–54, group meetings: months 6, 7, 8, 10, 12 and 14 provided women with additional behavioural skills, support and motivation, and offered 6-week refresher programmes (cooking demonstrations, low-fat taste panels, group walks, dance classes, exercise classes, mail and telephone follow-up continued, incentives and group competitions also, energy intake gradually increased as women met their weight goal, received individual small group consultation if experienced weight gain (two to three times	0 (SD 1.9) vs. 0.5 (SD 2.1), $p < 0.05$ **Dietary outcomes:** Change in energy intake (kcal/day) from baseline (intervention vs. control): –160 (SD 465) vs. –25 (SD 560) (–1.09 [SD 1.95] vs. –0.10 [SD 0.01] MJ/day), $p < 0.01$ Intervention group reported eating significantly less dietary fat and cholesterol than controls. **Physical activity outcomes (change from baseline):** Physical activity (kcal/day) (intervention vs. control): 275 (SD 1173) vs. –113 (SD 1261) (1.15 [SD 4.91] vs. –0.47 [SD 5.27] MJ/day), $p < 0.001$ Blocks walked [no further details reported*] (kcal/day) (intervention vs. control): 188 (SD 615) vs. –83 (SD 611) (0.79 [SD 2.57] vs. –0.35 [SD 2.56] MJ/day), $p < 0.001$ Change in sport and recreational activity from baseline (kcal/day) (intervention vs. control): 57 (SD 1023) vs. –47 (SD 1104) (0.24	

First author, study design, research type, quality	Study population	Intervention details and length of follow-up	Results	Confounders/ Comments
		per year), cholesterol rise (three to six individual consultations and cholesterol monitoring, emphasising soy protein, fruit and vegetable and fibre to lower cholesterol) or exercise relapse. The research team from the University of Pittsburgh and nurses from the Health Studies Clinic provided the intervention. **Control:** Assessment only control group. **Follow-up:** 54 months (follow-up assessment done at 6, 18, 30, 42 and 54 months).	[SD 4.28] vs. –0.20 [SD 4.62] MJ/day), $p < 0.0001$ Changes in activity monitor from baseline (counts/hour) (intervention vs. control): 2.3 (SD 9.1) vs. –0.26 (SD 7.8), $p < 0.01$ **Authors' conclusion:** In healthy women, weight gain and increased waist circumference during the peri- to postmenopause can be prevented with a long-term lifestyle dietary and PA intervention.	

Evidence of corroboration (external validity)					
Evidence of salience from studies conducted in the UK					
First author	**Study population**	**Research question**	**Length of follow-up**	**Main results**	**Confounders/com ments**
Evidence for implementation – Will it work in the UK?					