UNIVERSITY OF CAMBRIDGE
Institute of Public Health

DISABILITY, DEMENTIA AND FRAILTY IN LATER LIFE – MID-LIFE APPROACHES TO PREVENT OR DELAY THE ONSET OF THESE CONDITIONS

REVIEW 3

Effectiveness and cost-effectiveness of mid-life interventions for increasing the uptake and maintenance of healthy lifestyle behaviours and the prevention or delay of dementia, disability, frailty and non-communicable chronic diseases related to modifiable lifestyle risk factors.

APPENDIX A - Evidence Tables

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APPENDIX A.1 Evidence table PHYSICAL ACTIVITY - Primary studies

Authors: Anderssen E, Hostmark A, Holme I, Anderssen S.

Year: 2013

Citation: Journal of Immigrant and Minority Health 15(1): 101-110

Country of study: Norway

Aim of study: Increase the physical activity level in a group of Pakistani immigrant men, and to see whether any increase was associated with reduced serum glucose and insulin concentrations.

Study design: RCT

Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Men living in Oslo with a Pakistani background (either born in Pakistan or having had both parents born in Pakistan) in the 25–60 year age group, who were not physically active on a regular basis

Number of people
126

Locality
Oslo, Norway

Recruitment strategy
Brief oral presentation concerning the project at six mosques and at various Muslim festivals in Oslo.

Response rate
126/182

Characteristics of population
mean (SD)
Intervention group
Age (years) 35.7 (6.1); Weight (kg) 83.7 (12); Height (cm) 174 (6.2); BMI (kg m-2) 27.1 (3.2); Waist circumference (cm) 98 (9); Total PA (CPM) 328 (138); Inactive time (h day-1) 8.4 (1.6)

Control group
Age (years) 39.7 (9.2); Weight (kg) 84.1 (14.4); Height (cm) 174 (6.2); BMI (kg m-2) 27.4 (4.2); Waist circumference (cm) 99 (11); Total PA (CPM) 281 (118); Inactive time (h day-1) 8.9 (1.5)

Excluded populations
See opp.

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Structured group exercise, group lectures, individual counselling sessions and phone call

Setting
In community and exercise facilities

Delivery
Structured presentations and sessions

Length of follow-up
5 months

Method of allocation
Random computerised list

Measurement of exposure
Not reported

Comparator
Control

Outcomes and Analysis	
Outcomes PA habits and diabetes	**Outcome measurement** Venous blood samples and oral glucose test; habitual PA was assessed with an MTI Actigraph accelerometer **Analysis strategy** Repeated measures ANCOVA was used for analysing mean changes within each group and for testing differences between mean changes in the two groups. **Confounders** Adjusted for age and baseline differences
Results **Intervention group** Weight (kg) -1.7 (0.2) BMI (kg m-2) -0.5 (0.1) Waist circumference (cm) -1.9 (0.4) Total PA level (CPM) 65 (12) Inactive time (min day-1) -13 (11) MVPA (min day-1) 13 (2) Peak VO2 (mL kg-1 min-1) 7.3 (0.4) HbA1c (%) 0.06 (0.02) Glucose (mmol/L) -0.14 (0.05) Glucose-2 h (mmol/L) -0.6 (0.2)	**Results** **Control group** Weight (kg) 0.1 (0.3) BMI (kg m-2) 0.3 (0.1) Waist circumference (cm) 1.7 (0.4) Total PA level (CPM) 19 (13) Inactive time (min day-1) -14 (15) MVPA (min day-1) 4 (2) Peak VO2 (mL kg-1 min-1)b 3.7 (0.8) HbA1c (%) 0.04 (0.03) Glucose (mmol/L) -0.06 (0.1) Glucose-2 h (mmol/L) -0.6 (0.3)
Results – Group difference BMI (kg m-2) -0.2 (-1.5–0.9) Waist circumference (cm) -1.1 (-4.6–2.3) Total PA (CPM)a 46 (3–89) Inactive time (h day-1) -0.5 (-1.03–0.04) Moderate,vigorous and very vigorous intensity physical activity (min day-1) 6.4 (-0.4–13) HbA1c (%) -0.1 (-0.3–0.1) Glucose (mmol/L) -0.1 (-0.5–0.1 Glucose-2 h (mmol/L) -1.2 (-2.3 to -0.1) Multivariate analyses (n = 102) b coefficient (±95 % CI); t value; R^2; P Change total PA (CPM) -1.4 (-2.4 to -0.4); -3.0; 0.10; 0.003 Change inactive time (min day-1) 1.6 (0.72–2.5); 3.7; 0.13; <0.001	
Trends, Limitations, Comments and Source of Funding	
Significant trends There was a mean difference in PA between the two groups of 49 counts per minute per	**Reported limitations** Reviewer Did not ask when the participants performed

day, representing a 15 % (95 % CI = 8.7–21.2; P = 0.01) higher increase in total PA level in the intervention group than in the control group. **General comments** No comment	their last exercise session; no economic evaluation <u>Author</u> No comment **Source of funding** Norwegian ExtraFoundation for Health and Rehabilitation through EXTRA funds.

Authors: Anderssen SA, Carroll S, Urdal P et al
Year: 2007
Citation: Scandinavian Journal of Medicine & Science in Sports 17(6): 687-695
Country of study: Norway
Aim of study: Single and combined effects of a one-year diet and exercise intervention on metabolic syndrome
Study design: Randomised, controlled, 2x2 factorial intervention study
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Middle-aged men aged 40 from Oslo 1990-1991

Number of people
137

Locality
Oslo, Norway

Recruitment strategy
Included all men

Response rate
Not reported

Characteristics of population
Age, y 44.9 (2.5); BMI (kg/m2) 29.4 (3.4); Waist circumference (cm) 105.4 (8.5); Systolic blood pressure (mmHg) 134.0 (11.8); Diastolic blood pressure (mmHg) 89.9 (7.8); Total cholesterol (mmol/L) 6.40 (0.84); LDL cholesterol (mmol/L) 4.34 (0.82); HDL cholesterol (mmol/L) 0.98 (0.16); Fasting glucose (mmol/L) 5.64 (0.64)

Excluded populations
Women those not 40-41

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Dietary counselling and exercise program

Setting
Not reported

Delivery
Not reported

Length of follow-up
1 year

Method of allocation
Simple randomization without blocking

Measurement of exposure
The attendance of each workout was recorded, as was additional physical activity performed by some participants.

Comparator
diet alone, exercise alone, the combination of the diet and exercise

Outcomes and Analysis

Outcomes
Exercise and body composition

Outcome measurement
Blood samples and questionnaire

Analysis strategy
X^2 tests

Confounders
Not adjusted

Results **Intervention group**	**Results** **Control group**
Before **Exercise adherence (%)** – **Cardio-respiratory fitness (mL/kg/min)** 35.3 (0.4) **Body weight (kg)** 94.1 (1.0) **Total energy intake (kJ/day)** 10746 (260) **Energy from fat (%)** 33.4 (0.46) **Saturated fat (g/day)** 36.7 (1.2) **p/s fatty acids** ratio 0.47 (0.01) **Thiocyanate (mmol/L)** 68.9 (4.3) **After** **Exercise** **Exercise adherence (%)** 61.3 **Cardio-respiratory fitness (mL/kg/min)** 2.8 (0.8) **Body weight (kg)** - 1.3 (0.8) **Total energy intake (kJ/day)** - 938 (380) **Energy from fat (%)** - 2.0 (0.9) **Saturated fat (g/day)** - 5.3 (1.7) **p/s fatty acids ratio** - 0.02 (0.03) **Thiocyanate (mmol/L)** - 1.4 (4.9) **Diet+exercise** **Exercise adherence (%)** 64.7 **Cardio-respiratory fitness (mL/kg/min)** 4.7 (0.5) **Body weight (kg)** - 6.5 (0.6) **Total energy intake (kJ/day)** - 2168 (411) **Energy from fat (%) -** 5.5 (0.9) **Saturated fat (g/day)** - 14.4 (1.9) **p/s fatty acids ratio** 0.13 (0.03) **Thiocyanate (mmol/L)** - 11.7 (4.2)	**Before** **Exercise adherence (%)** – **Cardio-respiratory fitness (mL/kg/min)** 35.3 (0.4) **Body weight (kg)** 94.1 (1.0) **Total energy intake (kJ/day)** 10746 (260) **Energy from fat (%)** 33.4 (0.46) **Saturated fat (g/day)** 36.7 (1.2) **p/s fatty acids ratio** 0.47 (0.01) **Thiocyanate (mmol/L)** 68.9 (4.3) **After** **Cardio-respiratory fitness (mL/kg/min)** - 2.5 (0.6) **Body weight (kg)** 0.8 (0.6) **Total energy intake (kJ/day)** - 559 (588) **Energy from fat (%)** - 1.0 (1.0) **Saturated fat (g/day)** - 2.4 (2.5) **p/s fatty acids ratio** 0.01 (0.02) **Thiocyanate (mmol/L)** 2.3 (5.8)
Results – Group difference Not reported	
Trends, Limitations, Comments and Source of Funding	
Significant trends Both exercise and dietary intervention reduced metabolic syndrome prevalence compared with control after 1 year of intervention. However, the combined diet and exercise intervention was significantly more effective than diet or exercise alone in the treatment of the metabolic syndrome. **General comments**	**Reported limitations** Author: Alternative WHO and ATP III metabolic syndrome criteria have different thresholds for abdominal obesity and HDL level for each sex. **Source of funding** Research Council of Norway, The Norwegian Council of Cardiovascular Diseases and the Department of Sports Medicine, Norwegian School of Sports Sciences.

Authors: Arbour KP, Ginis KAM
Year: 2004
Citation: Journal of Applied Biobehavioral Research 9(3): 172-187
Country of study: Canada
Aim of study: Effects of forming implementation intentions on the relation between intentions and physical activity behaviour
Study design: Pre-test/post-test experimental design
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Female university and bank office employees

Number of people
47

Locality
Two cities in southern Ontario

Recruitment strategy
Poster advertisements around the university campus and in the bank office. Advertising on the university website, employee e-mail, and staff health newsletter

Response rate
Not reported

Characteristics of population
Control
Age 47.78 (7.03), BMI (kg/m2) 27.61 (5.41); Leisure-time exercise (in METs) Mild 2.39 (2.77), Moderate 0.67 (1.08), Strenuous 0.07 (0.31); Education High school or less 21.7%, College courses or more 73.9%; Family background Caucasian 69.6%, Noncaucasian 30.4%

Experimental
Age 45.38 (7.55); BMI (kg/m2) 25.96(4.51); Leisure-time exercise (in METs) Mild 3.17 (3.34), Moderate 1.57 (3.15), Strenuous 0.17 (0.58); Education High school or less 25.0%, College courses or more 75.0%; Family background Caucasian 54.2%, Noncaucasian 37.5%

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
30-min video promoting exercise

Setting
Not reported

Delivery
Video

Length of follow-up
2 months

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Theory of planned behaviour and control

Outcomes and Analysis	
Outcomes Leisure-time physical activity Scheduling self-efficacy Attitudes toward exercise Subjective norms Perceived behavioural control Intention Physical activity	**Outcome measurement** Self-reported questionnaire **Analysis strategy** Independent samples t-tests **Confounders** Not adjusted
Results **Intervention group**	**Results** **Control group**
Before **Attitude** 45.41 (7.15) **Intentions** 9.29 (2.98) **Perceived behavioural control** 10.92 (3.16) **Scheduling self-efficacy** 56.21 (22.27) **Subjective norm** 11.00 (2.92) **Physical activity 2 days per week** Not reported **Physical activity >3 days per week** Not reported **After** **Attitude** 47.27 (6.85) **Intentions** 9.87 (3.38) **Perceived behavioural control** 11.92 (2.10)	**Before** **Attitude** 47.00 (7.37) **Intentions** 10.79 (3.76) **Perceived behavioural control** 12.21 (3.06) **Scheduling self-efficacy** 68.63 (24.55) **Subjective norm** 10.89 (3.11) **Physical activity 2 days per week** Not reported **Physical activity >3 days per week** Not reported **After** **Attitude** 47.83 (7.13) **Intentions** 9.58 (3.92) **Perceived behavioural control** 11.68 (2.31)

Scheduling self-efficacy 63.37 (28.30) **Subjective norm** 10.87 (3.12) **Physical activity 2 days per week** 3.83 (2.68) **Physical activity >3 days per week** 2.44 (2.33)	**Scheduling self-efficacy** 58.84 (30.91) **Subjective norm** 11.47 (3.61) **Physical activity 2 days per week** 4.22 (2.98) **Physical activity >3 days per week** 2.91 (2.64)
Results – Group difference Not reported	
Trends, Limitations, Comments and Source of Funding	
Significant trends Intentions were a significant predictor of behaviour for women in the experimental condition. A significant Condition x Time interaction was found for scheduling efficacy **General comments**	**Reported limitations** <u>Author</u> Small sample size; study conducted during coldest months of the year; insufficient time period. **Source of funding** Not reported

Authors: Bowen DJ, Fesinmeyer MD, Yasui Y et al
Year: 2006
Citation: International Journal of Behavioral Nutrition and Physical Activity 3(1): 34
Country of study: USA
Aim of study: Test the effect of a moderate intensity physical activity intervention on the endogenous sex hormone profile of postmenopausal women
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Postmenopausal women, 50 to 75 years at entry, sedentary at baseline (< 60 mins/week of moderate- or vigorous-intensity recreational activity and a maximal oxygen consumption <25.0 ml/kg/min), with a BMI ≥ 25.0 kg/m2 (or a BMI between 24.0 and 25.0 if percent body fat >33.0), not taking hormone replacement therapy, no clinical diagnosis of diabetes and fasting glucose levels < 140 mg/dL, and non-smokers.

Number of people
173

Locality
Seattle

Recruitment strategy
Combination of mass mailings and media placements

Response rate
Not reported

Characteristics of population
Participants on average were aged 61 years and highly educated (91% were high school graduates). Less than a third of the participants worked full-time, and 86% were non-Hispanic White, 4% were African-American, and 6% were Asian American

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Exercise prescription. At least 45 minutes of moderate-intensity aerobic exercise 5 days per week for 12 months

Setting
Exercise facility

Delivery
Not reported

Length of follow-up
1 year

Method of allocation
Not reported

Measurement of exposure
Multiple visits per week to the exercise facility

Comparator
No exercise

Outcomes and Analysis	
Outcomes Mental, physical, and general health. Emotional symptoms	**Outcome measurement** Self-report questionnaire **Analysis strategy** Generalized-estimating-equation modification of the linear regression model **Confounders** Unadjusted regression. Predictors adjusted for baseline mental health and general health
Results **Intervention group**	**Results** **Control group**
Before **Anxiety** 94.49 (11.45) **Depression** 93.56 (11.19) **General health** 79.95 (14.88) **Physical functioning** 85.86 (14.45) **Perceived stress** 79.38 (16.95) **After** **Anxiety** 94.36 (10.94) **Depression** 94.31 (10.40) **General health** 83.55 (13.56) **Physical functioning** 88.60 (14.24) **Perceived stress** 78.13 (18.20)	**Before** **Anxiety** 94.08 (7.41) **Depression** 91.96 (9.63) **General health** 79.52 (11.83) **Physical functioning** 86.40 (11.55) **Perceived stress** 78.42 (16.03) **After** **Anxiety** 95.09 (8.16) **Depression** 93.45 (8.03) **General health** 78.74 (14.08) **Physical functioning** 83.18 (15.49) **Perceived stress** 79.39 (16.02)
Results – Group difference **Anxiety** 0.50 **Depression** 0.49 **General health 0.02** **Physical functioning <0.01** **Perceived stress** 0.36 **Predictors of Mental Health Scores in Intervention Women** **Change from baseline to 12 months** **Adherence** β 0.02 P 0.27 **Change in fitness** β -0.45 P 0.33 **Predictors of General Health Scores in Intervention Women** **Change from baseline to 12 months** **Adherence** β 0.01 P 0.40 **Change in fitness**	

β 0.58
P 0.23

Trends, Limitations, Comments and Source of Funding

Significant trends

Women achieved and maintained high levels of exercise in the intervention group, compared with controls, over a 12-month period

General comments

Reported limitations

Author

Participants were carefully screened before the study for their ability to perform the tasks of the research project; participants in this study reported higher functioning at baseline compared to the general population; residual confounding; the control group improved its quality of life, and therefore we might be underestimating the effects of exercise by comparing it to the improved control functioning

Reviewer

Source of funding

National Cancer Institute grants (CA69334, EF07262, CA09661, CA94880)

Authors: Cussler EC, Teixeira PJ, Going SB et al
Year: 2008
Citation: Obesity 16(5): 1052-1060
Country of study: USA
Aim of study: Compare weight regain in a group of perimenopausal women
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Perimenopausal women between 40 and 55 years of age, have a BMI between 25.0 and 38.0 kg/m2, be a nonsmoker, and be free from major illnesses

Number of people
135

Locality
Tucson, Arizona

Recruitment strategy
Newspaper and TV advertisements

Response rate
Not reported

Characteristics of population
Self-directed completers (n = 52)
Mean ± s.d.
Age 48.2 ± 4.2; Weight (kg) 82.0 ± 10.8; BMI 30.1 ± 3.4; Percent fat 43.2 ± 5.8; Exercise energy expenditure (kcal/day) 129 ± 123; Energy intake (kcal/day) 1,866 ± 492

Randomized (n = 135)
Mean ± s.d.
Age 48.2 ± 4.4; Weight (kg) 83.7 ± 11.8; BMI 30.7 ± 3.6; Percent fat 44.2 ± 5.4; Exercise energy expenditure (kcal/day) 128 ± 124; Energy intake (kcal/day) 1,952 ± 506

Excluded populations
dropped or did not meet inclusion criteria

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Weight maintenance Internet intervention or to self-directed weight maintenance after a 4-month weight loss treatment

Setting
Internet

Delivery
Internet

Length of follow-up
12 month

Method of allocation
Block-randomized

Measurement of exposure
Body weight, physical activity, dietary intake, and "mind-body" logs. Internet use was quantified from website logs that recorded electronically the number of times a web-based interactive log was accessed and filled out.

Comparator
Internet or self-directed groups

Outcomes and Analysis

Outcomes
Weight maintenance

Outcome measurement
Weight was monitored weekly

	Analysis strategy Paired and Student's t-tests were used to test the significance of weight changes within and between intervention groups. General linear model was then used to confirm. Baseline Observation Carried Forward Method was adopted. **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Internet **Baseline–4 months** (n = 66) Mean ± s.d. **Weight (kg)** −5.3 ± 3.6 **BMI** −1.9 ± 1.4 **Percent fat** −3.6 ± 3.3 **Total body fat (kg)** −5.1 ± 3.7 **Fat-free mass (kg)** −0.6 ± 1.4 **Exercise energy expenditure (kcal/day)** 151 ± 196 **Engergy intake (kcal/day)** −442 ± 545 **4–16 months (BOCF; n = 66)** Mean ± s.d. **Weight (kg)** 0.4 ± 5.0 **BMI** 1.3 ± 1.8 **Percent fat** 0.1 ± 3.6 **Total body fat (kg)** 0.6 ± 4.7 **Fat-free mass (kg)** 0.3 ± 1.2 **Exercise energy expenditure (kcal/day)** 55 ± 301 **Engergy intake (kcal/day)** 123 ± 390	Self-directed **Baseline-4 months** (n = 69) Mean ± s.d. **Weight (kg)** −5.2 ± 3.8 **BMI** −1.9 ± 1.4 **Percent fat** −3.3 ± 3.0 **Total body fat (kg)** −4.7 ± 3.5 **Fat-free mass (kg)** −0.6 ± −0.6 **Exercise energy expenditure (kcal/day)** 144 ± 151 **Engergy intake (kcal/day)** −370 ± 471 **4–16 months** (**BOCF; n = 69)** Mean ± s.d. **Weight (kg)** 0.6 ±4.0 **BMI** 0.9 ± 1.9 **Percent fat** 0.2 ± 3.8 **Total body fat (kg)** 0.5 ± 4.3 **Fat-free mass (kg)** 0.3 ± 1.3 **Exercise energy expenditure (kcal/day)** 62 ± 279 **Engergy intake (kcal/day)** 171 ± 399
Results – Group difference Baseline to 4 months: P < 0.001 Baseline to 4 months Student's t-test between groups: P = 0.8 Baseline to 16 months: P < 0.001 End of the maintenance period Student's t-test: P = 0.5	
Trends, Limitations, Comments and Source of Funding	
Significant trends While significant weight loss was maintained over follow-up by both groups of women, Internet use did not surpass self-direction in helping to sustain weight loss. The results of this study showed no significant differences in	**Reported limitations** <u>Author</u> a degree of uneasiness some participants felt using the Internet; attrition rate in the Internet group was 21.2% compared to 14.5% in the self-directed group; women

weight regain, exercise energy expenditure, and energy intake in those women using the Internet compared to the self-directed group. **General comments**	in the second of the two cohorts, who entered the study 6 months after the first cohort, received a more fully developed web-based intervention than the women in the first cohort; the "Avis" effect; study lacked a systematic method to track the group activities of the self-directed participants; underpowered to detect a very small difference in weight change between intervention groups; did not include men, other ages, and ethnicities <u>Reviewer</u> **Source of funding** National Institutes of Health grant DK57453

Authors: Elavsky S
Year: 2010
Citation: Journal of Sport Exercise Psychology 32(6): 862-880
Country of study: USA
Aim of study: Examination of exercise and self-esteem model in middle-aged women
Study design: Two-year prospective study, previously a randomized controlled trial
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Middle-aged (42–58 years of age at enrolment) women who previously participated in a 4-month randomized controlled exercise trial. Sedentary or low active, experiencing menopausal symptoms, no history of surgical menopause and no hormone therapy use in the last 6 months

Number of people
164

Locality
Not reported

Recruitment strategy
All participants received a letter announcing the follow-up study and were contacted by telephone within 2 weeks of receiving the letter

Response rate
74%

Characteristics of population

Walking

Age 50.5 (3.4); Body mass index 30.4 (7.8); Total body fat (%) 37.7 (6.7); Number of children* 1.8 (1.2); Marital status (%) Married/significant relationship 72.6, Divorced/separated 21.0, Single 6.5, Widow 0.0; Education (%) 1Oth-11th grade 0.0, High school graduate 9.7, 1-3 years of college 25.8, College/university degree 64.5; Annual income*(%) Percent reported 88.9, <$20,000 12.7, $20,001-$30,000 7.3, $30,001-$40,000 7.3, >$40,.001 63.5; Race(%) African American 14.5, White 83.9, Asian 1.6, Other 0.0; Ethnicity Hispanic/Latina 0.0; Smoking(%) Nonsmokers 90.5, Past smokers 36.8, smokers 9.5

Yoga

Age 50.0 (3.7); Body mass index 29.8 (6.8); Total body fat (%) 37.9 (5.7); Number of children* 2.3 (1.4); Marital status (%) Married/significant relationship 80.3, Divorced/separated 13.1, Single 4.9, Widow 1.6; Education (%) 1Oth-11th grade 0.0, High school graduate 11.5, 1-3 years of college 29.5, College/university degree 59.0; Annual income(%) Percent reported 83.6 <$20,000 0.0, $20,001-$30,000 6.6, $30,001-$40,000 1.6, >$40,.001 75.4; Race(%) African American 14.8, White 80.3, Asian 4.9, Other 1.6; Ethnicity Hispanic/Latina 0.0; Smoking(%) Nonsmokers 93.4, Past smokers 25.9, smokers 6.6

Control

Age 48.6 (3.5); Body mass index 28.1 (5.9); Total body fat (%) 36.9 (5.0); Number of children* 1.8 (1.0); Marital status (%) Married/significant relationship 69.2, Divorced/separated 20.5, Single 7.7, Widow 2.6; Education (%) 1Oth-11th grade 2.6, High school graduate 2.6, 1-3 years of college 25.6, College/university degree 69.2; Annual income*(%) Percent reported 87.2, <$20,000

	5.1, $20,001-$30,000 5.1, $30,001-$40,000 17.9, >$40,.001 59.0; Race(%) African American 7.7, White 84.6, Asian 7.7, Other 0.0; Ethnicity Hispanic/Latina 7.7; Smoking(%) Nonsmokers 92.3, Past smokers 8.3, Smokers 7.7 **Excluded populations** Women with a history of surgical menopause and those who used hormone therapy in the previous 6 months. **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Yoga or walking **Setting** Large gymnasium **Delivery** Two trained instructors **Length of follow-up** 2 years	**Method of allocation** Stratified based on menopausal symptom frequency **Measurement of exposure** Instructors monitored participants' adherence to prescribed exercise duration and intensity **Comparator** Yoga or walking with wait-list control condition
Outcomes and Analysis	
Outcomes Physical Activity and Body Mass Index, Self-Esteem, Self-Efficacy	**Outcome measurement** Self-report questionnaire **Analysis strategy** Longitudinal panel analysis and X^2 **Confounders** Not reported
Results **Intervention group**	**Results** **Control group**
Before **Walking** ***R*2 Change; β; *SE;* Critical Value; *p*-Value** **Direct Effects at T1** Physical activity 0.018; 0.133; 0.105; 1.269; 0.205 Self-efficacy 0.000; 0.000; 0.102; −0.004; 0.997 BMI 0.011; 0.103; 0.106; 0.972; 0.331 Physical condition 0.026; 0.160; 0.083; 1.930; 0.054	**Before** Not reported **After** Not reported

Strength 0.003; −0.057; 0.103; −0.550; 0.582 Physical self-worth 0.001; −0.037; 0.062; −0.601; 0.548 Global self-esteem 0.000; −0.001; 0.097; −0.013; 0.990 **Yoga** ***R*2 Change; β; *SE;* Critical Value; *p*-Value** **Direct Effects at T1** Physical activity 0.002; 0.047; 0.106; 0.439; 0.660 Self-efficacy 0.070; −0.265; 0.100; −2.642; 0.008 BMI 0.001; 0.036; 0.106; 0.343; 0.732 Physical condition 0.002; 0.044; 0.085; 0.517; 0.605 Strength 0.012; −0.111; 0.105; −1.056; 0.291 Physical self-worth 0.000; −0.017; 0.061; −0.279; 0.780 Global self-esteem 0.000; 0.004; 0.097; 0.042; 0.967 **After Walking** ***R*2 Change; β; *SE;* Critical Value; *p*-Value** **Indirect Effects at T2 (Through T1)** Physical activity 0.002; 0.043; 0.036; 1.196; 0.232 Self-efficacy 0.000; 0.000; 0.044; −0.004; 0.997 BMI 0.008; 0.091; 0.093; 0.971; 0.332 Physical condition 0.002; 0.048; 0.058; 0.830; 0.407 Strength 0.002; −0.039; 0.073; −0.535; 0.592 Physical self-worth 0.000; −0.003; 0.075; −0.045; 0.964 Global self-esteem 0.000; 0.001; 0.073; 0.020; 0.984 **Yoga** ***R*2 Change; β; *SE;* Critical Value; *p*-Value** **Indirect Effects at T2 (Through T1)** Physical activity 0.000; 0.015; 0.034; 0.436; 0.663 Self-efficacy 0.013; −0.115; 0.049; −2.361; 0.018 BMI 0.001; 0.032; 0.093; 0.342; 0.732 Physical condition 0.005; −0.072; 0.058; −1.240; 0.215 Strength 0.009; −0.094; 0.073; −1.278; 0.201 Physical self-worth 0.008; −0.088; 0.075; −1.199; 0.242	

Global self-esteem 0.002; −0.048; 0.073; −0.653; 0.514	
Results – Group difference Not reported	
Trends, Limitations, Comments and Source of Funding	
Significant trends Results indicate that middle-aged women can enhance how they perceive their condition and body attractiveness by continued participation in physical activity, increasing their self-efficacy, and maintaining healthy BMI levels **General comments** An incentive to participate was offered in the form of a lottery for one of four $250 cash prizes Demographic data from Elavsky S, McAuley E. Exercise and self-esteem in menopausal women: A randomized controlled trial involving walking and yoga. American Journal of Health Promotion. 2007b; 22(2):83–92. [PubMed: 18019884]	**Reported limitations** <u>Author</u> Self-report; physical activity assessment included estimates for leisure-time activities only; majority of participants were white, well educated, of above-average socioeconomic status, and overall healthy; low response rate; recall bias <u>Reviewer</u> Results of those in control group not reported **Source of funding** Grant Number K 12HD055882, "Career Development Program in Women's Health Research at Penn State," from the National Institute of Child Health and Human Development and the National Institute on Aging under Award No. AG12113.

Authors: Ferney SL, Marshall AL, Eakin EG et al
Year: 2009
Citation: Preventive Medicine 48(2): 144-150
Country of study: Australia
Aim of study: Evaluate the use of a local neighbourhood environment-focused physical activity website and its effects on walking and overall physical activity in middle-aged adults
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Aged between 45 and 60 years, had home Internet access, were able to speak and read English and were not meeting the current PA guidelines

Number of people
106

Locality
Brisbane, Australia

Recruitment strategy
Advertisements in the community newspaper and a letterbox drop

Response rate
Not reported

Characteristics of population
Intervention
Mean ± SD
Age 51.7 ± 4.1; Female 40 (77); Occupation Manager/administrator 29 (56); Other 24 (44) Education High school 14 (27); >High school 39 (75); Employment status Full time 27 (52), Other 25 (48), Retired 5 (10); Marital status Married/living with partner 36 (69); Single/widowed/divorced 17 (33); Children at home Yes 32 (62); BMI Normal 14 (27), Overweight/obese 36 (69)

Control
Mean ± SD
Age 52.2 ± 5.0; Female 36 (66); Occupation Manager/administrator 24 (46); Other 30 (44); Education High school 18 (33), > High school 36 (67); Employment status Full time 29 (54), Other 25 (46); Retired 5 (9); Marital status Married/living with partner 39 (72); Single/widowed/divorced 15 (26); Children at home Yes 30 (55); BMI Normal 28 (53), Overweight/obese 25 (47)

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Neighbourhood environment-focused website

Setting
Workplace

Delivery
Internet

Method of allocation
Single-blind computer generated randomization sequence

Measurement of exposure
Monitored website use, and self-reported total walking via telephone interviews

Comparator

Length of follow-up 26 week	Motivational-information website intervention
Outcomes and Analysis	
Outcomes Physical activity	**Outcome measurement** Self-report **Analysis strategy** Intention-to-Treat with one-way repeated measures ANOVAS with post hoc Scheffe tests **Confounders** Adjusted for group and time
Results **Intervention group**	**Results** **Control group**
Before Mean (SD) Walking anywhere in the neighbourhood (min/wk) Neighbourhood 59.2 (76.9) Walking along the community walking path (min/wk) Neighbourhood 38.5 (72.6) Total walking (min/wk) Neighbourhood 81.6 (77.9) Total physical activity (min/wk) Neighbourhood 160.3 (167.3) Neighbourhood walking (min/week) User 56.5 (67.2) Community walking path (min/week) User 36.6 (58.6) Total walking (min/week) User 80.8 (71.2) Total physical activity (min/week) User 172.4 (183.3) **After** Walking anywhere in the neighbourhood (min/wk) Neighbourhood 76.6 (81.0) Walking along the community walking path	**Before** Mean (SD) Walking anywhere in the neighbourhood (min/wk) Comparison 56.7 (54.0) Walking along the community walking path (min/wk) Comparison 23.6 (39.5) Total walking (min/wk) Comparison 103.8 (116.5) Total physical activity (min/wk) Comparison 194.8 (184.3) Neighbourhood walking (min/week) Non-user 63.3 (90.9) Community walking path (min/week) Non-user 41.2 (90.9) Total walking (min/week) Non-user 82.9 (88.8) Total physical activity (min/week) Non-user 142.4 (142.9) **After** Walking anywhere in the neighbourhood (min/wk) Comparison 72.4 (81.1) Walking along the community walking path

(min/wk) Neighbourhood 45.4 (68.5) Total walking (min/wk) Neighbourhood 108.5 (96.4) Total physical activity (min/wk) Neighbourhood 218.1 (175.7) Neighbourhood walking (min/week) User 89.7 (84.1) Community walking path (min/week) User 59.2 (78.4) Total walking (min/week) User 117.4 (94.4) Total physical activity (min/week) User 226.6 (169.7)	(min/wk) Comparison 35.6 (66.9) Total walking (min/wk) Comparison 108.6 (99.0) Total physical activity (min/wk) Comparison 207.5 (197.3) Neighbourhood walking (min/week) Non-user 57.4 (73.9) Community walking path (min/week) Non-user 25.0 (44.9) Total walking (min/week) Non-user 95.2 (100.1) Total physical activity (min/week) Non-user 205.5 (187.8)
Results – Group difference Not reported	
Trends, Limitations, Comments and Source of Funding	
Significant trends Meaningful increases in physical activity relative to the comparison website. **General comments**	**Reported limitations** <u>Author</u> Lack of a no-treatment control group; the Comparison group participants did report higher levels of PA at baseline; self-report measures of PA were used <u>Reviewer</u> Suburbs chosen based being deemed relatively 'high walkable' in terms of their aesthetics, street connectivity and access to services which may represent a selection bias **Source of funding** National Health and Medical Research Council of Australia (NHMRC) program grant (#301200) and by a research Infrastructure Grant from Queensland Health

Authors: Gaston MH, Porter GK, Thomas VG
Year: 2007
Citation: Journal of the National Medical Association 99(4): 428
Country of study: USA
Aim of study: To evaluate the effectiveness of Prime Time Sister Circles
Study design: Pre-test and post-test
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
African-American women aged >35

Number of people
134

Locality
Illinois; Washington, DC; Florida; and Maryland

Recruitment strategy
Recruitment from sites intervention was delivered

Response rate
Not reported at baseline, 77.7% at six months and 88.1% at 12 months.

Characteristics of population
Mean Age 54.4 years; SD=9.46; Age (Years) 35-44 18.0, 45-55 36.1, 56 45.9; Children Yes 79.9; Education Level High school or less 2.3, High school diploma 4.5, Some college/technical 26.5; College graduate 66.7; Marital Status Widowed 11.2, Divorced 20.1, Separated 5.2, Married 42.5, Not married, with live-in partner 3.7; Single, no live-in partner 17.2; Employment Status Employed 50.7, Retired 18.7, Not employed 4.5; Personal Yearly Income <$20,000 8.7, $20,001-30,000 15.9, $30,001-40,000 15.1, $40,001-50,000 15.1, >$50,001 45.2

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Educational workshop and a “sister-to-sister” support structure

Setting
Four churches, a state health education centre, a mental health centre, a community centre, a hospital, a feminist bookstore, a predominantly African-American college and a social club

Delivery
workshop conducted by the mid-life African-American female co-leaders of the project

Length of follow-up
12 months

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Comparison group received an educational book but did not receive a curriculum, facilitator, expert consultants or stipend.

Outcomes and Analysis

Outcomes	**Outcome measurement**

Perception of overall health, self-care, Nutrition and eating patterns	Self-report questionnaire **Analysis strategy** T tests **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Not reported **After** Percent Reported Change "a Lot" Utilized stress management strategies 66.0% Prioritized their health before care of others 65.3% Incorporated healthy eating habits 78.4% Engaged in regular exercise 58.5% Changed diet to prevent disease 100.0%	**Before** Not reported **After** Not reported
Results – Group difference	
Trends, Limitations, Comments and Source of Funding	
Significant trends Statistically significant increase in the women's involvement in physical activity at 12 months. A significant.10-week difference was found in the women's diet, with them reporting eating more nutritious foods **General comments**	**Reported limitations** <u>Author</u> Small number of comparison groups and sample size; non-random recruitment and assignment to the intervention and comparison groups; participants were mostly college-educated, middle-income women; self-report data <u>Reviewer</u> Does not report baseline measures; does not report intervention and comparison group data separately **Source of funding** The Ford Foundation and the Office of Policy & Planning, of the School of Medicine, University of Maryland.

Authors: Hageman PA, Walker SN, Pullen CH
Year: 2005
Citation: Journal of Geriatric Physical Therapy 28(1): 28-33
Country of study: USA
Aim of study: Examined the feasibility and effectiveness of using the Internet to deliver behaviour change interventions for promoting physical activity
Study design: Pre-test/post-test comparison experimental design
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Women ages 50-69 years, were English speaking, had access to a computer with Internet capacity in their home, and answered no to all questions on the Physical Activity Readiness Questionnaire.

Number of people
31

Locality
Not reported

Recruitment strategy
Newspaper advertisement

Response rate
Not reported

Characteristics of population
Control
n %
Ethnic - Racial Background White 16 (100.0), Black 0, Asian or Pacific Islander 0; Marital Status Married 13 (81.3), Widowed 1 (6.3), Divorced/separated 2 (12.5), Never married; Education Level High school graduate 3 (18.8), Some college 5 (31.3), College graduate or higher 8 (50.1); Employment Status Full time 5 (31.3), Part time 3 (18.8), Homemaker 3 (18.8), Retired 4 (25.0), Unemployed 1 (6.3); Yearly Income 20 K to 39 K 3 (18.8), 40 K to 59 K 7 (43.8), 60 K or above 4 (25.0), Prefer not to answer 2 (12.5)

Experimental
n (%)
Ethnic - Racial Background White 13 (86.7), Black 1 (6.7), Asian or Pacific Islander 1 (6.7); Marital Status Married 10 (66.7), Widowed 0, Divorced/separated 3 (20.0), Never married 2 (13.3); Education Level High school graduate 2 (13.3), Some college 5 (33.3), College graduate or higher 8 (53.3); Employment Status Full time 11 (73.3), Part time 1 (6.7), Homemaker 1 (6.7), Retired 1 (6.7), Unemployed 1 (6.7); Yearly Income 20 K to 39 K 4 (26.7), 40 K to 59 K 3 (20.0), 60 K or above 5 (33.3), Prefer not to answer 3 (20.0)

Excluded populations
Men, non-English speaking, those with no access to a computer with internet

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Newsletters from the Internet. Tailoring was accomplished by creating a library of 350 text

Method of allocation
Not reported

messages that corresponded to individual responses obtained at the baseline assessment related to level of self-reported physical activity, benefits and barriers to activity and self-efficacy and initial goals for activity **Setting** Internet **Delivery** Internet **Length of follow-up** 3 months	**Measurement of exposure** Not reported **Comparator** Tailored or standard newsletter groups
Outcomes and Analysis	
Outcomes Physical activity, perceived barriers and benefits	**Outcome measurement** Self-reported questionnaire **Analysis strategy** Repeated measures ANOVAs. Post-hoc analyses were completed using the Bonferroni adjustment for multiple comparisons. **Confounders** Not reported
Results **Intervention group**	**Results** **Control group**
Before Rockport Fitness Walking Test VO2max (ml/kg/min) 26.69 + 6.2 Modified Sit-and-Reach (cm) 27.63 + 4.3 Body Fat (%) 33.72 + 4.9 Modified 7-Day Activity Survey Kcal/Kg/Day 28.70 + 5.0 Calories Expended Daily 2076.29 + 567.3 Moderate or Greater Physical Activity in Past Week (min) 937.63 + 616.5 **After** Rockport Fitness Walking Test VO2max (ml/kg/min) 27.52 + 9.3 Modified Sit-and-Reach (cm) 29.50 + 7.0 Body Fat (%) 32.96 + 6.3 Modified 7-Day Activity Survey Kcal/Kg/Day 26.54 + 4.98 Calories Expended Daily 1910.08 + 457.5 Moderate or Greater Physical Activity in Past Week (min) 672.53 + 643.9	**Before** Rockport Fitness Walking Test VO2max (ml/kg/min) 25.59 + 7.4 Modified Sit-and-Reach (cm) 29.57 + 6.3 Body Fat (%) 34.10 + 5.6 Modified 7-Day Activity Survey Kcal/Kg/Day 28.89 + 5.7 Calories Expended Daily 2173.11 + 518.1 Moderate or Greater Physical Activity in Past Week (min) 1228.06 + 1194.7 **After** Rockport Fitness Walking Test VO2max (ml/kg/min) 23.59 + 9.3 Modified Sit-and-Reach (cm) 32.76 + 7.6 Body Fat (%) 30.81 + 7.8 Modified 7-Day Activity Survey Kcal/Kg/Day 27.34 + 4.62 Calories Expended Daily 2070.55 + 395.9 Moderate or Greater Physical Activity in Past Week (min) 906.00 + 775.8

Results – Group difference Tailored Rockport Fitness Walking Test VO2max (ml/kg/min) 3.1% increase Modified Sit-and-Reach (cm) 6.7% increase Body Fat (%) 0.7% decrease Modified 7-Day Activity Survey Kcal/Kg/Day 7.6% decrease Calories Expended Daily 8.0% decrease Moderate or Greater Physical Activity in Past Week (min) 8.0% decrease Standard Rockport Fitness Walking Test VO2max (ml/kg/min) 7.8% decrease Modified Sit-and-Reach (cm)10.8% increase Body Fat (%) 9.6% decrease Modified 7-Day Activity Survey Kcal/Kg/Day 5.4% decrease Calories Expended Daily 4.7% decrease Moderate or Greater Physical Activity in Past Week (min) 4.7% decrease	
Trends, Limitations, Comments and Source of Funding	
Significant trends Self-reported physical activity did not increase although selected biomarkers did improve. **General comments**	**Reported limitations** <u>Author</u> Did not separate tailored versus standard group responses <u>Reviewer</u> Unknown participation rate; some self-reported measures of physical activity **Source of funding** School of Allied Health Professions, College of Medicine, University of Nebraska Medical Center, Omaha, NE

Authors: Hardcastle PA, Taylor AH, Bailey MP et al
Year: 2013
Citation: International Journal of Behavioral Nutrition and Physical Activity 10(1): 40
Country of study: UK
Aim of study: Evaluated the effectiveness of a six-month low-intensity motivational interviewing intervention
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Aged 18–65 years and needed to exhibit at least one of the following CVD risk factors; excess weight (BMI of 28 or more, based on a value used in the recruiting GP practice), hypertension (SBP/DBP at least 150/90 mmHg), or hypercholesterolemia (at least 5.2 mmol.l-1).

Number of people
358

Locality

Recruitment strategy
Participants were drawn from a patient electronic database. Contacted by mail with an invitation letter and information sheet telling them about the study.

Response rate
28%

Characteristics of population
Control
Age (years) 50.41 (0.95); Blood Pressure SBP (mmHg) 132.45 (1.57); DBP (mmHg) 82.41 (0.91); BMI (kg/m2) 34.28 (0.61); Bodyweight (kg) 91.73 (1.50); Cholesterol (mmol/L) 5.42 (0.09); Triglycerides (mmol/L) 1.73 (0.09); HDL (mmol/L) 1.53 (0.04); LDL (mmol/L) 3.03 (0.10); Fat intake (% per day) 23.72 (0.67); Fruit and Vegetables (portions/ day) 6.88 (0.39); Total PA (Met-min/week) 2195.67 (243.83); Vigorous PA (Met-min/week) 709.27 (145.66); Moderate PA (Met-min/week) 554.39 (106.62); Walking PA (Met-min/week) 1011.92 (88.06)

Experimental
Age (years) 50.10 (0.74); Blood Pressure SBP (mmHg) 133.28 (1.25); DBP (mmHg) 83.52 (0.72); BMI (kg/m2) 33.67 (0.38); Bodyweight (kg) 93.70 (1.20); Cholesterol (mmol/L) 5.48 (0.08); Triglycerides (mmol/L) 1.96 (0.09); HDL (mmol/L) 1.46 (0.03); LDL (mmol/L) 2.94 (0.09); Fat intake (% per day) 23.85 (0.55); Fruit and Vegetables (portions/ day) 6.41 (0.31); Total PA (Met-min/week) 1828.45 (153.24); Vigorous PA (Met-min/week) 585.76 (93.22); Moderate PA (Met-min/week) 437.05 (81.82); Walking PA (Met-min/week) 1205.33 (137.36)

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Low-intensity motivational interviewing

Setting
Primary care

Method of allocation
The randomisation protocol was stratified by gender and age based on patient records. The patients within each stratum were divided into blocks of 12 and then randomly allocated to the MI intervention and minimal intervention groups

Delivery Face-to-face consultation with a physical activity specialist or registered dietician **Length of follow-up** 18 months	using computer generated random numbers by a ratio of 7:5. **Measurement of exposure** Not reported **Comparator** MI counselling intervention or minimal intervention
Outcomes and Analysis	
Outcomes Blood pressure, Cholesterol, Physical activity, Diet	**Outcome measurement** Self-report questionnaire and biomedical measures **Analysis strategy** Intent-to-treat analyses. Mixed-model ANCOVAs with repeated measures on the first factor and Bonferroni correction for multiple comparisons and hierarchical multiple linear regression **Confounders** Not reported
Results **Intervention group**	**Results** **Control group**
Before Total Met Minutes/wk 1854.08 (2174.67) Walking Met Minutes/wk 996.07 (1116.59) Moderate Met Minutes/wk 440.69 (1091.22) Vigorous Met Minutes p/wk 590.05 (1294.38) Stage of Change 3.22 (1.36) BMI 33. 66 (5.12) Bodyweight 93.64 (15.93) Fat Intake (% fat intake per day) 23.87 (7.67) Fruit & Vegetable Intake (portions per day) 6.31 (4.02) SBP (mmHg) 133.12 (16.53) DBP (mmHg) 83.42 (9.63) Cholesterol (mmol.l-1) 5.51 (1.01) HDL (mmol.l-1) 1.46 (0.38) LDL (mmol.l-1) 2.96 (1.14) Triglycerides (mmol.l-1) 1.96 (0.79) **After** Total Met Minutes/wk 3153.67 (3393.64) Walking Met Minutes/wk 1265.14 (1352.25) Moderate Met Minutes/wk 861.61 (1526.16) Vigorous Met Minutes p/wk 1060.74 (2119.54) Stage of Change 3.19 (1.61)	**Before** Total Met Minutes/wk 2278.56 (2820.37) Walking Met Minutes/wk 1242.45 (1432.69) Moderate Met Minutes/wk 576.15 (1159.23) Vigorous Met Minutes p/wk 746.55 (1672.04) Stage of Change 3.47 (1.40) BMI 33.37 (4.47) Bodyweight 91.38 (16.88) Fat Intake (% fat intake per day) 23.89 (7.70) Fruit & Vegetable Intake (portions per day) 6.94 (4.48) SBP (mmHg) 132.41 (17.33) DBP (mmHg) 81.92 (9.27) Cholesterol (mmol.l-1) 5.39 (0.93) HDL (mmol.l-1) 1.52 (0.43) LDL (mmol.l-1) 3.01 (1.08) Triglycerides (mmol.l-1) 1.77 (1.02) **After** Total Met Minutes/wk 3272.10 (3874.99) Walking Met Minutes/wk 1327.70 (1641.78) Moderate Met Minutes/wk 1086.24 (1670.45) Vigorous Met Minutes p/wk 972.04 (2023.38) Stage of Change 2.87 (1.68)

BMI 33.68 (4.77) Bodyweight 94.12 (15.66) Fat Intake (% fat intake per day) 22.97 (7.26) Fruit & Vegetable Intake (portions per day) 6.30 (3.76) SBP (mmHg) 128.98 (14.43) DBP (mmHg) 82.40 (9.03) Cholesterol (mmol.l-1) 5.36 (1.03) HDL (mmol.l-1) 1.33 (0.35) LDL (mmol.l-1) 3.28 (1.05) Triglycerides (mmol.l-1) 1.65 (1.01)	BMI 34.04 (4.88) Bodyweight 92.75 (17.37) Fat Intake (% fat intake per day) 20.41 (5.96) Fruit & Vegetable Intake (portions per day) 6.23 (3.58) SBP (mmHg) 129.96 (17.75) DBP (mmHg) 82.81 (8.13) Cholesterol (mmol.l-1) 5.52 (1.03) HDL (mmol.l-1) 1.39 (0.41) LDL (mmol.l-1) 3.48 (0.94) Triglycerides (mmol.l-1) 1.55 (0.78)
Results – Group difference Effect size (Partial eta-squared) Total Met Minutes/wk .016 Walking Met Minutes/wk .040 Moderate Met Minutes/wk .008 Vigorous Met Minutes p/wk .007 Stage of Change .033 BMI .028 Bodyweight .013 Fat Intake (% fat intake per day) .028 Fruit & Vegetable Intake (portions per day) .005 SBP (mmHg) .012 DBP (mmHg) .038 Cholesterol (mmol.l-1) .042 HDL (mmol.l-1) .000 LDL (mmol.l-1) .010 Triglycerides (mmol.l-1) .004	
Trends, Limitations, Comments and Source of Funding	
Significant trends A low-intensity MI counselling intervention is effective in bringing about long-term changes in some, but not all, health-related outcomes (walking, cholesterol levels) associated with CVD risk **General comments**	**Reported limitations** <u>Author</u> Low participation rate; low uptake of the intervention; other important biomedical markers such as insulin and HbA1C were not measured; measures of skinfold and other body composition outcomes were not measured; availability of resources; self-reported measures of physical activity and dietary behaviour; did not set out to determine a full the cost-benefit analysis of the intervention <u>Reviewer</u> **Source of funding** Eastbourne Downs Primary Care Trust

Authors: Hötting K, Reich B, Holzschneider K et al
Year: 2012
Citation: Health Psychology 31(2): 145-155
Country of study: Germany
Aim of study: To demonstrate feasibility and impact of a phone-based small-change weight loss intervention
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Sedentary, healthy, middle-aged adults between 40 and 56 years of age.

Number of people
68

Locality

Recruitment strategy
Advertisements in local newspapers, local radio stations, and announcements in shops, cinemas, and companies

Response rate
Not reported

Characteristics of population
Control
Age (mean, SD) 47.06 (4.33); Gender (female/male) 11/7; Depression score (mean, SD) 11.89 (7.94); Vocabulary scored (mean, SD) 125.22 (15.13); Body mass index (mean, SD) 24.91 (4.35); VO2peak (ml/min/kg; mean, SD) 30.41 (6.93); Self-reported physical activity (hours/week, mean, SD) 7.22 (7.35); Self-reported physical activity (MET per week, mean, SD) 25.90 (26.96)

Experimental
Cycling
Age (mean, SD) 48.06 (4.32); Gender (female/male) 23/13; Depression score (mean, SD) 9.60 (5.60); Vocabulary scored (mean, SD) 120.61 (12.48); Body mass index (mean, SD) 26.98 (4.38); VO2peak (ml/min/kg; mean, SD) 28.30 (6.04); Self-reported physical activity (hours/week, mean, SD) 5.65 (3.89); Self-reported physical activity (MET per week, mean, SD) 19.93 (13.68)

Stretching
Age (mean, SD) 48.22 (4.41); Gender (female/male) 22/10; Depression score (mean, SD) 9.97 (6.39); Vocabulary scored (mean, SD) 121.03 (15.59); Body mass index (mean, SD) 25.46 (3.28); VO2peak (ml/min/kg; mean, SD) 30.47 (4.81); Self-reported physical activity (hours/week, mean, SD) 6.71 (5.27); Self-reported physical activity (MET per week, mean, SD) 24.41 (20.02)

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention Cycling or stretching. The aerobic endurance group exercised on stationary indoor bicycles. The stretching program encompassed stretching and toning of the whole body as well as exercises to improve coordination and flexibility. **Setting** A hall **Delivery** Not reported **Length of follow-up** Not reported. Intervention took 6.8 months (range: 4.7–10.3 months, SD 1.1)	**Method of allocation** Not reported **Measurement of exposure** Recorded attendance **Comparator** Cycling or stretching with control
Outcomes and Analysis	
Outcomes Physical activity, cognition	**Outcome measurement** Self-report questionnaire and cognitive tasks **Analysis strategy** ANOVA **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Cycling Attention 162.00 (31.86) Episodic memory Learning score 58.92 (7.58) Episodic memory Recognition score 13.28 (1.56) Perceptual speed 72.93 (15.72) Executive functions 43.68 (9.98) Spatial reasoning 51.94 (16.59) Stretching Attention 163.47 (27.82) Episodic memory Learning score 60.72 (6.34) Episodic memory Recognition score 14.25 (1.37) Perceptual speed 74.31 (16.45) Executive functions 45.91 (12.60)	**Before** Attention 169.17 (30.20) Episodic memory Learning score 58.89 (8.55) Episodic memory Recognition score 13.67 (1.50) Perceptual speed 68.15 (12.78) Executive functions 44.67 (13.55) Spatial reasoning 56.72 (12.29) **After** Attention 179.61 (34.03) Episodic memory Learning score 60.11 (10.60) Episodic memory Recognition score 13.78 (1.52) Perceptual speed 64.83 (13.07) Executive functions 41.53 (10.23) Spatial reasoning 59.89 (10.36)

Spatial reasoning 54.47 (9.73) **After** Cycling Attention 169.44 (34.09) Episodic memory Learning score 63.75 (6.70) Episodic memory Recognition score 14.36 (0.99) Perceptual speed 67.86 (12.64) Executive functions 40.97 (10.92) Spatial reasoning 55.19 (15.00) Stretching Attention 180.19 (31.97) Episodic memory Learning score 66.69 (4.30) Episodic memory Recognition score 14.59 (0.80) Perceptual speed 69.54 (15.59) Executive functions 42.47 (13.82) Spatial reasoning 58.78 (10.54)	
Results – Group difference Not reported	
Trends, Limitations, Comments and Source of Funding	
Significant trends Cardiovascular fitness has beneficial effects even in high-functioning middle-aged participants, but that these benefits are very specific to memory functions rather than a wider range of cognitive functions. **General comments**	**Reported limitations** <u>Author</u> Control group consisted of participants who decided after the baseline assessment or after only a few training sessions not to participate in the six months training; changes in both exercise groups might be attributable to general enrichment effects rather than physical exercising; <u>Reviewer</u> **Source of funding** The German Research Foundation (DFG HO3924/1-1 and 1-2).

Authors: Kamada M, Kitayuguchi J, Inoue S et al
Year: 2013
Citation: International Journal of Behavioral Nutrition and Physical Activity 10(1): 44
Country of study: Japan
Aim of study: Evaluate the effectiveness of a community-wide campaign for promoting physical activity in middle-aged and elderly people
Study design: Cluster randomized controlled trial
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Residents aged 40 to 79 years.

Number of people
4414

Locality
Unnan, Shimane Prefecture, Japan

Recruitment strategy
Population-based random-sample.

Response rate
73.6%

Characteristics of population

Control

Male 510 (47.3), Age, years Mean ± SD 61.0 ± 10.6, 40-59 471 (43.7), 60-79 607 (56.3); Body mass index, kg/m2 Mean ± SD 22.5 ± 3.2, <18.5 83 (8.1), ≥18.5- < 25 744 (72.2), ≥25 204 (19.8); Self-rated health Excellent/good 878 (81.9), Fair/poor 194 (18.1); Years of education, mean ± SD 11.5 ± 2.3; Employed 695 (69.6), Engagement in farming 552 (52.4), Chronic disease history 659 (61.1), Regular physical activity 574 (64.6); Total walking time, mins/week Median (interquartile range) 60 (0–210), ≥150 311 (37.7); Flexibility activity Daily 253 (24.4), Not daily but occasionally 463 (44.7), Not at all 320 (30.9); Muscle-strengthening activity, days/week, Median (interquartile range) 0 (0–3), ≥2 348 (38.0); Median (interquartile range) VAS pain score Low back 5 (0–32), Knee 0 (0–7); Chronic musculoskeletal pain Low back 133 (13.1), Knee 95 (9.1)

Experimental

Male 1540 (46.2); Age, years Mean ± SD 60.7 ± 10.5, 40-59 1514 (45.4), 60-79 1822 (54.6); Body mass index, kg/m2 Mean ± SD 22.6 ± 3.1, <18.5 226 (7.0), ≥18.5- < 25 2352 (72.9), ≥25 650 (20.1); Self-rated health Excellent/good 2722 (82.7), Fair/poor 569 (17.3); Years of education, mean ± SD 11.5 ± 2.4; Employed 2101 (68.7), Engagement in farming 1626 (49.7), Chronic disease history 2059 (61.7), Regular physical activity 1745 (63.0); Total walking time, mins/week Median (interquartile range) 60 (0–200), ≥150 914 (36.4); Flexibility activity Daily 772 (23.8), Not daily but occasionally 1548 (47.7), Not at all 922 (28.4); Muscle-strengthening activity, days/week Median (interquartile range) 0 (0–3), ≥2 1080 (37.7); Median (interquartile range) VAS pain score Low back 8 (0–36), Knee 0 (0–13); Chronic musculoskeletal pain Low back 441 (14.1), Knee 360 (11.2)

	Excluded populations Respondents who could not walk unaided **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Physical activity, information, education, and support delivery **Setting** Community **Delivery** Information delivery. Flyers, leaflets, community newsletters, posters, banners, and local audio broadcasts Education delivery. Outreach health education program and mass- and individual encouragement by professionals during medical check-ups and various community events, including sports events and festivals. Support delivery. Development of social (peer) support **Length of follow-up** 1 year	**Method of allocation** 12 clusters were randomly sampled, with stratification by blocking within population density category strata, and randomly allocated to three intervention clusters per control cluster **Measurement of exposure** The intervention, flyers, leaflets, and community newsletters were delivered to the household directly in the intervention communities, and the audio messages were only delivered to households in the intervention communities by using the cable network. Educational activities were implemented only at community events in which all participants were residents living in the relevant intervention community **Comparator** Information leaflets or control
Outcomes and Analysis	
Outcomes Physical activity, pain	**Outcome measurement** Self-report **Analysis strategy** Generalized linear mixed model **Confounders** sex, age, BMI, self-rated health, years of education, employment, farming, chronic low back and knee pain, chronic disease history, category of population density, engagement in regular PA at baseline, group allocation and community
Results **Intervention group**	**Results** **Control group**
Before Not reported	**Before** Not reported

After Not reported	**After** Not reported

Results – Group difference

Control

No (%) Effect size

Engaging regular physical activity at follow-up 451 (60.3)

Change from not engaging to engaging 58 (26.9)

Total walking time, mins/week

Median (IQR) change 0 (−60-45)

≥150 at follow-up 232 (34.3)

Change from not ≥150 to ≥150 66 (18.9)

Flexibility activity

Daily at follow-up 190 (22.9)

Change from not daily to daily

Muscle-strengthening activity, days/week

Median (IQR) change 0 (0–0)

≥2 at follow-up 261 (32.5)

Change from not ≥2 to ≥2 52 (12.8)

Group A

No (%) Effect size

Engaging regular physical activity at follow-up 482 (60.3) 1.02 (0.84-1.23)

Change from not engaging to engaging 59 (27.6)

Total walking time, mins/week

Median (IQR) change 0 (−60-40) 11.1 (−7.02-29.3)

≥150 at follow-up 264 (35.4)

Change from not ≥150 to ≥150 63 (17.3)

Group FM

No (%) Effect size

Engaging regular physical activity at follow-up 429 (55.9) 0.94 (0.77-1.14)

Change from not engaging to engaging 63 (23.9)

Flexibility activity

Daily at follow-up 167 (19.6) 0.95 (0.75-1.19)

Change from not daily to daily

Muscle-strengthening activity, days/week

Median (IQR) change 0 (0–0) −0.14 (−0.30-0.02)

≥2 at follow-up 226 (27.5)

Change from not ≥2 to ≥2 60 (12.6)

Group AFM
No (%) Effect size
Engaging regular physical activity at follow-up 489 (60.0) 0.97 (0.80-1.17)
Change from not engaging to engaging 74 (30.7)

Total walking time, mins/week
Median (IQR) change 0 (−45-40) −13.4 (−29.9-3.13)
≥150 at follow-up 252 (34.0)
Change from not ≥150 to ≥150 66 (17.1)

Flexibility activity
Daily at follow-up 208 (23.2) 1.44 (0.59-3.53)
Change from not daily to daily

Muscle-strengthening activity, days/week
Median (IQR) change 0 (−1-0) 0.24 (−0.15-0.64)
≥2 at follow-up 314 (36.3)
Change from not ≥2 to ≥2 86 (19.2)

Trends, Limitations, Comments and Source of Funding

Significant trends

The 1-year CWC did not significantly promote the recommended level of physical activity (adjusted odds ratio: 0.97; 95% confidence interval: 0.84–1.14).

General comments

This paper also presents an evaluation of implementation (but no cost information).

Reported limitations

Author

Self-report; single items in questionnaire; recall bias; lack of objective methods to assess daily flexibility and muscle-strengthening activities in population-wide studies; contamination of the visual information in the intervention

Reviewer

Source of funding

Grant-in-aid from the Ministry of Health, Labour and Welfare of Japan (Comprehensive Research on Prevention of Cardiovascular Diseases and Other Lifestyle Related Diseases: H20-Junkankitou-Ippan-001)

Authors: King AC, Ahn DK, Oliveira BM et al
Year: 2008
Citation: American Journal of Preventive Medicine 34(2): 138-142
Country of study: USA
Aim of study: Evaluate the efficacy of a hand-held computer for increasing moderate intensity or more vigorous physical activity
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population	**Characteristics of population**
>50 years old; <60min/week of MOD+ PA over the previous 6 months and interested in learning ways to increase physical activity; free of medical conditions limiting participation in moderate-intensity activities; English language skills to enable informed consent and participate in study procedures; willing to use a PDA as directed; and willing to be randomized **Number of people** 37 **Locality** Not reported **Recruitment strategy** Local mass media outlets **Response rate** Not reported	<u>Control</u> Age, mean (SD) 59.6 (7.6); Years of education, 16.6 (2.2); Race (% white) 83.3; Gender (% women) 44.4; Married (%) 83.3; Employed (%) 66.7; Health status=excellent or very good (%) 66.7 <u>Experimental</u> Age, mean (SD) 60.7 (6.8); Years of education, 16.9 (2.2); Race (% white) 73.7; Gender (% women) 42.1; Married (%) 63.1; Employed (%) 57.9; Health status=excellent or very good (%) 63.2 **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention	**Method of allocation**
Self-regulatory behavioural strategies derived from social cognitive perspectives to motivate physical activity change. Daily and weekly individualized physical activity goal-setting. **Setting** Community-based **Delivery** Personal digital assistant/hand-held computer **Length of follow-up** 8 weeks	Not reported **Measurement of exposure** PDA, Pedometer and self-report questionnaire. **Comparator** Standard information control

Outcomes and Analysis

Outcomes	**Outcome measurement**

Caloric expenditure/kg/wk and reported minutes/wk in moderate intensity or more vigorous physical activity. Barriers and facilitators.	Each completed assessment was electronically date and time "stamped". **Analysis strategy** ANOVA **Confounders** Baseline-adjusted
Results **Intervention group**	**Results** **Control group**
Before Reported minutes/wk in MOD+PA 123.9 (114.5) Caloric expenditure/kg/wk in MOD+PA 7.8 (7.4) **After** Reported minutes/wk in MOD+PA 301.6 (298.3) Caloric expenditure/kg/wk in MOD+PA 18.1 (19.2) Most commonly reported facilitators of physical activity across 8 weeks were good weather (33% of the time), good location (25%), enjoyable scenery (19%), scheduling in physical activity (18%), and having others join the participant (12%). Exercise facilities and exercise equipment availability were rarely reported (<3% of the time). Most commonly reported physical activity barriers were lack of time (30% of the time), feeling too tired (16%), family or social obligations (9%), and traffic (6%).	**Before** Reported minutes/wk in MOD+PA 215.0 (166.2) Caloric expenditure/kg/wk in MOD+PA 13.4 (11.5) **After** Reported minutes/wk in MOD+PA 135.0 (208.2) Caloric expenditure/kg/wk in MOD+PA 8.9 (13.3)
Results – Group difference Difference between arms significant at $p<0.05$.	
Trends, Limitations, Comments and Source of Funding	
Significant trends Intervention participants reported significantly greater 8-week mean estimated caloric expenditure levels and minutes per week in MOD+ activity **General comments**	**Reported limitations** <u>Author</u> Small sample size; self-selected sample; unclear whether the PDA-delivered program would maintain its effectiveness beyond the 8 weeks <u>Reviewer</u> Self-reported measures of physical activity and dietary behaviour; did not set out to determine a full the cost-benefit analysis of the intervention **Source of funding**

	Stanford University's Office of Technology Licensing and by Public Health Service grant #5T32H107034 from the NIH/NHLBI

Authors: King AC, Hekler EB, Grieco LA et al
Year: 2013
Citation: PLoS One 8(4): e62613
Country of study: USA
Aim of study: To apply a behavioural science-informed user experience design process in developing smartphone applications to increase regular physical activity and decrease sedentary behaviour
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population	**Characteristics of population**
Community-dwelling adults ages 45 years and older who were insufficiently physically active, reported typically sitting for 10 or more hours per day **Number of people** 68 **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Not reported	<u>Control</u> Not applicable <u>Experimental</u> Average of 59.1±9.2 years old (range = 45–81 years), with 73.5% women. Seventy-six percent had a college degree, 51.4% had an annual household income of $70,000 or greater, 48.5% were working full-time, and 39.7% reported being currently married. Sixty-nine percent were non-Hispanic White, 13% were Hispanic/Latino, and 12% were Asian. Mean body mass index (BMI) was 29.6±6.2. **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention	**Method of allocation**
Self-regulatory behavioural strategies derived from social cognitive perspectives to motivate physical activity change. Daily and weekly individualized physical activity goal-setting. **Setting** Community-based **Delivery** Phone app. **Length of follow-up** 8 weeks	Computerised version of the Efron procedure **Measurement of exposure** Smart-phone app and self-report questionnaire. **Comparator** Analytic app, Social app, and Affect app

Outcomes and Analysis

Outcomes	**Outcome measurement**

Changes in Moderate-to-Vigorous intensity Physical Activity, changes in Discretionary Sitting Time	Self-report **Analysis strategy** Analysis of covariance **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Not reported **After** Not reported	**Before** Not applicable **After** Not applicable

Results – Group difference

Changes in Moderate-to-Vigorous intensity Physical Activity

Participants across all three apps reported significant mean increases in weekly minutes of brisk walking across the 8-week intervention period (paired t = 5.3, p<0.0001) (between-group difference non-significant, p>0.73).

Increase in weekly minutes of brisk walking across the three apps averaged 100.8±167.0 minutes (Group Mean minutes/week increase ± SD: Analytic = 71.1±147.3; Social = 122.9±153.3; Affect = 105.7±187.2).

Participants across all apps reported significant mean weekly increases in total moderate-to-vigorous physical activities (paired t = 4.5, p<0.0001) (between-group difference non-significant, p>0.99).

Increase in weekly minutes of moderate-to-vigorous physical activity across the three apps averaged 188.6±289.3 minutes/week (Analytic = 172.9±200.5; Social = 257.1±323.8; Affect = 134.3±319.1).

Changes in Discretionary Sitting Time

Significant decreases in the daily amount of discretionary time they spent sitting in front of the television (paired t = 2.5, p<0.02) (between-group difference non-significant, p>0.34).

Decrease in daily minutes of television viewing time averaged 29.1±84.5 minutes/day across the three apps.

(between-group difference non-significant p>0.34). Mean decreases larger in the Analytic and Social apps relative to the Affect app (mean for Analytic = 48.9±81.7; Social = 34.9±95.1; Affect = 6.5±74.3).

Trends, Limitations, Comments and Source of Funding

Significant trends The three applications were sufficiently robust to significantly improve regular moderate-to-vigorous intensity physical activity and decrease leisure-time sitting during the 8-week behavioural adoption period.	**Reported limitations** Author Lack of an appropriate control group; small sample size; short follow-up Reviewer Self-reported measures of physical activity and

General comments	dietary behaviour; did not set out to determine a full the cost-benefit analysis of the intervention **Source of funding** Public Health Service grant #RC1 HL099340 from the National Heart, Lung, & Blood Institute of the National Institutes of Health, awarded to ACK.

Authors: Maiorana A, O'Driscoll G, Dembo L et al
Year: 2001
Citation: Medicine and Science in Sports and Exercise 33(12): 2022-028
Country of study: Australia
Aim of study: Investigate the effect of eight weeks of exercise training on functional capacity, muscular strength, body composition, and vascular function in sedentary but healthy subjects
Study design: Randomized crossover protocol
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population Not reported **Number of people** 19 **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** <u>Control</u> Not applicable <u>Experimental</u> **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Exercise **Setting** Not reported **Delivery** Not reported **Length of follow-up** 16 week	**Method of allocation** Not reported **Measurement of exposure** Laboratory **Comparator** Not applicable

Outcomes and Analysis

Outcomes Body composition	**Outcome measurement** Haematological and biochemical profile, self-report **Analysis strategy** Presented as means and SD **Confounders**

	Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Body weight (kg) 84.5 ± 3.5 84.3 BMI 26.9 ± 0.1 26.8 Waist:Hip (%) 0.92 ± 0.02 Exercise Test Workload (60w) Heart rate 106 ± 3 Systolic BP 163 ± 5 Rate pressure product 17313 ± 676 Rate perceived exertion 8.9 ± 0.4 Exercise Test Workload (140 W) Heart rate 152 ± 4 Systolic BP (mm Hg) 220 ± 8 Rate pressure product 32433 ± 1487 Rate perceived exertion 14.9 ± 0.7 **After** Body weight (kg) 84.3 ± 3.4 BMI 26.8 ± 0.9 Waist:Hip (%) 0.90 ± 0.02 Exercise Test Workload (60w) Heart rate (beats•min-1) 100 ± 3‡ Systolic BP (mm Hg) 160 ± 5 Rate pressure product (beats•min-1•mm Hg) 15814 ± 579* Rate perceived exertion 8.9 ± 0.4 Exercise Test Workload (160 W) Heart rate 140 ± 4 Systolic BP (mm Hg) 207 ± 14 Rate pressure product 29335 ± 2446 Rate perceived exertion 13.0 ± 0.5	**Before** Not applicable **After** Not applicable
Results – Group difference Not applicable	
Trends, Limitations, Comments and Source of Funding	
Significant trends Moderate intensity circuit training designed to minimize the involvement of the arms improves functional capacity, body composition, and strength in healthy, middle-aged subjects without significantly influencing upper limb vascular function	**Reported limitations** Author None reported Reviewer Small sample size; no control; statistical power; economic evaluation **Source of funding**

General comments	Heart Foundation (Australia) and Medical Research Fund of Western Australia

Authors: Moustaka FC, Vlachopoulos SP, Kabitsis C et al
Year: 2012
Citation: Journal of Physical Activity and Health 9(1): 138-150
Country of study: Greece
Aim of study: Evaluated the effectiveness of an autonomy-supportive intervention
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Women aged 30 to 58 years

Number of people
35

Locality
Not reported

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Control
age 30 to 50 (mean = 41.94 ± 6.45) with 1 to 20 years of exercise experience (mean = 10.31 ± 5.22)

Experimental
Age 30 to 58 years (mean = 46.21 ± 7.74) with 2 to 20 years of exercise experience (mean = 11.32 ± 4.58)

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Autonomy-supportive intervention based on self-determination theory in influencing perceptions of autonomy support, basic psychological needs, behavioural regulations, subjective vitality, and exercise behaviour

Setting
Community

Delivery
Exercise instructor

Length of follow-up
8 week

Method of allocation
No capability to randomly allocate

Measurement of exposure
Not reported

Comparator
Autonomy-supportive or a lack of autonomy support instructing

Outcomes and Analysis

Outcomes
Regulations in exercise; psychological needs; frequency of exercise;

Outcome measurement
Self-report and monitoring the participants' exercise attendance

Analysis strategy

	Repeated measures MANOVA **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Before α (Self-Determination Theory) [C] Basic psychological needs Competence .90 (3.46 ± 0.81) [3.32 ± 0.73] Relatedness .88 (4.13 ± 0.75) [3.79 ± 0.54] Autonomy .84 (3.31 ± 0.34) [3.07 ± 0.82] Behavioral regulations External regulation .70 (0.97 ± 0.57) [0.84 ± 0.61] Introjected regulation .65 (2.65 ± 0.75) [2.21 ± 0.77] Identified regulation .72 (3.49 ± 0.43) [3.33 ± 0.50] Intrinsic motivation .83 (3.09 ± 0.78) [2.93 ± 0.73] Amotivation .81 (0.71 ± 0.51) [0.85 ± 0.65] Subjective vitality .84 (4.82 ± 1.12) [4.83 ± 0.72] Perceived autonomy support .97 (3.84 ± 0.28) [3.97 ± 0.10] **After** α (Self-Determination Theory) [C] Basic psychological needs Competence .96 (4.27 ± 0.38) [2.53 ± 0.44] Relatedness .93 (3.94 ± 0.50) [3.09 ± 0.54] Autonomy .98 (4.78 ± 0.37) [2.25 ± 0.44] Behavioral regulations External regulation .96 (0.11 ± 0.26) [1.31 ± 0.37] Introjected regulation .95 (3.05 ± 0.47) [1.35 ± 0.39] Identified regulation .91 (3.94 ± 0.22) [2.95 ± 0.45] Intrinsic motivation .96 (3.78 ± 0.32) [1.87 ± 0.39] Amotivation .95 (0.11 ± 0.35) [1.35 ± 0.41] Subjective vitality .95 (6.09 ± 0.50) [4.19 ± 0.59] Perceived autonomy support .99 (6.74 ± 0.29) [1.52 ± 0.58]	**Before** Not reported **After** Not reported
Results – Group difference Not reported	

Trends, Limitations, Comments and Source of Funding	
Significant trends The experimental group reported an increase in perceived autonomy support, the fulfillment of the needs for autonomy and competence, identified regulation, intrinsic motivation, and subjective vitality **General comments**	**Reported limitations** <u>Author</u> Limited to Greek middle-age healthy women; lack of a capability to randomly allocate; longer post-intervention assessment time frames; <u>Reviewer</u> Not reporting control; small sample size; statistical power; self-report; no economic evaluation **Source of funding** Not reported

Authors: Palumbo MV, Wu G, Shaner-McRae H et al
Year: 2012
Citation: Applied Nursing Research 25(1): 54-59
Country of study: USA
Aim of study: Assess the feasibility of a Tai Chi workplace wellness program as a cost effective way of improving physical and mental health, reducing work related stress, and improving work productivity among older nurses
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Registered Nurses or Licensed Practical Nurses who are 40 years or older, currently employed full time or part time in staff nurse position which involved lifting patients

Number of people
14

Locality
Not reported

Recruitment strategy
First come first serve from staff

Response rate
Not reported

Characteristics of population
Not reported

Excluded populations
Those unable to attend 15 weeks of class due to work or family scheduling conflicts

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Tai Chi

Setting
Workplace. Medical centre

Delivery
Tai Chi instructor

Length of follow-up
15 week

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Control

Outcomes and Analysis

Outcomes
Physical and mental health

Outcome measurement
Self-report

Analysis strategy
Wilcoxon Two-Sample

	Confounders Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Not reported **After** Not reported	**Before** Not reported **After** Not reported
Results – Group difference Control Mean (SD) SF36 General Health −4.0 (4.2) Mental Health 7.0 (9.1) Nursing Stress Scale Conflict with Physicians −1.6 (2.4) Lack of Support 0.0 (0.0) Conflict with Other Nurses −0.4 (2.3) Workload 0.8 (4.7) Overall NSS (max=102, highly stressful) 2.2 (5.4) Perceived Stress Scale (max=40, highly stressful) −1.4 (3.9) Sit and Reach (cm) 0.1 (2.3) Functional reach (cm) −3.1 (1.5) Work Limitations Questionnaire Physical Demands −2.5 (8.1) Mental Demands 0.0 (6.6) Overall WLQ (1–100 range) −0.8 (1.4) Tai Chi Mean (SD) SF36 General Health 0.6 (7.0) Mental Health 2.5 (9.3) Nursing Stress Scale Conflict with Physicians −0.8 (2.8) Lack of Support −0.8 (2.8) Conflict with Other Nurses −0.8 (0.8) Workload −1.8 (2.5) Overall NSS (max=102, highly stressful) −6.1 (14.2) Perceived Stress Scale (max=40, highly stressful) −2.8 (2.4) Sit and Reach (cm) 0.3 (1.7) Functional reach (cm) 1.9 (1.5) Work Limitations Questionnaire Physical Demands −10.4 (11.7) Mental Demands −11.1 (10.1) Overall WLQ (1–100 range) −3.1 (1.2)	

Trends, Limitations, Comments and Source of Funding

Significant trends

The Tai Chi group showed non-significant improvement in general health and mental health while the control group showed a decline in both. The Tai Chi group showed a greater reduction in work stress than the control group did post exercise. The reduction in "lack of support" related stress nearly reached significant group effect. The Tai Chi group also showed a larger reduction in general stress than the control group.

General comments

Reported limitations

Author: Small sample size; cost analysis; baseline differences could not be statistically controlled; intervention tested on "ready recruits"; study was done in a single geographic area; lacked underrepresented populations and men; instructor effects due to individual style

Reviewer

Source of funding

Support was received from: State of Vermont - Agency of Human Services, University of Vermont, General Clinical Research Center and Janice Bunn PhD, NIH Grant # M01 RR00109, Fletcher Allen Health Care

Authors: Pratley RE, Hagberg JM, Dengel DR et al
Year: 2000
Citation: Journal of the American Geriatrics Society 48(9): 1055-1061
Country of study: USA
Aim of study: Test the effects of aerobic exercise training on glucose-stimulated insulin responses in middle-aged and older individuals
Study design: Controlled trial
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population Healthy, non-smoking 45- to 75-year-old men **Number of people** 17 **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Age 59.0 ± 2.0. Other details not reported. **Excluded populations** Individuals with significant abnormalities on screening, including diabetes or other endocrine disorders, hypertension, or evidence of cardiovascular disease **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Moderate-intensity aerobic exercise **Setting** An academic medical centre **Delivery** Not reported **Length of follow-up** 9 months	**Method of allocation** Not reported **Measurement of exposure** Blood samples and self-report **Comparator** Not reported

Outcomes and Analysis

Outcomes Body fat, fat distribution, diet intake, PA, dietary control	**Outcome measurement** Blood samples and self-report **Analysis strategy** Two tailed paired t-tests and multiple regression analysis **Confounders** Not detailed

Results **Intervention group**	**Results** **Control group**
Before Body weight (kg) 80.8±2.1 Body mass index 26.6 ± 0.6 Body fat(%)22.8 ± 1.6 Fat free mass (kg) 62.2 ± 1 .7 Waist circumference (em) 93.3 ± 2.0 Hip circumference (em) 100.9 ± 1.3 Waist-hip ratio 0.92 ± 0.02 **After** Body weight (kg) 79.7 ± 2.2 Body mass index 25.9 ± 0.6 Body fat(%)20.8± 1.51 Fat free mass (kg) 62.9 ± 1.7 Waist circumference (em) 91.6 ± 1 .8 Hip circumference (em) 100.4± 1 .1 Waist-hip ratio 0.91 ± 0.01	**Before** Not reported **After** Not reported
Results – Group difference Not reported	
Trends, Limitations, Comments and Source of Funding	
Significant trends Aerobic exercise training of 9-month duration decreases plasma insulin concentrations in response to both oral and intravenous glucose stimuli in healthy older men. Significant decreases in the waist circumference and the WHR were observed after aerobic exercise training **General comments**	**Reported limitations** Author None reported Reviewer Small sample size; cost analysis; baseline differences were not described and could not be statistically controlled; study was done in a single geographic area; lacked underrepresented populations and men **Source of funding** NIA Clinical Investigator Award: K08-AG00494, R01-AG07660, K07 AG00608, NRSA F32-AG-05555; Johns Hopkins Academic Teaching Nursing Home Award: PO1 AF04402; General Clinical Research Center at Johns Hopkins Bayview Medical Center: MO1 RR02719

Authors: Ramos-Jiménez A, Hernandez-Torres RP, Wall-Medrano A et al
Year: 2009
Citation: International Journal of Yoga 2(2): 49-54
Country of study: Mexico
Aim of study: Evaluate the effect of an intensive Hatha Yoga intervention on cardiovascular risk factors
Study design: Prospective quasi-experimental
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Middle-aged and older women (1) to be healthy, (2) conventional HY practitioners and (3) not taking any drugs that affect either energy metabolism or hormonal status

Number of people
13

Locality
Chihuahua, in Northern Mexico

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Control
Not appropriate

Experimental
Middle-aged (43.2 ± 3.1 years) and older (62.2 ± 5.9 years)

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Hatha Yoga

Setting
YMCA

Delivery
Certified yoga instructor specialized in training older people.

Length of follow-up
11 week

Method of allocation
Not reported

Measurement of exposure
Self-report

Comparator
No comparator

Outcomes and Analysis

Outcomes
Body mass index, % body fat and Σ skin folds, systolic and diastolic blood pressure and cholesterol

Outcome measurement
Laboratory and self-report

Analysis strategy
PROC GLM ANOVA test

	Confounders Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Middle-aged Body weight (kg) 5 9 ± 7 BMI (kg/ m2) 23 ± 2 Body fat (%) 27 ± 5 Σ Skin folds (c m) 1 5 9 ± 3 5 Cardio v asc ular fitness BPs (mmHg) 1 1 6 ± 7 BPd (mmHg) 81 ± 1 0 Biochemistry Glucose (mg/ dl) 68 ± 9 TA G (mg/ dl) 1 0 2 ± 46 HDL-C (mg/ dl) 41 ± 8 TC (mg/ dl) 1 7 6 ± 22 LDL-C (mg/ dl) 1 47 ± 3 9 log (TA G/ HDL-C) 0 .41 ± 0 .3 0 Older Body weight (kg) 63 ± 7 BMI (kg/ m2) 26 ± 3 Body fat (%) 29 ± 5 Σ Skin folds (c m) 1 5 8 ± 3 3 Cardio vascular fitness BPs (mmHg) 1 29 ± 1 1 BPd (mmHg) 86 ± 7 Bio chemistry Glucose (mg/ dl) 7 1 ± 1 2 TAG (mg/ dl) 1 3 8 ± 62 HDL-C (mg/ dl) 43 ± 7 TC (mg/ dl) 1 86 ± 3 4 LDL-C (mg/ dl) 1 7 1 ± 3 5 Log (TA G/ HDL-C) 0 .48 ± 0 .21 **After** Middle-aged Body weight (kg) 60 ± 6 BMI (kg/ m2) 23 ± 2 Body fat (%) 25 ± 5 Σ Skin folds (c m) 1 40 ± 41 Cardio vascular fitness BPs (mmHg) 1 1 8 ± 1 0 BPd (mmHg) 83 ± 4 Bio chemistry Glucose (mg/ dl) 99 ± 9	**Before** Not appropriate **After** Not appropriate

TA G (mg/ dl) 1 45 ± 21 HDL-C (mg/ dl) 5 8 ± 1 2 TC (mg/ dl) 25 1 ± 62 LDL-C (mg/ dl) 1 5 4 ± 61 log (TA G/ HDL-C) 0 .43 ± 0 .1 1 Older Body weight (kg) 62 ± 8 BMI (kg/ m2) 26 ± 3 Body fat (%) 28 ± 5 Σ Skin folds (c m) 1 43 ± 3 6 Cardio vascular fitness BPs (mmHg) 1 24 ± 1 0 BPd (mmHg) 82 ± 6 Bio chemistry Glucose (mg/ dl) 88 ± 21 TA G (mg/ dl) 1 5 7 ± 5 6 HDL-C (mg/ dl) 5 6 ± 9 TC (mg/ dl) 23 3 ± 5 6 LDL-C (mg/ dl) 1 46 ± 47 Log (TAG/ HDL-C) 0 .43 ± 0 .1 7	
Results – Group difference Not appropriate	
Trends, Limitations, Comments and Source of Funding	
Significant trends Program improved different cardiovascular risk factors in middle-aged and older women **General comments**	**Reported limitations** <u>Author</u> Small sample size; no control; <u>Reviewer</u> Statistical power; economic evaluation; **Source of funding** Not reported

Authors: Sheeran P, Harris P, Vaughan J et al
Year: 2013
Citation: Health Psychology 32(7): 802-809
Country of study: UK
Aim of study: Study tested whether mental contrasting promotes rates of physical activity among overweight, middle-aged, and low-SES men
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population Among overweight, middle-aged, and low-SES men **Number of people** 467 **Locality** North of England **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Male, mean age of 53.88 years (SD 12.42). Predominantly working class and were holding, or had held, unskilled (23%) or semiskilled jobs (49%). 69% were currently employed; the remainder were retired (29.80%) or unemployed (1.00%). Mean BMI of 27.80 (SD 3.72). **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Mentally contrasting fantasy with reality **Setting** Community **Delivery** The intervention was embedded in the questionnaire for relevant participants. **Length of follow-up** 7 months	**Method of allocation** Random number generator **Measurement of exposure** Questionnaire **Comparator** Not applicable

Outcomes and Analysis

Outcomes Physical activity	**Outcome measurement** Self-report **Analysis strategy** Longitudinal analysis and intention-to-treat **Confounders**

	Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Physical activity scale was 4.25 (SD 2.28) Modal number of days during the previous week that participants were "active long enough to work up a sweat" was zero (27.90%) 53.80% of participants (n=56) were active on zero days or one day 70.10% of participants (n=73) reported being "rarely" or "never" active long enough to work up a sweat **After** Longitudinal analysis At 7-months difference in physical activity that favoured participants who had engaged in mental contrasting was highly significant F(1, 82) =15.50, p<.001, d=.87. Intention-to-treat analysis Mental contrasting engendered significant increases in physical activity at 7-month follow-up, F(1, 100) = 3.30, p<.08, d=.24.	**Before** Not presented **After** Not presented
Results – Group difference The rate observed among control participants, mental contrasting participants were physically active 38% more often during the previous month.	
Trends, Limitations, Comments and Source of Funding	
Significant trends Mental contrasting was effective in enhancing rates of physical activity **General comments** Participants were not aware that they were taking part in an experimental study	**Reported limitations** <u>Author</u> Unable to measure whether the desired future primes obstacles to its realisation or to assess energisation in the wake of mental contrasting; self-report measure; passive (no-intervention) comparison group <u>Reviewer</u> No economic evaluation **Source of funding** Not reported

Authors: Stadler G, Oettinge G, Gollwitzer PM.
Year: 2009
Citation: American Journal of Preventive Medicine 36(1): 29-34.
Country of study: Germany
Aim of study: Compare a health information intervention with an information + self-regulation intervention
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Primary data OR modelling
Primary data

Eligible population
Women aged 30–50 years

Number of people
256

Locality
Germany

Recruitment strategy
Mass mailing

Response rate
256/10,500

Characteristics of population
Age (years) M (SD) 41.28 (6.19); Working status (%) Employed full time 51.8, Employed part time 30.8, Not in paid job 17.4; Partner (%) With partner 73.2; Highest education level (%) <10 years of school 44.5; BMI (%) <25 57.4, 25–29 31.3, 30 11.3; Body fat M % (SD) 29.49 (6.45); Baseline physical activity Mean minutes per week (SD) 41.57 (45.03); Sedentary participants (%) 40.2

Excluded populations
Those restricted on changing their physical activity and diet; where medical supervision of behaviour change was necessary; participating in similar programs.

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
The information intervention consisted of (1) an information phase in which participants studied a health education leaflet (2) a knowledge self-check (multiple-choice test); and (3) a discussion phase in which participants compared their own answers with the correct answers provided by the interventionist.

In the information + self-regulation group, participants received the same, additionally (1) their most important current wish regarding physical activity; (2) the most positive outcome of realizing their wish and events and experiences they associated with this positive outcome; (3) the most critical obstacle; and (4) three implementation intentions

Method of allocation
Phone interviewers allocated the remaining women to the groups according to a computer-generated block-randomization list with a block size of three.

Measurement of exposure
Not reported

Comparator
All participants received the same information intervention; participants in the information + self-regulation group additionally learned a technique that integrates mental contrasting with implementation intentions.

Setting Not reported **Delivery** Not reported **Length of follow-up** 4 months	
Outcomes and Analysis	
Outcomes Self-reported minutes of moderate-to-vigorous physical activity per week.	**Outcome measurement** Participants received a diary equivalent to the baseline diary to take home and use to record their physical activity. **Analysis strategy** Mixed-effects model **Confounders** No comment
Results **Intervention group** Baseline 37.87 (25.94, 52.04) 16 weeks after intervention 96.06 (69.61, 126.79)	**Results** **Control group** Baseline 37.87 (25.94, 52.04) 16 weeks after intervention 49.08 (32.72, 68.76)
Results – Group difference The mixed-effects model showed an effect of condition (F[1,204] = 18.92, p<0.001) indicating that participants in the information + self-regulation group were more physically active than participants in the information group	
Trends, Limitations, Comments and Source of Funding	
Significant trends Participants in the information + self-regulation group were twice as physically active (i.e., nearly 1 hour more per week) as participants in the information group. This difference appeared as early as the first week after intervention and was maintained over the course of the 4 months. **General comments** No comment	**Reported limitations** <u>Reviewer</u> No economic analysis <u>Author</u> Self-reported physical activity; attrition might have introduced bias; participants in this study were more motivated; **Source of funding** DAK (a German Health Insurance Association) and the German Research Foundation (Deutsche Forschungsgemeinschaft).

Authors: Ueda M
Year: 2004
Citation: Journal of Physiological Anthropology and Applied Human Science 23(5): 143-148
Country of study: Japan
Aim of study: To ascertain the effects of this program on climacteric symptoms, QOL, and attitude towards exercise
Study design: Controlled trial
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
40- to 60-year-old women with climacteric symptoms

Number of people
35

Locality
Not reported

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Age (years)
premenopausal condition
40–44 6
45–49 5
50–54 0
55–59 0

perimenopausal condition
40–44 0
45–49 5
50–54 8
55–59 0

postmenopausal condition
40–44 0
45–49 0
50–54 5
55–59 6

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Structured education and exercise program, lecture provides basic information about climacteric symptoms and then women were divided into smaller groups to exchange opinions about treatments and measures.

Setting
Not reported

Delivery
Lecture format

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Education verses control

Length of follow-up 12 weeks	
Outcomes and Analysis	
Outcomes Climacteric symptoms, quality of life	**Outcome measurement** Self-report **Analysis strategy** Mean and standard deviations presented. Two-factor variance analysis. A multiple comparison test was then used for items with significant F values. **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Mean SD Kupperman's index 15.80 9.44 vasomotor 6.75 3.84 motorial 1.50 0.89 psychosomatic 7.55 5.95 vasomotor 6.20 3.55 paresthesia 1.70 2.08 insomnia 1.40 1.73 nervousness 1.70 1.75 melancholia 0.90 0.85 vertigo 0.15 0.37 weakness (fatigue) 1.10 0.91 arthralgia and myalgia 1.50 0.89 headache 0.60 0.68 palpitation 0.55 0.69 formication 0.00 0.00 Total score (Quality of life) 72.75 9.15 **After** Mean SD Kupperman's index 12.25 7.12 vasomotor 6.10 4.05 motorial 1.15	**Before** Mean SD Kupperman's index 18.20 8.62 vasomotor 7.53 4.22 motorial 1.73 1.16 psychosomatic 8.93 5.30 vasomotor 6.93 3.85 paresthesia 1.07 1.67 insomnia 1.33 1.95 nervousness 2.13 1.60 melancholia 1.13 0.74 vertigo 0.67 0.90 weakness (fatigue) 1.80 1.01 arthralgia and myalgia 1.73 1.16 headache 0.80 0.78 palpitation 0.60 0.74 formication 0.00 0.00 Total score (Quality of life) 68.67 9.80 **After** Mean SD Kupperman's index 18.73 5.39 vasomotor 8.20 4.06 motorial 1.33 0.98 psychosomatic 9.20 2.18 vasomotor 7.47 3.96

0.93		paresthesia	1.33 1.45
psychosomatic 4.80	5.00	insomnia	1.20 1.27
		nervousness	2.40 1.35
		melancholia	1.20 0.68
vasomotor 3.78	5.80	vertigo	0.33 0.49
		weakness (fatigue)	1.93 0.70
paresthesia 1.21	1.00	arthralgia and myalgia	1.33 0.98
		headache	0.73 0.70
insomnia 1.51	0.80	palpitation	0.73 0.70
		formication	0.07 0.26
nervousness 1.52	0.90		
		Total score (Quality of life)	68.73 10.99
melancholia 0.68	0.60		
vertigo 0.52	0.20		
weakness (fatigue) 0.73	1.00		
arthralgia and myalgia 0.93	1.15		
headache 0.61	0.45		
palpitation 0.57	0.30		
formication 0.22	0.05		
Total score (Quality of life) 73.95 8.33			

Results – Group difference

Kupperman's index $p<0.05$
psychosomatic $p<0.05$
nervousness $p<0.05$
palpitation $p<0.10$

Trends, Limitations, Comments and Source of Funding

Significant trends

Exercise could significantly alleviate psychosomatic symptoms, also nervousness and palpitations

General comments

Reported limitations

Author

None reported

Reviewer

Time of FU may not be enough to measure sustained lifestyle behavioural change; poor description of sample; self-reported measures of physical activity; small sample size; statistical power; did not set out to determine a full the cost-benefit analysis of the intervention

Source of funding

Not reported

Authors: Yoshikawa T, Miyazaki A, Fujimoto S
Year: 2009
Citation: Medical Science Monitor 15(6): PH65-73
Country of study: Japan
Aim of study: Examine the association between AGEs with metabolic abnormalities and oxidative stress parameters
Study design: Controlled trial
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population	**Characteristics of population**
Healthy non-smoking, and free of overt metabolic, cardiovascular, renal or inflammatory disease **Number of people** 47 **Locality** Osaka City, Japan **Recruitment strategy** Local newspapers **Response rate** Not reported	Age 56±8; height 157±6.7; weight 61.0±10.7; BMI 24.7±4.0; SBP 136.1±17.5; DPB 78.1±7.8; total cho 227.5±36.8; HDL-cho 66.1±13.6; glucose 95.4±10.3 **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention	**Method of allocation**
Life-style modification, exercise training, **Setting** Not reported **Delivery** Not reported **Length of follow-up** 3 months	Not reported **Measurement of exposure** Self-report and pedometer, food diary and blood tests **Comparator** Control

Outcomes and Analysis

Outcomes	**Outcome measurement**
BMI, % fat, SBP, DBP, T-Cho, HDL-Cho, Glucose, Insulin	Self-report and blood samples **Analysis strategy** Unpaired t tests

	Confounders Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Weight 65.7±10.7 BMI 26.3±5.2 % fat 34.6±8.0 SBP 135.9±20.4 DBP 78.9±9.0 T-Cho 230.9±37.4 HDL-Cho 67.2±11.8 Glucose 99.4±12.5 Insulin 6.3±3.6 **After** Weight 64.6±10.6 BMI 25.7±5.0 % fat 33.0±7.7 SBP 129.8±15.4 DBP 74.7±9.2 T-Cho 224.4±32.3 HDL-Cho 62.0±13.7 Glucose 98.9±11.6 Insulin 6.1±3.3	**Before** Weight 63.0±5.0 BMI 24.8±1.7 % fat 32.8±4.1 SBP 13408±16.6 DBP 76.9±7.6 T-Cho 206.1±27.6 HDL-Cho 65.4±11.6 Glucose 90.3±6.6 Insulin 4.8±1.1 **After** Weight 62.5±5.5 BMI 24.4±1.6 % fat 31.7±3.4 SBP 125.8±16.4 DBP 73.1±5.6 T-Cho 202.8±32.0 HDL-Cho 64.2±15.3 Glucose 88.1±5.9 Insulin 4.7±1.5
Results – Group difference Not reported	
Trends, Limitations, Comments and Source of Funding	
Significant trends Lifestyle modification as a promising approach to reducing circulating AGE levels even in healthy middle-aged females with neither overt diabetes nor renal dysfunction. **General comments**	**Reported limitations** <u>Author</u> Distinguish between effects of dietary and physical activity on change in serum AGEs; impact of unintended dietary changes; small sample size; cost analysis <u>Reviewer</u> **Source of funding** Not reported

APPENDIX A.2 Evidence table PHYSICAL ACTIVITY - Systematic Reviews

Specifically targeted at mid-life (since 2010)

Authors: Bolam KA, van Uffelen JG, Taaffe DR
Year: 2013
Citation: Osteoporosis International 24(11): 2749-62
Country of study: International
Aim of study: Assess the effect of physical exercise on bone density in middle-aged and older men
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population Middle-aged or older men (45 years and older) **Number of people** 1298 **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Average dropout rate was 3.3 %	**Characteristics of population** Not reported **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention The interventions included walking (n=2), resistance training (n=3), walking + resistance training (n=1), resistance training + impact-loading activities (n=1) and resistance training + Tai Chi (n=1). **Setting** Not reported **Delivery** Not reported **Length of follow-up** 3 months to 48 months	**Method of allocation** Not reported **Measurement of exposure** The majority of the programmes prescribed three exercise sessions a week (ranging from 2–5 each week). **Comparator** Not reported

Outcomes and Analysis

Outcomes BMD of the lumbar spine, femoral neck BMD, total hip BMD, trochanteric BMD, Ward's triangle, proximal femur BMD, and hip BMD.	**Outcome measurement** Not reported **Analysis strategy** Not reported. Studies outcomes are reported

	individually **Confounders** Not reported
Results **Intervention group** Not reported	**Results** **Control group** Not reported
Results – Group difference Braith: LS 18.7% FN 6.9% Huuskonen: LS ↔ Kukuljan (a): LS 1.5% FN 1.9% Kukuljan (b): FN 1.9% Paillard: Hip 2.1 % Ryan: Ward's 1.4 % Whiteford: LS ↔,FN 0.3 % Woo: LS 0.8 %	
Trends, Limitations, Comments and Source of Funding	
Significant trends Effects of exercise varied greatly among studies, with six interventions having a positive effect on BMD and two interventions having no significant effect. **General comments**	**Reported limitations** <u>Reviewer</u> Made little or no attempt at data synthesis, unclear data <u>Author</u> Inconsistent reporting; two of the four exercise interventions that reported significant within group improvements in BMD allowed participants to choose their group allocation **Source of funding** Not reported

Authors: Cavill JL, Jancey JM, Howat P
Year: 2012
Citation: Global Health Promotion 19(2): 44-53
Country of study: Australia
Aim of study: Review and recommendations for online physical activity and nutrition programmes targeted at over 40s
Study design: Systematic review
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
Middle aged and older population (40 years or more)

Number of people
PA: from 30 to 7,483 participants
PA/Nut: from 73 to 1,071 participants

Locality
The general community, workplace settings, university settings, a school and a church congregation

Recruitment strategy
Flyers, newspaper and newsletter advertisements, letterbox drops, face-to-face contacts and email contacts through workplaces

Response rate
Not reported.

Characteristics of population
Six of 10 PA online programmes studies consisted of participants with a mean age of over 40. The majority of PA/Nut website interventions (n=6) consisted of participants with a mean age over 40 years.

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
10 online physical activity programmes and eight online physical activity and nutrition programmes

Setting
Various

Delivery
Internet

Length of follow-up
8 weeks to 18 months

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Non-tailored or standard websites or offline or usual care methods

Outcomes and Analysis

Outcomes
Behaviour change or weight loss

Outcome measurement
Not reported

Analysis strategy
Not reported

	Confounders Not reported
Results **Intervention group** Not reported	**Results** **Control group** Not reported
Results – Group difference Five out of the 10 online PA programmes reviewed reported positive results in behaviour change. The online PA/Nut programme studies showed mixed results, with seven studies reporting positive outcomes	
Trends, Limitations, Comments and Source of Funding	
Significant trends Twelve of the studies showed significant short-term health effects from interaction with online health programmes **General comments** Authors noted supplementary online file but this is unavailable.	**Reported limitations** <u>Reviewer</u> Unclear reporting of participant characteristics etc, unclear heterogeneity in study designs, interventions, analyses, outcomes, and reporting. <u>Author</u> None reported **Source of funding** None reported

Authors: Ferreira ML, Sherrington C, Smith K et al
Year: 2012
Citation: Journal of Physiotherapy 58(3): 145-156
Country of study: International
Aim of study: Systematic review of physical activity to improve strength, balance and endurance in adults aged 40-65 years
Study design: Systematic review
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
Adults between 40 and 65 years old, no specific pathology, no recent surgery.

Number of people
2550

Locality
International

Recruitment strategy
Range of methods used for individual studies:-newspapers/ads/phone calls/city wide promotions/via physicians.

Response rate
Not reported for individual studies

Characteristics of population
Mean age of study participants' 41-60 y.
16 studies in women, 2 in men and 5 in mixed populations; majority of studies in post-menopausal women (n=11), 2 in pre- and peri-menopausal women, 4 in healthy sedentary adults, 1 in healthy active adults, 5 in community dwellers.

Excluded populations
Trials of post-surgical rehabilitation or involving participants with a specific pathology were excluded.

Low risk/high risk population
Generally midlife population, study aimed to examine long-term effect on falls but few studies found.

Intervention and Comparison

Intervention
Included studies:-
Physical activity program in community or Workplace:- Intended to develop the body or part of the body, intended to improve health.

Adherence was 48 to 96% to programmes in 12 of 22 studies that reported adherence.

PA dose ranged from 12 to 260 hours for overall programmes.

Method of allocation
Random

Measurement of exposure
Not reported for individual studies

Comparator
Physical activity program versus nothing/sham

Outcomes and Analysis

Outcomes
Strength/balance/endurance or a combination of two or three of these. Most programmes reported a strength component. Falls included as an outcome but long-term effect on falls only reported in one study.

Outcome measurement
Not reported for individual studies

Analysis strategy
Random-effects meta-analysis

Confounders

	Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Twenty-three eligible trials were included and 17 of these were pooled in the meta-analyses.

Meta-analysis of strength outcomes found a moderate effect of physical activity on strength (SMD = 0.54, 95% CI 0.38 to 0.70). Larger effects were observed from programs that specifically targeted strength (SMD = 0.68, 95% CI 0.49 to 0.87), when compared to those that did not (SMD = 0.32, 95% CI 0.09 to 0.55). This difference was statistically significant (effect of strength in meta-regression $p = 0.045$).

Physical activity also had a moderate effect on both balance (SMD = 0.52, 95% CI 0.24 to 0.79) and endurance (SMD = 0.73, 95% CI 0.50 to 0.96).

No trials reported effects of physical activity on falls soon after receiving the intervention. A statistically non-significant effect on falls 15 years after receiving a physical activity intervention was found in one trial (RR = 0.82, 95% CI 0.53 to 1.26).

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** The authors comment that muscle strength, balance, and endurance can be improved by physical activity in people aged 40–65 years. There were bigger effects on muscle strength from programs that used resistance exercises, indicating the need to include a resistance training component if strength enhancement is the goal. The authors reported that the effect of physical activity on falls has not been well investigated in this age group.	**Reported limitations** Reviewer Not reported Author None **Source of funding** Queensland Department of Health, Australia.

Authors: Hobbs N, Godfrey A, Lara J et al
Year: 2013
Citation: BMC Medicine 19;11:75.
Country of study: International
Aim of study: Systematic review of behavioural interventions effective in increasing physical activity at 12 to 36 months in adults aged 55 to 70 years, with a focus on long term effectiveness.
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Healthy participants or those 'at risk' of chronic disease with a mean or median age of 55 to 70 years. 'At risk' participants were those with at least one of the following disease risk factors: hypertension, impaired glucose tolerance, overweight/obese, hyperlipidaemia, dyslipidaemia, family history, metabolic syndrome or osteopenia.

Number of people
10,519 (32 publications, 21 individual trials)

Locality
Included studies with a country of origin 'most developed countries' from United Nations index.
Trials were conducted in the USA, Belgium, The Netherlands, UK, Finland, New Zealand, Japan, Australia and Canada.

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
61% of participants in included studies were female. The mean age of participants was 60.7 years (SD = 4.4; range 55 to 67.6).

Excluded populations
Trials involving participants who were institutionalized or recruited on the basis of taking a particular medication or having a pre-existing chronic or acute medical condition. Interventions less than 12 months, or that reported physiological proxy measures of PA not PA behaviour, were laboratory-based exercise studies, or promoted high or elite performance training.

Low risk/high risk population
See 'eligible population'

Intervention and Comparison

Intervention.
Randomized controlled trials of interventions to promote physical activity behaviour with a mean/median sample age of 55 to 70 years, published between 2000 and 2010.

Only trials reporting the long term effect (≥ 12 months) on objective or self-reported physical activity behaviour were included.

Sixteen interventions were delivered by health professionals, one intervention by the researcher, one was 'self-help' and the

Method of allocation
Randomisation. Allocation concealment of individual studies not reported.

Measurement of exposure
N/A

Comparator
No intervention, minimal or usual care intervention; or a different type of intervention.

intervention provider was unclear in 3 trials. The delivery format was multimodal for 14 trials (that is, face-to-face individual basis and via the telephone and/or printed material; face-to-face group basis and via the telephone and/or printed material; face-to-face individual and group basis plus via the telephone or printed material; via the internet and printed materials; or via the telephone and printed material; unimodal for four trials (that is, face-to-face individual only; face-to-face group only; or printed material only; it was unclear whether the format was face-to-face individual or group for three trials. Where the intervention setting was reported, included healthcare premises, the participant's home, in a university facility, in a community setting. Trial length on average, was 17 months from randomization (SD = 6.6), the 'active' intervention period was 8 months (SD = 4.6; range 1 to 11) with 37 contacts (SD = 60; range 1 to 228). Length of intervention was not specified in one trial.	
Outcomes and Analysis	
Outcomes Physical activity behaviour	**Outcome measurement** Of 21 trials included in meta-analyses, 6 assessed PA objectively (5 pedometer step count, 1 accelerometer). **Analysis strategy** Random effects meta-analysis **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below
Results – Group difference 32 publications from 21 individual trials included, of which 26 (15 individual trials) were included in meta-analysis and 6 were narratively synthesised. Interventions in the majority of studies were multimodal and provided physical activity and lifestyle counselling. <u>Physical activity</u> Interventions to promote physical activity were effective at 12 months (standardized mean	

difference (SMD) = 1.08, 95% confidence interval, 0.16 to 1.99) but not at 24 months based on a small subset of trials.

There was no evidence for a relationship between intervention effectiveness and mode of delivery or number of intervention contacts; however, interventions which involved individually tailoring with personalized activity goals or provision of information about local opportunities in the environment may be more effective.

Trends, Limitations, Comments and Source of Funding

Significant trends

General comments
The authors comment that interventions in adults aged 55 to 70 years led to long term improvements in physical activity at 12 months, but, maintenance beyond 12 months is unclear.

Reported limitations
Reviewer

Author
The information provided in publications did not always allow conclusive judgements of methodological quality to be made, which resulted in many uncertain judgements.

Source of funding
The work was part of the LiveWell program. LiveWell is supported by the Lifelong Health and Wellbeing initiative (LLHW), which is a funding collaboration between the UK Research Councils and Health Departments. The LLHW funding partners are: Biotechnology and Biological Sciences Research Council, Engineering and Physical Sciences Research Council, Economic and Social Research Council, Medical Research Council, Chief Scientist Office of the Scottish Government Health Directorates, National Institute for Health Research/The Department of Health, The Health and Social Care Research and Development of the Public Health Agency (Northern Ireland), and Wales Office of Research and Development for Health and Social Care, Welsh Assembly Government. MW is partly and FFS fully funded by Fuse, the Centre for Translational Research in Public Health, a UKCRC Public Health Research Centre of Excellence. Funding for Fuse from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council, and the National Institute for Health Research, under the auspices of the UK Clinical Research Collaboration.

Systematic reviews in which included studies are mainly in mid-life (since 2010)

Authors: Abioye AI, Hajifathalian K, Danaei G **Year:** 2013 **Citation:** Archives of Public Health 71(1): 20. **Country of study:** International **Aim of study:** Assess if mass media campaigns improve physical activity in adults **Study design:** Systematic review **Quality score: (++, + or -):** ++	
Study (eligible and selected) population	
Eligible population Those in the community **Number of people** 27,601 people **Locality** High-income countries. The media campaigns were conducted on local, regional or national levels **Recruitment strategy** Mass media **Response rate** Coverage ranging from 11 to 90%.	**Characteristics of population** Not reported **Excluded populations** Not reported **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Mass media campaigns **Setting** Community **Delivery** Mass media **Length of follow-up** Between 8 weeks to 3 years.	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Not reported
Outcomes and Analysis	
Outcomes Moderate intensity walking, reducing sedentary behaviour, increased PA	**Outcome measurement** Eleven different measures of physical activity. **Analysis strategy** Random-effects models to pool effect estimates **Confounders** Not reported
Results	**Results**

<table>
<tr><th>Intervention group</th><th>Control group</th></tr>
<tr><td>Not reported</td><td>Not reported</td></tr>
<tr><td colspan="2">Results – Group difference
Based on the pooled results from these studies, mass media campaigns had a significant effect on promoting moderate intensity walking (pooled relative risk (RR) from 3 studies=1.53, 95% Confidence Interval: 1.25 to 1.87), but did not help participants achieve sufficient levels of physical activity [4 studies pooled RR=1.02, 95% CI: 0.91 to 1.14)].</td></tr>
<tr><td colspan="2">Trends, Limitations, Comments and Source of Funding</td></tr>
<tr><td>Significant trends
Mass media campaigns may promote walking but may not reduce sedentary behavior or lead to achieving recommended levels of overall physical activity.

General comments</td><td>Reported limitations
<u>Reviewer</u>
No comment

<u>Author</u>
Did not have sufficient power to detect differences across studies by study-level characteristics due to the small number of selected studies, unable to evaluate the dose–response curve for mass media campaigns; few studies used validated questionnaires or objective measurements of activity; all conducted in developed countries

Source of funding
Not reported</td></tr>
</table>

Authors: Conn VS, Hafdahl AR, Mehr DR.
Year: 2011
Citation: American Journal of Public Health 101(4): 751-758
Country of study: International
Aim of study: Interventions to increase physical activity among healthy adults
Study design: Systematic review and meta-analysis
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Healthy adults

Number of people
99,011. Median sample size was 72 participants (range = 5 to 17,579). Sample size 358

Locality
Not reported

Recruitment strategy
Not reported

Response rate
RR not provided. Attrition from comparison group, % 12; Attrition from treatment group, % 16; Attrition from total sample, % 13

Characteristics of population
Median of 74% women, median for minority participants was 14%. Mean age, y 44. Female, % 74. Racial/ethnic minority, % 14

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Interventions ranged from a single motivational education session to extensive supervised exercise sessions occurring over many weeks.
Supervised exercise per session, min 45
No. of supervised exercise sessions 27
Education/motivation per session, min 60
No. of educational/motivational sessions 5
No. of wks intervention was delivered 10

Setting
Communities, worksites, and ambulatory health care settings

Delivery
Local community members or health care providers; face-to-face, mass media, mediated by telephone, mail, e-mail

Length of follow-up
At least six months after interventions

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Treatment groups versus control groups

Outcomes and Analysis

Outcomes Physical activity	**Outcome measurement** Objective and self-report **Analysis strategy** Random-effects analyses to synthesize data, and meta-analytic analogues of regression and analysis of variance to examine potential moderator variables **Confounders** Neither publication nor funding status was related to physical activity effect sizes. participants who exercised prior to the intervention reported lower effect size (0.14) than did studies of sedentary participants (0.27), but these findings were not robust in joint moderator analyses
Results **Intervention group** **estimated mean effect size** Treatment pre–post comparison 0.33 **P** Treatment pre–post comparison < .001	**Results** **Control group** **estimated mean effect size** Control pre–post comparison 0.00 **P** Control pre–post comparison .792

Results – Group difference

The overall mean effect size for comparisons of treatment groups versus control groups was 0.19 (higher mean for treatment participants than for control participants). A mean effect size (*d*) of 0.33 was documented for treatment pre–post comparisons. Control participants did not experience increased physical activity by participating in studies, mean effect size of 0.00 (*d*).

Estimated mean effect size

Treatment vs control post-intervention comparison 0.19
Treatment vs control pre–post comparison 0.19

P

Treatment vs control post-intervention comparison < .001
Treatment vs control pre–post comparison < .001

Trends, Limitations, Comments and Source of Funding

Significant trends Interventions designed to increase physical activity were modestly effective. **General comments**	**Reported limitations** <u>Reviewer</u> No comment <u>Author</u> Fidelity and allocation concealment, were poorly reported and could not be examined in moderator analyses; unable to assess publication bias; **Source of funding** Financial support was provided by the National Institutes of Health (grant R01NR009656).

Authors: Davies CA, Spence JC, Vandelanotte C et al
Year: 2012
Citation: International Journal of Behavioral Nutrition & Physical Activity 30(9): 52
Country of study: International
Aim of study: Evaluate the effectiveness of internet-delivered interventions to increase physical activity
Study design: Systematic review and meta-analysis
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population Adults **Number of people** 11,885 **Locality** International **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Avr. Age from 18 to 69.5. % female from 0% to 100%. The average age represented across studies was 43.06 years, 65% of the overall sample was female and, among the 18 articles that reported on ethnicity, 92% of the sample was Caucasian. **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Tailored or non-tailored internet delivered interventions with interactive features e.g. goal setting, quizzes, asynchronous communication; education; email reminders; a facilitator; feedback; synchronous communication; self-monitoring; and updated content. **Setting** Community via the internet **Delivery** The internet with either the use of a web page for the delivery and/or exchange of information, or in the form of email communication **Length of follow-up** From 2 weeks to 52, one study did not report duration	**Method of allocation** Not reported **Measurement of exposure** Number of intervention contacts **Comparator** Comparison group that did not receive internet-delivered materials

Outcomes and Analysis

Outcomes	**Outcome measurement**

Physical activity	Not reported **Analysis strategy** Fixed effects model **Confounders** The Bonferroni correction factor was applied to adjust the alpha value required for statistical significance within each of the three moderator categories
Results **Intervention group** Not reported	**Results** **Control group** Not reported

Results – Group difference

The estimated overall mean effect of internet-delivered interventions on physical activity was d = 0.14 ($p<0.001$). The overall mean effect for sustained physical activity at least 6 months post- intervention (n = 11) resulted in a small but significant effect size d = 0.11 ($p<0.01$). Initial physical activity level (Qb (1) = 8.83, $p<0.05$) was found to be significant moderator of physical activity change. Educational components was the only significant moderator (Qb (1) = 8.02, $p<0.005$) of physical activity change. Interventions consisting of educational components producing a larger effect size (d = 0.20) than interventions that did not (d = 0.08).

Trends, Limitations, Comments and Source of Funding

Significant trends The overall mean effect of internet-delivered interventions on physical activity was d = 0.14 (p = 0.00). Fixed-effect analysis revealed significant heterogeneity across studies (Q = 73.75; p = 0.00). **General comments** Moderating variables such as larger sample size, screening for baseline physical activity levels and the inclusion of educational components significantly increased intervention effectiveness.	**Reported limitations** <u>Reviewer</u> Breadth of intervention components, delivery and content <u>Author</u> limited reporting of login and other website engagement data; low number of articles; heterogeneity; self-report measures for physical activity; largely white and well education samples; effect size cannot be translated to represent a more meaningful and clinically relevant change in physical activity level **Source of funding** Dr. Vandelanotte was supported by a National Health and Medical Research Council of Australia (#519778) and National Heart Foundation of Australia (#PH 07B 3303) post-doctoral research fellowship. The other authors report no financial disclosures. No other funding was received for this study.

Authors: Foster C, Richards J, Thorogood M et al
Year: 2013
Citation: The Cochrane Library (9): CD010395
Country of study: International
Aim of study: Systematic review of remote and web 2.0 interventions for promoting physical activity
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population Community dwelling adults (aged 16 years and above). **Number of people** 5862 (11 studies) **Locality** International – all included studies were conducted in high income countries. **Recruitment strategy** Studies recruited from primary care and the community. **Response rate** Not reported for individual studies.	**Characteristics of population** Most included studies included men and women, three included women only. Age of populations in included studies 18 to 74+ years. 7 studies reported the ethnicity of participants, proportion from ethnic minority groups ranged from 7 to 33%. **Excluded populations** Studies that had more than a 20% loss to follow-up excluded if they did not apply an intention to- treat analysis. Studies of mass media or multiple risk factor interventions were excluded. **Low risk/high risk population** N/A – healthy adults

Intervention and Comparison

Intervention To compare the effectiveness of remote and web 2.0 interventions for PA promotion in community dwelling adults (aged 16 years andabove).	**Method of allocation** Randomisation **Measurement of exposure** N/A **Comparator** Placebo or no or minimal intervention.

Outcomes and Analysis

Outcomes Physical activity (PA) Cardiovascular fitness Adverse effects	**Outcome measurement** PA self-reported, cardio-respiratory fitness objectively measured. **Analysis strategy** Random-effects meta-analysis **Confounders** Not reported
Results **Intervention group**	**Results** **Control group**

See below	See below

Results – Group difference
11 studies were included.

Cardiovascular fitness
The effect of the interventions on cardiovascular fitness at one year (two studies; 444 participants) was positive and moderate with significant heterogeneity of the observed effects (SMD 0.40; 95% CI 0.04 to 0.76; high quality evidence).

Physical activity
The effect of the interventions on self-reported PA at one year (nine studies; 4547 participants) was positive and moderate (SMD 0.20; 95% CI 0.11 to 0.28; moderate quality evidence) with heterogeneity (I2 = 37%) in the observed effects. One study reported positive results at two years (SMD 0.20; 95% CI 0.08 to 0.32; moderate quality evidence). When studies were stratified by risk of bias, the studies at low risk of bias (eight studies; 3403 participants) had an increased effect (SMD 0.28; 95% CI 0.16 to 0.40; moderate quality evidence).

The most effective interventions applied a tailored approach to the type of PA and used telephone contact to provide feedback and to support changes in PA levels.

There were no differences in effectiveness between studies using different types of professionals delivering the intervention (for example health professional, exercise specialist). There was no difference in pooled estimates between studies that generated the prescribed PA using an automated computer programme versus a human, nor between studies that used pedometers as part of their intervention compared to studies that did not.

Adverse effects
There was no evidence of an increased risk of adverse events (seven studies; 2892 participants.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** Authors report that there is consistent evidence to support the effectiveness of remote and web 2.0 interventions for promoting PA. These interventions have positive, moderate sized effects on increasing self-reported PA and measured cardio-respiratory fitness, at least at 12 months. The effectiveness of these interventions was supported by moderate and high quality studies.	**Reported limitations** Reviewer Author **Source of funding** British Heart Foundation Core Grant NIHR Cochrane Incentive Scheme 2012

Authors: Foster C, Richards J, Thorogood M et al
Year: 2013
Citation: The Cochrane Library (9): CD010392
Country of study: International
Aim of study: Systematic review of face-to-face interventions for promoting physical activity.
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population Apparently healthy adults aged 16 or over **Number of people** 6292 (10 studies) **Locality** All included studies conducted in high income countries. **Recruitment strategy** Not reported for individual studies **Response rate** Not reported for individual studies	**Characteristics of population** Most of the ten included studies were conducted with both men and women, one study was in women only and one in men only. Age range in included studies was 16 to 90, with 5 (of 10) included studies specifically targeting adults between age of 40 and 65 years. **Excluded populations** Studies that had more than a 20% loss to follow-up excluded if they did not apply an intention to- treat analysis. **Low risk/high risk population** N/A – healthy adults

Intervention and Comparison

Intervention RCTs of face-to-face PA interventions for community dwelling adults. Studies were included if the principal component of the intervention was delivered using face to-face methods. To assess behavioural change over time the included studies had a minimum of 12 months follow-up from the start of the intervention to the final results.	**Method of allocation** Randomisation for all included studies **Measurement of exposure** N/A **Comparator** Placebo or no or minimal intervention

Outcomes and Analysis

Outcomes Physical activity (PA) Cardiovascular fitness Adverse events Long-term impact Cost-effectiveness	**Outcome measurement** PA self-reported, cardio-respiratory fitness objectively measured. **Analysis strategy** N/A – insufficient data for pooling **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Ten RCTs were included:

Effect on PA

The effect of interventions on self-reported PA at one year (eight studies; 6725 participants) was positive and moderate with significant heterogeneity (I^2 = 74%) (SMD 0.19; 95% CI 0.06 to 0.31; moderate quality evidence) but not sustained in three studies at 24 months (4235 participants) (SMD 0.18; 95% CI -0.10 to 0.46).

Effect on cardiovascular fitness

The effect of interventions on cardiovascular fitness at one year
(two studies; 349 participants) was positive and moderate with no significant heterogeneity in the observed effects (SMD 0.50; 95% CI 0.28 to 0.71; moderate quality evidence). Three studies (3277 participants) reported a positive effect on increasing PA levels when assessed as a dichotomous measure at 12 months, but this was not statistically significant (OR 1.52; 95% CI 0.88 to 2.61; high quality evidence).

Adverse events

From limited data, there was no evidence of an increased risk of adverse events (one study; 149 participants). Risk of bias was assessed as low (four studies; 4822 participants) or moderate (six studies; 1543 participants).

Long-term impact and cost-effectiveness

There was insufficient data to assess long-term impact and cost-effectiveness

Trends, Limitations, Comments and Source of Funding

Significant trends

General comments

There was some evidence that the most effective interventions were those that offered both individual and group support for changing PA levels using a tailored approach.

Reported limitations

Reviewer

There was significant heterogeneity in the observed effects so any conclusions drawn from the review should be interpreted with caution.

Author

Source of funding

British Heart Foundation Core Grant
NIHR Cochrane Incentive Scheme 2012

Authors: Foster C, Richards J, Thorogood M et al
Year: 2013
Citation: Face-to-face versus remote and web 2.0 interventions for promoting physical activity. The Cochrane Library (9): CD010393.
Country of study: International
Aim of study: Systematic review of face-to-face versus remote and web 2.0 interventions for promoting physical activity
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Apparently healthy adults aged 16 or over

Number of people
225 (1 study)

Locality
The one included study was conducted in a high income country (US)

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
Inactive community participants aged 50-65 years, male and female included and 11% of non-white ethnicity.

Excluded populations
Studies that had more than a 20% loss to follow-up excluded if they did not apply an intention to- treat analysis.

Low risk/high risk population
N/A – healthy adults

Intervention and Comparison

Intervention
Randomised trials that compared face-to-face versus remote and web 2.0 PA interventions for community dwelling adults. Studies were included if they compared an intervention that was mainly delivered face-to-face to an intervention that had principally remote and web 2.0 methods with minimum follow up of 12 months.

In the one study that met the inclusion criteria:- The face-to-face intervention was delivered to a group by a supervising physical educator at a local community senior centre. The participants attended exercise classes at least three times per week for 12months. The remote intervention was home based and was delivered individually without direct supervision. It included telephone calls weekly for the initial four weeks, biweekly for the next four weeks, and then monthly for 12 months.

Method of allocation
Randomisation for all included studies

Measurement of exposure
N/A

Comparator
Remote and web 2.0 physical activity interventions

Outcomes and Analysis

Outcomes Physical activity (PA) Cardiovascular fitness Adverse effects	**Outcome measurement** PA self-reported, cardio-respiratory fitness objectively measured. **Analysis strategy** Random-effects meta-analysis **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Only one study (n=225) met the inclusion criteria. This study took place in a high-income country (US) (King 1991).

This study reported the effect of a PA intervention on cardio-respiratory fitness. There were no data for PA, quality of life, or cost effectiveness. The difference between the remote and web 2.0 versus face-to-face arms was not significant (SMD -0.02; 95% CI -0.30 to 0.26; high quality evidence). The risk of bias in the included study was assessed as low, and there was no evidence of an increased risk of adverse events.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** The conclusion of the review is that there is insufficient evidence to assess whether face-to-face interventions or remote and web 2.0 approaches are more effective at promoting PA.	**Reported limitations** Reviewer Limited evidence (only one study). Author **Source of funding** British Heart Foundation Core Grant NIHR Cochrane Incentive Scheme 2012

Authors: Leavy JE, Bull FC, Rosenberg M et al
Year: 2011
Citation: Health Education Research 26(6): 1060-1085
Country of study:
Aim of study: Physical activity mass media campaigns and their evaluation: a systematic review of the literature 2003-2010
Study design: Systematic review
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
Adults, population level focus

Number of people
Sample sizes of included studies ranged from 250 to 3600.

Locality
The majority of the 18 mass media campaigns were conducted in high-income countries, the United States (n = 8), Australia (n = 3), Canada (n = 3), Belgium (n = 1) and New Zealand (n = 1).

Two were conducted in middle-income countries in South America (Columbia and Brazil).

Recruitment strategy
Across the 18 campaigns, 14 used random (representative) population samples, one used convenience sampling, a combined cluster and convenience sampling and an intercept technique. One study did not state the sampling strategy.

Response rate
Response rates in included studies varied from 17 to 70%.

Characteristics of population
Of 20 included studies, 6 were conducted specifically in midlife populations (40-65 in general); 8 in adult populations (in general 18 to 65); 3 in younger populations and 2 in older populations.

One study was conducted in men only, population gender not specifically reported for the remainder of individual studies. Ethnicity not reported for individual studies.

Excluded populations
Studies that focused on clinical populations, qualitative methods, children/adolescents and those that did not report evaluation data.

Low risk/high risk population
N/A

Intervention and Comparison

Intervention
18 individual physical activity adult mass media campaigns were included.

The evaluation designs used for the 18 campaigns included: quasi-experimental (n = 5), non-experimental (n = 12), and a mixed methods design (n = 1).

Included studies were published in English between 2003 and week 6, 2010, peer reviewed, full text; adult focus; population

Method of allocation
N/A – non-randomised studies included

Measurement of exposure
Awareness of campaigns was measured as the combination of 'unprompted recall' (respondents are asked if they have heard of any campaign promoting physical activity, open ended) and/or 'prompted recall/recognition' (respondents are told or shown the name of the campaign materials and asked if they recall/recognize them).

level focus; a clear mass media and/or social marketing component that relates specifically to physical activity OR fitness OR exercise; paid or unpaid media or a combination of both; primary prevention; evaluation methodology described and post-evaluation design as a minimum. Included studies used a diverse range of media channels for campaigns including: television commercials (network and/or cable), public service announcements, radio commercials, paid and unpaid print media inserts, bus backs and wraps, billboards, print media, website, traffic, public health activities, policy and environmental change. Campaign duration ranged from: 8–13 weeks (n = 6); around 6 months (n =3), 12 months (n = 2); several phases over 12–24 months (n = 2) and greater than 2 years (n = 5).	**Comparator** For studies with a quasi-experimental design, comparator groups were communities not exposed to campaigns, with similar demographics and media. Other studies used a pre-and post-campaign survey design in the same area.
Outcomes and Analysis	
Outcomes 'Dose', exposure, awareness, physical activity- related knowledge, attitudes, beliefs, intention, physical activity behaviour and campaign costs.	**Outcome measurement** Overall, the survey instruments were established and reliable self-report measures of physical activity and often the measures were consistent with the countries national physical activity surveillance measures. Most studies used self-report only, only one study used a combination of self-report and an objective measure (pedometer) to determine physical activity levels. Twelve studies used a telephone administered survey instrument. One used an existing online forum and offered a $3 incentive and one used face to-face intercept surveys. **Analysis strategy** Data not suitable for meta-analysis, data synthesised narratively. **Confounders** Not reported.
Results **Intervention group** See below	**Results** **Control group** See below
Results – Group difference 18 studies included on individual adult mass media campaigns, most were in high-income regions and two were in middle-income regions.	

Designs included: quasi experimental (n = 5); non experimental (n = 12); a mixed methods design (n = 1). One half used formative research. Awareness levels ranged from 17 to 95%. Seven campaigns reported significant increases in physical activity levels.

Change in physical activity behaviour was measured in 15 of the 18 campaigns and seven studies reported a statistically significant increase in physical activity levels. Four of these seven campaigns were quasi-experimental design and used a cohort sample which the authors reported adds strength in detecting campaign effects. Four of the campaigns were 5 months or longer in duration.

Non-significant findings on physical activity were found in eight campaigns; two studies were about 6 months in duration, three studies comprised multiple short-term phases delivered over a 12- to 18-month period. Three studies were longer campaigns over several years and also reported no overall effect on physical activity behaviour. The authors concluded there was little evidence of sustained campaign effects over time although there were limitations to study design and evaluation.

Campaign awareness levels, ranged from 95% to 17.4% the physical activity components. A number of campaigns reported higher awareness among women, among those with a tertiary level of education and among women who tended to be physically active or had children who were active.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments**	**Reported limitations** Reviewer Author All but two of the campaigns were delivered in high-income countries and many were from North America, which limits the generalisability of these findings on mass media campaigns to other countries or regions. Grey literature was not searched as a source of studies. **Source of funding** Heart Foundation (WA Division); Department of Health and University of Western Australia Scholarship.

Systematic reviews in disadvantaged groups:

Authors: Chapman J, Qureshi N, Kai J **Year:** 2013 **Citation:** British Journal of General Practice 63(607): e104-114 **Country of study:** Not reported **Aim of study:** Effectiveness of physical activity and dietary interventions in South Asian populations **Study design:** Systematic review **Quality score: (++, + or -):** +	
Study (eligible and selected) population	
Eligible population South Asians **Number of people** From 13 to 201 **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Only one study reported sample age range (13–81 years) **Excluded populations** Various inc. those received diabetes education, those planning a holiday during study, pregnant women, those with a knee/hip replacement **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Various inc. screening, education, exercise classes **Setting** Community, practices and health clinics **Delivery** Various inc. link workers, dieticians, fitness instructors, health visitors **Length of follow-up** From 1 month to 17 months	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Not reported
Outcomes and Analysis	
Outcomes Changes to anthropometric measures, blood pressure, and/or blood biochemistry	**Outcome measurement** Combined self-report and objective anthropometric and physiological measures **Analysis strategy** Not reported **Confounders** No studies adjusted for confounding in analyses

Results **Intervention group**	**Results** **Control group**
Not reported	Not reported
Results – Group difference All studies measuring changes in weight demonstrated a reduction in kilogrammes from baseline to follow-up, ranging from a 0.9% reduction over 6–12 months to 3.4% at 17 months. Waist girth in centimetres showed small percentage decreases of 0.6 and 2.1 and reductions in body and abdominal fat were also found. Males and females reported significant improvements in salt intake and consumption of fried meat snacks following a CHD-prevention service. 49% of participants reported taking more moderate exercise.	
Trends, Limitations, Comments and Source of Funding	
Significant trends Physical activity and dietary interventions with South Asian populations show modest promise but, given the paucity of controlled evaluations or use of objective measures, outcomes are difficult to interpret **General comments**	**Reported limitations** Reviewer Unclear reporting of analyses. Self-reporting outcomes and exposures Author None identified **Source of funding** This review was funded by a National Institute for Health Research Collaboration in Applied Health Research and Care (Nottinghamshire, Derbyshire and Lincolnshire) grant.

Authors: Cleland CL, Tully MA, Kee F et al.
Year: 2012
Citation: Preventive Medicine 54(6): 371-380.
Country of study: International
Aim of study: Assess the effectiveness of physical activity interventions in socio-economically disadvantaged communities
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population Socio-economically disadvantaged communities **Number of people** Not reported **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Aged 18 - 75 **Excluded populations** Included children but results are not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Individual and group targeted interventions such as exercise vouchers, education, counselling and pedometers **Setting** Not reported **Delivery** Face to face, by telephone or a combination of both **Length of follow-up** Between 7 weeks and 24 months	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Usual care or control group

Outcomes and Analysis

Outcomes Physical activity	**Outcome measurement** Various inc. recall, questionnaires, accelerometer **Analysis strategy** Attempted to calculate a Cohen's d effect size for each intervention **Confounders** Not reported

Results **Intervention group** Not reported	Results **Control group** Not reported

Results – Group difference

Two of the 12 interventions that targeted adults showed a moderate effect on PA. Each study is reported separately.

Individually targeted interventions

Lowther et al. (2002) Cohen's da: at 4 weeks FA: 0.33 (95% CI −0.84, 0.21); EC: 0.10 (95% CI−0.39, 0.59) 3months FA: 0.27 (95% CI−0.79, 0.26); EC: 0.35 (95% CI −0.16, 0.84) 6months FA: 0.42 (95% CI 1.19, 0.41); EC: 0.69 (95% CI−0.03, 1.35) One year FA 0.27 (95% CI−1.04, 0.54); EC: 0.43 (95% CI−0.27, 1.08)

Fahrenwald et al. (2004) Cohen's d: 2.1 (95% CI 1.37, 2.71) Increased moderate PA (Intervention: 89 min per week; Control: 1 min per week)

Emmons et al. (2005) No significant difference between or within groups

Black et al. (2010) Cohen's d: 11months, 0.03 (95% CI −0.26, 0.32); 24months, 0.10 (95% CI−0.42, 0.17) Decreased log PA counts (Intervention: 0.04 at 11 months; 0.07 at 24months; control: 0.08 at 11 months; 0.06 at 24 months)

Group interventions targeting adults

Reijneveld et al. (2003) No significant within or between group differences

Kim et al. (2004) Intervention group improved PA (p≤0.001) (no control group)

Staten et al. (2004) No significant difference between groups MVPA increased in all groups: PC+HE: 22.6min per week, p≤0.05; PC+HE+CHW 22.8 min per week, p≤0.01 PC: 15.1 min per week, p≤0.001

Kolbe-Alexander et al. (2006) Significantly greater increase in reported energy expenditure in intervention group than controls (pb0.001)

Stewart et al. (2006) Non-significant increased PA (0.8 h per week) in intervention groups (no control group)

White et al. (2006) No control group; no differences between intervention groups, minutes spent walking per 'active' day decreased

Yancey et al. (2006) Significant difference between groups at 2months (pb0.05);marginal at 12months (p=0.058) Intervention group: self-rated PA level increased among participants at 2months (pb0.001); 6 months (pb0.05); but not at 12 months Control: no increase

Clarke et al. (2007) Significant increase in percentage taking >10,000 steps per day (pb0.05) (from 11.8% to 46.2% at 8 weeks); energy expenditure increased (pb0.001) by 224 kcal/day (No comparative control group data)

Speck et al. (2007) Cohen's d: 0.47 (95% CI 0.01, 0.91) (number of steps); 0.06 (95% CI −0.50, 0.39) (MET score per day) Intervention: non-significant changes (decreased steps per day (5791.3 to 5369.6); increased MET score (42.9 to 48.8) Control: decreased steps per day 5314.6 to 4094.9 (pb0.05); non-significant increase in MET score per day 49.2 to 49.8

Hovell et al. (2008) Significantly greater increase in vigorous PA and walking in intervention group than controls at 6months; Vigorous activity at 12months significantly greater in intervention group Difference in percentage achieving ACSM PA guidelines (intervention group increased from 19.1% to 63.2%; control group, 13.6% to 16.7%) at 6 months intervention: increased vigorous activity and walking (pb0.001) at 6months. Subsequent decrease in vigorous activity (p≤0.01) and walking (p≤0.011) at 12 months but remained higher than baseline Control: increased vigorous activity (p≤0.001) and walking (pb0.05) at 6months; not at 12months

Keyserling et al. (2008) Intervention: significantly increased self-reported moderate (p=0.001) and vigorous activity (p=0.003) at 6 and 12 months compared with controls No significant difference between groups in accelerometer outcomes

Resnick et al. (2008) Cohen's d: 0.01 (95% CI −0.13, 0.67) Intervention: spent significantly (p<0.05) more time in exercise than those in the control group at 12 weeks

Community interventions

Jenum et al. (2006) Between group's comparison: greater reduction in proportion of inactive people in intervention group (6.9%) Intervention group: reduced proportion reporting no heavy activity (40.5% to 32.4%); number categorised as 'active' increased by 8.1% ($p<0.05$) Control: no significant changes in PA

Cochrane and Davey (2008) Significantly more of intervention group than controls reported increased level of PA ($p\leq0.001$) (30.6% of intervention group reported beingmore physically active after one year)

Brown and Werner (2007) Intervention: participants using the rail increased (pb0.05) from 50% to 68.75%; self-reported rail rides were significantly related to higher level of moderate activity ($p<0.01$) (no control group)

Wendel-Vos et al. (2009) Significant differences between groups: intervention group women walked 2.2 h per week more ($p\leq0.05$) and reported more leisure time PA (2.1 h per week) ($p\leq0.05$) compared with controls after 4 years

Hoelscher et al. (2010) No between group significant differences Intervention: increased number of days per week played outdoors (0.3, pb0.05), days played sports activity (0.3, $p\leq0.01$) and days participated in organised PA (0.2, $p\leq0.05$) Control: significant difference in number of days per week played outdoors (0.2, $p\leq0.05$) and number days participated in organised PA (0.3, $p\leq0.01$)

Trends, Limitations, Comments and Source of Funding

Significant trends

Found that group-based interventions were effective for adults; evidence for the effectiveness of interventions targeting individuals was insufficient; limited evidence suggested that community-wide interventions produced small changes in PA.

General comments

Reported limitations

Reviewer

Heterogeneity of interventions; presents little detail on study methodology, participants, analysis and duration

Author

Non-validated measurements, lack of detail regarding sampling and high attrition rates; small sample sizes (<150 participants) and are of relatively short duration (<6 months).

Source of funding

This work was carried out as part of the PARC Study, which is funded by the National Prevention Research Initiative. CLC conducted the review as part of a PhD funded by the Department of Employment and Learning Northern Ireland (DEL). MAT, FK and MEC are cofounded by the Centre of Excellence for Public Health (Northern Ireland), a UKCRC Public Health Research Centre of Excellence. Funding from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council, Research and Development Office for the Northern Ireland Health and Social Services, and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged.

Authors: Cleland, V, Granados A, Crawford D et al
Year: 2013
Citation: Obesity Reviews 14(3): 197-212
Country of study: International
Aim of study: Effectiveness of interventions to promote physical activity among socioeconomically disadvantaged women
Study design: Systematic review and meta-analysis.
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Socioeconomically disadvantaged healthy women (18–64 years)

Number of people
6,339

Locality
International

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Age from 25.1 to 59.

Excluded populations
Men

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Intervention: any intervention (individually, socially, environmentally or policy targeted) focused on increasing physical activity in any setting.

Setting
Various inc. home, church, community, face to face and telephony

Delivery
Group or individual, no details provided on who delivered the intervention

Length of follow-up
From 6 weeks to 6 years (median = 5 months).

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Any control group

Outcomes and Analysis

Outcomes
"physical activity outcomes"

Outcome measurement
Self-report questionnaire, one study used objective measure

Analysis strategy
Meta-analysis

	Confounders Not reported
Results **Intervention group** **Albright et al. (2005)** G0: Pre = 33.7 (SD: 2.2) 12 m = 33.5 (SD: 1.5) G1: Pre = 33.2 (SD: 1.7), 12 m = 33.2 (SD: 3.1) **Baranowski et al. (1990)** G0: Pre = 235.5 (SD: 16.1), 14 weeks = 248.0 (SD: 29.4) G1: Pre = 241.4 (SD: 22.8), 14 weeks = 247.8 (SD: 46.6) **Brown et al. (1996)** G0: Pre = 103.5 (SD: 11.5), 12 weeks = 98.7 (SD: 14.9) G1: Pre = 114.2 (SD: 19.0), 12 weeks = 98.5 (SD: 13.9) **Chang et al. (2010)** G0: Pre = 27.3 (SD: 29.9), 42 weeks = 36.0 (SD: 29.3) G1: Pre = 29.8 (SD: 26.7), 42 weeks Post = 53.2 (SD: 30.2) **Fahrenwald et al. (2004)** G0: Pre = 32.59 (SD: 0.38), 10 weeks (change) = -0.17 (SD: 0.41) G1: Pre = 32.52 (SD: 0.39), 10 weeks (change): 0.46 (SD: 0.45) **Fjeldsoe et al. (2010)** G0: Pre = 84.0 (SE: 26.0), 13 weeks = 159.8 (SE: 29.3) G1: Pre = 164.3 (SE: 25.4), 13 weeks = 149.8 (SE: 25.0) **Hovell et al. (2008)** G0: Pre = 13.6%, 12 m = 15.2% G1: Pre = 19.1%, 12 m = 38.2% **Jacobs et al. (2004)** G0: Pre = 12.68 (SD:5.96); 12 m = 12.98 (SD: 6.96) G1: Pre = 12.84 (SD: 6.51); 12 m = 12.86(SD: 6.69) **Lucumi et al. (2006)** G0: Pre = 5.3, 7 m = 5.3 G1: Pre = 27.8, 7 m = 33.3 **Lupton et al. (2002)** G0: Pre = 81.1%;	**Results** **Control group**

6 years = 83.2% G1: Pre = 76.5%; **Lupton et al. (2003)** G0: Pre = 81.2%, 6 years = 80.9% G1: Pre = 73.0%, 6 years = 80.9% **Olvera et al. (2010)** G0: Pre = 1.2 (SD: 1.5), 12 weeks = 1.2 (SD: 0.9) G1: Pre = 1.4 (SD: 0.9), 12 weeks = 2.1 (SD: 1.6) **Opdenacker et al. (2008)** G0: Pre = 1,664,013 (SD: 521,275), 6 m = 1,501,413 (SD: 594,714) G1: Pre = 1,702,474 (SD: 618,907), 6 m = 1,827,888 (SD: 687,279) **Shirazi et al. (2007)** G0: Pre = 73.9 (SD:131.2), 12 weeks = 78.9 (SD: 136.2) G1: Pre = 54.1 (SD:131.5) 12 weeks = 191.4 (SD: 231.4) **Speck et al. (2007)** G0: Pre = 5,314.6 (SD: 2,862.5) 23 weeks = 4,094.9 (SD: 2,735.9) G1: Pre = 5,791.3 (SD: 2,995.4) 23 weeks = 5,369.6 (SD: 2,786.5) **Stoddard et al. (2004)** G0: Pre = 45.8%, 12 m = 52.0% G1: Pre = 36.4%, 12 m = 54.5% **Watson et al. (2005)** G0: Pre = 22.9, 6 m = 35.4 G1: Pre = 33.3, 6 m = 43.3 **Wendel-Vos et al. (2009)** G0: Pre = 18.3 (SD: 12.8) 5 years = 17.4 (SD: 12.4) G1: Pre = 15.4 (SD: 11.7) 5 years = 17.2 (SD: 12.9) **Williams et al. (2005)** G0: 6 weeks = 31% G1: 6 weeks = 81%	
Results – Group difference Because of substantial statistical heterogeneity (X^2 = 53.61, df = 18, P < 0.0001, I^2 = 66%), an overall pooled effect is not reported. Subgroup analyses demonstrated that studies using	

group and those using group in combination with individual delivery modes had similar effect sizes of SMD 0.40 (95% CI 0.14–0.67) and 0.32 (95% CI 0.05–0.59), respectively. Studies with a group delivery component had a standardised mean difference of 0.38 greater than either individual or community-based delivery.

Trends, Limitations, Comments and Source of Funding

Significant trends

Programs with a group delivery mode significantly increase physical activity among women experiencing disadvantage

General comments

Reported limitations

Reviewer

14/19 studies had a high risk of bias

Author

Self-reported physical activity measures; studies did not account for clustering in their study design; had to calculate SMDs and SEs from dichotomous data; substantial clinical, methodological and statistical heterogeneity;

Source of funding

V.C. is supported by a National Health and Medical Research Council Public Health Training (Postdoctoral) Fellowship. A.G. is supported by a National Health and Medical Research Council Strategic Award. T.W. is supported by a National Health and Medical Research Council/Primary Health Care Research, Evaluation and Development Career Development Fellowship. K.B. is supported by a National Health and Medical Research Council Senior Research Fellowship. D.C. is supported by a Victorian Health Promotion Foundation Senior Research Fellowship.

Authors: Conn VS, Phillips LJ, Ruppar TM et al
Year: 2012
Citation: Journal of Health Care for the Poor & Underserved 23(1): 59-80
Country of study: USA
Aim of study: Physical activity interventions with healthy minority adults
Study design: Systematic review and meta-analysis
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
Minority adults.

Number of people
21,151

Locality
USA

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Percentage female 100; Percentage African-American 100; Percentage Hispanic 0; Percent European-American 0; Mean age (years) 44; body mass index=25–29.9),

Excluded populations
Children and youth younger than 18 years. Participants with acute or chronic mental (e.g., schizophrenia, clinical depression, drug abuse) or physical (e.g., hypertension, diabetes, cardiovascular diseases) illnesses

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Supervised, planned, structured, and repetitive physical activity focused on improving or maintaining physical fitness. Minutes of supervised exercise per session 38.5; Frequency per week of supervised physical activity 3; Total number of supervised exercise sessions 33

Setting
Not reported

Delivery
Twenty-five intervention delivery sites

Length of follow-up
Not reported

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
“Any type of comparison”

Outcomes and Analysis

Outcomes
Fitness, Anthropometric outcomes, diabetes risk, mood

Outcome measurement
Self-report questionnaire

Analysis strategy
Meta-analysis

	Confounders Not reported
Results **Intervention group** Estimates for supervised physical activity eS Fitness Treatment group pre- vs. post-test .584 Anthropometric outcomes Treatment group pre- vs. post-test .104 Diabetes risk Treatment group pre- vs. post-test -.064 Mood Treatment group pre- vs. post-test .410 P(eS) Fitness Treatment group pre- vs. post-test <.001 Anthropometric outcomes Treatment group pre- vs. post-test .010 Diabetes risk Treatment group pre- vs. post-test .793 Mood Treatment group pre- vs. post-test .021 95% Ci Fitness Treatment group pre- vs. post-test (.431, .737) Anthropometric outcomes Treatment group pre- vs. post-test (.025, .182) Diabetes risk Treatment group pre- vs. post-test (-.539, .412) Mood Treatment group pre- vs. post-test (.063, .757) Estimates for motivational and education physical activity eS, p (eS), (95% CI) Physical activity behaviour Treatment group pre- vs. post-test .312, <.001 (.237, .386) Anthropometric outcomes Treatment group pre- vs. post-test .070, .001 (.027, .112) Diabetes risk Treatment group pre- vs. post-test .041, .225 (-.025, .108) Quality of life Treatment group pre- vs. post-test .464, .108 (-.102, 1.031)	**Results** **Control group** Estimates for supervised physical activity eS Fitness Control group pre- vs. post-test .073 Anthropometric outcomes Control group pre- vs. post-test -.036 Diabetes risk Control group pre- vs. post-test — Mood Control group pre- vs. post-test .119 P(eS) Fitness Control group pre- vs. post-test .519 Anthropometric outcomes Control group pre- vs. post-test .563 Diabetes risk Control group pre- vs. post-test — Mood Control group pre- vs. post-test .308 95% Ci Fitness Control group pre- vs. post-test (-.149, .294) Anthropometric outcomes Control group pre- vs. post-test (-.156, .085) Diabetes risk Control group pre- vs. post-test (—) Mood Control group pre- vs. post-test (-.110, .348) Estimates for motivational and education physical activity eS, p (eS), (95% CI) Physical activity behaviour Control group pre- vs. post-test .053, .251 (-.037, .142) Anthropometric outcomes Control group pre- vs. post-test -.069, .195 (-.173, .035) Diabetes risk Control group pre- vs. post-test -.521, .414 (-1.771, .729) Quality of life Control group pre- vs. post-test — , — (—)

Results – Group difference Supervised exercise significantly improved fitness (ES=.571–.584). Interventions designed to motivate minority adults to increase physical activity changed subsequent physical activity behaviour (ES = .172–.312) and anthropometric outcomes (ES=.070–.124). Estimates for supervised physical activity eS Fitness Treatment vs. control groups at post-test .571 Anthropometric outcomes Treatment vs. control groups at post-test .041 Diabetes risk Treatment vs. control groups at post-test — Mood Treatment vs. control groups at post-test .198 P(eS) Fitness Treatment vs. control groups at post-test .012 Anthropometric outcomes Treatment vs. control groups at post-test .643 Diabetes risk Treatment vs. control groups at post-test — Mood Treatment vs. control groups at post-test .365 95% Ci Fitness Treatment vs. control groups at post-test (.127, 1.015) Anthropometric outcomes Treatment vs. control groups at post-test (-.132, .214) Diabetes risk Treatment vs. control groups at post-test (-) Mood Treatment vs. control groups at post-test (-.231, .627) Estimates for motivational and education physical activity eS, p (eS), (95% CI) Physical activity behaviour Treatment vs. control groups at post-test .172, .024 (.023, .321) Anthropometric outcomes Treatment vs. control groups at post-test .124, .077 (-.014, .262) Diabetes risk Treatment vs. control groups at post-test -.024, .899 (-.393, .345) Quality of life Treatment vs. control groups at post-test —, — (—)	
Trends, Limitations, Comments and Source of Funding	
Significant trends Interventions effectively increased PA behaviour as documented for both 2-group (ES=.172) and treatment-group pre-post (ES=.312) comparisons. Anthropometric	**Reported limitations** <u>Reviewer</u> XXX <u>Author</u>

outcomes improved significantly in the treatment group pre-post comparison, but the magnitude of the effect (ES=.070) is small and probably not clinically meaningful. The quality of life outcome ES was moderate sized (ES=.464) but did not achieve statistical significance **General comments**	Intervention content and delivery with minority populations were inconsistently reported; intervention dose were inconsistently reported **Source of funding** Financial support provided by a grant from the National Institutes of Health (R01NR009656) to Vicki Conn, principal investigator.

Authors: Ickes MJ, Sharma M
Year: 2012
Citation: Journal of Environmental & Public Health 156435
Country of study: US
Aim of study: A systematic review of physical activity interventions in Hispanic adults.
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Studies were included if the participants included >35% Hispanic or Latino population (over 18 years). Hispanics or Latinos were defined as persons of Cuba, Mexico, Puerto Rico, South or Central-America, or other Spanish culture or origin, regardless of race.

Number of people
Three of the interventions were very small (n <20, six were small (n= 20–75), five were medium (n=75–150), five were large (n=150–300), and one intervention was classified with very large sample size (n= 869).

Locality
All studies conducted in the US. Interventions were limited to those published in English.

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
Nine of the interventions included a 100% Hispanic population while the others ranged from 70–80% Hispanics (*n* = 6) and 40–50% (*n* = 4).

The age of participants in the interventions ranged from 18 to 95 years, although 85% (*n* = 17) targeted middle-aged adults. Half of the interventions (*n* = 10) specifically targeted females.

Excluded populations
Exclusion criteria were articles in languages other than English and case studies.

Low risk/high risk population
Several of the interventions recruited specific populations including low income (*n* = 6), sedentary (*n* = 4), obese (*n* = 3) those with diabetes (*n* = 3) and individuals at risk for cardiovascular disease (*n* = 1).

Intervention and Comparison

Intervention
Physical activity interventions with the goal of obesity prevention. All intervention studies were eligible for inclusion, except case studies.

20 intervention studies were included. 65% of included studies (*n* =13) were RCTs. Two of the interventions were quasi-experimental which did not randomize the participants, yet still had a control or comparison group. A non-experimental design was used in four of the interventions in which control and/or comparison groups were not delineated. One of the interventions used a qualitative non-experimental design.

Method of allocation
Studies did not have to be RCTs. 65% of included studies (*n* =13) were RCTs. Two of the interventions were quasi-experimental which did not randomize the participants, yet still had a control or comparison group. A non-experimental design was used in four of the interventions in which control and/or comparison groups were not delineated. One of the interventions used a qualitative non-experimental design.

Method of allocation concealment for RCTs not reported for individual studies.

Measurement of exposure
N/A

Theory was widely incorporated into the interventions, with 75% (*n* = 15) reporting the use of some theoretical framework. Community-based settings (*n* = 14), clinical settings (*n* = 2), family and home-based (*n* = 3), and faith-based settings (*n* = 1) were also represented. Duration of the interventions ranged from one to three sessions (*n* = 2) to twelve months (*n* = 2). The duration of 90% of the interventions lasted less than one year; 1.5 to 2 months (*n* = 6), three to four months (*n* = 6) six months (*n* =3) and 9 months (*n* = 1). Duration within sessions also varied with 20-30-minute phone calls to 90-minute educational and group-led exercise sessions. Culturally appropriate messages were incorporated into 45% of the interventions, including the use of focus groups to assist in the design and implementation of culturally relevant materials.	**Comparator** Not reported for all individual studies but were generally less intensive counselling, social support or phone contact, with less PA emphasis.
Outcomes and Analysis	
Outcomes Outcomes reported in individual studies varied and did not appear to be specifically specified in the design of the systematic review. Outcomes meeting inclusion criteria of NICE review included: behaviour change relating to PA (reported in 90% of studies), level, amount and frequency of PA, number of participants reaching recommended levels, type of PA; BMI, waist to hip ratio, body fat; total energy expenditure. Other outcomes:- Physical fitness, cognitive and behavioural processes of change, lipids, knowledge and social support, self efficacy and motivation, glycemic control, medications, levels of depressive symptoms and stress.	**Outcome measurement** Self-reported via logs and checklists (n=9 studies), 7 day recall (n=6), pedometers (n=1), accelerometers (n=2). BMI was measured in 55% (n=11) interventions. Other measures included clinical tests related to diabetes and/or CVD (n=9), other anthropometric measures (n=6), social support questionnaires (n=6), measures of acculturation (n=2), stage of change/motivation (n=2), fitness testing (n=4), physical activity attitudes/knowledge/awareness (n=4), self-efficacy for PA (n=2) and psychological well-being (n=2). **Analysis strategy** No statistical analysis or meta-analyses were conducted. The existing analysis reported in the reviewed articles was extracted and reported in a systematic format. **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Physical activity (PA)

In interventions that measured PA as an outcome, 72% (*n* = 13) indicated an improvement. Five interventions reported an increase in minutes walking and/or associated METS. Three interventions reported an increase in individuals meeting recommended physical activity levels. Two interventions indicated an increase in MVPA and one an increase in VPA.

Two of the interventions reported a significant decrease in BMI at follow-up. Only 25% (*n* = 5) of the interventions conducted a follow-up measure; two at 2 months, one at 6 months, and two at 12 months. There was insufficient data to make conclusions about sustainability of behaviour change.

Interventions that included staff from the same ethnic group of the population reportedly improved recruitment in one study. One study reported that participants responded favourably when receiving the intervention in Spanish and appreciated information addressing culture-specific barriers to PA for Latinos.

Social support increased the likelihood of participation in two of the interventions.

Trends, Limitations, Comments and Source of Funding

Significant trends

General comments

The authors provided a number of recommendations for improving interventions among Hispanic populations:-the importance of choosing activities that are appealing and fun as well as culturally relevant. Interventions among Hispanic populations should build on their sense of culture and incorporate social support .Building in educational opportunities as well as the ability for participants to enhance self-management skills resulted in higher PA levels.

Reported limitations

Reviewer

Author

This is a narrative review and not a quantitative meta-analysis. Interventions included were limited to those published in English.

Source of funding

Not reported.

Systematic reviews of cost-effectiveness:

Authors: Wu S, Cohen D, Shi Y et al. **Year:** 2011 **Citation:** American Journal of Preventive Medicine 40(2): 149-158. **Country of study:** International **Aim of study:** Economic analysis of physical activity interventions **Study design:** Systematic review **Quality score: (++, + or -):** +	
Study (eligible and selected) population	
Primary data OR modelling Review of primary data **Eligible population** Not reported **Number of people** Not reported **Locality** International **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Not reported **Excluded populations** Not reported. Review contains data on school-based physical activity intervention which has been excluded from this analysis **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Multiple. Point-of-decision prompts; community campaign (4 studies); Individually adapted behaviour change; Social support; creation or enhanced access to places for physical activity **Setting** Not reported. Review contains data on school-based physical activity intervention which has been excluded from this analysis **Delivery** Not reported **Length of follow-up** Not reported	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Multiple. Point-of-decision prompts; community campaign (4 studies); Individually adapted behaviour change; Social support; creation or enhanced access to places for physical activity

Outcomes and Analysis	
Clinical Outcomes (used in CE/CU) Physical activity **Service Use measures** MET-hour gained **Costing** Not reported **Discounting** Not reported	**Outcome measurement** Not reported **Perspective** **Analysis strategy (including key sensitivity analyses)** Point-of-decision prompts Costs/person ($)0.0025 (0.001–1.34) MET-hours gained/day/person 0.0026 (0.007–0.0142) Cost-effectiveness ratio as $ per MET-hour gained/person 0.07 (0.0022–4.72) Annual costs for 10,000 population reached ($)58 (58–13,441) Community campaign (4 studies) Costs/person ($) 0.14; 14.93; 0.46; 55.86 MET-hours gained/day/person 0.44; 0.01; 0.10; 0.48 Cost-effectiveness ratio as $ per MET-hour gained/person 0.009; 1.50; 0.01; 1.90 Annual costs for 10,000 population reached ($) 1,432; 74,655; 4563; 3,351,369 Individually adapted behaviour change (all) Costs/person ($)55.27 (0.25–422) MET-hours gained/day/person 0.50 (0.09–2.76) Cost-effectiveness ratio as $ per MET-hour gained/person 0.41 (0.01–7.25) Annual costs for 10,000 population reached ($) 1,166,667 (4,970–10,938,000) Low-intensity Costs/person ($)11.04 (0.25–274) MET-hours gained/day/person 0.50 (0.15–1.26) Cost-effectiveness ratio as $ per MET-hour gained/person 0.10 (0.01–5.95) Annual costs for 10,000 population reached ($)545,000 (4,970–6,632,903) High-intensity Costs/person ($) 64.80 (1.69–422) MET-hours gained/day/person 0.53 (0.09–2.76) Cost-effectiveness ratio as $ per MET-hour gained/person 0.84 (0.02–7.25) Annual costs for 10,000 population reached ($)

	1,452,089 (142,204–10,938,000) Social support (all) Costs/person ($)107.15 (5.25–1,609) MET-hours gained/day/person 0.65 (0.05–2.89) Cost-effectiveness ratio as $ per MET-hour gained/person 1.14 (0.07–60.2) Annual costs for 10,000 population reached ($)2,520,000 (317,581–16,932,192) Low-intensity Costs/person ($)21 (5.25–167.90) MET-hours gained/day/person 0.77 (0.11–2.39) Cost-effectiveness ratio as $ per MET-hour gained/person 0.47 (0.07–5.17) Annual costs for 10,000 population reached ($) 2,099,500 (630,000–5,648,275) High-intensity Costs/person ($)153.49 (10.72-1,609) MET-hours gained/day/person 0.65 (0.05–2.89) Cost-effectiveness ratio as $ per MET-hour gained/person 1.16 (0.13–0.22) Annual costs for 10,000 population reached ($) 3,040,625 (317,581–16,932,192) Creation or enhanced access to places for physical activity Costs/person ($)15.08; 5.07; 137.46 MET-hours gained/day/person 0.62; 0.98; 0.26 Cost-effectiveness ratio as $ per MET-hour gained/person 0.40; 0.17; 4.47 Annual costs for 10,000 population reached ($)50,273; 16,914; 458,207 **Confounders** Not reported
Results **Intervention group** Not reported	**Results** **Control group** Not reported
Results – CE & ICER (for basecase and sensitivity analyses) **Magnitude of study effects and summary of standardized intervention cost per 10,000 population reached** No. adding <1 MET hr/wk/ person Point-of-decision prompts (28) 28 Community campaign (4) 2 Individual adapted behaviour change (49) 2 Social support (31) 5	

School-based physical activity intervention (26) 5
Creation or enhanced access to places for physical activity (3) 0

No. adding 1–3 MET hr/wk/ person
Point-of-decision prompts (28) 0
Community campaign (4) 0
Individual adapted behaviour change (49) 20
Social support (31) 7
School-based physical activity intervention (26) 10
Creation or enhanced access to places for physical activity (3) 1

No. adding 3–5 MET hr/wk/ person
Point-of-decision prompts (28) 0
Community campaign (4) 2
Individual adapted behaviours change (49) 11
Social support (31) 5
School-based physical activity intervention (26) 4
Creation or enhanced access to places for physical activity (3) 1

No. adding >5 MET hr/wk/ person
Point-of-decision prompts (28) 0
Community campaign (4) 0
Individual adapted behaviour change (49) 16
Social support (31) 14
School-based physical activity intervention (26) 7
Creation or enhanced access to places for physical activity (3) 1

Median (range) annual cost for 10,000 people to add 3–5 MET hr/wk ($)
Point-of-decision prompts (28) N/A
Community campaign (4) 3,350,000; 1,431
Individual adapted behaviour change (49) 688,000 (71,000–11,000,000)
Social support (31) 9,500,000 (700,000–14,780,000)
School-based physical activity intervention (26) 300,000 (188,000–3,586,000,000)
Creation or enhanced access to places for physical activity (3) 50,000

Trends, Limitations, Comments and Source of Funding

Significant trends	**Reported limitations**
The most cost-effective strategies were for point of-decision prompts (e.g., signs to prompt stair use), with a median cost of $0.07/MET-hour/day/person; these strategies had tiny effects, adding only 0.2% of minimum recommended physical activity levels Most of the interventions targeting adults cost considerably less than $1.00/MET-hour, with 62/115 arms costing<$0.50/MET-hour.	<u>Reviewer</u> Studies with insignificant results were excluded; <u>Author</u> translating different original measurement tools to a common metric may not achieve comparability; systematic publication biases; variation in the quality of the underlying intervention evaluations; many studies in the current review had relatively small samples;

In 37/141 of the study arms, the average level of physical activity exceeded the national physical activity guidelines at baseline, from 113% to 371%. **General comments** No comment	**Source of funding** Grant 5R21CA122664-02 from the National Cancer Institute.

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APPENDIX A.3 Evidence table PHYSICAL ACTIVITY – Economic Studies

Primary Studies

Authors: Annemans L, Lamotte M, Clarys P et al. **Year:** 2007 **Citation:** European Journal of Cardiovascular Prevention & Rehabilitation 14(6): 815-824. **Country of study:** Belgium **Aim of study:** Health economic evaluation of controlled and maintained physical exercise in the prevention of cardiovascular and other prosperity diseases. **Study design:** Economic evaluation **Quality score: (++, + or -):**	
Study (eligible and selected) population	
Primary data OR modelling Markov model **Eligible population** Not applicable **Number of people** 3 **Locality** Belgium **Recruitment strategy** Not applicable **Response rate** Not applicable	**Characteristics of population** Person 1: 30 years old, BMI = 26, cholesterol = 190, systolic blood pressure = 120 Person 2: 40 years old, BMI = 30, cholesterol = 210, systolic blood pressure = 130 Person 3: 50 years old, BMI = 32, cholesterol = 250, systolic blood pressure = 140 **Excluded populations** Not applicable **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Physical exercise **Setting** Not applicable **Delivery** Not applicable **Length of follow-up** 12-month cycle-length, 25-year analytical time horizon	**Method of allocation** Not applicable **Measurement of exposure** Not applicable **Comparator** Physical exercise was compared with no intervention

Outcomes and Analysis	
Clinical Outcomes (used in CE/CU) (1) be healthy, (2) have coronary heart disease (CHD), (3) have cerebrovascular disease, (4) have diabetes, (5) have colon cancer or (6) have breast cancer. **Service Use measures** Not reported **Costing** Both from a healthcare payer perspective and from a total societal perspective. Cardiovascular disease cost data were obtained from published literature. **Discounting** Discounting of 3% is applied to future cost and effects	**Outcome measurement** XXX **Perspective** Costs were taken from a societal perspective **Analysis strategy (including key sensitivity analyses)** One way and probabilistic sensitivity analyses were carried out. Cost-utility analysis Clinical data in the model Percentage of fatal CHD 26% Percentage of fatal cerebrovascular disease 13% If history of MI Nonfatal stroke/year 0.58% Nonfatal MI/year 2.60% Vascular death/year 1.66% If history of stroke Nonfatal stroke/year 5.39% Nonfatal MI/year 0.62% Vascular death/year 1.71% If history of MI and stroke Nonfatal stroke/year 5.39% Nonfatal MI/year 2.60% Vascular death/year 2.06% If History of MI and stroke: other death/year 1.05% Relative risk for CHD with exercise 0.60 (0.44–0.83) Relative risk for cerebrovascular disease with exercise 0.73 (0.67–0.79) **Confounders** Adjusted for age; cigarette smoking; intake of alcohol, red meat, and vegetables; and early parental mortality. Assumption: worst of values related to history of MI or stroke.
Results **Intervention group** Not reported	**Results** **Control group** Not reported
Results – CE & ICER (for basecase and sensitivity analyses) Size of the public payment per year for controlled exercise **Cohort 1** **€0** Societal Cost no exercise 14 281 QALY no exercise 17.96 Cost exercise 11 195	

QALY exercise 19.11
Incr. cost – 3086
Incr. effect 1.15
Dominant

Healthcare payer
Cost no exercise 6174
QALY no exercise 17.96
Cost exercise 4719
QALY exercise 19.11
Incr. cost – 1455
Incr. effect 1.15
Dominant

€500
Societal
Cost no exercise 14 281
QALY no exercise 17.96
Cost exercise 30 289
QALY exercise 19.11
Incr. cost 16 008
Incr. effect 1.15
13 920

Healthcare payer
Cost no exercise 6174
QALY no exercise 17.96
Cost exercise 23 813
QALY exercise 19.11
Incr. cost 17 639
Incr. effect 1.15
15 338

Cohort 2
€0
Societal
Cost no exercise 36 044
QALY no exercise 17.12
Cost exercise 28 930
QALY exercise 18.29
Incr. cost – 7114
Incr. effect 1.16
Dominant

Healthcare payer
Cost no exercise 13 425
QALY no exercise 17.12
Cost exercise 10 561
QALY exercise 18.29

Incr. cost – 2864
Incr. effect 1.16
Dominant

€500
Societal
Cost no exercise 36 044
QALY no exercise 17.12
Cost exercise 46 892
QALY exercise 18.29
Incr. cost 10 847
Incr. effect 1.16
9351

Healthcare payer
Cost no exercise 13 425
QALY no exercise 17.12
Cost exercise 28 522
QALY exercise 18.29
Incr. cost 15 098
Incr. effect 1.16
13 016

Cohort 3
€0
Societal
Cost no exercise 63 854
QALY no exercise 15.57
Cost exercise 50 614
QALY exercise 16.79
Incr. cost – 13 240
Incr. effect 1.23
Dominant

Healthcare payer
Cost no exercise 25 135
QALY no exercise 15.57
Cost exercise 19 498
QALY exercise 16.79
Incr. cost – 5637
Incr. effect 1.23
Dominant

€500
Societal
Cost no exercise 63 854
QALY no exercise 15.57
Cost exercise 66 743
QALY exercise 16.79

Incr. cost 2 889
Incr. effect 1.23
2349

Healthcare payer
Cost no exercise 25 135
QALY no exercise 15.57
Cost exercise 35 627
QALY exercise 16.79
Incr. cost 10 492
Incr. effect 1.23
8530

Cost effectiveness of exercise versus no exercise for different time horizons (assuming public payment of h400 per year)
Time horizon (year) - 5
Perspective
Societal
Cost no exercise 300
QALY no exercise 4.22
Cost exercise 2840
QALY exercise 4.48
Incr. cost 2539
Incr. effect 0.26
Incremental cost-effectiveness 9587

Healthcare payer
Cost no exercise 160
QALY no exercise 4.22
Cost exercise 2735
QALY exercise 4.48
Incr. cost 2574
Incr. effect 0.26
Incremental cost effectiveness 9719

Time horizon (year) - 25
Perspective
Societal
Cost no exercise 14 281
QALY no exercise 17.96
Cost exercise 26 470
QALY exercise 19.11
Incr. cost 12 189
Incr. effect 1.15
Incremental cost-effectiveness 10 577

Healthcare payer
Cost no exercise 6174
QALY no exercise 17.96

Cost exercise 19 995
QALY exercise 19.11
Incr. cost 13 821
Incr. effect 1.15
Incremental cost effectiveness 11 992

Cost effectiveness of exercise versus no exercise in function of compliance (time horizon=25 years, assuming public payment of h400 per year)
Cohort 1
Compliance
0.5, 25 235
0.625, 19 939
0.75, 16 407
0.875, 13 884
1, 12 018

Cohort 2
0.5, 22 175
0.625, 17 260
0.75, 13 983
0.875, 11 641
1, 9918

Cohort 3
0.5, 16 358
0.625, 12 191
0.75, 9407
0.875, 7413
1, 5907

Trends, Limitations, Comments and Source of Funding

Significant trends
For each of the cohorts, physical exercise is predicted to increase the QALYs and to offset a large part of the initial investment. The cost per QALY varies from h2000 to 15 000 per QALY depending on the risk levels, which is better compared with a majority of secondary preventions that are currently publicly financed.

General comments
Controlled exercise offers value for money, even if society would cover for its expenses completely.

Reported limitations
Reviewer
Population attributable risk not used;

Author
Lack of prospective long-term data; predictive validity; model assumed 100% compliance with physical exercise; only three cohorts; did not take into account the cost of travel time or time spent exercising; risks for colon or breast cancer were based on age and sex.

Source of funding
This study was sponsored by an unrestricted grant from the Fitness Organisation.

Authors: Anokye NK, Trueman P, Green C et al.
Year: 2011
Citation: BMC Public Health 11(1): 954.
Country of study: UK
Aim of study: examines the cost-effectiveness of ERS in promoting physical activity compared with usual care
Study design: Economic evaluation
Quality score: (++, + or -):

Study (eligible and selected) population

Primary data OR modelling Decision analytic model **Eligible population** Not applicable **Number of people** Not applicable **Locality** UK **Recruitment strategy** Not applicable **Response rate** Not applicable	**Characteristics of population** The model considers a cohort of individuals, aged between 40-60 years, who present in a sedentary state. The age of the population was selected to reflect the evidence on the effectiveness of ERS. **Excluded populations** Not applicable **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Physical activity **Setting** Primary care setting **Delivery** Not applicable **Length of follow-up** Not reported	**Method of allocation** Not applicable **Measurement of exposure** Not applicable **Comparator** Usual care

Outcomes and Analysis

Clinical Outcomes (used in CE/CU) Incremental cost per quality-adjusted life-year **Service Use measures** Not applicable **Costing**	**Outcome measurement** QALY **Perspective** NHS and personal social services perspective (third-party payer perspective) **Analysis strategy (including key sensitivity**

NHS **Discounting** Future costs and benefits are discounted at a rate of 3.5% per annum	**analyses)** Deterministic and probabilistic sensitivity analyses investigated the impact of varying ERS cost and effectiveness assumptions. Sub-group analyses explored the cost-effectiveness of ERS in sedentary people with an underlying condition. **Estimates of the inputs to the model** **Probability of experiencing an outcome associated with physical activity** Probability of experiencing CHD when active 0.014 Probability of experiencing CHD when sedentary 0.027 Probability of experiencing stroke when active 0.011 Probability of experiencing stroke when sedentary 0.015 Probability of experiencing type II diabetes when active 0.022 Probability of experiencing type II diabetes when sedentary 0.044 Inputs used in calculating QALYs/treatment costs Utility/health state value of being in CHD state 0.55 Utility/health state value of being in stroke state 0.52 Utility/health state value of being in type II diabetes state 0.7 Utility/health state value of being in a non-disease health state 0.83 Average age of cohort (in years) 50 Average age of mortality (in years) 84 Assumed average age of onset of a disease health state (in years) 55 Life years remaining after onset of CHD 18.41 Life years remaining after onset of stroke 5.12 Life years remaining after onset of type II diabetes 28.13 Lifetime treatment costs*/QALYs associated with health states (per person) Lifetime treatment costs associated with CHD state £17,728 Lifetime treatment costs associated with stroke state £1,965 Lifetime treatment costs associated with type II diabetes state £50,309 Lifetime treatment costs associated with non-disease health state - QALYs associated with CHD state 9.94 QALYs associated with stroke state 5.15 QALYs associated with type II diabetes state 14.18 QALYs associated with non-disease health

	state 17.18 *Costs are in 2010 prices. **Confounders** No comment
Results **Intervention group** Not applicable	**Results** **Control group** Not applicable

Results – CE & ICER (for basecase and sensitivity analyses)

Base-case cost-effectiveness results comparing ERS with usual care

ERS
Lifetime total healthcare costs per person £2,492
Total QALYs per person 16.743

Usual care
Lifetime total healthcare costs per person £2,322
Total QALYs per person 16.735

Difference
Lifetime total healthcare costs per person £170
Total QALYs per person 0.008

Incremental cost per QALY (ICER)
Lifetime total healthcare costs per person £20,876

Cost-effectiveness results (after deterministic sensitivity analyses) comparing ERS with usual care

Incremental cost per person (Incremental effect per person) ICER

Base case analysis £170 (0.008) £20,876
Parameters
Intervention costs to participants £290 (0.008) £35,652
Less intensive ERS £58 (0.008) £7,085
Effectiveness of ERS (based on lower limit of 95% CI) £226 (-0.001) Dominated*
Effectiveness of ERS (based upper limit of 95% CI) £122 (0.015) £7,947

Scenarios
Worst cases of cost and effectiveness £346 (-0.001) Dominated*
Best cases of cost and effectiveness £10 (0.015) £679
Worst case cost and best case effectiveness £242 (0.015) £15,734
Best case cost and worst case effectiveness £114 (-0.001) Dominated*
*ERS more costly and less effective than control

Cost-effectiveness results (disease specific cohorts) comparing ERS with usual care

Cohort Incremental cost per person(£)
Obese £168
Hypertensive £168
Depressive £147

Cohort Incremental effect per person(QALY)
Obese 0.011
Hypertensive 0.013
Depressive 0.017

Cohort ICER (£)
Obese £14,618
Hypertensive £12,834
Depressive £8,414

At a threshold of £20,000 per QALY, there is a 0.508 probability that ERS is cost-effective. This increases to 0.879 when a threshold of £30,000 per QALY is considered.

In terms of effectiveness, ERS (compared with usual care) is more effective leading to improved QALY gains which are higher than in the base case (ranging from 0.011 to 0.017). The cost per QALY of ERS compared with usual care is between £8,414 and £14,618 and thus can be considered cost-effective at the £20,000 per QALY threshold.

Trends, Limitations, Comments and Source of Funding

Significant trends
Compared with usual care, the mean incremental lifetime cost per patient for ERS was £169 and the mean incremental QALY was 0.008, generating a base-case incremental cost-effectiveness ratio (ICER) for ERS at £20,876 per QALY in sedentary individuals without a diagnosed medical condition. There was a 51% probability that ERS was cost-effective at £20,000 per QALY and 88% probability that ERS was cost-effective at £30,000 per QALY.

General comments
ERS is associated with modest increase in lifetime costs and benefits.

Decision analytic models may not be well suited to interventions which involve complex behaviour change components.

Reported limitations
Reviewer
No comment

Author
Limited evidence to show that ERS has a significant and lasting effect on participation in physical activity; the model assumed that the active state last long enough to enable health benefits to be obtained, this could not be addressed in the sensitivity analysis due lack of data and the type of model used;

Source of funding
NIHR Health Technology Assessment programme (project number 08/72/01)

Authors: Dalziel K, Segal L, Elley CR.
Year: 2006
Citation: Australian and New Zealand Journal of Public Health 30(1): 57-63.
Country of study: New Zealand
Aim of study: To evaluate the economic performance of the 'Green Prescription' physical activity counselling program in general practice.
Study design: Cost utility analysis
Quality score: (++, + or -):

Study (eligible and selected) population

Primary data OR modelling Cost utility analysis using a Markov model **Eligible population** Not reported **Number of people** Not reported **Locality** New Zealand **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Participants' mean age was 58 years (range 40-79) and 66% were female (582/878), mean BMI was 30 kg/m2, mean diastolic blood pressure was 82mmHg and average number of medications was 2.5. **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention 'Green Prescription' physical activity counselling program **Setting** General practice **Delivery** Not reported **Length of follow-up** Study was 12 months. The model was extended over full life expectancy (with one, 10 and 25 years presented in sensitivity analyses).	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Usual care

Outcomes and Analysis

Clinical Outcomes (used in CE/CU) Change in proportion of people who became	**Outcome measurement** XXX

active and change in quality of life over 12 months **Service Use measures** Not reported **Costing** Costs were collected as part of the trial for program set-up and co-ordination; regional sports trusts' patient support; and general practice advice and follow-up **Discounting** Discounted at 5% per annum	**Perspective** Health system **Analysis strategy (including key sensitivity analyses)** Conducted A state transition model (Markov) and simultaneous multivariate stochastic sensitivity analysis **Confounders** Not reported
Results **Intervention group** Not reported	**Results** **Control group** Not reported

Results – CE & ICER (for basecase and sensitivity analyses)

Cost effectiveness/utility results – preliminary, base case and probabilistic sensitivity analyses.

Green Prescription program

Base case analysis (modelling)

Total costs $NZ161

Total life years 24.478

Total QALYs 9.821

Probabilistic sensitivity analysis

Total costs $NZ161

Total QALYs 9.799

'Usual care' group

Base case analysis (modelling)

Total costs$NZ0

Total life years 24.267Total QALYs 9.742

Probabilistic sensitivity analysis

Total costs$NZ0

Total QALYs 9.677

Base case analysis (modelling)

Discounted $/QALY gained $NZ2,053

Probabilistic sensitivity analysis

Discounted $/QALY gained $NZ1,330

Results of one-way sensitivity analyses

Assumptions Cost per QALY ($NZ)

BASE CASE $2,053

Length of intervention benefit – 1 year $10,381

Length of intervention benefit – 5 years $1,663

Length of intervention benefit – 10 years $1,160

RR of activity gain for intervention group – 1.85 $3,778
RR of activity gain for intervention group – 4.77 $1,191
Utility – active 0.75 and inactive 0.73 $2,241
Utility – active 0.78 and inactive 0.75 $1,912
RR of mortality – 1.0 (active and inactive) $2,713
Population – age 50 and 55% female $2,607
Undiscounted $827
Discount rate 7% $2,722
Length of consults – doubled $2,259
Length of consults – halved $1,931
Time horizon – 1 year $37,516
Time horizon – 10 years $6,451
Time horizon – 45 years $2,702

At 12 months, the relative risk of achieving 2.5 hours of physical activity a week was 2.98 (95% CI 1.85-4.77) for the intervention group compared with control. One-way sensitivity analyses gave results ranging from $NZ827 per QALY to $NZ37,516 per QALY

Trends, Limitations, Comments and Source of Funding

Significant trends
Incremental, modelled cost utility of the Green Prescription program compared with 'usual care' was $NZ2,053 per QALY gained over full life expectancy (range $NZ827 to $NZ37,516 per QALY). Based on the probabilistic sensitivity analysis, 90% of ICERs fell below $NZ7,500 per QALY.

General comments
Given the lack of longer-term data and uncertainty regarding the sustainability of the increased activity and the longer-term health effects, the current model provides conservative estimates

Reported limitations
Reviewer
Funder not reported

Author
short follow-up period in the primary clinical trial; proportion of the cohort who remained active was not observed, nor was the impact on mortality or quality of life beyond the 12 months; relative risk adjustment that was applied to the population death rate for the active and inactive states assumed a constant adjustment over the first five years of the model;

Source of funding
Not reported

Authors: Goyder E, Hind D, Breckon J et al.

Year: 2014

Citation: Health Technology Assessment 18(13).

Country of study: International

Aim of study: To determine whether objectively measured physical activity is increased in those receiving physical activity 'booster' consultations delivered in a motivational interviewing style, either face to face or by telephone.

Study design: Three-arm, parallel-group, pragmatic, superiority randomised controlled trial with nested qualitative research fidelity and geographical information systems and health economic substudies.

Quality score: (++, + or -): ++

Study (eligible and selected) population

Primary data OR modelling
Primary data

Eligible population
Previously sedentary people, aged 40–64 years, living in deprived areas of Sheffield, UK, who had increased their physical activity levels after receiving a brief intervention

Number of people
282

Locality
Deprived areas of Sheffield, UK.

Recruitment strategy
Letters

Response rate
282/70,388

Characteristics of population
Gender, n (%) Male 130 (46.1), Female 152 (53.9); Employment status, n (%) Part-time 52 (18.4), Full-time 93 (33.0), Not employed 134 (47.5), Missing 3 (1.1); Ethnicity, n (%) White British 246 (87.2), Other 33 (11.7), Missing 3 (1.1); Marital status, n (%) Single 45 (16.0), Married 151 (53.5), Co-habiting 20 (7.1), Divorced/separated 55 (19.5), Widowed 11 (3.9); Stage of change, n (%) Contemplation 12 (4.3), Preparation 125 (44.3), Action 91 (32.3), Maintenance 50 (17.7), Missing 4 (1.4); Age (years) n (%) 282 (100.0), Mean (SD) 54.6 (7.3), Median (IQR) 55.3 (48.8 to 61.4), Min. to max. 40.4 to 65.5; Weight (kg) n (%) 282 (100.0), Mean (SD) 85.2 (18.7), Median (IQR) 82.9 (72.5 to 96.6), Min. to max. 46.9 to 160.0; BMI (kg/m2), n (%) 281 (99.6), Mean (SD) 30.3 (5.9), Median (IQR) 29.8 (26.3 to 33.0), Min. to max. 17.1 to 53.4

Excluded populations
Already meeting activity guidelines, if limited by chronic ill-health, if unable or unwilling to participate.

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Motivational interviewing

Setting
Community

Delivery

Method of allocation
Block size of 200 with no stratification

Measurement of exposure
'Behaviour counts' were recorded, which included giving information, MI adherent behaviours (e.g. asking permission, affirming, emphasising personal control), MI non-

DVD and information sheet **Length of follow-up** 6 month	adherent behaviours (e.g. advising, confronting, directing), open compared with closed questions and simple and complex reflections. The calculations for MITI were based on existing standards, **Comparator** Face to face or by telephone
Outcomes and Analysis	
Clinical Outcomes (used in CE/CU) Total energy expenditure (TEE) per day in kcal **Service Use measures** Not reported **Costing** The interventions will be costed, as will the consequences for the use of health and social services in general. **Discounting** Discounting QALY gains at a rate of 3.5% per annum.	**Outcome measurement** Actiheart device (CamNtech Ltd, Cambridge, UK). Chest-worn device that records heart rate, interbeat interval and physical activity. It calculates and measures activity energy expenditure. **Perspective** NHS **Analysis strategy (including key sensitivity analyses)** Intention-to-treat **Confounders** Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
Results **Intervention group** Mean (SD) Multiple imputation (≥ 4 days) (n = 55); 2235.2 (395.5); Regression imputation (≥ 4 days) (n = 52) 2281.7 (379.8); Complete cases (n = 39) 2315.5 (726.2); Complete cases (n = 38); 2217.5 (395.5); Multiple imputation (≥ 1 days) (n = 61) 2215.9 (395.5); Per protocol (n = 55) 2308.2 (646.3); Per protocol (n = 54) 2239.1 (397.1)	**Results** **Control group** Mean (SD) Multiple imputation (≥ 4 days) ; (n = 36); 2163.0 (298.9); Regression imputation (≥ 4 days) (n = 34); 2202.0 (371.3); Complete cases (n = 21); 2118.1 (298.9); Complete cases (n = 21); 2118.1 (298.9); Multiple imputation (≥ 1 days) (n = 37); 2168.4 (298.9); Per protocol (n = 36) 2177.2 (390.7); Per protocol (n = 36) 2177.2 (390.7)
Results – CE & ICER (for basecase and sensitivity analyses) **Sensitivity analysis: difference in mean TEE per day between the booster intervention group (mini plus full) and the control group at 9 months** Adjusted Mean difference 95% CI); Multiple imputation (≥ 4 days); 18.1 (−102.9 to 139.1); Regression imputation (≥ 4 days) 13.9 (−80.1 to 107.9); Complete cases 118.6 (−152.7 to 389.9); Complete cases 31.7 (−88.7 to 152.1); Multiple imputation (≥ 1 days) 14.5 (−105.6 to 134.6); Per protocol 51.5 (−137.2 to 240.2); Per protocol −7.1 (−115.8 to 101.6) p-value Multiple imputation (≥ 4 days) 0.766 Regression imputation (≥ 4 days) 0.769	

Complete cases 0.384
Complete cases 0.599
Multiple imputation (≥ 1 days) 0.811
Per protocol 0.589
Per protocol 0.897

Long-term physical activity scenarios assumed
Control
Scenario A
Extra years lived Mean (SE) 26.73 (0.02)
QALYs accrued Mean (SE) 12.75 (0.01)

Scenario B
Extra years lived Mean (SE) 26.73 (0.02)
QALYs accrued Mean (SE) 12.75 (0.01)

Scenario C
Extra years lived Mean (SE) 26.90 (0.02)
QALYs accrued Mean (SE) 12.81 (0.01)

Mini booster
Scenario A
Extra years lived Mean (SE) 26.71 (0.02)
QALYs accrued Mean (SE) 12.73 (0.01)

Scenario B
Extra years lived Mean (SE) 26.82 (0.02)
QALYs accrued Mean (SE) 12.78 (0.01)

Scenario C
Extra years lived Mean (SE) 26.14 (0.02)
QALYs accrued Mean (SE) 12.52 (0.01)
Full booster
Scenario A
Extra years lived Mean (SE) 26.58 (0.02)
QALYs accrued Mean (SE) 12.69 (0.01)
Scenario B
Extra years lived Mean (SE) 26.67 (0.02)
QALYs accrued Mean (SE) 12.72 (0.01)
Scenario C
Extra years lived Mean (SE) 26.18 (0.02)
QALYs accrued Mean (SE) 12.53 (0.01)

Shift in physical activity quintile
Quintiles moved between
Mean utility gain (SE) Maximum acceptable intervention cost (£)
1 (most sedentary) to 2 0.122 (0.0119) 2430.70
2 to 3 0.046 (0.0102) 914.36
3 to 4 0.043 (0.0094) 853.83

4 to 5 (most physically active)	0.032 (0.0088)	649.66

Trends, Limitations, Comments and Source of Funding

Significant trends

The mean difference in TEE per day between baseline and 3 months favoured the control arm over the combined booster arm but this was not statistically significant (–39 kcal, 95% confidence interval −173 to 95, p = 0.57).

General comments

No comment

Reported limitations

Reviewer

XXX

Author

Neither the process evaluation survey nor the topic guide for the interviews was piloted; interviews were conducted by those who delivered the intervention; economic model does not directly consider the relationship between physical activity levels and morbidity risks;

Source of funding

HTA programme as project number 07/25/02

APPENDIX A.4 Evidence table DIET - Primary studies

Authors: Hjerkin EM, Sandvik L, Hjermann I et al
Year: 2004
Citation: Journal of Internal Medicine 255(1): 68-73 (and previous method papers)
Country of study: Norway
Aim of study: Effect of diet intervention on long term mortality in healthy middle-aged men with combined hyperlipidaemia
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Middle-aged men with combined hyperlipidaemia

Number of people
104

Locality
Oslo, Norway

Recruitment strategy
All men in the city of Oslo aged 40-49 (in 1972-75) were invited to a screening examination. Men with mean serum total cholesterol >6.45 mmol/L and systolic BP <150 mm Hg were invited to enrol in the trial

Response rate
Of 26000 men invited to initial screening, 17,965 attended the screening exam and 1,232 met the inclusion criteria and were recruited

Characteristics of population
Control
Age 46 (3), BMI (kg/m2) 26.9 (2.9), total cholesterol (fasting, mmol/L) 7.9 (0.6), triglycerides (fasting) 4.0 (1.9), fasting blood glucose 5.0 (0.6), systolic BP 132 (9), diastolic BP 87 (6), % smokers 73%

Intervention
Age 46 (3), BMI (kg/m2) 26.0 (2.9), total cholesterol (fasting, mmol/L) 7.9 (0.6), triglycerides (fasting) 3.5 (1.0), fasting blood glucose 5.0 (0.5), systolic BP 132 (10), diastolic BP 86 (8), % smokers 65%.

Excluded populations
Not reported

Low risk/high risk population
Men with hyperlipidaemia

Intervention and Comparison

Intervention
The intervention diet was a lipid lowering diet with emphasis on reduction of saturated fat, total energy intake and body weight

Participants were given individual dietary advice based on assessment of diet by questionnaire and advised to reduce total energy intake (mainly by reducing sugar, alcohol and fat) and reduce saturated fat and slightly increase polyunsaturated fat consumption. They were advised to eat fish and low fat meat with potatoes and vegetables for main meals and use polyunsaturated oil for cooking, baking and sauces, fruit for dessert, fibre-rich bread, fish or vegetable spreads preferably but low fat cheese or meat were also acceptable. The use of

Method of allocation
Not reported

Measurement of exposure
Not reported

Control group
Details not reported

skimmed milk and to restrict egg consumption to one a week was also recommended Note: Intervention participants also received anti-smoking advice. However, there was no significant difference between the proportion of smokers in the intervention and control groups at baseline and after five years **Setting** Community **Delivery** Not reported **Length of follow-up** Participants were followed up for 24 years with a follow up examination every six months and adherence to the diet assessed at each follow-up	
Outcomes and Analysis	
Outcomes Mortality Total cholesterol Triglycerides BMI	**Outcome measurement** Statistics Norway Blood samples **Analysis strategy** Cox regression analysis **Confounders** Adjusted for smoking, age
Results: Intervention group	**Results: Control group**
Results – Group difference After a total of 24 years (from baseline) overall mortality was significantly lower in the intervention group compared to the control group (and remained significant in regression after adjusting for age and smoking status. (RR 0.47, 95% CI 0.23- 0.96), p= 0.038).Mortality was 42.9% in the control group and 21.8 % in the diet intervention group, p = 0.022 After five years (at the end of the intervention) total cholesterol, triglycerides and BMI were all significantly lower in the diet group compared to the control group	
Trends, Limitations, Comments and Source of Funding	
Significant trends NR **General comments** Small sample size Diff in % smokers between groups at baseline but difference remained after 5 years and adjustment made for smoking	**Reported limitations** <u>Author</u> <u>Reviewer</u> Small sample size **Source of funding** Norwegian Cardiovascular Council and the Norwegian retail company RIMI

Authors: Turner LW, Wallace LS, Hunt SB et al
Year: 2003
Citation: Psychological Reports 93: 521-526
Country of study: USA
Aim of study: Changes in behaviour and behavioural intentions among middle-aged women from an osteoporosis prevention program.
Study design: Before and after study
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population Middle-aged women (mean age 49) **Number of people** 342 **Locality** Not reported **Recruitment strategy** Volunteers in an Osteoporosis Prevention Program **Response rate** Not reported	**Characteristics of population** Mean age 49.5 (SD 13.2) years Most well educated with mean of 16 years education, degree equivalent **Excluded populations** Women those not middle aged **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Osteoporosis prevention program – educational classes, hip and spine bone mineral density testing and individual consultation **Setting** Not reported **Delivery** Not reported **Length of follow-up** Not reported	**Method of allocation** N/A **Measurement of exposure** Not reported **Control group** Not applicable – before and after study

Outcomes and Analysis

Outcomes Participation in weight bearing and non-weight bearing physical activity, consumption of caffeinated beverages, intake of milk, yogurt and cheese	**Outcome measurement** Validated 'osteoporosis preventing behaviours survey' **Analysis strategy** Not reported **Confounders** Not adjusted/not reported
Results **Intervention group**	**Results** **Control group**
Before (% participants)	Not applicable

Weight bearing PA 44 Non weight bearing PA 34 Excessive caffeine containing beverages 28 Consumption of one or more servings of milk per day 25 Consumption of one or more servings of yogurt per day 9 Consumption of one or more servings of cheese per day 15 **After (% participants)** Weight bearing PA 55 Non weight bearing PA 44 Excessive caffeine containing beverages 11 Consumption of one or more servings of milk per day 35 Consumption of one or more servings of yogurt per day 10 Consumption of one or more servings of cheese per day 20 (No error limits reported)	
Results – Group difference Not applicable	
Trends, Limitations, Comments and Source of Funding	
Significant trends 60% reported they had increased their intake of dairy products, 42% increased consumption of calcium fortified products, 28% increased intake of calcium rich vegetables, 25% modified food preparation techniques to increase calcium **General comments**	**Reported limitations** Author Reviewer (No error limits reported) Very little methodological detail reported **Source of funding** Not reported

Authors: Wright JL, Sherriff JL, Dhaliwal SS et al
Year: 2011
Citation: International Journal of Behavioural Nutrition and Physical Activity 8: 43
Country of study: Australia
Aim of study: Effectiveness of tailored, iterative, printed dietary feedback
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Men and women aged 40 to 65 years with one or more risk factors for CVD (overweight, obesity, hypercholesterolaemia, hypertension, smoking, family history or a previous cardiac event)

Number of people
178 (85 men, 93 women)

Locality
Australia

Recruitment strategy
Newspapers, community announcements, radio, TV

Response rate
Not reported

Characteristics
Control (waiting list)
n= 62 (M30/F32)
Education 12y or less 45%
>12y 55%
Smokers 5%
Age 54 (7)
Mean BMI 29.0 (5.7)

Control (small group nutrition education)
n= 58 (M26/F32)
Education 12y or less 53%
>12y 47%
Smokers 2%
Age 53.4 (6.5)
Mean BMI 30.1 (6.1)

Intervention
n= 58 (M29/F29)
Education 12y or less 57%
>12y 43%
Smokers 0%
Age 54.6 (7.0)
Mean BMI 29.0 (4.6)

Excluded populations
NIDD, non-English speaking, unable to read or write, already undertaking dietary modification, major illness

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Tailored, iterative, printed dietary feedback with three instalments mail delivered over a three month period that were re-tailored to most recent assessment of dietary change

Setting
Community

Delivery
Mailed reports

Method of allocation
Computer generated using a three block design stratified for gender

Measurement of exposure
Food frequency and psychosocial questionnaires at baseline

Control group
Small group nutrition education sessions consisting of 2 x 90 min dietitian-led nutrition education sessions and also a waiting list

Length of follow-up 3 months	control group
Outcomes and Analysis	
Outcomes Intake of: Saturated fat Fruit Vegetables Grains Wholegrains	**Outcome measurement** 7 day estimated diet records **Analysis strategy** Not reported **Confounders** Not reported
Results **Intervention group**	**Results** **Control group**
Intervention group: Tailored printed feedback n=58 Sat fat g/d 24.1 (1.25 Fruit (servings/d) 2.1 (0.1) Veg (servings/d) 2.4 (0.1) Grains (serves/d) 2.3 (0.2) Wholegrains (servings/d) 1.3 (0.1)	**Control group: nutrition education n=58** Sat fat g/d 22.7 (1.1) Fruit (servings/d) 1.7 (0.2) Veg (servings/d) 2.9 (0.2) Grains (serves/d) 2.5 (0.1) Wholegrains (servings/d) 1.2 (0.1) **Control group: waiting list n= 62** Sat fat g/d 25.0 (1.2) Fruit (servings/d) 1.7 (0.1) Veg (servings/d) 2.5 (0.2) Grains (serves/d) 2.5 (0.1) Wholegrains (servings/d) 1.0 (0.1)
Results – Group difference	
Tailored intervention gp vs waiting list control Sat fat g/d -2.4 p=0.561 Fruit (servings/d) +0.3 p=0.047 Veg (servings/d) +0.1 p=0.685 Grains (serves/d) -0.1 p= 0.359 Wholegrains (servings/d) +0.1 p=0.094	
Trends, Limitations, Comments and Source of Funding	
Significant trends **General comments**	**Reported limitations** Author Reviewer **Source of funding** Australian Health Promotion Foundation

APPENDIX A.5 Evidence table DIET - Systematic Reviews Included

Authors: Esposito K, Kastorini C, Panagiotakos D et al
Year: 2011
Citation: Metabolic Syndrome and Related Disorders 9: 1-12
Country of study: International
Aim of study: Systematic review and meta-analysis of Mediterranean diet and weight loss
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
No restrictions reported

Number of people
3436 (in 16 RCTs)

Locality
International (both English language and non-English language studies included and from any country eligible)

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
Age of participants in included studies ranged from 35 y to 70 y at baseline, with 13 of 16 included studies in midlife, 2 in older populations and 1 in a younger population (35 y).

Most studies in mixed male and female populations. Only 2 were in females alone and one in males alone.

BMI at baseline ranged from 25 to 35 kg/m^2.

Participants in studies ranged from healthy to those with type 2 diabetes, obesity, risk factors for CVD, hypercholesterolaemia, MeTS, with MI or CAD.

Excluded populations
None reported

Low risk/high risk population
No restrictions on population of included studies specified in inclusion criteria but studies generally conducted in populations at risk of CVD e.g. overweight, diabetes, hypercholesterolaemia.

Intervention and Comparison

Intervention
Included studies:-
RCTs that reported the effects of a Mediterranean
diet on body weight, which could be either the primary
or a secondary outcome.

Included trials were reported from 1994 through 2010, spanning 16 years. The countries in which the
trials were conducted were as follows:

Method of allocation
Randomisation
Allocation concealment not assessed in quality rating (used 5 point quality scale)

Measurement of exposure
Not reported how assessed other than 'Mediterranean diet'.

Comparator
Control diets were a low-fat
diet, a high-carbohydrate diet, a prudent

United States, Italy, Spain, France, Israel, Greece, Germany, and The Netherlands. The range of follow-up periods was 4 weeks to 24 months. *Excluded studies*:- Lack of randomization, lack of a control diet group, samples with less than 15 patients, or a follow up less than 4 weeks.	diet, the usual patient treatment, the American Diabetes Association diet, a high-saturated fat diet, a general healthy dietary information, or less counselling on a Mediterranean diet prescription
Outcomes and Analysis	
Outcomes Change in body weight and body mass index (BMI).	**Outcome measurement** Weight (kg) BMI, height and weight, not reported if outcomes are self-reported or objectively measured for individual included studies. **Analysis strategy** Random effects meta-analysis of the selected trials was applied based on within-trial comparisons. **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below
Results – Group difference 16 RCTs included <u>BMI</u> In the Mediterranean diet group, BMI loss was significantly greater compared with the control diet group (mean difference between Mediterranean diet and control diet, _0.57 kg/m2; 95% CI, _0.93 to _0.21 kg/m2) with significant heterogeneity [Cohran Q 197.42, degrees of freedom (df) I^2, 91.45, P<0.001]. There was no evidence for publication bias in the selected trials (the Begg funnel plot was symmetrical; for the Egger test, P for bias 0.14). <u>Weight</u> In the Mediterranean diet group, weight loss was greater compared with the control diet group (mean difference, _1.75 kg; 95% CI, _2.86 to _0.64 kg), with significant heterogeneity (Cohran Q 275.64, df 13, I^2 94.93, P<0.001). There was no evidence for publication bias (P for bias¼0.24). No trial reported weight gain with a Mediterranean diet respect to the control diet.	
Trends, Limitations, Comments and Source of Funding	
Significant trends Not reported **General comments**	**Reported limitations** <u>Reviewer</u> Not reported

The authors comment that there is consistent evidence from the study, that Mediterranean diet does not cause weight gain, which removes the objection to its relatively high fat content.	<u>Author</u> Not reported **Source of funding** Not reported

Authors: Hopper I, Billah B, Skiba M et al

Year: 2011

Citation: European Journal of Cardiovascular Prevention & Rehabilitation 18(6): 813-823

Country of study: International

Aim of study: Prevention of diabetes and reduction in major cardiovascular events in studies of subjects with prediabetes: meta-analysis of randomised controlled clinical trials.

Study design: Systematic review

Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population People with impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) **Number of people** 23192 (10 studies). The number of subjects in each study ranged from 207 to 9306. **Locality** International **Recruitment strategy** Not reported for individual studies **Response rate** Not reported for individual studies	**Characteristics of population** Trials included participants with established cardiovascular disease, one or more cardiac risk factors, risk factors for diabetes, or elevated body mass index. Mean age of participants was 52 years, range 45–64 years, and overall 47% of participants were male. **Excluded populations** Studies with less than 100 participants or follow up of less than one year. **Low risk/high risk population** Some trials included subjects with cardiovascular risk factors, others with previous cardiovascular events, so there is marked variation in risk between the trials.

Intervention and Comparison

Intervention Interventions (including diet, exercise and pharmacological therapy), directed towards prevention of diabetes in people with IGT and IFG, with macrovascular outcomes, including all-cause and cardiovascular mortality, and/or the incidence of major cardiovascular events. Duration of follow-up ranged from 2.8 to 6 years, with mean intervention 3.75 years. Most trials had follow-up only for the time of the intervention, but three studies reported extended follow-ups of 10.6, 20 and 6.5 yrs.	**Method of allocation** Randomisation **Measurement of exposure** Not reported for individual trials. **Comparator** Usual care or standard health advice or limited diet advice or placebo.

Outcomes and Analysis

Outcomes Diabetes All-cause and cardiovascular related mortality or the incidence of major	**Outcome measurement** Mortality data were obtained from adjudicated end-points, or extracted from death records or hospital records.

cardiovascular events. Secondary outcomes: whether lifestyle or drug treatment was the more effective intervention. (Only data relevant to health behaviours has been extracted)	**Analysis strategy** Fixed and random effects models for meta-analysis. The fixed effect model was used if the p value was greater than 0.05 indicating homogeneity of the studies, and the random effect model was used if the p value was less than 0.05 indicating heterogeneity of the studies. **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Included lifestyle studies included interventions on tailored, detailed advice on diet, weight reduction, diet, education and exercise.

Non-drug approaches (n=3495) were superior to drug-based approaches (n=20,872) in diabetes prevention (0.52, 0.46–0.58 vs 0.70, 0.58–0.85, P<0.05). There was no difference in risk of all-cause mortality in the intervention versus control group (0.96, 0.84–1.10) and no difference in CV death (1.04, 0.61–1.78). There was a non-significant trend towards reduction in fatal and non-fatal myocardial infarction (0.59, 0.23–1.50). Fatal and non-fatal stroke was borderline reduced (0.76, 0.58–0.99) with intervention versus control.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** All included studies in midlife populations (40 to 64 years).	**Reported limitations** <u>Reviewer</u> The review integrated drug and non drug trials but only non-drug trials are relevant to the review. <u>Author</u> Some studies relied on reporting from national agencies or hospital records of cardiovascular endpoint, so, the reliability of these reports compared with adjudicated reports is questionable. 'A further limitation of this specific study is the revising downwards of the definition of IGT and IFG over time, meaning that in earlier studies, some participants would have been enrolled in the study with what would later be considered diabetes; however given the size of the changes in the definition, we expect this effect to be minimal'. **Source of funding** Alfred Health and National Health and Medical Research.

Authors: Rees K, Dyakova M, Wilson N et al
Year: 2013
Citation: Cochrane Database of Systematic Reviews (3): CD002128
Country of study: International
Aim of study: Systematic review of dietary advice for reducing cardiovascular risk
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Healthy community-dwelling adults aged 18 years or older.

Number of people
18,175 participants or clusters were randomised (from 44 trials).

Locality
European, North American, Australasian and Japanese populations. However, 29 of the 44 included trials were conducted in the US.

Recruitment strategy
Eighteen trials enrolled participants without screening. Two recruited American women through direct contact and mailings, three via American health maintenance organisations. Two recruited from healthcare settings in Italy and the UK, two from American churches, three involved American women with high prevalence of food poverty and three from US worksites.
Nineteen trials recruited through screening programmes, and 2 recruited relatives of those with CHD or diabetes.

Response rate
Not reported for individual studies

Characteristics of population
Less than 25% of the participants in any trial had diagnosed cardiovascular disease (CVD) at recruitment.

Twenty-nine trials enrolled men and women. Ten trials enrolled women only and five men only.

Excluded populations
Trials involving pregnant women or children, trials to reduce weight or those involving supplementation were excluded.

Multifactorial interventions such as those also involving advice on physical activity were excluded.

Trials of weight reducing diets were excluded.

Interventions less than 3 months.

Studies with more than 20% loss to follow up.

Low risk/high risk population
N/A

Intervention and Comparison

The review only included interventions on *advice* on diet, involving verbal or written advice delivered in person or over the phone to individuals or small groups. The advice could include a combination of these methods and be delivered by health professionals or other personnel. Trials could include additional interventions such as posters in a work canteen.

Dietary advice was to decrease consumption of one or more of fat, saturated fatty acids, cholesterol or salt; or increase consumption

Method of allocation
Randomisation.

Four of the 33 individually randomised trials used an adequate allocation concealment method. Eleven studies involved cluster randomisation and allocation concealment was considered adequate in one study.

Measurement of exposure
N/A

of one or more of fruit, vegetables, polyunsaturated fatty acids, monounsaturated fatty acids, fish, fibre or potassium; or both. Randomised studies with no more than 20% loss to follow-up, lasting at least three months and involving healthy adults comparing dietary advice with no advice or minimal advice. From included studies, advice was delivered in a variety of ways, including one-to-one contact, group sessions and written materials. There were variations in intensity of the intervention, ranging from one contact per study participant to 50 hours of counselling over four years. The duration of the trials ranged from three months to four years, with a median follow-up period of 12 months.	**Comparator** Control groups received no or minimal dietary advice.
Outcomes and Analysis	
Outcomes Outcomes of primary relevance to the NICE review were:- <u>Change in dietary intake</u> (included outcomes were: self-reported measures of dietary intake, including fat, fat fractions, dietary fibre, fish, fruit and vegetables, vitamin C (ascorbic acid), vitamin E (tocopherols), carotenoids, flavonoids and folic acid). <u>Cardiovascular events</u> <u>Weight change</u> Twenty-four of the 33 individually randomised trials provided information on initial weight or weight loss during follow-up. Baseline body mass index (BMI) was approximately 30 kg/m2 in two trials while other trials involved participants with lower BMI. Net mean weight loss in the intervention groups during follow-up was 1 kg or less in 14 trials, 1.1 kg in one and 1.8 kg in one trial Two trials showed more substantial weight loss during the trial with the intervention, of 2.7 kg and 5.2 kg.	**Outcome measurement** Self-reported measures of dietary intake **Analysis strategy** Meta-analysis (random effects) **Confounders** Not reported

[Other outcomes were reported in the review but these were not of primary relevance to the NICE review:- Cardiovascular risk factors: resting blood pressure, blood lipids and lipoproteins (cholesterol), blood or red cell folate and homocysteine. Bio-markers of dietary intake: urinary sodium, urinary potassium and blood diet-derived antioxidants such as _-carotene].	
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Effect of diet interventions on cardiovascular disease (CVD)

Dietary advice

The review included 44 RCTs in healthy adults and in the majority (n=37) of included trials the mean age was at midlife, 4 were in younger populations and in the remaining 3 studies age was unclear.

Effect on diet behaviour

Compared to no advice, dietary advice increased fruit and vegetable intake by 1.18 servings/day (95% CI 0.65 to 1.71). Dietary fibre intake increased by 6.5 g/day (95% CI 2.2 to 10.82), while total dietary fat as a percentage of total energy intake fell by 4.48% (95% CI 2.47 to 6.48) with dietary advice, and saturated fat intake fell by 2.39% (95% CI 1.4 to 3.37).

Effect on CVD events

There was data from two trials of incident cardiovascular disease (CVD) eventsin populations aged mean age 43.7 at baseline and age range 30-54 at baseline. Follow-up was 77% complete at 10 to 15 years after the end of the intervention period and there was a lack of precision in CVD events estimates. Data suggested a reduction in CVD events with lower dietary sodium but results were not significant.

(The authors noted that these data were collected many years after the end of each intervention period and it was unclear how participants may have changed their dietary patterns during this period).

Effect on other outcomes (lipids and blood pressure)

As there was limited evidence available relating to cardiovascular events, the secondary outcomes of effect on lipids and blood pressure, are also included here for information although these were not outcomes specified for the NICE review:- Dietary advice reduced total serum cholesterol by 0.15 mmol/L (95% CI 0.06 to 0.23) and LDL cholesterol by 0.16 mmol/L (95% CI 0.08 to 0.24) after three to 24 months. Mean HDL cholesterol levels and triglyceride levels were unchanged. Dietary advice reduced blood pressure by 2.61 mm Hg systolic (95% CI 1.31 to 3.91) and 1.45 mm Hg diastolic (95% CI 0.68 to 2.22).

There was some limited evidence that dietary advice was more effective when individuals were recruited on the basis of increased risk of CVD or cancer,

Trends, Limitations, Comments and Source of Funding

Significant trends	**Reported limitations**

General comments The author's conclusions were that dietary advice appears to be effective in bringing about modest beneficial changes in diet and cardiovascular risk factors over approximately 12 months, but longer-term effects are not known.	Reviewer Author **Source of funding** **Internal sources** • Department of Epidemiology and Public Health, University College London, UK. • University of Warwick Medical School, UK. • Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, UK. **External sources** • Coronary Prevention Group, UK. • Department of Health Cochrane Review Incentive Scheme 2006, UK. • NIHR Cochrane Programme Grant, UK.

Authors: Rees K, Hartley L, Flowers N et al
Year: 2013
Citation: Cochrane Database of Systematic Reviews (8): CD009825
Country of study: International
Aim of study: Systematic review of 'Mediterranean' dietary pattern for the primary prevention of cardiovascular disease.
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Healthy adults and adults at high risk of CVD, from the general population.

Number of people
Eleven trials (15 papers) were included with 52,044 participants.
The majority of participants were enrolled in one large multicentre trial (48,835 women)

Locality
International - the included trials were conducted in the US, Italy, Spain, Norway, Iran and the UK.

Recruitment strategy
Participants in studies were recruited from health clinics, media campaigns, community and worksite adverts and physician referrals.

Response rate
Not reported for individual studies

Characteristics of population
The majority of participants (49,185 randomised) were classified as healthy and were recruited by five of the trials.
The remaining six trials recruited previously untreated hypercholesteraemic participants (n=2), elderly participants with long-standing hypercholesterolaemia (n=1), overweight or obese participants with untreated hypertension (n=1), sedentary people with metabolic syndrome, and one trial recruited participants at high risk of colorectal cancer.

Three trials including the largest trial recruited only women who were postmenopausal and one trial recruited only women aged 25 to 65 years. Two trials recruited only men and the remaining five recruited both men and women.

The majority of included studies were in midlife populations. One included study was conducted in an older population.

Excluded populations
Studies were excluded where more than 25% of participants had CVD at baseline including people who had experienced a previous myocardial infarction (MI), stroke, revascularisation procedure (coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)), people with angina, or angiographically defined CHD, cerebrovascular disease (stroke) and peripheral arterial disease or where >25% of the participants had type 2 diabetes.

Low risk/high risk population
N/A

Intervention and Comparison

All trials found examined the effects of dietary advice to follow a Mediterranean style

Method of allocation
Randomisation

dietary pattern; none of the trials examined the effects of provision of foods relevant to a Mediterranean diet. Intervention was a Mediterranean dietary pattern defined as comprising at least two of the following components: (1) high monounsaturated/saturated fat ratio, (2) low to moderate red wine consumption, (3) high consumption of legumes, (4) high consumption of grains and cereals, (5) high consumption of fruits and vegetables, (6) low consumption of meat and meat products and increased consumption of fish, and (7) moderate consumption of milk and dairy products. Duration of the intervention and follow-up periods varied from 3 months to 8 years. One trial had a dietary intervention that comprised five components From above definition of a Mediterranean-style diet, one trial had four components, five trials had three components. Four trials had a dietary intervention comprising two components	The methods of allocation concealment were unclear in eight of the 11 included studies. Where this was clear, methods were assessed as low risk of bias **Measurement of exposure** Not reported for each individual study but FFQ appears to have been used in 2 studies. **Comparator** Either no intervention or minimal intervention (e.g. leaflet to follow a dietary pattern with no person-to-person intervention or reinforcement).
Outcomes and Analysis	
Outcomes for inclusion in NICE review 1. Cardiovascular mortality. 2. All-cause mortality. 3. Non-fatal endpoints such as MI, CABG, PTCA, angina, or angiographically defined CHD, stroke, carotid endarterectomy or peripheral arterial disease (PAD). 4. Occurrence of type 2 diabetes. 5. Health-related quality of life. 6. Adverse effects (as defined by the authors of the included trials). 7. Costs. **Other outcomes (out of scope for NICE review)** 1. Changes in blood lipids (total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, triglycerides), and blood pressure (systolic and diastolic blood pressure). 2. Occurrence of type 2 diabetes as a major CVD risk factor. 3. Health-related quality of life.	**Outcome measurement** Not reported for individual studies **Analysis strategy** Only one study met inclusion criteria for NICE review so reported narratively. Meta-analysis for other outcomes e.g. lipids (fixed and random effects) **Confounders** Not reported

4. Adverse effects (as defined by the authors of the included trials). 5. Costs.	
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

11 studies included in qualitative synthesis and 8 in quantitative synthesis (meta-analysis).

Mediterranean dietary pattern

The review included 11 RCTs in healthy adults and in the majority of included trials the mean age was at mid-life.

Clinical events (meet inclusion criteria for NICE review)

Clinical events were reported in only one trial (Women's Health Initiative conducted in 48,835 postmenopausal women, aged 50-79, not described as a Mediterranean Diet, but increased fruit and vegetable and cereal intake). No statistically significant effects of the intervention were seen on fatal and non-fatal endpoints at eight years.

Adverse events

None of the trials reported adverse events.

Other outcomes (excluded for NICE review)

[As limited data on clinical events was available, the secondary outcomes are also reported here as follows: small reductions in total cholesterol (-0.16 mmol/L, 95% confidence interval (CI) -0.26 to -0.06; random-effects model) and low-density lipoprotein (LDL) cholesterol (-0.07 mmol/L, 95% CI -0.13 to -0.01) were seen with the intervention. Reductions in blood pressure were seen in three of five trials].

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** Insufficient data to make conclusions about midlife Mediterranean diet on long-term cardiovascular events and mortality, diabetes, health related QoL and costs.	**Reported limitations** Reviewer Author **Source of funding** Internal sources • Warwick Medical School, University of Warwick, UK. External sources • NIHR Cochrane Programme Grant, UK.

APPENDIX A.5 Evidence table DIET – Included Economic Studies

Authors: Bós AM, Howard BV, Beresford SA et al. **Year:** 2011 **Citation:** Journal of the American Dietetic Association 111(1): 56-66 **Country of study:** USA **Aim of study:** assess how cost-effective the WHI-DM would be if implemented as a public health intervention and under the sponsorship of private health insurers and Medicare **Study design:** Cost effectiveness analysis **Quality score: (++, + or -):**	
Study (eligible and selected) population	
Primary data OR modelling Modelling. **Eligible population** Participants consuming >36.8% of energy from fat at baseline, and participants at high risk for breast cancer with 32% or more of energy from fat at baseline. **Number of people** Not reported **Locality** USA **Recruitment strategy** Not applicable **Response rate** Not applicable	**Characteristics of population** Simulations were performed for hypothetical cohorts of women aged 50, 55, 60, 65 **Excluded populations** Not applicable **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Women's Health Initiative **Setting** Community **Delivery** Not reported **Length of follow-up** Not reported	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Not reported
Outcomes and Analysis	
Clinical Outcomes (used in CE/CU)	**Outcome measurement**

Breast and ovarian cancers **Service Use measures** Not reported **Costing** Not reported **Discounting** Discounted to present-day values using a real rate of 3.0%.	Health outcomes are estimated by quality-adjusted life years (QALYs), **Perspective** Societal and health care payer perspectives **Analysis strategy (including key sensitivity analyses)** Markov cohort modelling. cost-effectiveness analysis is summarised by the incremental cost-effectiveness ratio **Confounders** Adjusted for age
Results **Intervention group** Not applicable	**Results** **Control group** Not applicable

Results – CE & ICER (for basecase and sensitivity analyses)

Intervention costs per participant in the Women's Health Initiative Randomized Controlled Dietary Modification Trial (WHI-DM) in 2008 dollars, according to intervention year

Opportunity Costs±SD

Age<65 y

1 540.96±15.53
2 110.55±1.00
3 108.43±0.88
4 103.21±0.98
5 99.07±1.13
6 95.50±1.18
7 85.73±1.20
8 69.11±1.07

Age>65 y

1 445.86±12.80
2 94.81±0.85
3 92.99±0.75
4 88.02±0.84
5 84.56±0.96
6 80.82±0.99
7 68.91±0.96
8 51.87±0.80

Monetary Costs±SD

Staff

1 452.27±110.91
2 76.94±18.87
3 76.94±18.87
4 76.94±18.87
5 76.94±18.87

6 76.94±18.87
7 76.94±18.87
8 76.94±18.87

Other
1 340.34±83.46
2 61.45±15.07
3 61.43±15.07
4 61.43±15.07
5 69.68±17.09
6 61.43±15.07
7 62.89±15.42
8 67.05±16.44

Average Diet Costs±SD
Comparison
1 1,649.09±5.76
3 1,635.40±6.86
6 1,628.32±6.26

Intervention
1 1,719.31±6.76
3 1,713.03±8.36
6 1,654.97±7.30

Cost-effectiveness of the Women's Health Initiative Randomized Controlled Dietary Modification Trial following societal perspective
Hazard Ratios from Randomization Date
Start age Group Total cost Effectiveness ICER (95% CIb)
Participants with high fat intake at baseline (>36.8% of energy from fat)
50 y Comparison $44,100 15.841 QALYs
Intervention $45,264 15.926 QALYs $13,773/QALY (7,482-20,916)
55 y Comparison $40,692 13.847 QALYs
Intervention $41,907 13.921 QALYs $16,560/QALY (8,988-25,233)
60 y Comparison $36,720 12.368 QALYs
Intervention $38,004 12.431 QALYs $20,349/QALY (11,282-31,824)
65 y Comparison $32,143 10.695 QALYs
Intervention $33,465 10.746 QALYs $26,146/QALY (14,552-41,293)
70 y Comparison $27,267 8.911 QALYs
Intervention $28,806 8.949 QALYs $41,085/QALY (24,689-63,929)
Participants at high risk for breast cancer with >32% of energy from fat
50 y Comparison $58,730 15.395 QALYs
Intervention $60,259 15.474 QALYs $19,199/QALY (7,988-38,446)
55 y Comparison $54,620 13.455 QALYs
Intervention $56,116 13.525 QALYs $21,394/QALY (8,037-46,886)
60 y Comparison $49,601 12.023 QALYs
Intervention $51,078 12.084 QALYs $24,059/QALY (7,315-59,582)
65 y Comparison $43,398 10.413 QALYs
Intervention $44,836 10.463 QALYs $28,442/QALY (8,296-78,367)

70 y Comparison $36,655 8.695 QALYs
Intervention $38,235 8.734 QALYs $40,769/QALY (12,333-125,315)

Hazard Ratios from Intervention Start
Total cost Effectiveness ICER (95% CI)
Participants with high fat intake at baseline (>36.8% of energy from fat)
50 y Comparison $44,100 15.841 QALYs
Intervention $45,211 15.927 QALYs $12,944/QALY (6,170-22,026)
55 y Comparison 40,692 13.847 QALYs
Intervention $41,852 13.922 QALYs $15,551/QALY (7,155-26,581)
60 y Comparison $36,720 12.368 QALYs
Intervention $37,983 12.431 QALYs $20,009/QALY (9,356-35,818)
65 y Comparison $32,143 10.695 QALYs
Intervention $33,463 10.745 QALYs $26,312/QALY (12,429-48,764)
70 y Comparison $27,267 8.911 QALYs
Intervention $28,827 8.947 QALYs $42,842/QALY (21,834-80,347)
Participants at high risk for breast cancer with >32% of energy from fat
50 y Comparison $58,730 15.395 QALYs
Intervention $59,733 15.490 QALYs $10,544/QALY (2,096-23,673)
55 y Comparison $54,620 13.455 QALYs
Intervention $55,611 13.538 QALYs $14,885/QALY (1,725-28,767)
60 y Comparison $49,601 12.023 QALYs
Intervention $50,701 12.093 QALYs $15,604/QALY (2,324-42,915)
65 y Comparison $43,398 10.413 QALYs
Intervention $44,555 10.469 QALYs $20,461/QALY (3,394-59,610)
70 y Comparison $36,655 8.695 QALYs
Intervention $38,071 8.736 QALYs $34,450/QALY (8,861-115,219)

Sensitivity analysis for the Women's Health Initiative Randomized Controlled Dietary Modification Trial cost-effectiveness

Group	Total cost	Effectiveness	ICER (95% CI)
20% reduction in direct costs			
Comparison	$44,100	15.841 QALYs	
Intervention	$44,934	15.926 QALYs	$9,873/QALY (4,591-15,902)
0% discount rate			
Comparison	$74,333	25.226 QALYs	
Intervention	$73,745	25.414 QALYs	-$3,083/QALY (-5,949-123)
5% discount rate			
Comparison	$33,352	12.371 QALYs	
Intervention	$35,041	12.424 QALYs	$31,939/QALY (22,124-43,890)

Half of the hourly wage to measure opportunity cost
Comparison $44,100 15.841 QALYs
Intervention $44,949 15.926 QALYs $10,050/QALY (3,928-17,033)
6 participants/group and 228 participants/site
Comparison $44,100 15.841 QALYs
Intervention $47,315 15.926 QALYs $38,034/QALY (26,159-51,415)

Trends, Limitations, Comments and Source of Funding

Significant trends	**Reported limitations**

Following the societal perspective, the ICERs for the 50-year old cohort are $13,773/QALY (95% confidence interval $7,482 to $20,916) for women consuming >36.8% of energy from fat at baseline and $10,544/QALY ($2,096 to $23,673) for women at high risk for breast cancer. The comparable ICER from a private health care payer perspective is $66,059/QALY ($30,155 to $121,087) and from a Medicare perspective, it is $15,051/QALY ($6,565 to $25,105). **General comments** No comment	Reviewer XXX Author XXX **Source of funding** Tusculum College Summer and Extended Research Grant. The WHI program is funded by the National Heart, Lung, and Blood Institute, National Institutes of Health, US Department of Health and Human Services through contracts N01WH22110, 24152, 32100-2, 32105-6, 32108-9, 32111-13, 32115, 32118-32119, 32122, 42107-26, 42129-32, and 44221.

APPENDIX A.7 Evidence table SMOKING - Primary Studies

Authors: Begh RA, Aveyard P, Upton P et al
Year: 2011
Citation: Trials 12(1): 197
Country of study: UK
Aim of study: Compare the effectiveness of Pakistani and Bangladeshi smoking cessation outreach workers with standard care to improve access to and the success of English smoking cessation services
Study design: Exploratory Phase II cluster randomised controlled trial
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population	**Characteristics**
Pakistani and Bangladeshi residents **Number of people** 271 intervention 169 control 524 external control **Locality** UK **Recruitment strategy** Approach people on main roads and side streets, signposting the stop smoking services **Response rate** Not reported	<u>Intervention</u> Age in years mean (SD) 35.8 (12.6); Ethnicity n (%) Bangladeshi 8 (15.4), Pakistani 44 (84.6); Marital status n (%) Single 18 (34.6), Separated 1 (1.9), Married living with partner 28 (53.8), Unknown 5 (9.6); Employment In paid employment 18 (34.6), Unemployed 24 (46.2), Pensioner 0 (0), Full time student 5 (9.6), Unknown 5 (9.6); Type of Work n (%), Manual 29 (55.8), Clerical secretarial 4 (7.7), Managerial professional 6 (11.5), Not worked 5 (9.6), Unknown 8 (15.4); Highest Education n (%) None 14 (26.9), GCSE or equivalent 16 (30.8), A-level or equivalent 8 (15.4), Degree or equivalent 5 (9.6), Other 3 (5.8), Unknown 6 (11.5); Age of starting smoking in years mean (SD) 17.6 (6.5); Cigarettes per day mean (SD) 15 (10); Number past quit attempts mean (SD) 1 (1); Maximum length of previous quit attempt in days, median (range) 21 (1-336) <u>Combined control</u> Age in years mean (SD) 34.3 (10.4); Ethnicity n (%) Bangladeshi 26 (37.7), Pakistani 43 (62.3); Marital status n (%) Single 25 (36.2), Separated 2 (2.9), Married living with partner 42 (60.9), Unknown 0 (0); Employment In paid employment 38 (55.1), Unemployed 24 (34.8), Pensioner 1 (1.4), Full time student 6 (8.7), Unknown 0 (0); Type of Work n (%) Manual 46 (66.7), Clerical secretarial 3 (4.3), Managerial professional 9 (13.0), Not worked 7 (10.1), Unknown 4 (5.8); Highest Education n (%) None 21 (30.4), GCSE or equivalent 22 (31.9), A-level or equivalent 12 (17.4), Degree or equivalent 8 (11.6), Other 5 (7.2), Unknown 1 (1.4); Age of starting smoking in years mean (SD) 17.7 (5.0); Cigarettes per day mean (SD) 17 (7); Number past quit attempts mean (SD) 1 (1); Maximum length of previous quit attempt in days, median (range) 21 (1-672) **Excluded populations** Not reported

	Low risk/high risk population Low risk population Control 58/1000 High risk population Intervention 63/1000 External control areas 80/1000
Intervention and Comparison	
Intervention Community based stop smoking advisors **Setting** Community **Delivery** 'Street outreach' **Length of follow-up** Six month	**Method of allocation** Census lower layer super output areas were used as the unit of allocation. Permuted blocks of four to randomise **Measurement of exposure** Outreach workers kept a copy of referral records and checked on clinic attendance **Comparator** Outreach workers with standard care
Outcomes and Analysis	
Outcomes Smoking cessation **Economic analysis** • Perspective of the NHS as payer; assessed the costs of the intervention, with benefits and costs discounted at 3.5%. • Calculated the estimated total costs and quality adjusted life years (QALYs) gained from the programme as a whole. • Costs such as the salary costs of the outreach workers included as fixed costs, as they did not change with the number of smokers recruited, while costs such as additional treatment costs were multiplied by the number of people treated. • Modelled from the short-term abstinence rate the projected long-term abstinence rate using data from the evaluation of NHS SSS [6] & studies with long-term follow up [41] to produce the number of lifetime abstainers. • Assumed no health benefit from anything other than lifetime abstinence and we	**Outcome measurement** Self-report **Analysis strategy** Multilevel logistic regression model and X^2 tests **Confounders** Adjusted for quit proportion achieved in the seven months prior to the intervention starting

calculated an estimate of the QALYs gained using a previously developed model [42]. • As quit rates are generally the primary driver of cost-effectiveness estimates [43], we used the 95% confidence interval of the rate ratio for abstinence as the only sensitivity analysis of cost-effectiveness.	
Results **Intervention group**	**Results** **Control group**
Adherence to treatments Intervention vs control RR (95%CI) Session 1 0.98 (0.94-1.02) Session 2 1.22 (0.56-2.66) Session 3 1.28 (0.59-2.78) Session 4 0.94 (0.52-1.70) Session 5 - Intervention vs external control RR (95%CI) Session 1 1.00 (0.95-1.05) Session 2 0.89 (0.61-1.30) Session 3 0.99 (0.63-1.56) Session 4 1.00 (0.57-1.76) Session 5 1.00 (0.60-1.66) Intervention vs combined control RR (95%CI) Session 1 1.00 (0.95-1.04) Session 2 0.95 (0.65-1.39) Session 3 1.08 (0.69-1.68) Session 4 0.97 (0.59-1.61) Session 5 1.50 (0.76-2.98) **Attendance at weekly clinics** Intervention vs control RR (95%CI) Session 1 1 Session 2 0.92 (0.40-2.14) Session 3 0.80 (0.34-1.90) Session 4 0.49 (0.19-1.29) Session 5 0.62 (0.17-2.19) Intervention vs external control RR (95%CI) Session 1 1 Session 2 0.90 (0.50-1.61) Session 3 1.47 (0.69-3.14) Session 4 1.02 (0.41-2.51) Session 5 1.02 (0.35-2.96) Intervention vs combined control	**Before** **After**

RR (95%CI) Session 1 1 Session 2 0.90 (0.52-1.57) Session 3 1.23 (0.63-2.39) Session 4 0.82 (0.37-1.82) Session 5 0.88 (0.34-2.33)	
Results – Economic analysis The total cost of the intervention to achieve this was £124,000; an estimated cost per QALY gained of £8,500. Applying the upper limit of the 95% confidence interval gave an estimated cost/QALY gained of £2,000. Apply- ing the lower limit for the rate ratio for increased use resulted in an estimated cost/QALY gained of over £100,000.	
Trends, Limitations, Comments and Source of Funding	
Significant trends More Pakistani and Bangladeshi men made quit attempts with NHS services in intervention areas compared with control areas **General comments** The total cost of the intervention was £124,000; an estimated cost per quality-adjusted life year (QALY) gained of £8,500. The number of smokers achieving abstinence as a proportion of all those trying to quit in the intervention areas was lower than in the control areas; retention in the behavioural support programme was somewhat lower for outreach workers than for typical SSS providers	**Reported limitations** Author Imprecisely estimated rate of uptake; clinically relevant 30% change in the number of abstinent smokers, but, as might be expected from a pilot trial, this was not statistically significant; sample size in the study precludes definitive conclusions Reviewer **Source of funding** National Prevention Research Initiative [grant number G0501288] with support from the following organisations: British Heart Foundation; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Health & Social Care Research & Development Office for Northern Ireland; Medical Research Council; The Wellcome Trust; Welsh Assembly Government; and World Cancer Research Fund. Service support funding was provided by the Midlands General Practice Research Consortium (MidRec)

Authors: Brown J, Michie S, Geraghty AW et al
Year: 2012
Citation: Addictive Behaviors 37(12): 1365-1370.
Country of study: UK
Aim of study: Evaluate whether cessation, website usage and satisfaction were sufficiently high to warrant a randomised controlled trial
Study design: Uncontrolled pilot study
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Adults from the UK who smoked every day; willing to make a serious quit attempt; willing to use a stop-smoking website which sends email reminders; willing to be followed up at 2 months post-enrolment; able to provide informed consent; and able to be contacted by email and telephone

Number of people
204

Locality
Not reported

Recruitment strategy
Advert placed on the UK Department of Health's smoking cessation portal

Response rate
204/1310

Characteristics of population
Mean age in years (SD) 37.8 (11.8); % Female (n) 57% (116); % Routine and manual occupation (n) 38% (77); % Without post-16 educational qualifications (n) 29% (59); Mean cigs per day (SD) 17.4 (9.4); Mean years of smoking (SD) 20.8 (12.1); Mean dependence (FTND) score (SD) 4.5 (2.8); Mean cravings (MPSS-C) score (SD) 6.3 (1.7); Mean physical withdrawal (MPSS-M) score (SD) 11.4 (3.8); % Never quit or for less than a week (n) 27% (55); % Never quit or last attempt over a year ago (n) 63% (129); Mean confidence in stopping at this attempt (1–7) (SD) 4.6 (1.7)

Excluded populations
See opp.

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Structured quit plan and a variety of evidence-based behaviour change techniques for smoking cessation

Setting
Community

Delivery
Interactive and tailored website

Length of follow-up
8 weeks

Method of allocation
Not applicable

Measurement of exposure
Number of log ins

Comparator
Not applicable

Outcomes and Analysis

Outcomes
Abstinence

Outcome measurement
Saliva cotinine level

	Analysis strategy Intention to treat of all participants with those lost to follow-up counted as relapsed **Confounders** Socio-economic status
Results **Intervention group** 19.6% (40/204) of participants were biochemically-verified as abstinent according to the primary outcome criteria (95% C.I.=14.1% to 25.1%).	**Results** **Control group** Not applicable
Results – Group difference Not applicable	
Trends, Limitations, Comments and Source of Funding	
Significant trends At 8 weeks post-enrolment, 19.6% (40/204) of participants were abstinent according to the primary outcome criteria (95% C.I.=14.1% to 25.1%) **General comments** No comment	**Reported limitations** <u>Reviewer</u> No comment <u>Author</u> Uncontrolled **Source of funding** National Prevention Research Initiative (G0802035).

Authors: Hall S, Bishop AJ, Marteau TM
Year: 2003
Citation: Nicotine and Tobacco Research 5(6): 821-826.
Country of study: UK
Aim of study: Evaluated the impact of informing women smokers of the link between smoking and cervical cancer
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population Women smokers aged 20–64 years **Number of people** 172 **Locality** Not reported **Recruitment strategy** Practice records **Response rate** 36%	**Characteristics of population** The mean age of the women was 42.7 years (SD~11.4), 166 (97%) were White, 49 (28%) had no educational qualifications, 55 (32%) had one or more General Certificate of Secondary Education or ‘‘O’’ level, and 65 (38%) had one or more General Certificate of Education ‘‘A’’ level or higher. **Excluded populations** Women with serious illnesses, those who had undergone a hysterectomy, or those who had never had a cervical smear test **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Both leaflets contained two threat and two efficacy messages. The extended leaflet included an explanation of how smoking adversely affects the cervix. **Setting** Not reported **Delivery** Leaflet **Length of follow-up** Not reported	**Method of allocation** A computer-generated random numbers table **Measurement of exposure** Self-report **Comparator** An extended leaflet, a brief leaflet, or no leaflet.

Outcomes and Analysis

Outcomes Readiness to stop smoking within the next 6 months; Severity of cervical cancer; Vulnerability; Response-efficacy; Self-efficacy; Understanding of the leaflet	**Outcome measurement** Self-report **Analysis strategy** Chi-square tests were used for comparing proportions. One-way analysis of variance with Tukey’s b-tests for post hoc analyses and

	independent t-tests were used for comparing means. **Confounders** Not reported
Results **Intervention group** Extended leaflet Readiness to quit Within next 6 months 22 (46%) Not within 6 months 26 (54%) Severity of cervical cancer Severe illness 6.0 (1.5) Severe negative consequences 5.7 (1.4) Vulnerability Much higher 35 (72%) A bit higher 7 (14%) About the same/lower 7 (14%) Response-efficacy 5.0 (1.5)1 Self-efficacy 3.1 (1.7) Understanding of the leaflet 2.0 (1.2) Brief leaflet Readiness to quit Within next 6 months 39 (75%) Not within 6 months 13 (25%) Severity of cervical cancerb Severe illness 6.4 (1.1) Severe negative consequences 5.8 (1.4) Vulnerability Much higher 36 (68%) A bit higher 13 (24%) About the same/lower 4 (8%) Response-efficacy 5.2 (1.3) Self-efficacy 2.5 (1.4) Understanding of the leaflet 1.6 (0.9)	**Results** **Control group** No leaflet Readiness to quit Within next 6 months 27 (40%) Not within 6 months 41 (60%) Severity of cervical cancer Severe illness 6.2 (1.2) Severe negative consequences 5.3 (1.6) Vulnerability Much higher 21 (31%) A bit higher 30 (44%) About the same/lower 17 (25%) Response-efficacy 4.3 (1.3) Self-efficacy 3.2 (1.6) Understanding of the leaflet NA
Results – Group difference Compared with the other two groups, more women sent the briefer leaflet were planning to stop smoking within the next 6 months (x2 [2, N=168]=15.9, p=.0001; brief vs. extended leaflet: 75% vs. 46%, difference=29%, 95% CI=11%–48%; brief vs. no leaflet: 75% vs. 40%, difference=35%, 95% CI=19%–52%).	
Trends, Limitations, Comments and Source of Funding	
Significant trends Women sent the briefer leaflet were more likely to be ready to stop smoking within the next 6 months compared with those sent the extended leaflet (75% vs. 46%, 95% CI~11%–48%) and those not sent a leaflet (75% vs. 40%, 95% CI~19%–52%).	**Reported limitations** <u>Reviewer</u> No comment <u>Author</u> The response rate was low, some of the

General comments No comment	outcomes were assessed using single items, and smoking cessation was not assessed. **Source of funding** Guy's & St Thomas' Charitable Foundation (R001103).

Authors: Hall SM, Humfleet G, Muñoz RF et al.
Year: 2009
Citation: Addiction 104(6): 1043-1052.
Country of study: USA
Aim of study: determine the efficacy of extended cognitive behavioural and pharmacological interventions in smokers
Study design: Open randomized clinical trial
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Smokers of >10 cigarettes per day, 50 years of age or older.

Number of people
402

Locality
Not reported

Recruitment strategy
Advertising, public service announcements and flyers.

Response rate
Attrition: week 12 = 3.2%; week 24 = 4.0%, week 52 = 7.0%; week 64 = 9.0%; week 104 = 13.4%.

Characteristics of population
The mean age was 56.7 years [standard deviation (SD) = 5.87]. The mean years of regular smoking was 37.8 (SD = 8.23).The mean number of cigarettes smoked per day was 20.5 (SD = 8.72). 12.1% were high school graduates or less; 35.5% had some college, 30.5% were college graduates and 21.9% had a graduate degree.

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Group counselling, nicotine replacement therapy (NRT) and bupropion.

Setting
A free-standing, smoking treatment research clinic.

Delivery
Eleven individual extended treatment sessions were provided after the five group sessions included in the ST protocol, from weeks 10 to 52.

Length of follow-up
104 weeks

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Standard care with, extended cognitive behavioural treatment; or extended nicotine replacement therapy; or extended cognitive behavioural treatment plus extended NRT combined

Outcomes and Analysis

Outcomes
7-day point prevalence cigarette abstinence

Outcome measurement
expired air carbon monoxide (CO) levels <10

	parts per million **Analysis strategy** ANOVA for continuous variables and Pearson's x^2 tests for categorical variables. **Confounders** Not reported
Results **Intervention group** **Week 12** E-CBT: extended cognitive behavioural treatment; 63 64% E-NRT: extended nicotine replacement therapy; 64 66% E-combined: extended cognitive behavioural treatment plus extended NRT combined. 62 63% **Week 104** E-CBT: extended cognitive behavioural treatment; 46 55% E-NRT: extended nicotine replacement therapy; 39 45% E-combined: extended cognitive behavioural treatment plus extended NRT combined 35 40%	**Results** **Control group** **Week 12** ST: standard treatment; 59 63% **Week 104** ST: standard treatment; 31 36%
Results – Group difference The E-CBT condition produced high cigarette abstinence rates that were maintained throughout the 2-year study period [(week 24 (58%), 52 (55%), 64 (55%) and 104 (55%)], and was significantly more effective than E-NRT and ST across that period.	
Trends, Limitations, Comments and Source of Funding	
Significant trends The E-CBT condition produced high cigarette abstinence rates that were maintained throughout the 2-year study period [(week 24 (58%), 52 (55%), 64 (55%) and 104 (55%)], and was significantly more effective than E-NRT and ST across that period. **General comments** No comment	**Reported limitations** <u>Reviewer</u> Unclear reporting of exposure and allocation <u>Author</u> Generalizability as the population treated was relatively well-educated, willing to participate in research and to attend multiple treatment sessions. They were also predominantly Caucasian and able to read and speak in English.

	Source of funding Not specified. Grant numbers R01 DA02538, K05 DA016752, K23 DA018691 and P50 DA 09253.

Authors: Halpin HA, McMenamin SB, Rideout J et al..

Year: 2006

Citation: Inquiry - Excellus Health Plan; 43, 1

Country of study: USA

Aim of study: Estimated the costs and effectiveness of treating tobacco dependence: drugs only; drugs and counselling; and drugs if counselling (drugs conditional on enrolment in counselling).

Study design: RCT

Quality score: (++, + or -): +

Study (eligible and selected) population

Primary data OR modelling
Primary data

Eligible population
Enrolees in the individual and family plans of a large preferred provider organisation, 18 years of age or older and a current smoker who had smoked at least one cigarette in the last seven days

Number of people
393

Locality
California, USA

Recruitment strategy
Mailing

Response rate
393/113,000

Characteristics of population
Age 18 to 39 127, 40 to 49 113, 50+ 148; Gender (female) 256 ; Income <$50,000 174, $50,000-$75,000 89, >$75.000 115, Race (white) 351; Number of cigarettes smoked per day 1 to 10 143, 11 to 20 183, 20+ 62; Age started smoking regularly <16 years old 77, 16 to 20 years .217, >20 yean; 90; Made quit attempt in lifetime 334; Tried to quit last year 145; Number quit attempts 1 time 64, 2 times 36, 3+ times 44

Excluded populations
Respondents were not eligible to participate in the study if they had any of the following disqualifying health conditions: pregnancy, poor health, coronary artery disease, heart disease, arrhythmia, bean attack or myocardial infarction, cardiovascular disease, angina pectoris, and congestive heart failure

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Drugs only (nicotine replacement therapy patch, nasal spray, inhaler, and Zyhan); drugs and counselling (drugs and proactive telephone counselling); and drugs if counselling (drugs conditional on enrolment in counselling).

Setting
Community

Delivery
Telephone

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Drugs only; drugs and counselling; and drugs if counselling

Length of follow-up 8 months	
Outcomes and Analysis	
Clinical Outcomes (used in CE/CU) Making a quit attempt (stopped smoking for one or more days during the study because they were trying to quit and not for some other reason), quitting during the study (stopped smoking for seven or more days in a row during the study because they were trying to quit and not for some other reason), and prevalent abstinence (had not smoked a cigarette for seven or more days in a row at the eight month follow-up interview). **Service Use measures** Doctor visit during the study period **Costing** Costs of treatment for each group were estimated based on utilization of the treatments and the costs of each covered drug (for a 12-week course of treatment) to the PPO, the cost of enrolment in the proactive telephone counselling program, and the cost of the self-help kit sent to all study participants. **Discounting** Not reported	**Outcome measurement** self-report in the follow-up telephone survey **Perspective** Not reported **Analysis strategy (including key sensitivity analyses)** Multivariate analyses (Chi-square) and logistic regression models using an intent-to-treat model **Confounders** The models were run controlling for: 1) smoking characteristics at baseline (made a quit attempt in lifetime, number of cigarettes smoked per day, age started smoking regularly, stage of readiness to quit. used drugs in a prior quit attempt, prior use of Wellbutrin for non-smoking related diagnosis), 2) demographic characteristics (age. gender, income, race), and 3) doctor visit during the study period.
Results **Intervention group** No comment	**Results** **Control group** No comment
Results – CE & ICER (for basecase and sensitivity analyses) The average rate of making a quit attempt across all groups was 48%. ranging from 43% to 55%. Quit rates during the study averaged 31% across all groups, ranging from 26% to 37%. Prevalent abstinence rates at eight months averaged 16% across all groups, ranging from 13% to 19%. Utilisation of the pharmacotherapy benefit did not vary across treatment groups. On average, 20% of subjects filled a prescription for one of the covered medications **Adjusted odds ratios (ORs) and p value of quitting behaviours by treatment group** Quit attempt Group: Drugs only (referent) 1.0 Quit during study Group: drugs and counselling .6 (3-1.0) .06 Prevalent abstinence Group: drugs if counselling 1.0 (.5-1.9) 1.0	

Cost per covered treatment
Drugs only
Self-help kit 3,402
Zyban 2870
NRT patch 2360
NRT nasal spray/inhaler 2135
Proactive telephone counselling -
Total cost of treatment 10767
Standardised cost/outcome
Cost/study participant 85
Cost/quit attempt during study 156
Cost/quit during study 234
Cost/prevalent abstinence 449

Drugs and counselling
Self-help kit 3780
Zyban 3075
NRT patch 4130
NRT nasal spray/inhaler 2135
Proactive telephone counselling 2035
Total cost of treatment 15115
Standardised cost/outcome
Cost/study participant 108
Cost/quit attempt during study 253
Cost/quit during study 410
Cost/prevalent abstinence 842

Drugs if counselling
Self-help kit 3294
Zyban 2870
NRT patch 2360
NRT nasal spray/inhaler 1708
Proactive telephone counselling 5365
Total cost of treatment 15597
Standardised cost/outcome
Cost/study participant 128
Cost/quit attempt during study 274
Cost/quit during study 410
Cost/prevalent abstinence 709

Trends, Limitations, Comments and Source of Funding

Significant trends	**Reported limitations**
After eight months, there were no significant increases in quit attempts or quit rates in the groups with covered drugs and counselling compared to the group with drug coverage only	Reviewer Low response rate Author Only generalisable to smokers enrolled in

General comments No comment	individual and family preferred provider organisation in the private health insurance market **Source of funding** Grant (no. 9RT -0096) from the Tobacco-Related Disease Research program

Authors: Hollis JF, McAfee TA, Fellows JL et al
Year: 2007
Citation: Tobacco Control 16 (Suppl 1): i53-i59
Country of study: USA
Aim of study: Examined the effectiveness and cost effectiveness of offering callers single session versus multisession counselling, with or without free nicotine patches
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population	**Characteristics of population**
Tobacco quitline callers who were 18 years of age or older, spoke English or Spanish, smoked five or more cigarettes per day over the past six months and were planning to quit within the next month **Number of people** 4,614 **Locality** Oregon, USA **Recruitment strategy** Mass media campaigns, direct mailings to select populations (for example, Medicaid) and encouragement to physicians and health plans to recruit tobacco users **Response rate** 60%-62%.	<u>No NRT offer</u> Brief (n = 872) Female 59.5 ; Age (years), mean (SD) 41.1 (13.1) ; Some college (%) 51.6; White (%) 89.6 ; Hispanic (%) 6.0 ; Spanish speaker (%) 0.1 ; Married/partnered (%) 43.0; Medical coverage (%) 70.2 ; Cigarettes, mean (SD) 21.9 (10.5); Other smoker in home (%) 40.3 Moderate (n = 718) ; Female 59.2 ; Age (years), mean (SD) 41.4 (13.1); Some college (%) 51.7; White (%) 92.6 ; Hispanic (%) 3.3 ; Spanish speaker (%) 0 ; Married/partnered (%) 46.2; Medical coverage (%) 73.7 ; Cigarettes, mean (SD) 21.8 (10.2); Other smoker in home (%) 47.1 Intensive (n = 720) ; Female 62.2 ; Age (years), mean (SD) 40.8 (12.7); Some college (%) 47.6; White (%) 89.3 ; Hispanic (%) 6.0; Spanish speaker (%) 0.4; Married/partnered (%) 42.6; Medical coverage (%) 74.6; Cigarettes, mean (SD) 21.5 (11.2); Other smoker in home (%) 43.6 <u>NRT offer</u> Brief (n = 868) ; Female 60.3 ; Age (years), mean (SD) 41.0 (13.4) ; Some college (%) 52.2 ; White (%) 91.8 ; Hispanic (%) 5.7 ; Spanish speaker (%) 0.5 ; Married/partnered (%) 43.1 ; Medical coverage (%) 72.0 ; Cigarettes, mean (SD) 21.8 (10.7) ; Other smoker in home (%) 45.5 Moderate (n = 715) ; Female 59.2 ; Age (years), mean (SD) 41.4 (13.0) ; Some college (%) 53.7 ; White (%) 90.2 ; Hispanic (%) 5.3 ; Spanish speaker (%) 0 ; Married/partnered (%) 43.5; Medical coverage (%) 75.4 ; Cigarettes, mean (SD) 22.0 (10.7) ; Other smoker in home (%) 43.9

	Intensive (n = 721) Female 59.0; Age (years), mean (SD) 40.5 (13.8); Some college (%) 51.3; White (%) 88.9; Hispanic (%) 4.7; Spanish speaker (%) 0.3; Married/partnered (%) 42.6; Medical coverage (%) 71.7; Cigarettes, mean (SD) 21.6 (10.7) ; Other smoker in home (%) 43.0 **Excluded populations** Callers with health plan providing multisession telephone counselling through Free and Clear, Inc, as a covered benefit, or if they had medical conditions that would contraindicate patch use, including pregnancy, breast feeding, plans to become pregnant or a history of heart attack within the preceding month Initially, callers with no health insurance were excluded because state policy provided free access to the multisession phone counselling with free NRT patches. When this state benefit ended midway through the recruitment period, uninsured callers became eligible for the study **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Brief, moderate and intensive telephone counselling, with or without an offer of free NRT patches **Setting** Community **Delivery** Telephone line **Length of follow-up** 12 month	**Method of allocation** 3 (behavioural) x 2 (NRT) randomised trial **Measurement of exposure** Recording phone calls **Comparator** brief (one 15-minute call), moderate (one 30-minute call and a follow-up call) and intensive (five proactive calls) intervention protocols
Outcomes and Analysis	
Outcomes Tobacco cessation, satisfaction	**Outcome measurement** Self-report **Analysis strategy** Logistic regression **Confounders** Unadjusted

Results **Intervention group**	**Results** **Control group**
Before Not reported **After** Abstinence 12 months (%) Brief 11.7 Moderate13.8 Intense 14.3	**Before** Not reported **After** Abstinence12 months (%) Brief17.1 Moderate 20.1 Intense 21.2
Results – Group difference P< 0.0001	
Trends, Limitations, Comments and Source of Funding	
Significant trends Offering free NRT and multisession telephone support within a state tobacco quitline led to higher quit rates, and similar costs per incremental quit, than less intensive protocols **General comments**	**Reported limitations** <u>Author</u> Self- report; did not obtain quit data beyond one year; could not use a placebo NRT <u>Reviewer</u> **Source of funding** National Cancer Institute (grant R01 CA86242), and we want to thank GlaxoSmithKline for supplying the nicotine patches used in the study

Authors: McDermott MS, Marteau TM, Hajek P
Year: 2011
Citation: Journal of Smoking Cessation 6(02): 112-118
Country of study: UK
Aim of study: Assess the impact of an intervention aimed at communicating the negative reinforcement explanation for smoking
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Smokers attending for treatment at the NHS SSS at The Royal London Hospital in East London, aged 16 or over who were able to fill in the study forms in English

Number of people
205

Locality
East London

Recruitment strategy
Self-referred or were referred by a medical practitioner

Response rate
Not reported

Characteristics of population
Experimental (n = 80–81)
Gender Males 43 (53.1) ; Females 38 (46.9) ; Age Mean (SD, range) 43.15 (13.45, 20–79) ; Ethnicity White 64 (79.0) ; Other ethnic group 17 (21.0) ; In paid employment? 44 (55.0) ; Qualifications GCSE or less 44 (55.0); More than GCSE 36 (45.0) ; Nicotine dependence (FTND) 5.12 (2.38); No. cigarettes smoked per day 20.88 (10.27)

Control (n = 61–54)
Males 31 (48.4) ; Females 33 (51.6); Age Mean (SD, range) 42.33 (13.81, 17–75); Ethnicity White 51 (79.7); Other ethnic group 13 (20.3) ; In paid employment? 38 (62.3); Qualifications GCSE or less 27 (43.5) ; More than GCSE 35 (56.5); Nicotine dependence (FTND) 4.66 (2.15) ; No. cigarettes smoked per day 20.12 (8.63)

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
(a) a 10-minute presentation detailing the main points of the negative reinforcement explanation for smoking with group discussion; (b) a leaflet summarising the presentation; and (c) a self-monitoring task. The second part of the intervention consisted of 10 minutes of revision and group discussion one week later

Setting
NHS SSS at The Royal London Hospital in East London

Delivery

Method of allocation
Random numbers table

Measurement of exposure
Self-report

Comparator
Received either an additional brief intervention aimed at communicating the negative reinforcement explanation for smoking, or an additional control intervention matched on contact time with patients

Not reported **Length of follow-up** 1 week	
Outcomes and Analysis	
Outcomes Participants' acceptance of the negative reinforcement explanation for smoking, positive outcome expectations for smoking, self-efficacy and urges to smoke reported at one week post-cessation	**Outcome measurement** Self-report **Analysis strategy** T tests, chi-square or Mann-Whitney U-tests, ANCOVA **Confounders** Adjusted but no details provided
Results **Intervention group**	**Results** **Control group**
Before Positive outcome expectations for smoking 10.34 (2.78) Self-efficacy 7.78 (1.80) **After** Urges to smoke: mean (SD) 2.72 (0.92) 1-week abstinence: n (%) 33 (40.7) Self-efficacy 8.00 (1.79)	**Before** Positive outcome expectations for smoking 9.97 (2.59) Self-efficacy 6.97 (2.21) **After** Urges to smoke: mean (SD) 3.07 (1.06) 1-week abstinence: n (%) 33 (51.6) Self-efficacy 7.42 (2.07)
Results – Group difference Adjusted (p) Urges to smoke: mean (SD) .33 1-week abstinence: n (%) .19 Self-efficacy .99	
Trends, Limitations, Comments and Source of Funding	
Significant trends Post-cessation urges to smoke were similar in the two groups. Other cognitive measures were also unchanged **General comments**	**Reported limitations** <u>Author</u> Non-significant small effect; limited room for the intended cognitive shift; small sample size; we could not explore mediators; compliance with the self-monitoring task was not high <u>Reviewer</u> No economic evaluation of intervention **Source of funding** Cancer Research UK as part of a Cancer Research UK PhD Studentship (Ref: C4770/A7173)

Authors: Vogt F, Marteau TM
Year: 2012
Citation: Nicotine & Tobacco Research 14(2): 200-208
Country of study: UK
Aim of study: Investigates the impact of visual and numerical representations of effectiveness and different lengths of follow-up upon the perceived effectiveness of stop smoking interventions
Study design: Experimental trial
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population	**Characteristics of population**
Smokers older than 18 years **Number of people** 318 participants in Experiment 1 320 participants in Experiment 2 **Locality** Not reported **Recruitment strategy** Advertisements placed via Google Ltd on the online versions of UK national newspapers **Response rate** Not reported	<u>Experiment 1</u> 45 years (SD = 14, range = 18–83 years) 49.7% were men 89.7% were White 61.2% had achieved educational qualifications allowing them to enter university 66.7% being able to correctly answer at least two of three numeracy problems (Experiment 2 = 60.7%; Mean Heaviness of Smoking Index (HSI), the combination of cigarettes smoked per day and time to first cigarette was 3.09 (SD = 1.68, range 0–6) 22.4% smoking 1–10 cigarettes/day 43.5% smoking 11–20 34.1% smoking more than 20 <u>Experiment 2</u> 46 years in (SD =15, range = 18–87 years), 58.3% were men 93.3% were White 63.5% had achieved educational qualifications allowing them to enter university 60.7% being able to correctly answer at least two of three numeracy problems Mean Heaviness of Smoking Index (HSI), the combination of cigarettes smoked per day and time to first cigarette was 3.12 (SD = 1.65, range 0–6), 20.7% smoking 1–10 cigarettes/day 36.2% smoking 11–20 40.2% smoking more than 20 **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention	**Method of allocation**
Group 1 received a brief introduction of a	Not reported

stop smoking program that mirrored that offered by the NHS in the United Kingdom Group 2 received the same information as Group 1, and in addition, information used by the NHS to demonstrate the effectiveness of the program Group 3) received the same information as Group 1, and in addition, numerical and visual absolute effectiveness information about the program **Setting** Online **Delivery** Not reported **Length of follow-up** 12 months	**Measurement of exposure** Self-report **Comparator** "No Effectiveness Information" or "Standard Numerical Effectiveness Information" or "Numerical and Visual Absolute Effectiveness Information"
Outcomes and Analysis	
Outcomes Perceived effectiveness of stop smoking interventions and intentions to use them	**Outcome measurement** Self-report **Analysis strategy** *t* tests and chi-square tests **Confounders** Not reported
Results **Intervention group**	**Results** **Control group**
Before Not reported **After** Not reported	**Before** Not reported **After** Not reported
Results – Group difference Smokers who saw the short-term quit rate perceived the stop smoking intervention as more effective than smokers who saw the long-term quit rate: t(318) = 3.2, p = .002, d = 0.35. Intentions to use stop smoking interventions differed depending on whether they saw the short-term quit rate (M = 4.3, SD = 2.1) or the long-term quit rate (M = 3.9, SD = 2.0; No significant differences in intentions between smokers who saw the short-term and the long-term quit rates: t(318) = 1.59, p = .112, d = 0.18.	
Trends, Limitations, Comments and Source of Funding	

Significant trends Numerical and visual absolute effectiveness information compared with no effectiveness information resulted in greater perceived effectiveness. Short-term quit rate compared with long-term quit rate resulted in greater perceived effectiveness **General comments**	**Reported limitations** <u>Author</u> Follow-up of actual behaviour is lacking; Experiment 1 must be considered a complex intervention given that more than one component differed across Groups 2 and 3; no measure of delay discounting; all participants were Internet users; several aspects of the format were not investigated, including different denominators and different shading of icon arrays <u>Reviewer</u> No effort made to evaluate cost effectiveness **Source of funding** Cancer Research UK (C9009/A7655)

APPENDIX A.6 Evidence table SMOKING – Systematic Reviews

Authors: Lindson-Hawley N, Aveyard P, Hughes JR
Year: 2010
Citation: Cochrane Database of Systematic Reviews (3): CD008033
Country of study: International
Aim of study: Systematic review of reduction versus abrupt cessation in smokers who want to quit.
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population Adult cigarette smokers with an aim to quit smoking. **Number of people** 3760 (included in meta-analysis), from ten studies. When only the conditions relevant to the review were taken into account, sample sizes ranged from 14 to 1277, with a mean of 376. **Locality** International **Recruitment strategy** Seven studies recruited participants from the community using advertisements. One study recruited work-sites to take part and then recruited their employees by posting advertisements and internal memos. Another recruited students using advertisements at a university and another recruited patients consulting a hospital based smoking counselling service. **Response rate** Not reported for individual studies.	**Characteristics of population** The 10 included studies all recruited adult cigarette smokers with an aim to quit. Participant gender was reported in 8 studies - on average evenly split between males and females, and the average reported age of participants (averaged across seven studies) was 42.8 years. Eight studies reported average baseline cigarettes per day in all participants, range from 23 to 28 cigarettes per day, with an average of 25.4. **Excluded populations** Trials that enrolled smokers who did not intend to quit soon were excluded, as they are covered by the Cochrane review of harm reduction (Stead 2007). Trials where participants spontaneously reduced before quitting without being advised to do so, were excluded. Trials with a follow up of less than six months. Studies where behavioural support differed substantially in type or duration between arms. **Low risk/high risk population** N/A

Intervention and Comparison

Intervention Randomized controlled trials (RCTs) that recruited adults who wanted to quit smoking. Studies that compared any instruction to participants to reduce the amount of	**Method of allocation** Randomisation In one study these participants were randomised in clusters (work-sites) to study

cigarettes smoked before quitting, with any instruction to stop smoking abruptly without prior reduction, were included Interventions included anything from no behavioural support to extensive behavioural support, but behavioural support pre- and post-quit could vary between the reduction and abrupt quit arms as long as overall contact was roughly equal. Trials could also include pharmacotherapy to support cessation, as long as it was equivalent in all trial arms after cessation. Pharmacotherapy used prior to quit day could vary as a necessary component of the intervention i.e. to support smoking reduction. In four of the studies, participants were advised on either abrupt or gradual cessation by self-help manuals or a handheld computer Programme. Participants in another five studies were given face-to-face or telephone based behavioural support. In the remaining study one reduction arm and one abrupt arm consisted of self help therapy, and participants in the other reduction and abrupt arms were provided with behavioural support.	arm however for all other included studies participants were individually randomised. **Measurement of exposure** N/A **Comparator** Abrupt cessation of smoking
Outcomes and Analysis	
Outcomes Abstinence from smoking after at least six months follow-up. Adverse effects (in pharmacotherapy studies)	**Outcome measurement** In three studies smoking abstinence was reported as point prevalence and in six studies as prolonged/continuous. One study did not report how abstinence was defined. Abstinence was verified in eight of the included studies, by either expired carbon monoxide saliva cotinine, saliva thiocyanate, or asking a relative or friend to confirm the participant had stopped smoking. In one study the abstinence data was not verified. **Analysis strategy** Meta-analysis **-** Included trials pooled using a Mantel-Haenszel fixed-effect model. Trials were split for two sub-group analyses: pharmacotherapy vs no pharmacotherapy, self help therapy vs behavioural support. Adverse events were summarised as a narrative. It was not possible to compare them quantitatively as there was variation in the reporting across studies. **Confounders**

	Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Ten studies were included. (Three of these studies used pharmacotherapy as part of the interventions).

Abstinence

There was no significant difference between reduction versus abrupt quitting for abstinence rates when all the studies were combined in the main analysis (RR= 0.94, 95% CI= 0.79 to 1.13), whether pharmacotherapy was used (RR= 0.87, 95% CI= 0.65 to 1.22), or not (RR= 0.97, 95% CI= 0.78 to 1.21), whether studies included behavioural support (RR= 0.87, 95% CI= 0.64 to 1.17) or self-help therapy (RR= 0.98, 95% CI=0.78 to1.23).

Adverse effects

There was insufficient data to draw conclusions about the difference in adverse events between interventions.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** The authors concluded that reducing cigarettes smoked before quit day and quitting abruptly, with no prior reduction, produced comparable quit rates. Therefore patients can be given the choice to quit in either of these ways. Reduction interventions can be carried out using self-help materials. Or aided by behavioural support, and can be carried out with the aid of pre-quit NRT.	**Reported limitations** Reviewer Author **Source of funding** Internal University of Birmingham University of Vermont External National Institute for Health Research and the National Health Service of the UK UK Centre for Tobacco Control Studies, a UKCRC Public Health Research: Centre of Excellence. British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council, and the Department of Health, under the auspices of the UK Clinical Research Collaboration Fletcher Allen Health Care

Authors: Webb MS, Rodríguez-Esquivel D, Baker EA
Year: 2010
Citation: American Journal of Health Promotion 25(2): 109-118
Country of study: US
Aim of study: Systematic review of smoking cessation interventions among Hispanics in the United States.
Study design: Systematic reviews
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
Healthy Hispanic adults living in the US

Number of people
Not reported for individual studies or meta-analysis

Locality
US

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
The age range of included studies was 35-44 (mean 40.70 SD 3.21).

Excluded populations
Non- Hispanic adults, non US studies

Pregnant women, medical patients, adolescents, or non-U.S. smokers were excluded, studies without a control group were excluded from meta-analysis.

Low risk/high risk population
N/A

Intervention and Comparison

Smoking cessation interventions in healthy Hispanic adults living in the US.

Interventions consisted of self-help, nicotine replacement therapy, and community-based interventions, as well as individual, group, and telephone counselling.

Method of allocation
Any intervention eligible for inclusion but studies included in meta-analysis had to be RCTs.
Methods of randomisation or allocation concealment not reported for individual studies.

Measurement of exposure
N/A

Comparator
No control group for some studies. Details of control group for individual studies reported in results section.

Outcomes and Analysis

Outcomes
Smoking abstinence, quit rates or current smoking rates.

Outcome measurement
Self-reported and biochemically verified

Analysis strategy
Meta-analysis of 5 RCTs and narrative synthesis of 12 studies.

Confounders

	Authors report for some studies there were differences in intensity and frequency of contact between intervention and control groups.
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

12 studies were included in the systematic review and 5 RCTs in the meta-analysis.

From meta-analysis of 5 studies, there was evidence for the efficacy of smoking cessation interventions at the end of treatment (odds ratio, 1.54; 95% confidence interval, 1.09-2.16), which was attenuated in the longer term.

Self-help: Two studies examined self-help smoking cessation. One trial examined a Spanish language mood management and written smoking cessation messages delivered immediately or delayed (3 months). There was greater 7-day point prevalence abstinence for the immediate intervention compared to the delayed group at 3 months (22.5% vs 10.8%, however results were not significant based on biochemical confirmation of smoking status. Another study examined the effect of self-help materials, including an incentive postcard in a quasi-experimental trial (no control group). Respondents reported abstinence rates of 21% at 3 months and 14% at 14 months of which 8% were biochemically verified.

Nicotine-replacement therapy (NRT): Two studies included: One was a double-blind RCT in which smokers were randomly assigned to receive 10 weeks of NRT or placebo patches. All participants received additional behavioural support by telephone and clinic visits. Biochemically confirmed abstinence rates were greater for the nicotine patch compared to placebo (63% vs 35%) at 6 weeks and 10 weeks (46% vs 35%). In another descriptive quasi-experimental trial, smokers interested in quitting were provided with nicotine patches, lozenges, gum or buproprion. Based on self-report, 63% of participants reported smoking cessation at 8 to 12 weeks and 44% were abstinent at 6 months.

Individual counselling: Two studies examined individual counselling for smoking cessation. One RCT examined culturally specific individual counselling delivered during home visits by community health advisors. Biochemically confirmed abstinence rates were greater for the intervention (19%) compared to the control (7%). However, there were differences in intensity and frequency between arms of the study. Another study examined brief individual counselling based on motivational interviewing and NRT. Less acculturated Hispanics were more likely to quit smoking compared to bicultural Hispanics and non-Hispanic white groups at 3 months (34% vs 20% vs 24%) and 6 months (21% vs 9% vs 18%).

Group counselling: Two studies examined group counselling smoking cessation interventions. One RCT tested a culturally specific group based cessation intervention (weekly 2 hour sessions, story therapy, a buddy system, maintenance self-help materials plus supportive telephone calls) versus a self-help control (self-help materials and a bimonthly telephone call). There were no significant differences between groups at 6 and 12 month follow up. Another study used group counselling based on cognitive behavioural therapy. A non-controlled intervention consisted of 6 group counselling sessions conducted in Spanish and NRT. At the end of treatment 14% (biochemically confirmed) had quit with 18% and 13% self-reported cessation rates at 3 and 6 month follow up.

Telephone counselling: One trial tested a telephone based behavioural intervention. Callers to the National Cancer Information service received either enhanced counselling (4 telephone

contacts) or standard counselling (one telephone contact plus self-help materials). The calls consisted of practical counselling (identification of triggers to smoke and strategies for coping), supportive counseling, and strategies to increase social support from significant others. Motivational enhancement and a culturally tailored approach were also used. The enhanced programme produced greater 7 day point prevalence abstinence (27.4%) compared with the standard condition (20.5%) at the 3 month follow up.

Community based interventions: Three studies used community based interventions to promote smoking cessation. One study compared a comprehensive intervention (cessation counselling, media campaign and community network with a media only campaign or no intervention. There were no statistically significant differences in smoking results across the three follow-up assessments, which occurred over 4 years. Biochemically confirmed smoking cessation rates were also low. Another non-controlled community study found that exposure to a campaign involving widely distributed self-help materials, a media campaign and outreach by community health workers was unrelated to smoking cessation. However smokers exposed to the campaign were more likely to make an attempt to quit. In another trial in which 20 communities were randomised to either a community cancer prevention intervention or no intervention there were no differences in current smoking (15.7%) between the intervention and control communities (13.6%). However, the smoking cessation intervention was a minor part of the overall intervention.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments**	**Reported limitations** Reviewer Author Short follow up periods for some studies, lack of RCTs, small sample sizes, self-report data for some studies. Participants in most of the studies were Mexican American which limits generalizability to other US Hispanic populations. **Source of funding** Not reported

Systematic Reviews not included but presented for information:

Rooke S, Thorsteinsson E, Karpin A, Copeland J, Allsop D. (2010). Computer-delivered interventions for alcohol and tobacco use: a meta-analysis. Addiction 105(8): 1381-139

Aims: To quantify the overall effectiveness of computer-delivered interventions for alcohol and tobacco use.

Methods: Meta-analysis of 42 effect sizes from randomized controlled trials, based on the responses of 10 632 individuals.

Results: The weighted average effect size (d) was 0.20, P < 0.001. While lower effect sizes were associated with studies addressing tobacco use (d = 0.14) this may well reflect differences in the types of outcome measure used. Effect sizes did not vary significantly as a function of treatment location, inclusion of entertaining elements, provision of normative feedback, availability of a discussion feature, number of treatment sessions, emphasis on relapse prevention, level of therapist involvement or follow-up period.

Conclusion: Findings of the meta-analysis suggest that minimal contact computer-delivered treatments that can be accessed via the internet may represent a cost-effective means of treating uncomplicated substance use and related problems.

Zbikowski S, Magnusson B, Pockey J, Tindle H, Weaver K. (2012). A review of smoking cessation for smokers aged 50 and older. Maturitas 71(2): 131-141

Objectives: Cigarette smoking poses substantial health risks at any age, but is particularly dangerous for older smokers, who are already at heightened risk for various health conditions. Studies suggest that older smokers are motivated to quit and succeed, but few of these have been randomized controlled trials. There is a need to systematically evaluate the research on effective interventions in older smokers.

Methods: We followed PRISMA guidelines in the development of this systematic review, which included randomized controlled trials of cessation interventions with smokers aged 50 or older.

Results: We found 740 unique titles matching specified search criteria; 13 met final eligibility criteria. Nearly all the cessation treatments combined counseling with other strategies. Eight studies provided smoking cessation medications. None of the studies used newer forms of technology such as web- or text-based interventions. Nine of the 13 studies reported a significant intervention effect at one or more time points, with three studies reporting sustained treatment effects at 12 mos or longer. In general, more intensive interventions and those with combined approaches including medications and follow-up counseling achieved the best outcomes.

Conclusion: The quit rates from these studies and the relative effectiveness of different intervention approaches are consistent with the general smoking cessation literature. However, in most studies, treatment effects were of short duration, and absolute quit rates were low, leaving the vast majority of older smokers at high risk for smoking-related health conditions. This SR suggests a need for additional research to design and test future interventions specifically tailored for older smokers.

APPENDIX A.7 Evidence table SMOKING – Economic Studies

INCLUDED

Authors: Smith MW, An LC, Fu SS et al..
Year: 2011
Citation: Journal of Telemedicine and Telecare 17(8): 437-440.
Country of study: USA
Aim of study: calculate the incremental cost per quit of a telephone care intervention versus usual care
Study design: Economic evaluation
Quality score: (++, + or -): -

Study (eligible and selected) population

Primary data OR modelling Primary data **Eligible population** Women **Number of people** 819 **Locality** USA **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Standard care No of subjects 412; Mean age, y 57 (11); Male, % 88; White, % 94; More than 12 y education, % 53; Cigarettes/day 27 (12); Fair or poor health, % 38 Telephone care No of subjects 407; Mean age, y 57 (11); Male, % 91; White, % 94; More than 12 y education, % 48; Cigarettes/day 26 (13); Fair or poor health, % 40 **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention The Active Living program consisted of 8 sessions that provided information on the basic components of fitness, including aerobics, strengthening, and flexibility. **Setting** Primary care **Delivery** Telephone **Length of follow-up** 12 months	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Usual care

Outcomes and Analysis

Clinical Outcomes (used in CE/CU)
Physical activity

Service Use measures
VA outpatient prescriptions, nicotine-replacement, buproprion, VA outpatient encounters, primary care, mental health and substance abuse, other medicine and surgery, allied health, VA-funded FFS* outpatient, VA inpatient days of stay, VA-funded FFS* inpatient

Costing
VA records were used to extract the cost of VA services over 12 months, and the cost of care purchased by the VA from others. Intervention costs were derived through micro-costing.

Discounting
Discounting was deemed unnecessary for costs during a study period of only 12 months.

Outcome measurement
Not reported

Perspective
Provider

Analysis strategy (including key sensitivity analyses)
Significance testing employed chi-square tests or t-tests as appropriate.

Confounders
Inflation adjustments were made using the US chain-weighted Consumer Price Index for all urban consumers.

Results
Intervention group
Not reported

Results
Control group
Not reported

Results – CE & ICER (for basecase and sensitivity analyses)
On average, the intervention cost $142 per person, excluding medications. The average cost of all VA-funded medical care during the study period was $8959 in the telephone-care arm and $7939 in the usual care arm (P = 0.37). Under a standard intent-to-treat analysis the average cost per quit was $11,408 and thus the intervention was cost-effective by conventional standards.

VA costs over 12 months. Values in parentheses are SD

Standard care	
Telephone care, $	–
VA outpatient, $	5461 (7288)
VA inpatient, $	2064 (10,770)
VA-funded FFS* , $	414 (1998)
Total	7939 (15,439)
Telephone care	
Telephone care, $	142 (36)
VA outpatient, $	5756 (5953)
VA inpatient, $	2624 (14,089)
VA-funded FFS* , $	437 (1795)
Total	8959 (17,087)
P value	
Telephone care, $	–

VA outpatient, $ 0.81
VA inpatient, $ 0.52
VA-funded FFS* , $ 0.86
Total 0.37

Use of VA-funded health care over 12 months. Values shown are the mean number of items

Standard care
VA outpatient prescriptions 17.2 (14.8)
nicotine-replacement 1.0 (2.2)
buproprion 1.3 (3.9)
VA outpatient encounters 26.1 (23.8)
primary care 2.4 (2.6)
mental health and substance abuse 1.9 (6.7)
other medicine and surgery 1.7 (3.3)
allied health 20.0 (18.2)
VA-funded FFS* outpatient 2.3 (8.5)
VA inpatient days of stay 1.3 (6.3)
VA-funded FFS* inpatient 0.2 (1.6)

Telephone care
VA outpatient prescriptions 18.2 (14.4)
nicotine-replacement 2.9 (3.3)
buproprion 1.3 (2.9)
VA outpatient encounters 28.5 (22.4)
primary care 2.5 (2.7)
mental health and substance abuse 1.8 (7.8)
other medicine and surgery 1.6 (2.9)
allied health 22.7 (17.6)
VA-funded FFS* outpatient 2.7 (13.6)
VA inpatient days of stay 2.1 (13.7)
VA-funded FFS* inpatient 0.4 (3.5)

P value
VA outpatient prescriptions 0.33
nicotine-replacement ,0.01
buproprion .84
VA outpatient encounters 0.13
primary care 0.98
mental health and substance abuse 0.89
other medicine and surgery 0.48
allied health 0.03
VA-funded FFS* outpatient 0.54
VA inpatient days of stay 0.31
VA-funded FFS* inpatient 0.35

Cost per quit: intention-to-treat analysis
Mean cost per quit ($) 95% CI ($)
Intention to Treat (ITT) 11,408 0, 36,952

ITT with multiple imputation 10,352 0, 27,973
Trends, Limitations, Comments and Source of Funding

Significant trends

On average, the intervention cost $142 per person, excluding medications. The average cost of all VA-funded medical care during the study period was $8959 in the telephone-care arm and $7939 in the usual care arm (P = 0.37).

There were no significant differences in other VA outpatient care, inpatient VA care or VA-funded fee-for-service care, although total spending for nicotine replacement therapy and bupropion (part of the VA outpatient category) were significantly higher for telephone care enrollees ($253 vs. $73, P, 0.01; data not shown).

General comments

No comment

Reported limitations

Reviewer

limited to a 12-month period; no discounting

Author

Self-reported abstinence;

Source of funding

Department of Veterans Affairs Health Services Research and Development Service (SUI 99101-1) and the University of Minnesota Medical School.

ECONOMIC STUDIES NOT INCLUDED BUT PRESENTED FOR INFORMATION

Rasmussen SR. (2013). The cost effectiveness of telephone counseling to aid smoking cessation in Denmark: A modelling study. Scandinavian Journal of Public Health 41(1): 4-10

Aim: To assess the cost-effectiveness of the Danish smoking cessation telephone service "quitline".

Methods: The study was based on the number of quitline callers in 2005. The outcome was measured as costs per life year saved (LYS) based on the assessment in 2001 of continued abstinence over a 12-month period (19.0%) and point prevalence of abstinence at 12 months of follow up (29.7%), respectively. The costs per LYS are estimated as the annual running costs of reactive telephone counselling service divided by the total number of LYS, which has been estimated as the difference between current smokers' and ex-smokers' life expectancies according to age group and gender based on Danish smoking proportions, relative risks of smoking-related mortality of all causes, and standard life tables.

APPENDIX A.10 Evidence table ALCOHOL - Primary Studies

Authors: Boon B, Risselada A, Huiberts et al
Year: 2011
Citation: Journal of Medical Internet Research 13(2): e43
Country of study: Netherlands
Aim of study: Assess the effectiveness of computer-based personalized feedback on heavy alcohol use in male adults
Study design: RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Heavy drinker male

Number of people
450

Locality
Not specified

Recruitment strategy
Screener from a sampling frame of 25,000 households. Additional participants were recruited through advertisements in national newspapers

Response rate
Screening questionnaire administered to all men aged 18 to 65 (n = 9000) in two nationally representative panels consisting of 25,000 households that can receive online questionnaires. 817 men fulfilled the inclusion criteria and were willing to consider participation in the study. 70 eligible men responded to advert.
A total of 450 out of the 887 (50.7%) men contacted agreed to participate and gave informed consent. After one month, 413 participants were successfully followed-up (Lost to follow-up 8.2% at one month; total at six month 10.4%)

Characteristics of population
Mean age 40.4 (SD 15.1)

Most men had a high level of education; almost half of all respondents (214/450, 47.8%) indicated they were living with a partner, and the majority of the men reported being employed (253/450, 56.5%).

Mean weekly alcohol consumption at baseline was equal across both groups, with 31 units for the experimental condition and 32 units for the brochure condition.

Excluded populations
Men who had received any professional help for alcohol-related problems or any medication to reduce alcohol consumption in the 12 months preceding

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Drinktest (www.drinktest.nl) a single 10-minute online session in which tailored feedback is delivered, with no therapist involved. Components: overview of mean weekly alcohol intake, associated health risks, self-help guidelines to reduce alcohol intake, normative feedback to compare one's own alcohol consumption to the level of one's own cohort.

Method of allocation
Randomisation stratified by age and educational level

Measurement of exposure
Presenting with either heavy alcohol use (> 20 units of alcohol weekly) and/or binge drinking (> 5 units of alcohol at a single occasion at least one day per week) in the past six months.

Setting General population **Delivery** Online **Length of follow-up** One month, six month	**Comparator** Information-only
Outcomes and Analysis	
Outcomes Percentage of the participants that had successfully reduced their drinking levels to below the Dutch guideline threshold for at-risk drinking	**Outcome measurement** Self-report of alcohol consumption **Analysis strategy** Intention-to-treat analysis; completers-only analysis **Confounders** Not reported
Results **Intervention group**	**Results** **Control group**
Results – Group difference **1 month** - 42% (97/230) of the participants were successful in reducing their drinking levels to below the threshold at the one-month follow-up as compared with 31% (67/220) in the control group (odds ratio [OR] = 1.7, number needed to treat [NNT] = 8.6), which was statistically significant ($\chi^2_1 = 6.67$, $P = .01$). **6 month** - At the six-month follow-up, the success rates were 46% (105/230) and 37% (82/220) in the experimental and control conditions, respectively (OR = 1.4, NNT = 11.9), but no longer statistically significant ($\chi^2_1 = 3.25$, $P = .07$). NNT = 8.6	
Trends, Limitations, Comments and Source of Funding	
Significant trends Personalised online feedback on alcohol consumption appears to be an effective and easy way to change unhealthy drinking patterns in adult men, at least in the short-term. **General comments**	**Reported limitations** <u>Author</u> Potential selection bias Relied on self-reported measures No blinding possible Sample limited to adult men; so not generalised to women **Source of funding** Netherlands Health Research Council (ZonMw), Grant # 50-50110-98- 235.

Authors: Blankers M, Koeter M, Schippers G
Year: 2011
Citation: Journal of Consulting and Clinical Psychology 79(3): 330-341
Country of study: Netherlands
Aim of study: Examined the effectiveness of Internet-based therapy (therapy alcohol online; TAO) and internet-based self-help (self-help alcohol online; SAO) for problematic alcohol users.
Study design: Three-arm open RCT
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
- Problematic alcohol users, defined as reporting current drinking of more than 14 standard drinks while obtaining a score of 8 or above on the Alcohol Use Disorders Identification Test (AUDIT)
- Be between 18 and 65 years old
- Be a resident of the Netherlands with health care insurance
- Have Internet access at home

So suitable for low-intensity outpatient treatment

Number of people
Website has 650,000 visitors annually

Locality
Amsterdam

Recruitment strategy
Participants were recruited through the website of a collaborating substance abuse treatment centre. Website visitors who expressed an interest in Internet-based interventions for problematic alcohol users were referred to the pages with information about the study. There they could complete a screening instrument to determine whether they met the inclusion criteria

Characteristics of population
Mean age 42.4 years; 50% female; most participants were employed (81%)

No significant difference across control and experimental groups

Excluded populations
Prior substance abuse treatment, a history of alcohol delirium or a drug overdose, a severe coronary or intestinal disease, schizophrenia, epilepsy, or suicidal tendencies in the last 12 months; if they used cocaine or amphetamine for more than four days of during the last month or used cannabis for more than nine days during the last month

Low risk/high risk population
Not reported

Response rate
1,720 completed questionnaire, 832 eligible, **205** decided to participate, were randomised to one of three treatment arms.
A total of 156 participants (76%) completed at least one follow-up assessment. The proportion of participants who completed the three-month and six-month follow-up assessment did not differ among the three trial arms.

Intervention and Comparison

Intervention
SAO: Internet-based self-help. A stand-alone, Internet-based, non-therapist involved, fully automated, self-guided treatment program that is based on a CBT/MI treatment protocol. Four tier (monitor, feedback, help acquire skills and knowledge, social support)

TAO: Internet-based therapy. A synchronous online therapy that is based on the same

Method of allocation
Restricted randomisation by minimization; sex, AUDIT composite score, and years of alcohol problems were selected as prognostic of outcome and their variance among the trial arms was minimised. Concealed participants' allocation in advance from themselves, the research assistants, and the therapists

Measurement of exposure
Internet based questionnaires at baseline

CBT/MI treatment protocol as SAO. Includes up to seven text based chat therapy, with pre-session homework assignment. Trained CBT therapist. Contact only through text based chat and email **Setting** Internet based; strategies in place to maximise retention, including small payments, emails, phone calls. **Delivery** Online **Length of follow-up** Three and six months	**Comparator** This study compared the effectiveness of Internet-based therapy (therapy alcohol online; TAO) with Internet-based self-help (self- help alcohol online; SAO) for problematic alcohol users. TAO and SAO were also evaluated against an untreated waiting list control group (WL).
Outcomes and Analysis	
Outcomes <u>Primary</u> • Self-reported consumption during prior seven days (time follow-back technique TFLB). • Treatment response: drinking within the BMA (1995) guidelines for safe drinking (a maximum of 14 standard drinks of alcohol/week for women, 21 standard drinks for men) and having less than a 10% deterioration on the AUDIT, the Flanagan Quality of Life Scale, and the Global Severity Index (GSI) of the Brief Symptom Inventory between baseline and follow-up <u>Secondary</u> • AUDIT total score • Quality- of-life measures: QOLS and EuroQol's EQ-5D (using UK references) • Marlowe–Crowne Social Desirability Scale • Integrity of the CBT/MI that was delivered was assessed with the Yale Adherence and Competence Scale, Second Edition (YACS-II)	**Outcome measurement** As described above. **Analysis strategy** • Intent to treat; Multiple imputation (Amelia-II) to deal with missing data • Differences between the three groups were tested for significance with Fisher's exact test or one-way analysis of variance (ANOVA), as appropriate. Skewed distributions were log- transformed. Significant main effects in one-way ANOVAs were explored using post-hoc *t* tests with Bonferroni correction for multiple comparisons • Effects of the interventions on the primary and secondary out- come variables were analysed with generalised estimating equations (GEE) in a three (trial arm) x three (time) design. **Confounders** Not reported as such (but analyses account for potential biases)
Results **Intervention group**	**Results** **Control group**
<u>3 month wk. consumption: mean standard drinks in the last week (SD)</u> TAO: from M=46.6 (26.4) to M=22.4 (21.3) SAO: from M=43.6 (23.8) to M=27 (24.8) <u>3mth / 6mth post rando.:</u> <u>mean standard drinks (SD)</u> TAO: 22.4 / 18.7	<u>3 month wk. consumption: mean standard drinks in the last week (SD)</u> WL: from 47.2 (28.2) to 27.0 (24.8) <u>3mth post rando.:</u> <u>mean standard drinks (SD)</u> WL= 35.5

SAO: 27.0 / 26.2 <u>Treatment response 3mth / 6mth</u> TAO: 26 (38%) / 36 (53%) SAO: 19 (28%) / 20 (29%) <u>Audit 3mth / 6mth</u> TAO: 13.7 (4.6) / 12.6 (6.0) SAO: 14.8 (5.9) / 15.0 (6.4) <u>QoLs 3mth / 6mth</u> TAO: 84.9 (16.0) / 87.8 (17.5%) SAO: 83.9 (16.2) / 78.9 (23.4%) <u>EQ5D3mth / 6mth</u> TAO: 0.85 (0.33) / 0.89 (0.20) SAO: 0.83 (0.24) / 0.78 (0.34)	Treatment response WL: 11 (16%) <u>Audit 3mth</u> WL: 16.4 (4.7) <u>QoLs 3mth</u> WL: 77.0 (18.5) <u>EQ5D3mth</u> WL: 0.72 (0.33)
Results – Group difference **Overall** - In all three arms, participants reported less alcohol consumption at the three-month follow-up than at baseline (p<0.001) **3 month** - Participants in the TAO (*t*(135) =3.15, *p* = .002, one-tailed, *d* = 0.59) and SAO (*t*(135) = 2.04, *p*= .03, one-tailed, *d* =0.36) arms drank significantly less at the three-months-post-randomisation assessment than did participants in the WL arm. The difference between TAO and SAO participants was not significant at three months post randomisation. **6 month -** TAO participants drank significantly fewer standard drinks than did SAO participants in the week before the six-months-post-randomisation assessment (*t*(134)= 2.06, *p* =.03, one-tailed, *d* = 0.38). According to the Wald criterion, participants in the TAO arm had non-significantly higher odds of being a treatment responder after six months than did participants in the SAO arm, mean $Chi^2(1) = 7.0$, *OR* = 2.6, *NNT*= 1/(48/68) = (32/68) = 5, 95% CI [2.5, 13.4], pooled one-tailed, *p* = .06 **Secondary outcomes** In general, differences between WL and the two interventions on the secondary outcome variables were significant at three months post-randomisation. Differences between TAO and SAO did not reach significance at three months, but they were significant at six months post-randomisation	
Trends, Limitations, Comments and Source of Funding	
Significant trends The results of the current study support the effectiveness of Internet-based therapy and Internet-based self- help for problematic alcohol users. After six months, the more intensive Internet-based therapy program with synchronous therapist contacts led to better outcome than did the less intensive self-help program. Internet-based interventions are able to attract a new population of problematic drinkers into treatment, including men and women who are often gainfully employed but have a clear need for assistance in tackling their drinking problems. Internet- based self-help is effective, but Internet-based therapy is more effective for reducing problematic alcohol use	**Reported limitations** <u>Author</u> <u>Reviewer</u> **Source of funding**

Authors: Lock CA, Kaner E, Heather N et al
Year: 2006
Citation: Journal of Advanced Nursing 54(4): 426-439
Country of study: UK
Aim of study: Evaluation of the effectiveness and cost-effectiveness of nurse-led screening and brief intervention in reducing excessive alcohol consumption among patients in primary health care
Study design: Cluster randomised controlled trial
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Unit of analysis: General practices

Sample pool: 369 general practices

Number of unit
Control n=186 (50.4%)
Intervention n=183 (49.6%)
Power: need 76 practices to detect 20% daily alcohol consumption at one year

Locality
Five health authority areas in the north-east of England

Recruitment strategy
Nurse: via telephone bet Aug 2000 and Jan 2002

Participants:
Patients aged 16 years and over presenting to primary care were opportunistically screened by trial nurses using the AUDIT questionnaire to identify those drinking at 'risk' levels (cut-off points of 8+ for men and 7+ for women).

Response rate
Practice Control: 143 general practices contacted; 47 recruited; 25 in study sample; 19 completed protocol

Practice Intervention: 130 contacted; 46 recruited; 24 in study sample, 21 completed protocol

Participants: Screened 498, recruited to control 60, recruited to intervention 67. Patients who declined more likely to be younger

Characteristics of practices
* Stat. Sig difference between control & intervention

Control
- Group practice: 14 (74%)*****
- Solo practice: 5 (26%)

- Practice location, n (%)
  - Urban practice: 12 (63%)
  - Rural practice: 2 (11%)
  - Mixed (urban/rural): 5 (26%)

- Mean nurses involved (SD): 1 (0.6)
- Female, n (%): 100%
- Mean age of nurse (SD) : 46 (7.2)
- Mean years in practice (SD) : 9 (5.2)*****
- Mean hours/week (SD): 23.6 (7.2)

Intervention
- Group practice: 18 (86%)
- Solo practice: 3 (14%)

- Practice location, n (%)
  - Urban practice: 10(48%)
  - Rural practice: 5(24%)
  - Mixed (urban/rural): 6 (28%)

- Mean nurses involved (SD): 1.5 (0.9)
- Female, n (%): 100%
- Mean age of nurse (SD): 46 (6.3)
- Mean years in practice (SD) : 10 (5.0)
- Mean hours/week (SD): 29.1 (9.1)

Characteristics of participants (intervention/control):
- Males: 32 (49%) vs 31 (52%)
- Mean Age (SD): 42.7 (15.5) vs 45.7 (14.9)
- Mean audit score: 10.6 (4.7) vs 10.3 (5.6)

Excluded populations
Aged <16 years, had current major physical or psychiatric illness, were severely alcohol dependent or had severe brain damage or

	mental impairment **Low risk/high risk population** Men scoring 15+ and women scoring 13+ on AUDIT referred for medical advice and specialist services due to high likelihood of alcohol dependence
Intervention and Comparison	
Intervention Nurse: Brief intervention protocol Participants: AUDIT-positive patients received brief intervention using the 'drink-less' protocol (five-ten minutes to deliver). This involved structured advice on alcohol including: standard drink units; recommended low-risk consumption levels; benefits of cutting down drinking; tips on helping patients reduce consumption; advice on how to set goals, determine action and review progress; and a self-help booklet/diary for patients to take away **Setting** Primary care **Delivery** Face-to-face	**Method of allocation** Computer-generated random allocation of practices to one of two groups **Measurement of exposure** Nurse carried out baseline assessment. **Comparator** Nurse: Standard advice on alcohol issues Participants: AUDIT-positive patients offered standard treatment, i.e. nurses' usual advice on cutting down drinking and a UK Government Health Education Authority leaflet entitled 'Think about Drink'. This leaflet contained daily benchmark guides for adult men and women and basic advice on alcohol **Length of follow-up : one year** A total of 71 (56%) and 78 (61%) patients, respectively, completed six and 12 month follow-up questionnaires
Outcomes and Analysis	
Outcomes • Alcohol consumption • Quality of Life • Cost **Confounders** Not reported **Cost/Economics** Perspective: NHS & Individuals' personal costs incurred during and after nurse-led management of alcohol problems in primary care Costing: Patient-based (self-completion questionnaires) costing approach to identify patient resource use • Use: Total number of GP consultations, nurse consultations, Accident & Emergency Department attendances, inpatient stays and outpatient visits, time related to travelling to and waiting at surgeries and hospitals, time spent in	**Outcome measurement** Alcohol Use Disorders Identification Test Mean number of drinks per drinking day [alcohol timeline followback (TLFB)] Drinking Problems Index Health-related Quality of Life (SF-12) **Analysis strategy** • Blinded intent-to-treat analysis • Analysis of characteristics between intervention and control practices was undertaken using the Chi-square test for categorical data and two-tailed t-tests for continuous data • Analysis of differences between intervention groups at baseline, six and 12 months was undertaken at the level of the cluster using mean scores for AUDIT, DPI, units consumed per week and SF-12 • Groups were compared using analysis of

appointments and transport costs, number and length of absences from work and other out-of-pocket expenses related to property damage or accidents for a one-year period pre- and post-intervention • Valuing: £23.24/patient for expenditure committed to programme materials (equivalent to annual cost method); £5.33 per patient for nurse time. Total: £28.57	variance with a weighted least squares estimation procedure to allow for varying cluster size (the weights were the cluster sizes) • Analysis of differences between intervention groups across the three time points of baseline, six and 12 months was undertaken using univariate analysis of covariance (ANCOVA) with the baseline measure as the covariate. Analysis of the whole sample data from baseline to 12 months was carried out using paired sample t-tests. Statistical significance was accepted at $P < 0.05$
Results **Intervention group, mean score (SD)**	**Results** **Control group , mean score (SD)**
AUDIT Baseline • 6 months: 10.58 (6.42) • 12 months: 8.81 (5.82) • Baseline: 7.5 (3.01) Units/week • 6 months: 23.00 (20.7) • 12 months: 15.80 (12.31) • Baseline: 16.08 (22.84) DPI Baseline • 6 months: 5.44 (5.08) • 12 months: 3.92 (4.79) • Baseline: 2.05 (3.40) SF-12 physical health • 6 months: 49.15 (8.76) • 12 months: 50.40 (8.11) • Baseline: 47.00 (9.31) SF-12 mental health • 6 months: 50.53 (8.85) • 12 months: 51.81 (6.93) • Baseline: 53.84 (6.55)	AUDIT Baseline • 6 months: 10.31 (9.64) • 12 months: 10.77 (12.85) • Baseline: 10.60 (9.83) Units/week • 6 months: 26.48 (29.77) • 12 months: 24.96 (40.10) • Baseline: 19.60 (23.57) DPI Baseline • 6 months: 5.17 (15.01) • 12 months: 7.21 (21.76) • Baseline: 6.05 (15.70) SF-12 physical health • 6 months: 50.56 (13.80) • 12 months: 49.53 (12,48) • Baseline: 51.38 (7.01) SF-12 mental health • 6 months: 51.86 (12.26) • 12 months: 52.44 (10.13) • Baseline: 53.03 (5.58)
Results – Group difference <u>Outcome measures:</u> ANOVA and ANCOVA revealed *no statistically significant differences between intervention groups in relation to any outcome measures*. However, AUDIT scores, standard drink units per week and the DPI scores all fell between baseline and follow-up in intervention clusters, whereas only standard drink units per week fell in control patients across this period <u>Analysis of the whole sample</u> A majority of patients in each arm of the trial reduced their alcohol consumption between baseline assessment and 12 months follow-up (55% brief intervention, 59% control) Mean consumption in standard drink units this change was *not statistically significant*. There was a statistically significant reduction in AUDIT score for the whole sample across this period. (i.e. baseline Audit 11.5 (5.0); 12 month AUDIT 9.7 (6.6); *t* 2.038, p: 0.046) <u>Cost</u>	

The mean healthcare costs were higher in the control group, but there were no statistically significant differences in costs between the groups at 12 months. No difference in travel costs. No patients reported the occurrence of expenditure related to accidents, nor payment of higher motor vehicle or household insurance premiums as a result of accidents

Trends, Limitations, Comments and Source of Funding

Significant trends No evidence that screening and brief alcohol intervention by nurses was superior to standard advice on alcohol, plus a health education leaflet in primary care settings **General comments** Screening per se may produce an effect. Refusal rate from patients higher in younger patients	**Reported limitations** High withdrawal rates from general practices so trial underpowered. Poor retention of nurses due possibly to time, consent, low enthusiasm. No attempt to measure long-term outcomes. Large CI so great uncertainty **Source of funding:** NHS Executive (Northern & Yorkshire) Research and Development Regionally Commissioned Project Grant

Authors: Williams E, Achtmeyer C, Kivlahan DR et al
Year: 2010
Citation: Journal of Studies on Alcohol and Drugs 71(5): 720-725
Country of study: USA
Aim of study: Evaluation of an electronic clinical reminder to facilitate brief alcohol-counselling interventions in primary care
Study design: Evaluation in naturalistic real-life clinical setting
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
All providers practicing in a VA primary care clinic (Washington) and the patients who visited them between October 01, 2002, and September 30, 2005

Number of people
N = 22,863 (10 392 control; 12 471 intervention)

Locality
Veteran affairs

Recruitment strategy
No active recruitment of providers or patients

Response rate
N/A

Excluded populations
Not reported

Low risk/high risk population
Not reported

Characteristics of population
Demographics: Mean age 58.5 (14.0); 94% male; 645 white, 54% unmarried. A total of 4,202 patients (18%) on either hallway screened positive for unhealthy alcohol use on the AUDIT-C during the study period

Intervention vs control (significant differences):

- female: 4% vs. 7%, p < .001
- patients screened positive for severe unhealthy alcohol use: 4% vs. 3%, p < .01
- had diagnoses for substance-use disorders: 26% vs. 24%, p < .01
- medical conditions associated with AUDIT-C scores: 30% vs. 28%, p = .02
- Physical comorbidities: 78% vs. 76%, p < .001

Control (descriptive cohort)
All intervention hallway patients who screened positive for unhealthy alcohol use:

Any clinical reminder (p<.01)
Details available for specific components

- Total: 398 (15%)
- Mild/moderate: 302 (14%)
- Severe: 96 (20%)

Experimental (outcome cohort)

Any clinical reminder (p<.001)
Details available for specific components

- Total: 156 (39%)
- Mild/moderate: 77 (26%)
- Severe: 79 (82%)

Intervention and Comparison

Intervention
Electronic clinical reminder to encourage

Measurement of exposure
Electronic clinical and administrative data.

providers to offer brief interventions to patients who screened positive for unhealthy alcohol use and to facilitate documentation **Setting** Primary care **Delivery** Electronic **Length of follow-up** **Method of allocation** Some kind of randomisation (i.e. reminder triggered by a positive alcohol screen for providers on one randomly selected hallway ("intervention hallway"). No further details provided	Patients with positive AUDIT screen; were considered to have clinical-reminder use if any of the following data elements from the reminder was found in their records: (a) assessment of prior treatment history and levels of consumption; (b) brief intervention, including any documentation of advice to reduce or abstain from drinking, feedback linking alcohol use to health, and/or agreement on a drinking goal; (c) referral to specialty care; (d) use of optional assessment tools; and (e) documentation in the reminder that alcohol was not addressed during that visit. Use of optional assessment tools included clinical-reminder documentation of assessment for alcohol-use disorders readiness to change, and alcohol-related problems (ten-item AUDIT) or a review of alcohol-related laboratory or blood pressure results. Intervention hallway providers - including staff physicians, residents, nurse practitioners, or physician assistants - were considered the user of the reminder if they had a visit with the patient the day the clinical reminder was used. **Comparator** Providers and participants in control "hallway" not receiving reminder.
Outcomes and Analysis	
Outcomes Descriptive: frequency of clinical reminder, according to severity of unhealthy alcohol use **Confounders** Not reported	**Outcome measurement** **Analysis strategy** Adjusted logistic regression evaluated the association between the intervention and resolution of unhealthy drinking at follow-up among all screen-positive patients who completed a second Alcohol Use Disorders Identification Test Consumption questionnaire 18 months or longer after the first visit ("outcomes cohort")
Results **Intervention group**	**Results** **Control group (descriptive cohort)**
Only 39% (156 of 398) of patients with clinical-reminder use had documented brief intervention; advice to abstain was most common. Access to the clinical reminder was not significantly associated with resolution of unhealthy drinking in 1,358 patients in the outcomes cohort	Fifteen percent (398 of 2,640) of descriptive cohort patients with unhealthy drinking had clinical-reminder use, which varied by severity (14% [n = 302 of 2,165] with mild/moderate and 20% [n = 96 of 475] with severe unhealthy drinking, p = .001)
Results – Group difference N/A	

Trends, Limitations, Comments and Source of Funding	
Significant trends Availability of a clinical reminder to facilitate brief intervention did not, alone, result in substantial use of the clinical reminder. More active implementation efforts may be needed to get brief interventions onto the agenda of busy primary care providers **General comments**	**Reported limitations** Author Reviewer **Source of funding** National Institute on Alcohol Abuse and Alcoholism career development award; Veterans Affairs (VA) Substance Use Disorders Quality Enhancement Research Initiative (SUD QuERI); VA's Northwest Center of Excellence for Health Services Research and Development

APPENDIX A.11 Evidence table ALCOHOL – Systematic Reviews

There are no included systematic reviews.

SYSTEMATIC REVIEWS NOT INCLUDED BUT PRESENTED FOR INFORMATION:

Bryden A, Roberts B, McKee M, Petticrew M. (2012). A systematic review of the influence on alcohol use of community level availability and marketing of alcohol. Health & Place 18(2): 349-357

Purpose: Exposure to a high number of alcohol outlets and adverts within a community may lead to higher alcohol use by local residents. The aim of this systematic review was to explore evidence on the influence on alcohol use of community level availability and marketing of alcohol.

Results: 26 studies met the eligibility criteria. While the findings were not conclusive, there was some indication that higher outlet density and greater exposure to advertising in a local community may be associated with an increase in alcohol use, particularly among adolescents.

Conclusions: This review disentangled the existing evidence on the overall relationships between availability, marketing and alcohol use at a community level. Further studies are required to better understand the influence of these factors on alcohol use.

Bryden A, Roberts B, Petticrew M, McKee M. (2013). A systematic review of the influence of community level social factors on alcohol use. Health and Place 21: 70-85

Purpose: To explore evidence on the influence of community level social factors on alcohol use among adults and adolescents.

Methods and results: Major bibliographic databases were searched for quantitative studies meeting inclusion criteria. After screening, narrative synthesis and a quality review were applied. Forty-eight studies met the eligibility criteria. While the findings were inconclusive for associations between alcohol use and deprivation, poverty, income, unemployment, social disorder and crime, there was some indication that social capital characteristics were protective.

Conclusions: Social capital has a potentially important association with reducing alcohol use. Further studies are required to better understand social influences on alcohol use. 2013.

Khadjesari Z, Murray E, Hewitt C, Hartley S, Godfrey C. (2011). Can stand-alone computer-based interventions reduce alcohol consumption? A systematic review. Addiction 106(2): 267-282

Aim: To determine the effects of computer-based interventions aimed at reducing alcohol consumption in adult populations.

Methods: The review was undertaken following standard Cochrane and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance for systematic reviews. The literature was searched until December 2008, with no restrictions on language. Randomised trials with parallel comparator groups were identified in the form of published and unpublished data. Two

authors independently screened abstracts and papers for inclusion. Data extraction and bias assessment was undertaken by one author and checked by a second author. Studies that measured total alcohol consumption and frequency of binge drinking episodes were eligible for inclusion in meta-analyses. A random-effects model was used to pool mean differences.

Results: Twenty-four studies were included in the review (19 combined in meta-analyses). The meta-analyses suggested that computer-based interventions were more effective than minimally active comparator groups (e.g. assessment-only) at reducing alcohol consumed per week in student and non-student populations. However, most studies used the mean to summarise skewed data, which could be misleading in small samples. A sensitivity analysis of those studies that used suitable measures of central tendency found that there was no difference between intervention and minimally active comparator groups in alcohol consumed per week by students. Few studies investigated non-student populations or compared interventions with active comparator groups.

Conclusion: Computer-based interventions may reduce alcohol consumption compared with assessment-only; the conclusion remains tentative because of methodological weaknesses in the studies. Future research should consider that the distribution of alcohol consumption data is likely to be skewed and that appropriate measures of central tendency are reported.

Rooke S, Thorsteinsson E, Karpin A, Copeland J, Allsop D. (2010). Computer-delivered interventions for alcohol and tobacco use: a meta-analysis. Addiction *105*(8): 1381-1390

Aims: To quantify the overall effectiveness of computer-delivered interventions for alcohol and tobacco use.

Methods: Meta-analysis of 42 effect sizes from randomised controlled trials, based on the responses of 10 632 individuals.

Results: The weighted average effect size (d) was 0.20, $P < 0.001$. While lower effect sizes were associated with studies addressing tobacco use ($d = 0.14$) this may well reflect differences in the types of outcome measure used. Effect sizes did not vary significantly as a function of treatment location, inclusion of entertaining elements, provision of normative feedback, availability of a discussion feature, number of treatment sessions, emphasis on relapse prevention, level of therapist involvement or follow-up period.

Conclusion: Findings of the meta-analysis suggest that minimal contact computer-delivered treatments that can be accessed via the internet may represent a cost-effective means of treating uncomplicated substance use and related problems.

White A, Kavanagh D, Stallman H, Klein B, Kay-Lambkin F, Proudfoot J… Young R. (2010). Online alcohol interventions: a systematic review. Journal of Medical Internet Research 12(5): e62

Background: There has been a significant increase in the availability of online programs for alcohol problems. A systematic review of the research evidence underpinning these programs is

timely.

Objectives: Our objective was to review the efficacy of online interventions for alcohol misuse. Systematic searches of Medline, PsycINFO, Web of Science, and Scopus were conducted for English abstracts (excluding dissertations) published from 1998 onward. Search terms were: (1) Internet, Web*; (2) online, computer*; (3) alcohol*; and (4) E\effect*, trial*, random* (where * denotes a wildcard). Forward and backward searches from identified papers were also conducted. Articles were included if (1) the primary intervention was delivered and accessed via the Internet, (2) the intervention focused on moderating or stopping alcohol consumption, and (3) the study was a randomized controlled trial of an alcohol-related screen, assessment, or intervention.

Results: The literature search initially yielded 31 randomized controlled trials (RCTs), 17 of which met inclusion criteria. Of these 17 studies, 12 (70.6%) were conducted with university students, and 11 (64.7%) specifically focused on at-risk, heavy, or binge drinkers. Sample sizes ranged from 40 to 3216 (median 261), with 12 (70.6%) studies predominantly involving brief personalized feedback interventions. Using published data, effect sizes could be extracted from 8 of the 17 studies. In relation to alcohol units per week or month and based on 5 RCTs where a measure of alcohol units per week or month could be extracted, differential effect sizes to posttreatment ranged from 0.02 to 0.81 (mean 0.42, median 0.54). Pre-post effect sizes for brief personalized feedback interventions ranged from 0.02 to 0.81, and in 2 multi-session modularized interventions, a pre-post effect size of 0.56 was obtained in both. Pre-post differential effect sizes for peak blood alcohol concentrations (BAC) ranged from 0.22 to 0.88, with a mean effect size of 0.66.

Conclusions: The available evidence suggests that users can benefit from online alcohol interventions and that this approach could be particularly useful for groups less likely to access traditional alcohol-related services, such as women, young people, and at-risk users. However, caution should be exercised given the limited number of studies allowing extraction of effect sizes, the heterogeneity of outcome measures and follow-up periods, and the large proportion of student-based studies. More extensive RCTs in community samples are required to better understand the efficacy of specific online alcohol approaches, program dosage, the additive effect of telephone or face-to-face interventions, and effective strategies for their dissemination and marketing.

Hyman Z. (2006). Brief interventions for high-risk drinkers. Journal of Clinical Nursing 15(11): 1383-1396

Aims and objectives: The purpose of this paper is to explore the literature on brief alcohol intervention and to review the literature that examines the status of the clinic nurse in the delivery of these interventions. The objective is to review critically the literature on brief intervention to create links for nurse developed and delivered brief intervention to high-risk drinkers. Background: Population estimates suggest that more than one-third of North Americans drink excessively with even higher rates for individuals treated in primary care settings. Alcohol use has been identified as the third leading cause of mortality in the United States. This problem is not unique to the US

and, worldwide, agencies and governmental offices and ministries have issued recommendations to screen patients for alcohol misuse and deliver brief interventions to individuals considered to be high-risk drinkers. Numerous randomized controlled trials and recent meta-analyses have supported the use of screening and brief intervention for reducing alcohol consumption in primary healthcare settings. The vast majority of studies reporting on brief interventions have focused on the role of the physician with minimal if any involvement of the clinic nurse. A scant number of studies have been conducted that define and assess the role or potential role of the clinic nurse in providing screening and brief intervention to high-risk drinkers in the primary care setting.
Methods: Systematic review.
Results: Six systematic reviews and meta-analyses from an international base of studies support the use of brief intervention in the primary care setting. Three randomized control trials have highlighted the role of the staff or clinic nurse but there are no meta-analyses addressing nurse-delivered brief interventions. Numerous studies have explored factors effecting the implementation of brief intervention into the primary care setting. Conclusion: Brief intervention is recognized as a legitimate nursing role but little has been done to develop and define the role of the nurse in delivering brief interventions to high-risk drinkers. This represents a major lacuna in both the nursing and alcoholism literature, where only a handful of studies have investigated nurse-delivered brief intervention. Relevance to clinical practice: As health screening and health promotion are hallmarks of nursing care, nurses need to explore the use of brief intervention in their daily practice. (PsycINFO Database Record (c) 2012 APA, all rights reserved) (journal abstract).

Vasilaki EI, Hosier SG, Cox WM. (2006). The efficacy of motivational interviewing as a brief intervention for excessive drinking: a meta-analytic review. Alcohol & Alcoholism 41(3): 328-335

Aims: (1) To examine whether or not motivational interviewing (MI) is more efficacious than no intervention in reducing alcohol consumption; (2) to examine whether or not MI is as efficacious as other interventions.
Method: A literature search followed by a meta-analytic review of randomized control trials of MI interventions. Aggregated between-group effect sizes and confidence intervals were calculated for each study.
Results: Literature search revealed 22 relevant studies, of which nine compared brief MI with no treatment, and met methodological criteria for inclusion. In these, the aggregate effect size was 0.18 (95% C.I. 0.07, 0.29), but was greater 0.60 (95% C.I. 0.36, 0.83) when, in a post-hoc analysis, the follow-up period was three months or less. Its efficacy also increased when dependent drinkers were excluded. There were nine studies meeting methodological criteria for inclusion which compared brief MI with another treatment (one of a diverse set of interventions), yielding an aggregate effect size of 0.43(95% C.I. 0.17, 0.70). The literature review pointed to several factors

which may influence MI's long-term efficacy effectiveness of MI.

Conclusions: Brief MI is effective. Future studies should focus on possible predictors of efficacy such as gender, age, employment status, marital status, mental health, initial expectations, readiness to change, and whether the population is drawn from treatment-seeking or non-treatment-seeking populations. Also, the components of MI should be compared to determine which are most responsible for maintaining long-term changes.

Whitlock EP, Polen MR, Green CA, Orleans T, Klein J. (2004). Behavioral counseling interventions in primary care to reduce risky/harmful alcohol use by adults: a summary of the evidence for the US Preventive Services Task Force. Annals of Internal Medicine 140(7): 557-568+I564

Background: Primary health care visits offer opportunities to identify and intervene with risky or harmful drinkers to reduce alcohol consumption.

Purpose: To systematically review evidence for the efficacy of brief behavioral counseling interventions in primary care settings to reduce risky and harmful alcohol consumption.

Data Sources: Cochrane Database of Systematic Reviews, Database of Research Effectiveness (DARE), MEDLINE, Cochrane Controlled Clinical Trials, PsycINFO, HealthSTAR, CINAHL databases, bibliographies of reviews and included trials from 1994 through April 2002; update search through February 2003.

Study Selection: An inclusive search strategy (alcohol* or drink*) identified English-language systematic reviews or trials of primary care interventions to reduce risky/harmful alcohol use. Twelve controlled trials with general adult patients met our quality and relevance inclusion criteria. Data Extraction: Investigators abstracted study design and setting, participant characteristics, screening and assessment procedures, intervention components, alcohol consumption and other outcomes, and quality-related study details.

Data Synthesis: Six to 12 months after good-quality, brief, multicontact behavioral counseling interventions (those with up to 15 minutes of initial contact and at least 1 follow-up), participants reduced the average number of drinks per week by 13% to 34% more than controls did, and the proportion of participants drinking at moderate or safe levels was 10% to 19% greater compared with controls. One study reported maintenance of improved drinking patterns for 48 months.

Conclusions: Behavioral counseling interventions for risky/harmful alcohol use among adult primary care patients could provide an effective component of a public health approach to reducing risky/harmful alcohol use. Future research should focus on implementation strategies to facilitate adoption of these practices into routine health care.

Ballesteros J, Duffy JC, Querejeta I, Ariño J, González-Pinto A. (2004). Efficacy of brief interventions for hazardous drinkers in primary care: Systematic review and meta-analyses. Alcoholism-Clinical and Experimental Research 28(4): 608-618

Background: Because recent research in primary care has challenged the findings of previous reviews on the efficacy of brief interventions (BIs) on hazardous drinkers, we conducted a systematic review and meta-analysis to update the evidence of BIs as applied in the primary care setting.

Methods: We obtained source material by searching electronic databases and reference lists and hand-searching journals. We selected randomized trials providing frequency data that allowed assessment of the efficacy of BIs on an intention-to-treat basis. Results were summarized by the odds ratio (OR) of response. When appropriate, risk difference (RD) and its inverse (number needed to treat [NNT] to achieve a positive result) were also computed. Fixed and/or random effect models were fitted according to heterogeneity estimates.

Results: Thirteen studies provided data for a dose-effect analysis, 12 for comparison of BIs with reference categories. No clear evidence of a dose-effect relationship was found. BIs outperformed minimal interventions and usual care (random effects model OR = 1.55, 95% confidence interval [CI] = 1.27-1.90; RD = 0.11, 95% CI = 0.06-0.16; NNT = 10, 95% CI = 7-17). Similar results were obtained when two influential studies were removed (fixed effect model OR = 1.57, 95% CI = 1.32-1.87; RD = 0.11, 95% CI = 0.07-0.15; NNT = 9, 95% CI = 7-15). The heterogeneity between individual estimates was accounted for by the type of hazardous drinkers (heavy versus moderate) and by the characteristics of the included individuals (treatment seekers versus nontreatment seekers). The funnel plot did not show evidence of publication bias. Conclusion: Our results, although indicating smaller effect sizes than previous meta-analyses, do support the moderate efficacy of BIs. Further research is outlined.

Ballesteros J, González-Pinto A, Querejeta I, Ariño J. (2004). Brief interventions for hazardous drinkers delivered in primary care are equally effective in men and women. Addiction 99(1): 103-108

Aim: Despite the accumulated evidence on the efficacy of brief interventions in hazardous drinkers some ambiguity remains regarding their differential effectiveness by gender.

Methods: Meta-analysis of independent studies conducted in primary health care settings with a follow-up of 6-12 months which report results separately by gender. Two outcome measures were selected: the quantity of typical weekly alcohol consumption and the frequency of drinkers who reported consumption below hazardous levels after the intervention.

Results: Seven studies were included in the meta-analysis. The standardized effect sizes for the reduction of alcohol consumption were similar in men (d=- 0.25; 95% CI=- 0.34 to -0.17) and women (d=- 0.26; 95% CI=- 0.38 to - 0.13). The odds ratios (OR) for the frequency of individuals who drank below harmful levels were also similar (four studies; OR for men=2.32; 95% CI=1.78-2.93; OR for women=2.31; 95% CI=1.60-3.17). The difference between genders was negligible.

Conclusion: Our results support the equality of outcomes among men and women achieved by brief interventions for hazardous alcohol consumption in primary care settings.

D'Onofrio G, Degutis LC. (2002). Preventive care in the emergency department: screening and brief intervention for alcohol problems in the emergency department: a systematic review. Academic Emergency Medicine 9(6): 627-638

Objective: To systematically review the medical literature in order to determine the strength of the recommendation for screening and brief intervention (SBI) for alcohol-related problems in the emergency department (ED) setting.

Methods: The review followed the methodology of systematic reviews and was facilitated through the use of a structured template, a companion explanatory piece, and a grading and methodological scoring system based on published criteria for critical appraisal. The primary outcome measure was the prevention of mortality and morbidity secondary to alcohol-related illnesses/injuries. The secondary outcome measures included: decreased consumption; fewer ED/outpatient visits and hospitalizations; a decrease in social consequences; and increased referrals for follow-up and/or treatment. Three Medline searches as well as a search of the Cochrane Library were performed. Two team members reviewed the abstracts and selected pertinent articles. References were screened for additional pertinent articles.

Results: Twenty-seven articles were identified and reviewed, in addition to the 14 primary articles included in the 1996 U.S. Preventive Services Task Force Report. The study populations were diverse, including inpatient, outpatient, and college settings, with ages ranging from 12 to 70 years. Four studies were ED-based and two included EDs as one of multiple sites. Thirty-nine studies on SBI, 30 randomized controlled and nine cohort, were used to formulate the current recommendation. A positive effect of the intervention was demonstrated in 32 of these studies.

Conclusions: The authors recommend that SBI for alcohol-related problems in the ED be incorporated into clinical practice.

APPENDIX A.12 Evidence table ALCOHOL – Economic Studies

INCLUDED

Authors: Blankers M, Nabitz U, Smit F et al.

Year: 2012

Citation: Journal of Medical Internet Research 14(5): 71-83

Country of study: the Netherlands

Aim of study: To evaluate the cost effectiveness and cost utility of Internet-based interventions for harmful use of alcohol through the assessment of the incremental cost effectiveness of Internet-based therapy compared with Internet-based self-help

Study design: Pragmatic Randomized Controlled Trial

Quality score: (++, + or -): ++

Study (eligible and selected) population

Primary data OR modelling
Primary data

Eligible population
(1) be between 18 and 65 years old, (2) live in the Netherlands with health care insurance coverage, (3) have Internet access at home, (4) score above 8 on the Alcohol Use Disorders Identification Test (5) report a weekly consumption of more than 14 standard (10 g ethanol) drinking units, and (6) provide informed consent.

Number of people
136

Locality
Amsterdam, the Netherlands

Recruitment strategy
Recruited applicants through jellinek.nl, a substance abuse treatment centre website

Response rate
Not reported

Characteristics of population
IT (n = 68) ; Women, n (%) 35 (51%) ; Age (years), mean (SD) 41.9 (10.1) ; Education, n (%) Low 2 (3%) ; Medium 24 (38%) ; High 38 (59%) ; Employed, n (%) 58 (85%) ; Residential urbanization level, n (%) ; Low 9 (13%) ; Medium 21 (31%) ; High 37 (55%) ; AUDIT composite score, mean (SD) 18.8 (4.8) ; Duration of alcohol problems (years), mean (SD) 5.2 (5.7) ; Drinks per week, mean (SD) 45.2 (26.3) ; EQ-5D score 0.79 (0.20) ; Work absenteeism 756 (2289); Work presenteeism 1137 (2386)

IS (n = 68) ; Women, n (%) 35 (51%) ; Age (years), mean (SD) 41.1 (9.6) ; Education, n (%) Low 7 (11%) ; Medium 30 (46%) ; High 29 (44%) ; Employed, n (%) 55 (82%) ; Residential urbanization level, n (%) Low 6 (9%) ; Medium 22 (32%) ; High 40 (59%) ; AUDIT composite score, mean (SD) 19.6 (5.6) ; Duration of alcohol problems (years), mean (SD) 5.4 (5.7) ; Drinks per week, mean (SD) 43.4 (24.0) ; EQ-5D score 0.80 (0.18) ; Work absenteeism 1863 (6983) ; Work presenteeism 794 (1922)

Excluded populations
(1) prior substance abuse treatment, (2) a history of alcohol delirium or drug overdose, (3) a history of severe cardiovascular or gastrointestinal diseases, (4) a history of schizophrenia, epilepsy, or suicidal tendencies, (5) extensive substance use in the last month, and (6) unavailability of more than 2 weeks during the study

	Low risk/high risk population Not reported
Intervention and Comparison	
Intervention Both IT and IS were based on a cognitive behavioural therapy and motivational interviewing treatment protocol **Setting** Community **Delivery** Internet **Length of follow-up** 6 months	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Self-help and internet therapy
Outcomes and Analysis	
Clinical Outcomes (used in CE/CU) Alcohol consumption **Service Use measures** Cost data were extracted from the treatment centre's cost records **Costing** All costs related to IT and IS interventions, health care uptake, opportunity costs of the participant's time, and productivity losses. IT and IS intervention costs consisted of software development costs, information and computer technology service costs, overhead costs (based on the treatment centre's cost records), and—for IT only—therapist-related costs. Restricted participant costs to a valuation of their time investment, valued as leisure time at €9.18 per hour. **Discounting** Indexed to the reference year 2010 using an inflation correction based on the Harmonized Index of Consumer Prices	**Outcome measurement** The central clinical outcome for the cost effectiveness analysis was treatment response, based on alcohol consumption during the last 7 days. **Perspective** Societal **Analysis strategy (including key sensitivity analyses)** Carried out all analyses on an intention-to-treat basis. To test the robustness of the economic evaluation, performed a sensitivity analysis in which we varied the most relevant cost drivers. **Confounders** Not reported
Results **Intervention group** Not reported	**Results** **Control group** Not reported
Results – CE & ICER (for basecase and sensitivity analyses) The mean incremental societal costs for 1 additional QALY gained by IT compared with IS	

were €845 / 0.06 = €14,083. The median ICER for 1 extra QALY was estimated too be €14,710.

Cost type Unit Internet therapy
No. of units (€/unit)
Intervention costs
Therapist therapy Hour 2.49 (79.20)
Therapist administration Hour 0.55 (79.20)
Software development Participant 1 (23.25)
ICT service Participant 1 (14.92)
Software overhead Participant 1 (4.27)
Total intervention costs Participant 1 (283.21)
Participant's leisure time Hour 10.33 (9.18)
Work absenteeismd Hour 32.12 (22.21–52.91)
Work presenteeismf Hour 8.15 (22.21–52.91)

Cost type Unit Internet self-help
No. of units (€/unit)
Intervention costs
Therapist therapy Hour NA (NA)
Therapist administration Hour NA (NA)
Software development Participant 1 (4.87)
ICT service Participant 1 (2.49)
Software overhead Participant 1 (4.27)
Total intervention costs Participant 1 (11.63)
Participant's leisure time Hour 2.43 (9.18)
Work absenteeism Hour 18.35 (22.21–52.91)
Work presenteeism Hour 12.15 (22.21–52.91)

Costs and increments in the 6-month period preceding follow-up of the Internet-based therapy (IT) and Internet-based self-help (IS) groups

Cost type IT
Mean SD
Intervention costs
Therapist labor 241 236
Software development 23 0
Software/hardware service 15 0
Software overhead 4 0
Total intervention costs 283 236
Participant time investment costs 95 103
Productivity costs
Work absenteeism 1114 5704
Work presenteeism 217 847
Total productivity costs 1331 5774
Societal costs
Additional societal costs 301 1305
Total societal costs 2010 7141
Treatment response (proportion) 0.53
EQ-5D score 0.89 0.20

Cost type IS

	Mean	SD
Intervention costs		
Therapist labor	0	0
Software development	5	0
Software/hardware service	2	0
Software overhead	4	0
Total intervention costs	12	0
Participant time investment costs	22	37
Productivity costs		
Work absenteeism	536	3800
Work presenteeism	350	1637
Total productivity costs	886	4215
Societal costs		
Additional societal costs	200	953
Total societal costs	1120	5167
Treatment response (proportion)	0.29	
EQ-5D score	0.78	0.34

Cost type Bootstrapped difference

	Median	95% CI
Intervention costs		
Therapist labor	240	187–296
Software development	18	18–18
Software/hardware service	12	12–12
Software overhead	0	0–0
Total intervention costs	271	217–327
Participant time investment costs	72	48–99
Productivity costs		
Work absenteeism	555	–967 to 2234
Work presenteeism	–119	–609 to 256
Total productivity costs	417	–1215 to 2208
Societal costs		
Additional societal costs	94	–275 to 499
Total societal costs	845	–1157 to 3048
Treatment response (proportion)	0.24	0.07–0.38
EQ-5D score	0.12	0.05–0.18
ICER treatment response	3683	–5703 to 20,366
ICER QALY	14,710	–18,337 to 71,664

Cost effectiveness analysis of base case, health care provider perspective, and additional sensitivity analyses.

Cost drivers	Base case: societal
Incremental costs (median)	845
Treatment response	
Incremental effects (median)	0.24
ICER (median)	3683
ICER (95%low)	–5703
ICER (95%high)	20,366

WTP €4000 53%
WTP €8000 76%
WTP €12,000 87%
Upper right quadrant 79%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 20%
QALYs
Incremental QALYs (median) 0.06
ICER QALY (median) 14,710
ICER QALY (95%low) –18,337
ICER QALY (95%high) 71,664
WTP €10,000 40%
WTP €20,000 60%
WTP €40,000 85%
Upper right quadrant 80%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 20%

Cost drivers Alternative case: health care provider
Incremental costs (median) 271
Treatment response
Incremental effects (median) 0.24
ICER (median) 1157
ICER (95%low) 665
ICER (95%high) 3722
WTP €4000 95%
WTP €8000 98%
WTP €12,000 99%
Upper right quadrant 99%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 0%
QALYs
Incremental QALYs (median) 0.06
ICER QALY (median) 4693
ICER QALY (95%low) 2783
ICER QALY (95%high) 10,848
WTP €10,000 95%
WTP €20,000 99%
WTP €40,000 100%
Upper right quadrant 100%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 0%

Cost drivers Sensitivity analyses
I –40%

Incremental costs (median) 739
Treatment response
Incremental effects (median) 0.24
ICER (median) 3187
ICER (95%low) –6441
ICER (95%high) 19,410
WTP €4000 57%
WTP €8000 78%
WTP €12,000 89%
Upper right quadrant 76%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 23%
QALYs
Incremental QALYs (median) 0.06
ICER QALY (median) 12,932
ICER QALY (95%low) –20,177
ICER QALY (95%high) 67,913
WTP €10,000 45%
WTP €20,000 64%
WTP €40,000 87%
Upper right quadrant 76%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 23%

Cost drivers Sensitivity analyses
I +40%
Incremental costs (median) 954
Treatment response
Incremental effects (median) 0.24
ICER (median) 4172
ICER (95%low) –5050
ICER (95%high) 21,409
WTP €4000 50%
WTP €8000 74%
WTP €12,000 86%
Upper right quadrant 82%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 17%
QALYs
Incremental QALYs (median) 0.06
ICER QALY (median) 16,584
ICER QALY (95%low) –16,241
ICER QALY (95%high) 75,671
WTP €10,000 36%
WTP €20,000 57%
WTP €40,000 83%

Upper right quadrant 83%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 17%

Cost drivers Sensitivity analyses
P –40%
Incremental costs (median) 681
Treatment response
Incremental effects (median) 0.24
ICER (median) 2977
ICER (95%low) –3227
ICER (95%high) 14,724
WTP €4000 62%
WTP €8000 85%
WTP €12,000 92%
Upper right quadrant 83%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 16%
QALYs
Incremental QALYs (median) 0.06
ICER QALY (median) 11,876
ICER QALY (95%low) –10,291
ICER QALY (95%high) 52,202
WTP €10,000 44%
WTP €20,000 70%
WTP €40,000 93%
Upper right quadrant 84%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 16%

Cost drivers Sensitivity analyses
P +40%
Incremental costs (median) 1012
Treatment response
Incremental effects (median) 0.24
ICER (median) 4387
ICER (95%low) –8313
ICER (95%high) 25,979
WTP €4000 48%
WTP €8000 69%
WTP €12,000 82%
Upper right quadrant 76%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 22%
QALYs

Incremental QALYs (median) 0.06
ICER QALY (median) 17,683
ICER QALY (95%low) –26,220
ICER QALY (95%high) 91,101
WTP €10,000 38%
WTP €20,000 54%
WTP €40,000 77%
Upper right quadrant 77%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 23%

Cost drivers Sensitivity analyses
I and P –40%
Incremental costs (median) 573
Treatment response
Incremental effects (median) 0.24
ICER (median) 2494
ICER (95%low) –3821
ICER (95%high) 13,738
WTP €4000 66%
WTP €8000 87%
WTP €12,000 93%
Upper right quadrant 79%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 20%
QALYs
Incremental QALYs (median) 0.06
ICER QALY (median) 9946
ICER QALY (95%low) –12,282
ICER QALY (95%high) 48,403
WTP €10,000 50%
WTP €20,000 74%
WTP €40,000 94%
Upper right quadrant 80%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 20%

Cost drivers Sensitivity analyses
I and P +40%
Incremental costs (median) 1120
Treatment response
Incremental effects (median) 0.24
ICER (median) 4868
ICER (95%low) –7576
ICER (95%high) 26,957
WTP €4000 46%

WTP €8000 67%
WTP €12,000 80%
Upper right quadrant 79%
Upper left (inferior) quadrant 1%
Lower left quadrant 0%
Lower right (dominant) quadrant 20%
QALYs
Incremental QALYs (median) 0.06
ICER QALY (median) 19,436
ICER QALY (95%low) –24,352
ICER QALY (95%high) 94,958
WTP €10,000 35%
WTP €20,000 51%
WTP €40,000 74%
Upper right quadrant 80%
Upper left (inferior) quadrant 0%
Lower left quadrant 0%
Lower right (dominant) quadrant 20%

Trends, Limitations, Comments and Source of Funding

Significant trends

The median incremental cost-effectiveness ratio was estimated at €3683 per additional treatment responder and €14,710 per quality-adjusted life-year (QALY) gained. At a willingness to pay €20,000 for 1 additional QALY, IT had a 60% likelihood of being more cost effective than IS. Sensitivity analyses attested to the robustness of the findings.

General comments

No comment

Reported limitations

Reviewer

No comment

Author

generalisability of the cost data; time horizon in this analysis;

Source of funding

Grant #31160006 from the Netherlands ZonMw Addiction II Program (Risk Behavior and Dependency)

Economic Studies not included but presented for information:

Tariq L, van den Berg M, Hoogenveen RT, van Baal P H. (2009). Cost-effectiveness of an opportunistic screening programme and brief intervention for excessive alcohol use in primary care. PLoS One 4(5): e5696

Effective prevention of excessive alcohol use has the potential to reduce the public burden of disease considerably. We investigated the cost-effectiveness of Screening and Brief Intervention (SBI) for excessive alcohol use in primary care in the Netherlands, which is targeted at early detection and treatment of 'at-risk' drinkers.

Methodology and Results: We compared a SBI scenario (opportunistic screening and brief intervention for 'at-risk' drinkers) in general practices with the current practice scenario (no SBI) in The Netherlands. We used the RIVM Chronic Disease Model (CDM) to extrapolate from decreased alcohol consumption to effects on health care costs and Quality Adjusted Life Years (QALYs) gained. Probabilistic sensitivity analysis was employed to study the effect of uncertainty in the model parameters. In total, 56,000 QALYs were gained at an additional cost of 298,000,000 euros due to providing alcohol SBI in the target population, resulting in a cost-effectiveness ratio of 5,400 euros per QALY gained.

Conclusion: Prevention of excessive alcohol use by implementing SBI for excessive alcohol use in primary care settings appears to be cost-effective.

Månsdotter AM, Rydberg MK, Wallin E, Lindholm LA, Andréasson S. (2007). A cost-effectiveness analysis of alcohol prevention targeting licensed premises. European Journal of Public Health 17(6): 618-623

Background: A multi-component alcohol prevention programme targeting licensed premises has been ongoing in Stockholm since 1996. An earlier study as established that this led to a 29% reduction in police-reported violence. The objective of the present study is to calculate the programme's cost-effectiveness from a societal perspective; the cost of implementation, the savings made as a result of fewer assaults, unlawful threats and violence towards officials, and the health gains in terms of quality-adjusted life-years (QALYs).

Methods: The costs included administration, studies of alcohol serving practices, community mobilization, responsible beverage service training and stricter alcohol law enforcement. For the purpose of estimating how the decrease in violence affected savings and health gains, a survey among victims of violence (N=604) was performed.

Results: The cost of the programme was estimated at Euro 796,000. The average cost of a violent crime was estimated at Euro 19,049, which implies overall savings of Euro 31.314 million related to the judicial system (78%), production losses (15%), health care issues (5%) and other damages (2%). Accordingly, the base case cost-saving ratio was 1:39. The average loss of health state weighting among the victims at 0.09 translates into 236 gained QALYs for society as a whole, which should be compared with the modest proportion of savings in the health sector.

Conclusion: The most significant concern is the low response rate (35%), and caution needs to be exercised when interpreting our results. Yet, a reasonable conclusion is that the monetary and human benefits have been considerable.

Barrett B, Byford S, Crawford MJ, Patton R, Drummond C, Henry JA, Touquet R. (2006). Cost-effectiveness of screening and referral to an alcohol health worker in alcohol misusing patients attending an accident and emergency department: A decision-making approach. Drug and Alcohol Dependence 81(1): 47-54

We present the cost and cost-effectiveness of referral to an alcohol health worker (AHW) and information only control in alcohol misusing patients. The study was a pragmatic randomised controlled trial conducted from April 2001 to March 2003 in an accident and emergency department (AED) in a general hospital in London, England. A total of 599 adults identified as drinking hazardously according to the Paddington Alcohol Test were randomised to referral to an alcohol health worker who delivered a brief intervention (*n* = 287) or to an information only control (*n* = 312). Total societal costs, including health and social services costs, criminal justice costs and productivity losses, and clinical measures of alcohol consumption were measured. Levels of drinking were observably lower in those referred to an AHW at 12 months follow-up and statistically significantly lower at 6 months follow-up. Total costs were not significantly different at either follow-up. Referral to AHWs in an AED produces favourable clinical outcomes and does not generate a significant increase in cost. A decision-making approach revealed that there is at least a 65% probability that referral to an AHW is more cost-effective than the information only control in reducing alcohol consumption among AED attendees with a hazardous level of drinking.

Mortimer D, Segal L. (2005). Economic evaluation of interventions for problem drinking and alcohol dependence: Cost per QALY estimates. Alcohol and Alcoholism 40(6): 549-555

To compare the performance of competing and complementary interventions for prevention or treatment of problem drinking and alcohol dependence. To provide an example of how health maximising decision-makers might use performance measures such as cost per quality adjusted life year (QALY) league tables to formulate an optimal package of interventions for problem drinking and alcohol dependence.

Methods: A time-dependent state-transition model was used to estimate QALYs gained per person for each intervention as compared to usual care in the relevant target population.

Results: Cost per QALY estimates for each of the interventions fall below any putative funding threshold for developed economies. Interventions for problem drinkers appear to offer better value than interventions targeted at those with a history of severe physical dependence.

Conclusions: Formularies such as Australia's Medicare should include a comprehensive package of interventions for problem drinking and alcohol dependence.

Fleming MF, Mundt MP, French MT, Manwell LB, Stauffacher EA, Barry KL. (2002). Brief physician advice for problem drinkers: long-term efficacy and benefit-cost analysis. Alcoholism: Clinical and Experimental Research 26(1): 36-43

This report describes the 48-month efficacy and benefit-cost analysis of Project TrEAT (Trial for Early Alcohol Treatment), a randomized controlled trial of brief physician advice for the treatment of problem drinking.

Methods: Four hundred eighty-two men and 292 women, ages 18-65, were randomly assigned to a control (n = 382) or intervention (n = 392) group. The intervention consisted of two physician visits and two nurse follow-up phone calls. Intervention components included a review of normative drinking, patient-specific alcohol effects, a worksheet on drinking cues, drinking diary cards, and a drinking agreement in the form of a prescription.

Results: Subjects in the treatment group exhibited significant reductions ($p < 0.01$) in 7-day alcohol use, number of binge drinking episodes, and frequency of excessive drinking as compared with the control group. The effect occurred within 6 months of the intervention and was maintained over the 48-month follow-up period. The treatment sample also experienced fewer days of hospitalization ($p = 0.05$) and fewer emergency department visits ($p = 0.08$). Seven deaths occurred in the control group and three in the treatment group. The benefit-cost analysis suggests a 43,000 dollars reduction in future health care costs for every 10,000 dollars invested in early intervention. The benefit-cost ratio increases when including the societal benefits of fewer motor vehicle events and crimes.

Conclusions: The long-term follow-up of Project TrEAT provides the first direct evidence that brief physician advice is associated with sustained reductions in alcohol use, health care utilization, motor vehicle events, and associated costs. The report suggests that a patient's personal physician can successfully treat alcohol problems and endorses the implementation of alcohol screening and brief intervention in the US health care system.

APPENDIX A.13 Evidence table WEIGHT MANAGEMENT – Primary Studies

Authors: Maiorana A, O'Driscoll G, Dembo L, Goodman C, Taylor R, Green D
Year: 2001
Citation: Medicine and Science in Sports and Exercise 33(12): 2022-2028.
Country of study: Australia
Aim of study: To investigate the effect of eight weeks of exercise training on functional capacity, muscular strength, body composition, and vascular function in sedentary but healthy subjects
Study design: Randomised crossover protocol
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population Not reported **Number of people** 19 **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** Control Non-training control Experimental **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Exercise : 8 weeks of supervised moderate intensity exercise -circuit training, combined aerobic and resistance exercise. Exercise bicycle, seven resistance exercises (dual seated leg press, left and right hip extension, pectoral exercises, shoulder extension, seated abdominal flexion, and dual leg flexion) **Setting** Not reported **Delivery** Not reported **Length of follow-up** 16 week	**Method of allocation** Not reported **Measurement of exposure** Laboratory **Comparator** Not applicable

Outcomes and Analysis

Outcomes Body composition	**Outcome measurement** Haematological and biochemical profile, self-report **Analysis strategy** Presented as means and SD

	Confounders Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Body weight (kg) 84.5 ± 3.5 84.3 BMI 26.9 ± 0.1 26.8 Waist:Hip (%) 0.92 ± 0.02 Exercise Test Workload (60w) Heart rate 106 ± 3 Systolic BP 163 ± 5 Rate pressure product 17313 ± 676 Rate perceived exertion 8.9 ± 0.4 Exercise Test Workload (140 W) Heart rate 152 ± 4 Systolic BP (mm Hg) 220 ± 8 Rate pressure product 32433 ± 1487 Rate perceived exertion 14.9 ± 0.7 **After** Body weight (kg) 84.3 ± 3.4 BMI 26.8 ± 0.9 Waist:Hip (%) 0.90 ± 0.02 Exercise Test Workload (60w) Heart rate (beats•min-1) 100 ± 3‡ Systolic BP (mm Hg) 160 ± 5 Rate pressure product (beats•min-1•mm Hg) 15814 ± 579* Rate perceived exertion 8.9 ± 0.4 Exercise Test Workload (160 W) Heart rate 140 ± 4 Systolic BP (mm Hg) 207 ± 14 Rate pressure product 29335 ± 2446 Rate perceived exertion 13.0 ± 0.5	**Before** Not applicable **After** Not applicable
Results – Group difference Not applicable	
Trends, Limitations, Comments and Source of Funding	
Significant trends Moderate intensity circuit training designed to minimize the involvement of the arms improves functional capacity, body composition, and strength in healthy, middle-aged subjects without significantly influencing upper limb vascular function **General comments**	**Reported limitations** <u>Author</u> None reported <u>Reviewer</u> Small sample size; no control; statistical power; economic evaluation **Source of funding** Heart Foundation (Australia) and Medical Research Fund of Western Australia

Authors: Lee HJ, Kang KJ, Ju SJ, Jin MH, Park BN
Year: 2012
Citation: Healthcare Informatics Research 2012 18(3): 199-207
Country of study: Korea
Aim of study: Evaluated the effectiveness of an integrated personalised health care system
Study design: Pre and post test
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population Middle-aged and elderly women **Number of people** 69 **Locality** Gyeonggi-do and Gyeongsangnam-do **Recruitment strategy** Communities and Monastery **Response rate** Not reported	**Characteristics of population** <u>Control</u> Not applicable <u>Experimental</u> Age (yr) 35-44 25 (36.2), 45-54 17 (24.7), 55-64 5 (7.2), ≥65 22 (31.9), Mean (SD) 53.36 (14.3); Female 69 (100.0); Location Middle city in Gyeonggi-do 25 (36.2), Middle city in Gyeongsangnam-do 44 (63.8); Religion Christianity 7 (10.1), Catholicism 33 (47.8), Buddhism 18 (26.1), None 10 (14.5), Others 1 (1.4); Occupation White-collar 32 (46.4), Nuns 25 (36.2), Housewife 10 (14.5), Blue-collar 2 (2.9); Marriage Married 40 (58.0), Single 28 (40.6), Divorce 0 (0.0), Widowed 1 (1.4) **Excluded populations** those who used the system only once and gave up in the middle of the experiment **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Personalised health care system which instantly provides subjects with biofeedback on their measured body weight, BMI, body fat and blood pressure using a database that stores subjects-customized information **Setting** Not reported **Delivery** Internet **Length of follow-up** 8 weeks	**Method of allocation** Not applicable **Measurement of exposure** Not reported **Comparator** Not applicable

Outcomes and Analysis

Outcomes Body weight, body mass index, body fat, and blood pressure	**Outcome measurement** Self-report **Analysis strategy** paired samples t-test method and Pearson's correlation method

	Confounders Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Mean (SD) SE Pair 1 Pre_Weight (kg) 58.36 (8.24) 0.99 Pair 2 Pre_BMI (kg/m2) 23.59 (2.88) 0.35 Pair 3 Pre_BodyFat (%) 32.47 (4.32) 0.52 Pair 4 Pre_BP-Systolic (mmHg) 130.01 (21.31) 2.56 Pair 5 Pre_BP-Diastolic (mmHg) 82.29 (12.02) 1.45 **After** Mean (SD) SE Pair 1 Post_Weight (kg) 57.75 (7.88) 0.95 Pair 2 Post_BMI (kg/m2) 23.35 (2.82) 0.34 Pair 3 Post_BodyFat (%) 32.26 (4.26) 0.51 Pair 4 Post_BP-Systolic (mmHg) 123.29 (18.10) 2.18 Pair 5 Post_BP-Diastolic (mmHg) 77.70 (11.43) 1.38	**Before** Not applicable **After** Not applicable
Results – Group difference Correlation (r) p-value Pair 1 Pre_Weight & post_Weight (kg) 0.99 <0.001 Pair 2 Pre_BMI & post_BMI (kg/m2) 0.99 <0.001 Pair 3 Pre_BodyFat & post_BodyFat (%) 0.93 <0.001 Pair 4 Pre_BP-Systolic & post_BP-Systolic (mmHg) 0.70 <0.001 Pair 5 Pre_BP-Diastolic & post_BP-Diastolic (mmHg) 0.75 <0.001 Paired differences Mean (SD) SE [*t*] p-value Pair 1 Post_Weight - Pre_Weight (kg) -0.62 (1.24) 0.15 [-4.13] <0.001 Pair 2 Post_ BMI - Pre_BMI (kg/m2) -0.24 (0.49) 0.06 [-4.00] <0.001 Pair 3 Post_BodyFat-Pre_BodyFat (%) -0.21 (1.57) 0.19 [-1.12] 0.267 Pair 4 Post_BP-Systolic-Pre_BP-Systolic (mmHg) -6.72 (15.65) 1.88 [-3.57] <0.001 Pair 5 Post_BP-Diastolic-Pre_BP-Diastolic (mmHg) -4.59 (8.29) 1.00 [-4.60] <0.001	
Trends, Limitations, Comments and Source of Funding	
Significant trends Subjects' body weight, BMI, and blood pressure decreased significantly with respect to their individual usage of the system **General comments**	**Reported limitations** <u>Author</u> None reported <u>Reviewer</u> Did not confirm official IRB approval; no control; small sample size; statistical power; self-report; did not include any other physiological or behavioural measures; no economic evaluation **Source of funding** Korea Health 21 R&D Project, Ministry of Health & Welfare, Korea (A020602).

APPENDIX A.14 Evidence table WEIGHT MANAGEMENT – Systematic Reviews

Authors: Ali MK, Echouffo-Tcheugui JB, Williamson DF
Year: 2012
Citation: Health Affairs 31(1): 67-75
Country of study: USA
Aim of study: Assess how effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
General population

Number of people
2,916 participants with complete follow-up data

Locality
community centres, recreation centres, and faith-based organizations, health care facilities and
electronic media

Recruitment strategy
Not reported

Response rate
Study attrition (range: 0–49 percent)

Characteristics of population
55.1 years old, with body mass index of 34:0 kg=m2; 69.9 percent were female, and 70.9 percent were non-Hispanic white.

Excluded populations
Studies were excluded if they applied other weight-loss principles or commercial programs that differed from those tested in the trial.

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Lifestyle intervention aimed at weight loss (in order to prevent diabetes). Only included studies based on the Diabetes Prevention trial

Setting
Most studies were conducted in urban areas—twelve were based primarily in community environments

Delivery
Delivered by clinically trained professionals or lay educators.

Length of follow-up
Median study duration was twelve months (range: 3–12 months; mean±standard deviation: 8.8±3.9 months).

Method of allocation
Not reported

Measurement of exposure
The number of core sessions attended

Comparator
Delivered by clinically trained professionals or lay educators. Included both controlled and uncontrolled studies

Outcomes and Analysis

Outcomes Percentage change from participants' starting weight	**Outcome measurement** Not reported **Analysis strategy** Meta-analysis **Confounders** participants' characteristics, such as sex and race or ethnicity, in relation to weight loss achieved
Results **Intervention group** Not reported	**Results** **Control group** Not reported

Results – Group difference

Across all studies, mean weight change was −3.99 percent (95% confidence interval: −5.16, −2.83; I2 = 52:4 percent) at twelve-month follow-up. Weight change was comparable in studies using medical and allied health professionals (−4.27 percent;95%confidence interval: −5.85, −2.70), those using lay community educators (−3.15 percent; 95% confidence interval: −5.46, −0.83), and those using electronic media–assisted interventions (−4.20 percent; 95% confidence interval: −7.62, −0.77).

Studies with a nine-month or greater follow-up assessment showed similar weight change. With every additional lifestyle session attended, weight loss increased by 0.26 percentage point.

Trends, Limitations, Comments and Source of Funding

Significant trends Lifestyle intervention programs that adapted the Diabetes Prevention Program curriculum achieved clinically significant (4–5 percent) weight loss and maintained this over nine months of follow-up. **General comments**	**Reported limitations** <u>Reviewer</u> XXX <u>Author</u> Precision of estimates was limited by the small number of participants included in published studies and by heterogeneity in study designs, interventions, analyses, outcomes, and reporting across studies; studies predominantly included female, non-Hispanic white participants; lack of descriptive details in some published studies may have resulted in minor misclassification of some program features **Source of funding** Not reported

Authors: Armstrong MJ, Mottershead TA, Ronksley PE et al
Year: 2011
Citation: Obesity Reviews 12(9): 709-723
Country of study: International
Aim of study: Motivational interviewing to improve weight loss in overweight and/or obese patients: a systematic review and meta-analysis of randomized controlled trials.
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population Adults **Number of people** 22 to 599 **Locality** Not reported **Recruitment strategy** Not reported **Response rate** Not reported	**Characteristics of population** 41-62 years (included studies), proportion of women from 3% to 100%. Mean baseline BMI ranged from 27.1 to 37.9 while mean age ranged from 41 to 62 years. **Excluded populations** Children or adolescents **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Motivational interviewing to improve weight loss in overweight and/or obese participants. **Setting** Not reported **Delivery** Various. Individual face-to-face to telephone and group sessions. Led by nurses, psychologists, graduate students in psychology, dieticians, health counsellors and exercise scientists **Length of follow-up** Range from 3 to 18 months.	**Method of allocation** Not reported **Measurement of exposure** The dose of motivational interviewing, calculated as a product of the number of motivational interviewing sessions multiplied by mean session duration, ranged from 50 to 323 min **Comparator** Any relevant control

Outcomes and Analysis

Outcomes Body mass index (BMI; kg m^{-2}) or body weight (kg)	**Outcome measurement** Body mass index (BMI; kg m^{-2}) or body weight (kg) **Analysis strategy** Meta-analysis **Confounders** Methodological and statistical heterogeneity.

Results Intervention group	Results Control group
Not reported	Not reported

Results – Group difference

Motivational interviewing was associated with a significant reduction in body weight (kg) for those in the intervention group compared with those in the control group (WMD = -1.47 kg [95% CI -2.05, -0.88]).

For BMI the WMD was -0.25 kg m-2 (95% CI -0.50, 0.01), not sig.

Results of individual studies in overweight participants

Amrit 2009 (age not reported) n=136 inactive adults: Counselling for physical activity delivered as a 30-min individual counselling session followed by three 10- to 15-min phone calls over 12 weeks

Those in intervention group (3 months) lost 0.1 (4.6) kg from 28.3 (4.6) to 28.2 (4.6) kg and control group gained weight 1.8 (5.1) kg (from 27.9 (5.1) kg pre to 29.7 (5.1) kg post intervention.

Elliot 2007 (mean age 41) n=599 firefighters; MI for PA and diet behaviours delivered as four face-to-face sessions. Those in intervention group (12 months) gained 0.2 (3.9) kg from 27.1 (3.9) to 27.3 (3.9) kg and control group gained 0.5 (4.2) kg (from 27.9 kg pre to 28.4 kg post intervention.

Mhurchu 1998 (mean age not reported) n=97 people with hyperlipidaemia: MI for diet, 3 sessions of MI with dietary counselling. Those in intervention group (3 months) lost 0.45 (0.7) kg from and control group lost 0.44 (0.6) kg.

Trends, Limitations, Comments and Source of Funding

Significant trends

There is some evidence that motivational interviewing appears to enhance weight loss in overweight and obese patients. However the 3 individual studies in overweight populations found no significant differences between MI and control groups.

General comments

The review aimed to include studies in overweight as well as obese participants but in most of the included studies mean BMI was >30kg/m2. Nineteen studies were included but only 2 were in overweight, BMI 25-30 kg/m2 (rather than obese) populations:

Reported limitations

Reviewer

Unclear is outcomes were self-reported

Author

Heterogeneity of dose, delivery and duration of motivational interviewing interventions. Half of the included studies lacked allocation concealment and/or blinding; small number of participants; use of varying outcome measures, such as body weight
and BMI

Source of funding

Ms Armstrong is supported by the Alliance for Canadian Health Outcomes Research in Diabetes and the Gerald Webber Cosmopolitan International Club Graduate Scholarships. Mr Ronksley is supported by the Frederick Banting and Charles Best Canada Graduate Scholarship from the Canadian Institutes of Health Research. Dr Sigal is supported by a Health Senior Scholar award and Dr Hemmelgarn by a Population Health Investigator award, from the Alberta Heritage Foundation for Medical Research.

Authors: Osei-Assibey G, Kyrou I, Adi Y et al
Citation: Obesity Reviews 11(11): 769-776
Country of study: US
Aim of study: Systematic review of dietary and lifestyle interventions for weight management in adults from minority ethnic/non-White groups
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Studies were included if at least 50% of the participants were non-White minority adults (aged >18 yrs) who were overweight or obese at baseline.
Number of people

Locality
Searches for studies were not limited by country but all 19 included studies were conducted in the US.
Recruitment strategy

Response rate

Characteristics of population
Of 19 included studies, 14 involved African–Americans, one non-White Hispanics, one Japanese Americans and three in both African–Americans and non-White Hispanics.

Mean age 45-59 (in studies in overweight populations)

Excluded populations
Studies designed specifically to deal with eating disorders such as anorexia nervosa and bulimia nervosa were excluded.

Low risk/high risk population
N/A

Intervention and Comparison

Nineteen studies met the inclusion criteria.

Studies were included if:-
(i) At least 50% of the participants were non-White minority adults (aged _ 18 years). For studies with <50% non-White minorities, authors would be contacted for subgroup analysis on non-White minorities;
(ii) Interventions were RCTs involving only dietary and lifestyle changes (dietary, physical activity or behaviour modification or any of these combinations);
(iii) At least 6-month duration and
(iv) The primary outcome measure was change in weight/body mass index (BMI) between baseline and intervention end-point.

The review aimed to include studies in overweight as well as obese participants but in 17 of the 19 included studies mean baseline BMI was >30kg/m^2 so were in obese groups.

So when reporting results we have included separate analysis of 1) the studies that were

Method of allocation
Randomisation – only RCTs included.

Measurement of exposure
Not reported

Comparator
Varies across studies but generally usual care or less intervention or less intensive intervention.

See results section for control groups of individual studies in overweight populations.

in overweight participants and 2) the combined analysis and conclusions from the overall review which includes people who were overweight and/or obese at baseline.	

Outcomes and Analysis

Outcomes Weight or BMI change between baseline and endpoint.	**Outcome measurement** Not reported for individual studies **Analysis strategy** No meta-analysis conducted – narrative synthesis **Confounders** Note that majority of included studies in obese populations. However data for individual studies in overweight populations has also been reported separately (in this review and below).
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

The review aimed to include studies in overweight as well as obese participants but in most of the included studies mean baseline BMI was >30kg/m^2 so were in obese groups.

Nineteen studies were included but only 2 were in overweight, BMI 25-30 kg/m^2 (rather than obese) populations:

The overall conclusions of the review (narrative synthesis) and the conclusions of the individual studies in overweight people are reported below.

Overall conclusions (overweight and obese included)

Most of the included dietary and lifestyle interventions achieved positive weight management results in people from minority ethnic groups.

1) There is some evidence that group/family based interventions are effective in African Americans compared to individual interventions; 2) that low fat diets are effective in Black and Hispanic populations 3) that nutrition education and cookery classes with provision of fruit and vegetables are effective in African Americans; 4) there is some evidence that web based tailored weight management programmes (healthy eating and PA) are more effective than web based information only.

Interventions in overweight people

Interventions in people with pre-diabetes or diabetes

One study (Liao et al 2009) in people with impaired glucose tolerance . Significant weight loss was achieved in intervention group (-1.8 +/- 0.5 vs 0.7 +.- 0.6 kg, p= 0.002). Intervention was dietary advice based on AHA step 2 diet plus endurance exercise. Control group followed AHA step 1 diet plus stretching exercise.

Low fat diet vs general dietary info

One study (Hall et al 2003). Intervention group received dietary advice to reduce fat intake to < 20% E, control group received a pamphlet on general dietary guidelines. Both groups lost

weight but difference between groups not stat sig.

Peer educator intervention

One study aimed at weight gain prevention (mean BMI 33, but prevention intervention) (Kennedy et al 2009). Nutrition education and cookery classes delivered by peer educators to African American women and provision of fruit and veg. Significant weight loss in the intervention group compared to control (-2.0 +/-3.2 vs 1.1 +/- 2.0 kg).

Web based tailored weight management programme vs web based information only

One study (Rothert et al, mean BMI 32 but prevention/management intervention). Significantly greater weight loss in web based weight management programme (healthy eating and PA) compared with information only group -1.21 +/-0.1 vs -0.48 +/- 0.2 kg (p=0.007).

Trends, Limitations, Comments and Source of Funding

Significant trends

General comments

As the Ossei-Assibey review aimed to include studies in both overweight and obese participants, and only overweight participants were included in the review for NICE, both the overall results of the review and the results of individual studies in overweight participants have been included.

Reported limitations

Reviewer

Author

Significant drawbacks were noted for several of these studies, such as small sample size, high attrition rates and lack of follow-up data. Better quality and long-term trials are required in order to investigate in detail the effectiveness of lifestyle changes for weight management in these populations.

Source of funding

Not reported

Authors: Rioux J, Ritenbaugh C
Year: 2013
Citation: Alternative Therapies in Health & Medicine 19(3)
Country of study: International
Aim of study: Narrative review of yoga intervention clinical trials including weight-related outcomes.
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Adults and children

Number of people
665 people from 17 studies included in qualitative synthesis. Sample sizes ranged from 9 to 106.

Locality
International studies sought but all included studies conducted in US (n=5), India (n=10), Thailand (n=1), Sweden (n=1).

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
Seven of 17 included studies had healthy population samples, 10 studies enrolled participants with risk profiles for or diagnoses of obesity, CVD, hypertension, and diabetes, some with multiple risk factors or diagnoses.

Excluded populations
Mechanistic studies, systematic reviews, studies with no quantitative weight related outcomes, studies on binge eating or anorexia.

Low risk/high risk population
N/A

Intervention and Comparison

Yoga intervention studies in adults or children with quantitative weight or obesity-related outcomes. Only RCTs and uncontrolled pre-post designs included.

Study quality and effectiveness assessed using the study's (1) duration, (2) frequency of yoga practice, (3) intensity of (length of) each practice, (4) number of yogic elements, (5) inclusion of dietary modification, (6) inclusion of a residential component, (7) the of weight-related outcome measures, and (8) a discussion of the details of the yogic elements.

Method of allocation
Randomisation or pre-post test design

Measurement of exposure
N/A

Comparator
Wait-list control, usual care (including recommended diet and lifestyle advice in some instances), health education materials, therapeutic advice.

Outcomes and Analysis

Outcomes
<u>Weight and BMI</u>
Only one study directly compared individual weight change scores between groups, 4 studies provided data on pre-post individual

Outcome measurement
Not reported if outcomes were self-reported or measured.

Analysis strategy
Narrative synthesis and tabulation of individual

change scores related to weight, 8 included BMI as an outcome measure. Body composition Body composition measures reported included % body fat (4 studies), fat mass (4 studies), lean mass (3 studies), waist and hip circumference (3 studies), waist to hip ratio (2 studies).	study results. **Confounders** Not reported.
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Of 17 included studies, 8 were randomised controlled trials and 9 were of pre-post test design.

Effect on weight and BMI
Weight was reported in 7 of the RCTs and BMI was reported in 3 RCTs.

Of the 7 RCTs that reported weight outcomes, only one appears to have reported between group difference which was not significant, 6 reported pre-post changes in intervention group of which 4 were significant, one not significant and for one the significance was unclear.

Of the 3 RCTs that reported BMI outcomes, only one reported between group difference which was not significant, one reported pre-post reduction in intervention group which was significant and for one the significance was unclear.

The authors concluded that yoga interventions achieve gradual moderate reductions in weight and BMI.

Effect on body composition
Of the 17 included studies, 3 reported no significant change, 13 reported significant improvement in one or more aspects, one reported no measures of significance.

None of the studies provided data on longer term follow up.

Overall conclusions of the narrative synthesis: 1) programmes with a dietary component appear to be more successful 2) programmes with a residential component appear to be more successful 3) higher frequency of practice appears to be more effective than intensity (length of session) 4) practice sessions including 60 minutes of sustained asana practice appear to be adequate in achieving a beneficial result when combined with pranayama and meditation as the 3 core components of an intervention 5) programmes incorporating a higher number of yogic elements appear to be more effective 6) yoga interventions for weight loss also appear to be effective for prevention of obesity or weight maintenance.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** The data is limited. While 8 of 17 included studies were RCTs only one appears to have	**Reported limitations** Reviewer While there is evidence of effectiveness of yoga interventions on weight and BMI reduction and improvement of body

reported between group difference as an outcome the rest appear to have reported pre-post differences.	composition, the quality and analysis of the data is limited. <u>Author</u> Small sample size and short duration of studies. Studies vary in overall quality and methodological rigour. Sample sizes are often small, and studies may not be randomized, blinded, or controlled. The orientation, intensity, comprehensiveness, and duration of yoga therapy for obesity also vary widely across reported studies, making direct comparisons difficult. **Source of funding** NIH-NCCAM grant, the Arizona Complementary and Alternative Medicine Research Training Program.

APPENDIX A.15 Evidence table MULTIPLE COMPONENT - Primary Studies

Authors: Gaston MH, Porter GK, Thomas VG
Year: 2007
Citation: Journal of the National Medical Association 99(4): 428
Country of study: USA
Aim of study: To evaluate the effectiveness of Prime Time Sister Circles
Study design: Pre-test and post-test
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population African-American women aged >35 **Number of people** 134 **Locality** Illinois; Washington, DC; Florida; and Maryland **Recruitment strategy** Recruitment from sites intervention was delivered **Response rate** Not reported at baseline, 77.7% at six months and 88.1% at 12 months.	**Characteristics of population** Mean Age 54.4 years; SD=9.46; Age (Years) 35-44 18.0, 45-55 36.1, 56 45.9; Children Yes 79.9; Education Level High school or less 2.3, High school diploma 4.5, Some college/technical 26.5; College graduate 66.7; Marital Status Widowed 11.2, Divorced 20.1, Separated 5.2, Married 42.5, Not married, with live-in partner 3.7; Single, no live-in partner 17.2; Employment Status Employed 50.7, Retired 18.7, Not employed 4.5; Personal Yearly Income <$20,000 8.7, $20,001-30,000 15.9, $30,001-40,000 15.1, $40,001-50,000 15.1, >$50,001 45.2 **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Educational workshop and a “sister-to-sister” support structure **Setting** Four churches, a state health education centre, a mental health centre, a community centre, a hospital, a feminist bookstore, a predominantly African-American college and a social club **Delivery** workshop conducted by the mid-life African-American female co-leaders of the project **Length of follow-up** 12 months	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** Comparison group received an educational book but did not receive a curriculum, facilitator, expert consultants or stipend

Outcomes and Analysis

Outcomes Perception of overall health, self-care, Nutrition and eating patterns	**Outcome measurement** Self-report questionnaire **Analysis strategy** T tests

	Confounders Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Not reported **After** Percent Reported Change "a Lot" Utilized stress management strategies 66.0% Prioritized their health before care of others 65.3% Incorporated healthy eating habits 78.4% Engaged in regular exercise 58.5% Changed diet to prevent disease 100.0%	**Before** Not reported **After** Not reported
Results – Group difference	
Trends, Limitations, Comments and Source of Funding	
Significant trends Statistically significant increase in the women's involvement in physical activity at 12 months. A significant.10-week difference was found in the women's diet, with them reporting eating more nutritious foods **General comments**	**Reported limitations** <u>Author</u> Small number of comparison groups and sample size; non-random recruitment and assignment to the intervention and comparison groups; participants were mostly college-educated, middle-income women; self-report data <u>Reviewer</u> Does not report baseline measures; does not report intervention and comparison group data separately **Source of funding** The Ford Foundation and the Office of Policy & Planning, of the School of Medicine, University of Maryland.

Authors: Lakerveld J, Bot SD, Chinapaw MJ et al
Year: 2013
Citation: International Journal of Behavioral Nutrition and Physical Activity 10(1): 47
Country of study: Netherlands
Aim of study: Assess the effectiveness of a primary care based lifestyle intervention to reduce the estimated risk of developing T2DM and for CVD mortality, and to motivate changes in lifestyle behaviours
Study design: Parallel group randomized controlled trial
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population	**Characteristics of population**
Adults with ≥10% estimated risk of T2DM and/or CVD mortality **Number of people** 622 **Locality** West-Friesland, the Netherlands **Recruitment strategy** Invitation letter asking people to participate **Response rate** Not reported	Control Female 185 (60.1); Age (yrs), mean (SD) 43.4 (5.5); Level of education ≤Primary 103 (33.6), Secondary 145 (47.1) , College, university 59 (19.2); Family history of diabetes 77 (25.0); Anthropometrics, mean (SD) Body weight (kg) 90.7 (15.4); Waist circumference (cm) 96.7 (9.7); Blood pressure Systolic (mmHg) 129.3 (13.3); Diastolic (mmHg) 73.8 (9.0) Experimental Female 178 (56.7); Age (yrs), mean (SD) 43.6 (5.1); Level of education ≤Primary 101 (32.5), Secondary 141 (44.9), College, university 69 (22.0); Family history of diabetes 94 (29.9); Anthropometrics, mean (SD) Body weight (kg) 90.2 (15.5); Waist circumference (cm96.7 (9.8); Blood pressure Systolic (mmHg) 128.7 (13.2) , Diastolic (mmHg) 73.0 (9.9) **Excluded populations** Participants with a fasting glucose >7.0 mmol/L **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention	**Method of allocation**
Theory-based lifestyle intervention based on an innovative combination of motivational interviewing and problem solving treatment **Setting** 12 general practices **Delivery** Trained practice nurses **Length of follow-up** 12 month	Computerized random number generator **Measurement of exposure** Self-report **Comparator** Control group received existing health brochures

Outcomes and Analysis

Outcomes	**Outcome measurement**
Estimated diabetes risk, estimated risk for	Self-report

CVD mortality, diet, physical activity and smoking	**Analysis strategy** Linear and logistic regression analysis **Confounders** Adjusted for baseline
Results **Intervention group**	**Results** **Control group**
Before Risk scores ARIC 19.0 (7.8) SCORE 4.0 (3.0) Physical activity light activities 283 (163;392) moderate activities 56 (19;150) vigorous activities 0 (0;17) meeting recommendations n (%) 201 (64.0) Dietary behaviors pieces of fruit per day 1.1 (0.9) meeting recommendations fruit intake n (%) 63 (20.1) vegetable intake (grams per day) 148 (69.5) meeting recommendations veg. intake n (%)d 72 (22.9) Smoking behavior smokers n (%) 74 (23.9) **After** Risk scores ARIC 18.5 (8.3) SCORE 4.0 (3.0) Physical activity light activities 266 (171;378) moderate activities 52 (21;138) vigorous activities 0 (0;17) meeting recommendations n (%) 162 (51.6) Dietary behaviors pieces of fruit per day 1.1 (0.9) meeting recommendations fruit intake n (%) 58 (18.5) vegetable intake (grams per day) 156 (74.6) meeting recommendations veg. intake n (%)d 62 (19.7) Smoking behaviors smokers n (%) 46 (18.3)	**Before** Risk scores ARIC 18.8 (8.5) SCORE 3.8 (2.9) Physical activity light activities 270 (150;371) moderate activities 47 (19;120) vigorous activities 0 (0;17) meeting recommendations n (%) 184 (59.7) Dietary behaviours pieces of fruit per day 1.1 (0.8) meeting recommendations fruit intake n (%) 67 (21.8) vegetable intake (grams per day) 150 (70.4) meeting recommendations veg. intake n (%)d 63 (20.5) Smoking behaviour smokers n (%) 54 (17.6) **After** Risk scores ARIC 17.8 (9.2) SCORE 3.7 (4.6) Physical activity light activities 261 (137;364) moderate activities 56 (26;126) vigorous activities 0 (0;17) meeting recommendations n (%) 160 (51.9) Dietary behaviors pieces of fruit per day 1.2 (0.9) meeting recommendations fruit intake n (%) 68 (22.1) vegetable intake (grams per day) 157 (89.9) meeting recommendations veg. intake n (%)d 56 (18.2) Smoking behavior smokers n (%)43 (17.0)
Results – Group difference β of between group difference Risk scores ARIC 0.3 (−0.6 to 1.2) SCORE −0.2 (−0.7 to 0.4)	

Physical activity
light activities 7.2 (−14.5 to 28.8)
moderate activities −9.4 (−22.0 to 3.2)
vigorous activities −0.1 (−3.3 to 3.1)
meeting recommendations n (%) OR 0.9 (0.6 to 1.4)

Dietary behaviors
pieces of fruit per day −0.1 (−0.2 to 0.0)
meeting recommendations fruit intake n (%) OR 1.4 (0.9 to 2.4)
vegetable intake (grams per day) −0.4 (−12.7 to 11.9)
meeting recommendations veg. intake n (%)d OR 0.9 (0.6 to 1.5)

Smoking behavior
smokers n (%) OR 1.1 (0.4 to 3.1)

Trends, Limitations, Comments and Source of Funding

Significant trends

Intention-to-treat analyses showed no significant differences in outcomes between the two groups at 6 or 12-months follow-up.

General comments

Reported limitations

Author

Low attendance rate; may not be enough to induce a sustainable; lifestyle behavioural change; participants in study were younger, and had a lower absolute risk of developing T2DM; sample was not culturally diverse

Reviewer

Self-reported measures of physical activity and dietary behaviour; did not set out to determine a full the cost-benefit analysis of the intervention

Source of funding

Netherlands Organisation for Health Research and Development.

Authors: Lee WK, Bang HJ
Year: 2010
Citation: Stress and Health 26(4): 341-348
Country of study: Korea
Aim of study: To ascertain whether participation in the mindfulness-based programme was associated with an increase in psychological well-being and the improvement of psychological symptoms
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population women aged 37–55 with no prior meditation experience of any form and who complained depressive mood **Number of people** 60 **Locality** Not reported **Recruitment strategy** Community newspaper advertisements **Response rate** Not reported	**Characteristics of population** Control Age (years) 40.36 (6.17); Education (years) 13.80 (2.24); Marital status (married) [n (%)] 24 (80) Experimental Age (years) 41.46 (5.41); Education (years) 14.60 (1.90); Marital status (married) [n (%)] 26 (86.7) **Excluded populations** Those under medication for depression or any other psychiatric illness **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Mindfulness-based cognitive therapy and self-compassion. Participants received materials and a meditation audiofile **Setting** Not reported **Delivery** Via clinical psychologist **Length of follow-up** 8 week	**Method of allocation** Not reported **Measurement of exposure** Self-report **Comparator** Wait-list control

Outcomes and Analysis

Outcomes Psychological well-being, depression, anxiety, hostility, somatization, positive affect and negative affect	**Outcome measurement** Self-report **Analysis strategy** ANOVA with Bonferroni correction **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Before	**Before**

Psychological well-being 71.83 (10.64) positive affect 24.77 (6.68) Negative affect 23.26 (9.26) Depression 12.53 (7.52) Anxiety 20.33 (7.81) Hostility 15.03 (5.14) Somatic 21.20 (6.46) Mindfulness 45.10 (16.69) Self-compassion 77.96 (17.24) **After** Psychological well-being 86.26 (12.91) positive affect 30.36 (6.50) Negative affect 18.43 (7.83) Depression 5.90 (6.96) Anxiety 13.77 (5.86) Hostility 10.30 (3.28) Somatic 16.77 (6.03) Mindfulness 56.60 (11.64) Self-compassion 87.83 (16.97)	Psychological well-being 69.47 (7.09) positive affect 24.37 (6.41) Negative affect 24.73 (9.41) Depression 14.07 (8.36) Anxiety 22.37 (8.37) Hostility 13.27 (5.32) Somatic 23.63 (8.25) Mindfulness 49.46 (17.60) Self-compassion.86 (13.45) **After** Psychological well-being 70.93 (10.78) positive affect 23.73 (6.78) Negative affect 24.36 (8.99) Depression 13.20 (8.14) Anxiety 23.20 (7.48) Hostility 15.93 (5.51) Somatic 24.43 (7.16) Mindfulness 47.36 (16.04) Self-compassion. 71.93 (14.37)
Results – Group difference F Time × group Psychological well-being 15.38 positive affect 16.85 Negative affect 7.61 Depression 15.60 Anxiety 14.03 Hostility 34.11 Somatic 15.88 Mindfulness 9.42 Self-compassion 47.78 Effect size Time × group Psychological well-being 0.458 positive affect 0.474 Negative affect 0.349 Depression 0.460 Anxiety 0.441 Hostility 0.608 Somatic 0.463 Mindfulness 0.374 Self-compassion 0.672	
Trends, Limitations, Comments and Source of Funding	
Significant trends Participants in the mindfulness and self-compassion group programme appeared to have enhanced psychological well-being and improved psychological distress. **General comments**	**Reported limitations** <u>Author</u> Most participants were middle-aged females; small sample size; statistical power; self-report; did not include any other physiological or behavioural measures of well-being; did not include follow-up data <u>Reviewer</u> Little demographic data provided; no economic evaluation **Source of funding** Not reported

APPENDIX A.16 MULTIPLE COMPONENT Included Systematic Reviews

Authors: Aalbers T, Baars MA, Rikkert MG
Year: 2011
Citation: Ageing Research Reviews 10(4): 487-497
Country of study: International
Aim of study: evaluate whether Internet mediated lifestyle interventions can successfully change lifestyle in people aged 50 and older
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population People aged 50 and older **Number of people** A total of 4.984 participants were recruited for these studies **Locality** International **Recruitment strategy** Five different types of recruitment strategies were used. Recruitment through the general practitioner or other health care services, and newspapers both occurred five times, followed by four times mass mailings, flyers and posters. Once people were screened by telephone. **Response rate** Not reported. Interventions had an attrition rate of 18.3%.	**Characteristics of population** An average age of 54.9 years (±8.3). Overall 62.2% were female participants. When the two studies that only recruited women were excluded 55.8% of the participants were female. **Excluded populations** Not reported **Low risk/high risk population** Not reported

Intervention and Comparison

Intervention Complex and simple interventions, with tailored or generic information, and personal or automated information delivery. A total of 18 different intervention components were identified. On average 4.4 techniques were used per study with a range of 1–8 **Setting** Various **Delivery** Various **Length of follow-up** Average length of follow up time was 7	**Method of allocation** The majority of studies lacked a concise description on the sequence generation in randomisation, allocation concealment, and protection against contamination **Measurement of exposure** Out of the ten unique studies only two provided information on dose/response relationships. The first study reported that meeting the login goal for over ten weeks significantly increased weight loss in comparison to using it less than ten weeks (−4.50±3.29 kg versus −0.60±1.87 kg respectively, $p < 0.05$). In the second study participants in the highest exposure quartile lost significantly ($p = 0.0007$) more weight than people in the two lowest

months, with a range of 1.5 to 30 months	exposure quartiles **Comparator** Two types; comparing offline controls with online intervention groups and comparing online controls with online intervention groups
Outcomes and Analysis	
Outcomes Body weight; neighbourhood walking; total physical activity; % Body fat; Body weight regain; BMI; Perceived social support	**Outcome measurement** Various. **Analysis strategy** All scores reported are group differences between pre- and posttest. Cohen's d effect sizes were calculated when possible, and were computed as: d = M1− M2/σ_{pooled}, where σ_{pooled} = [(σ 1 + σ 2)/2]. **Confounders** Not reported
Results **Intervention group** **Study** **Barrera (2002)** ISELb 0.19 DSSb 1.20 **Bennett (2010)** Body weight (kg) −2.28 **Ferney (2009)** Neighborhood walking (min/wk) 17.4 Total physical activity (min/wk) 57.8 Community walking path users/non-users (min/wk) 22.6 **Hageman (2005)** Moderate or great physical activity per week (min) −265 % Body fat −0.76 VO2 max (ml/kg/min) 0.83 **Pullen (2008)** Body weight (kg) −5.0 **Svetkey (2008)** Body weight regain (kg) 5.2 **Verheijden (2004)** BMI (kg/m2) −0.02 Perceived social support −0.17	**Results** **Control group** **Study** **Barrera (2002)** ISEL −0.08 DSS 0.10 **Bennett (2010)** Body weight (kg) 0.28 **Ferney (2009)** Neighborhood walking (min/wk) 15.7 Total physical activity (min/wk) 12.7 Community walking path users/non-users (min/wk) −16.2 **Hageman (2005)** Moderate or great physical activity per week (min) −322 % Body fat −3.29 VO2 max (ml/kg/min) −2.00 **Pullen (2008)** Body weight (kg) −2.4 **Svetkey (2008)** Body weight regain (kg) 5.5 **Verheijden (2004)** BMI (kg/m2) −0.01 Perceived social support −0.07
Results – Group difference The average effect size for the online interventions in comparison to the offline and online control groups is 0.19 (±0.21) and 0.39 (±0.37), respectively. The simple interventions, both online versus online comparison, have an average effect size of	

0.15 (±0.20)

The complex offline versus online interventions the average effect size is 0.19 (±0.21)

The average effect size for complex online versus online interventions is 0.51 (±0.33)

Study
p
Barrera (2002)
ISEL p < 0.01
DSS p < 0.01
Bennett (2010)
Body weight (kg) p < 0.05
Ferney (2009)
Neighborhood walking (min/wk) p = 0.44
Total physical activity (min/wk) p = 0.32
Community walking path users/non-users (min/wk) p = 0.04
Hageman (2005)
Moderate or great physical activity per week (min) p > 0.05
% Body fat p > 0.05
VO2 max (ml/kg/min) p > 0.05
Pullen (2008)
Body weight (kg) p ≤ 0.05
Svetkey (2008)
Body weight regain (kg) p = 0.51
Verheijden (2004)
BMI (kg/m2) p = 0.12
Perceived social support p = 0.31

Cohen's d
Barrera (2002)
ISEL 0.82
DSS 0.76
Bennett (2010)
Body weight (kg) 0.41
Ferney (2009)
Neighborhood walking (min/wk) 0.05
Total physical activity (min/wk) 0.06
Community walking path users/non-users (min/wk) 0.54
Hageman (2005)
Moderate or great physical activity per week (min) 0.33
% Body fat −0.30
VO2 max (ml/kg/min) 0.42
Pullen (2008)
Body weight (kg) 0.82
Svetkey (2008)
Body weight regain (kg) 0.38
Verheijden (2004)
BMI (kg/m2) 0.06

Perceived social support −0.08	
Trends, Limitations, Comments and Source of Funding	
Significant trends On average the effect sizes are small to moderate-small however there are multiple studies reporting positive lifestyle changes in an older population **General comments**	**Reported limitations** <u>Reviewer</u> XXX <u>Author</u> Small amount of articles in this area makes it hard to draw generalised conclusions. Some studies compare online groups with online control groups, while other studies compare online groups with offline control groups, makes comparison difficult and meta-analysis impossible. All study populations (but one) are unrepresentative of the general population. Limit the literature search to articles published in English and Dutch. **Source of funding** Not reported

Authors: Ebrahim S, Taylor F, Ward K et al
Year: 2011
Citation: Cochrane Database of Systematic Reviews (1): CD001561
Country of study: International
Aim of study: To assess the effects of multiple risk factor interventions for reducing total mortality, fatal and non-fatal events from CHD and cardiovascular risk factors among adults assumed to be without prior clinical evidence CHD.
Study design: Systematic review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
General populations included workforce populations and high-risk groups (hypertension, obesity, hyperlipidaemia, type 2 diabetes or a combination of these) as well as subjects that did not have a high risk of developing CHD.

Number of people
139,256

Locality
Not reported

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
The majority of trials randomised only middle-aged adults, although younger adults were recruited by some studies. The mean age in all the trials was 50 years.

Excluded populations
Aged less than 35, over 24% had CHD

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
A health promotion activity to achieve behaviour change; more specifically counselling or educational interventions, with or without pharmacological treatments, which aim to alter more than one cardiovascular risk factor (i.e. diet, reduce blood pressure, smoking, total blood cholesterol or increase physical activity).

Setting
Individuals, families and work sites

Delivery
A variety of health professionals including physicians, nurses, nutritionists, dieticians, nurses, exercise trainers, cooks, psychotherapists and physiotherapists.

Length of follow-up
Six months to 12 years; the median follow-up

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Comparison group

time was one year.	

Outcomes and Analysis

Outcomes Total (all-cause) mortality, fatal CHD and fatal stroke events. Non-fatal CHD (including myocardial infarction, unstable angina, need for coronary bypass grafting and or percutaneous coronary intervention) and stroke events requiring hospital admission, net change in blood pressure, total blood cholesterol and smoking.	**Outcome measurement** Combined self-report and objective measures **Analysis strategy** Fixed-effect models **Confounders** Sensitivity analysis for age of trial and cluster-randomisation
Results **Intervention group** Not reported	**Results** **Control group** Not reported

Results – Group difference

Total mortality - there was no strong evidence of any reduction in the pooled analysis (RR 1.00; 95% CI 0.96 to 1.05) using a fixed-effect model.

Heart disease mortality – the pooled OR was 0.99 (95% CI 0.92 to 1.07) using a fixed-effect model

Only one of these trials reported a significant reduction in stroke mortality but the pooled relative risk favoured intervention (RR0.75; 95%CI 0.60 to 0.95)

For both systolic and diastolic blood pressure there was a significant reduction favouring intervention. The weighted mean difference between intervention and control was -2.71 mm Hg (95% CI -3.49 to -1.93) for systolic blood pressure and -2.13mmHg (95%CI -2.67 to -1.58) for diastolic blood pressure using random-effects models

Blood cholesterol levels showed a small but highly significant fall (weighted mean net difference -0.07 mmol/L; 95% CI -0.08 to -0.06)

Pooled analysis indicated a non-significant reduction in smoking prevalence (RR 0.87; 95% CI 0.75 to 1.00)

Trends, Limitations, Comments and Source of Funding

Significant trends The pooled ORs for total and CHD mortality were 1.00 (95% CI 0.96 to 1.05) and 0.99 (95% CI 0.92 to 1.07), respectively. Net changes (weighted mean differences) in systolic and diastolic blood pressure and blood cholesterol were -2.71 mmHg (95% CI -3.49 to -1.93), -2.13 mmHg (95% CI -2.67 to -1.58) and -0.24 mmol/l (95% CI -0.32 to -0.16), respectively. The OR for reduction in smoking prevalence was 0.87 (95% CI 0.75 to 1.00). Marked heterogeneity (I2 > 85%) for all risk factor analyses was not explained by co-morbidities, allocation concealment, use of antihypertensive or cholesterol-lowering drugs, or by age of trial. **General comments**	**Reported limitations** <u>Reviewer</u> No comment <u>Author</u> Not reported **Source of funding** Not reported

Authors: Hopper I, Billah B, Skiba M et al
Year: 2011
Citation: European Journal of Cardiovascular Prevention & Rehabilitation 18(6): 813-823.
Country of study: International
Aim of study: Prevention of diabetes and reduction in major cardiovascular events in studies of subjects with prediabetes: meta-analysis of randomised controlled clinical trials.
Study design: Systematic review
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
People with impaired glucose tolerance (IGT) and impaired fasting glucose (IFG)

Number of people
23192 (10 studies). The number of subjects in each study ranged from 207 to 9306.

Locality
International

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
Trials included participants with established cardiovascular disease, one or more cardiac risk factors, risk factors for diabetes, or elevated body mass index.

Mean age of participants was 52 years, range 45–64 years, and overall 47% of participants were male.

Excluded populations
Studies with less than 100 participants or follow up of less than one year.

Low risk/high risk population
Some trials included subjects with cardiovascular risk factors, others with previous cardiovascular events, so there is marked variation in risk between the trials.

Intervention and Comparison

Intervention
Interventions (including diet, exercise and pharmacological therapy), directed towards prevention of diabetes in people with IGT and IFG, with macrovascular outcomes, including all-cause and cardiovascular mortality, and/or the incidence of major cardiovascular events.

Duration of follow-up ranged from 2.8 to 6 years, with mean intervention 3.75 years. Most trials had follow-up only for the time of the intervention, but three studies reported extended follow-ups of 10.6, 20 and 6.5 years.

Method of allocation
Randomisation

Measurement of exposure
Not reported for individual trials.

Comparator
Usual care or standard health advice or limited diet advice or placebo.

Outcomes and Analysis

Outcomes
Diabetes
All-cause and cardiovascular related

Outcome measurement
Mortality data were obtained from adjudicated end-points, or extracted from death/hospital records.

mortality or the incidence of major cardiovascular events. Secondary outcomes: whether lifestyle or drug treatment was the more effective intervention. (Only data relevant to health behaviours has been extracted)	**Analysis strategy** Fixed and random effects models for meta-analysis. The fixed effect model was used if the p value was greater than 0.05 indicating homogeneity of the studies, and the random effect model was used if the p value was less than 0.05 indicating heterogeneity of the studies. **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Included lifestyle studies included interventions on tailored, detailed advice on diet, weight reduction, diet, education and exercise.

Non-drug approaches (n=3495) were superior to drug-based approaches (n=20,872) in diabetes prevention (0.52, 0.46–0.58 vs 0.70, 0.58–0.85, P<0.05). There was no difference in risk of all-cause mortality in the intervention versus control group (0.96, 0.84–1.10) and no difference in CV death (1.04, 0.61–1.78). There was a non-significant trend towards reduction in fatal and non-fatal myocardial infarction (0.59, 0.23–1.50). Fatal and non-fatal stroke was borderline reduced (0.76, 0.58–0.99) with intervention versus control.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments** All included studies in midlife populations (40 to 64 years).	**Reported limitations** <u>Reviewer</u> The review integrated drug and non drug trials but only non-drug trials are relevant to the review. <u>Author</u> Some studies relied on reporting from national agencies or hospital records of cardiovascular endpoint, so, the reliability of these reports compared with adjudicated reports is questionable. 'A further limitation of this specific study is the revising downwards of the definition of IGT and IFG over time, meaning that in earlier studies, some participants would have been enrolled in the study with what would later be considered diabetes; however given the size of the changes in the definition, we expect this effect to be minimal'. **Source of funding** Alfred Health and National Health and Medical Research.

Systematic Reviews in disadvantaged groups

Authors: Osei-Assibey G, Kyrou I, Adi Y et al
Year: 2010
Citation: Obesity Reviews 11(11): 769-776
Country of study: US
Aim of study: Systematic review of dietary and lifestyle interventions for weight management in adults from minority ethnic/non-White groups
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Studies were included if at least 50% of the participants were non-White minority adults (aged >18 yrs) who were overweight or obese at baseline.
Number of people

Locality
Searches for studies were not limited by country but all 19 included studies were conducted in the US.
Recruitment strategy

Response rate

Characteristics of population
Of 19 included studies, 14 involved African–Americans, one non-White Hispanics, one Japanese Americans and three in both African–Americans and non-White Hispanics.

Mean age 45-59 (in studies in overweight populations)

Excluded populations
Studies designed specifically to deal with eating disorders such as anorexia nervosa and bulimia nervosa were excluded.

Low risk/high risk population
N/A

Intervention and Comparison

Nineteen studies met the inclusion criteria.

Studies were included if:-
(i) At least 50% of the participants were non-White minority adults (aged _ 18 years). For studies with <50% non-White minorities, authors would be contacted for subgroup analysis on non-White minorities;
(ii) Interventions were RCTs involving only dietary and lifestyle changes (dietary, physical activity or behaviour modification or any of these combinations);
(iii) At least 6-month duration and
(iv) The primary outcome measure was change in weight/body mass index (BMI) between baseline and intervention end-point.

The review aimed to include studies in overweight as well as obese participants but in 17 of the 19 included studies mean baseline BMI was >30kg/m^2 so were in

Method of allocation
Randomisation – only RCTs included.

Measurement of exposure
Not reported

Comparator
Varies across studies but generally usual care or less intervention or less intensive intervention.

See results section for control groups of individual studies in overweight populations.

obese groups. So when reporting results we have included separate analysis of 1) the studies that were in overweight participants and 2) the combined analysis and conclusions from the overall review which includes people who were overweight and/or obese at baseline.	
Outcomes and Analysis	
Outcomes Weight or BMI change between baseline and endpoint.	**Outcome measurement** Not reported for individual studies **Analysis strategy** No meta-analysis conducted – narrative synthesis **Confounders** Note that majority of included studies in obese populations. However data for individual studies in overweight populations has also been reported separately (in this review and below).
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

The review aimed to include studies in overweight as well as obese participants but in most of the included studies mean baseline BMI was >30kg/m^2 so were in obese groups.

Nineteen studies were included but only 2 were in overweight, BMI 25-30 kg/m^2 (rather than obese) populations:

The overall conclusions of the review (narrative synthesis) and the conclusions of the individual studies in overweight people are reported below.

Overall conclusions (overweight and obese included)

Most of the included dietary and lifestyle interventions achieved positive weight management results in people from minority ethnic groups.

1) There is some evidence that group/family based interventions are effective in African Americans compared to individual interventions; 2) that low fat diets are effective in Black and Hispanic populations 3) that nutrition education and cookery classes with provision of fruit and vegetables are effective in African Americans; 4) there is some evidence that web based tailored weight management programmes (healthy eating and PA) are more effective than web based information only.

Interventions in overweight people

Interventions in people with pre-diabetes or diabetes

One study (Liao et al 2009) in people with impaired glucose tolerance . Significant weight loss was achieved in intervention group (-1.8 +/- 0.5 vs 0.7 +.- 0.6 kg, p= 0.002). Intervention was dietary advice based on AHA step 2 diet plus endurance exercise. Control group followed AHA

step 1 diet plus stretching exercise.

Low fat diet vs general dietary info

One study (Hall et al 2003). Intervention group received dietary advice to reduce fat intake to < 20% E, control group received a pamphlet on general dietary guidelines. Both groups lost weight but difference between groups not stat sig.

Peer educator intervention

One study aimed at weight gain prevention (mean BMI 33, but prevention intervention) (Kennedy et al 2009). Nutrition education and cookery classes delivered by peer educators to African American women and provision of fruit and veg. Significant weight loss in the intervention group compared to control (-2.0 +/-3.2 vs 1.1 +/- 2.0 kg).

Web based tailored weight management programme vs web based information only

One study (Rothert et al, mean BMI 32 but prevention/management intervention). Significantly greater weight loss in web based weight management programme (healthy eating and PA) compared with information only group -1.21 +/-0.1 vs -0.48 +/- 0.2 kg (p=0.007).

Trends, Limitations, Comments and Source of Funding

Significant trends

General comments

As the Ossei-Assibey review aimed to include studies in both overweight and obese participants, and only overweight participants were included in the review for NICE, both the overall results of the review and the results of individual studies in overweight participants have been included.

Reported limitations

Reviewer

Author

Significant drawbacks were noted for several of these studies, such as small sample size, high attrition rates and lack of follow-up data. Better quality and long-term trials are required in order to investigate in detail the effectiveness of lifestyle changes for weight management in these populations.

Source of funding

Not reported

Authors: Coles E, Themessl-Huber M, Freeman R
Year: 2012
Citation: Health Education Research 27(4): 624-644
Country of study: International
Aim of study: Investigating community-based health and health promotion for homeless people
Study design: Mixed-methods review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Homeless people

Number of people
1,897

Locality
Developed industrialized countries

Recruitment strategy
Various inc. locating programme at shelters, and by rapport between staff and participants

Response rate
Not reported

Characteristics of population
16 to 61 years.

Excluded populations
Non-industrialized countries and target populations who are not homeless

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Various inc. oral health promotion interventions, smoking cessation programmes, chronic disease programmes

Setting
Community setting to include hostels, shelters, drop-in centres, food banks, churches, centres for homelessness, kerbside

Delivery
Not reported

Length of follow-up
Not reported

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Control group received usual care or alternative intervention group

Outcomes and Analysis

Outcomes
Various inc. abstinence, physical health status, trust in physician, self-efficacy, intention to use service, sexual risk taking

Outcome measurement
Self-report and service utilisation

Analysis strategy
Thematic analysis

	Confounders One study adjusted for health status
Results **Intervention group** **Goldade et al.** Importance of reminding participants of follow-up visits via effective communications to promote **Okuyemi et al.** Majority of participants attended 60% of intervention sessions, 68% of participants took part in week 26 follow-up. **Lashley** 279 residents received oral health education. 203 residents received oral health screening. 218 residents received dental treatment. 18 residents completed exit questionnaire.	**Results** **Control group**

Results – Group difference

Mares and Rosenheck CICH clients receive more mental health services and substance abuse treatment, more case management and more outpatient treatment services than comparison group. CICH clients housed an average of 52% more days than comparison group participants.

Padgett et al. Housing First participants have lower rates of substance use and are less likely to leave the programme.

Rew et al. Increased self-reported knowledge between intervention and control groups. Males report more sexual risk-taking behaviours. Females score higher on cognitive and behavioural outcomes. Findings support gender-specific interventions for increased engagement

Okuyemi et al. Abstinence and quit rates higher in group receiving NRT in combination with MI addressing smoking and other barriers to quitting. Evidence of beneficial role of MI in changing addictive behaviours and engagement with smoking cessation programme.

Bradford et al. Participants receiving intervention more likely to engage with CMHC appointment (but not 2nd/3rd appointments). Substantial effect on engagement with the substance misuse programme.

Trends, Limitations, Comments and Source of Funding

Significant trends All seven intervention studies reported positive effects in participants' engagement **General comments**	**Reported limitations** <u>Reviewer</u> No comment <u>Author</u> small sample sizes, sample selection from single sites or geographic locations; losses to follow-up; self-reporting biases were evident; **Source of funding** This work was supported by the Scottish Government Health Department [grant number 121.804497].

Systematic Reviews of cost effectiveness

Authors: Bertram MY, Lim SS, Barendregt JJ et al.
Year: 2010
Citation: Diabetologia 53(5): 875-881.
Country of study: Australia
Aim of study: evaluate the cost-effectiveness of a screening programme for pre-diabetes
Study design: Modelling
Quality score: (++, + or -):

Study (eligible and selected) population

Primary data OR modelling
Microsimulation approach

Eligible population
(1) age >55 years; or (2) age >45 plus high BMI, family history of type 2 diabetes or hypertension; or (3) people from 'high-risk' groups

Number of people
8,000 individual life-histories

Locality
Australia

Recruitment strategy
Not applicable

Response rate
Not applicable

Characteristics of population
Not applicable

Excluded populations
Not applicable

Low risk/high risk population
Not applicable

Intervention and Comparison

Intervention
Three pharmaceutical therapies (acarbose, metformin and orlistat) and three lifestyle interventions (diet alone, exercise alone, and diet and exercise).

Setting
Australia

Delivery
Not applicable

Length of follow-up
Not applicable

Method of allocation
Australia

Measurement of exposure
Modelled

Comparator
pharmaceutical therapies and lifestyle interventions with a 'do nothing' scenario

Outcomes and Analysis	
Clinical Outcomes (used in CE/CU) Transitions were modelled for four health states: (1) glucose tolerance; (2) CVD; (3) stroke; and (4) renal failure in diabetes. **Service Use measures** Patient contributions to medication prescribed during GP visits. Time and travel costs attributed to the patient are also calculated **Costing** Costs are measured per patient identified and treated **Discounting** Calculated using a 3% discount rate	**Outcome measurement** Main outcome measures was estimated by calculating 1,000 second-order simulations **Perspective** Healthcare system **Analysis strategy (including key sensitivity analyses)** Discrete-time micro-simulation model, which estimates the health impact and costs of preventing diabetes among people with pre-diabetes **Confounders** Not reported
Results **Intervention group** Not reported	**Results** **Control group** Not reported

Results – CE & ICER (for basecase and sensitivity analyses)

Intervention efficacy and yearly costs of delivering each intervention

RR (SE) from meta-analysis
Diet and exercise 0.486 (0.079)
Exercise 0.488 (0.213)
Diet 0.667 (0.161)
Acarbose 0.602 (0.273)
Metformin 0.679 (0.232)
Orlistat 0.437 (0.232)

Government cost (AUD)
Diet and exercise 126
Exercise 121
Diet 102
Acarbose 248
Metformin 58
Orlistat 1,290

Patient cost (AUD)
Diet and exercise 265
Exercise 164
Diet 118
Acarbose 291
Metformin 200
Orlistat 320

Effects of six interventions as indicated per 100,000 identified cases of pre-diabetes

DALYs averted

Diet plus exercise 4,730
Exercise 4,000
Diet 2,290
Acarbose 5,700
Metformin 4,290
Orlistat 6,880
Metformin+diet plus exercise 1,100

Diabetes cases avoided
Diet plus exercise 8,150
Exercise 6,650
Diet 4,070
Acarbose 13,140
Metformin 9,900
Orlistat 15,830
Metformin+diet plus exercise 2,490

CER (AUD/DALY)a
Diet plus exercise 23,000
Exercise 30,000
Diet 38,000
Acarbose 37,000
Metformin 22,000
Orlistat 100,000
Metformin+diet plus exercise 81,000

95% uncertainty interval
Diet plus exercise 19,000–35,000
Exercise 23,000–89,000
Diet 23,000–148,000
Acarbose 25,000–134,000
Metformin 17,000–36,000
Orlistat 94,000–130,000
Metformin+diet plus exercise 14,000–130,000

CER<AUD50,000/DALY averted
Diet plus exercise 100
Exercise 86
Diet 75
Acarbose 76
Metformin 100
Orlistat 0
Metformin+diet plus exercise 64

Trends, Limitations, Comments and Source of Funding

Significant trends	**Reported limitations**
The most cost-effective intervention options	Reviewer

are diet and exercise combined, with a cost-effectiveness ratio of AUD 22,500 per disability-adjusted life year and metformin with a cost-effectiveness ratio of AUD 21,500 per DALY averted **General comments** No comment	No comment <u>Author</u> No comment **Source of funding** Australian National Health and Medical Research Council Health Services Research Grant (NHMRC HSR Grant 331558)

APPENDIX A.17 Evidence table MULTIPLE COMPONENT Economic Studies (since 2000)

Authors: Barton P, Andronis L, Briggs A et al. **Year:** 2011 **Citation:** BMJ 343: d4044 **Country of study:** England and Wales **Aim of study:** Effectiveness and cost effectiveness of cardiovascular disease prevention in whole populations: modelling study **Study design:** Modelling **Quality score: (++, + or -):**	
Study (eligible and selected) population	
Primary data OR modelling Model **Eligible population** People aged between 40 and 79 years **Number of people** Not applicable **Locality** England and Wales **Recruitment strategy** Not applicable **Response rate** Not applicable	**Characteristics of population** Not applicable **Excluded populations** See opp. **Low risk/high risk population** Not reported
Intervention and Comparison	
Intervention Legislation to reduce salt intake, ban industrial fats, **Setting** England and Wales **Delivery** Not applicable **Length of follow-up** 10 years	**Method of allocation** Not reported **Measurement of exposure** Not reported **Comparator** 'Do nothing'
Outcomes and Analysis	
Clinical Outcomes (used in CE/CU)	**Outcome measurement**

Cardiovascular events avoided, quality adjusted life years gained, and savings in healthcare costs for a given effectiveness; estimates of how much it would be worth spending to achieve a specific outcome. **Service Use measures** Not reported **Costing** Adapted the principles of the Sheffield prevention model, updating unit costs and otherwise inflating to 2008. Estimated the expected lifetime costs, life years, and QALYs after a first cardiovascular event as a function of age and sex **Discounting** Rate of 3.5% for both costs and outcomes	Modelling **Perspective** Not reported **Analysis strategy (including key sensitivity analyses)** Spreadsheet model to quantify the reduction in cardiovascular disease over a decade, assuming the benefits apply consistently for men and women across age and risk groups. And series of sensitivity analyses **Confounders** Not reported
Results **Intervention group** Not appropriate	**Results** **Control group** Not appropriate

Results – CE & ICER (for basecase and sensitivity analyses)
Discounted outcomes for intervention achieving given relative risk reduction sustained over 10 years
Relative risk reduction Cases prevented (×1000)
0.001 2
0.005 12
0.01 25
0.02 50
0.03 75
0.04 100
0.05 125
0.06 150
0.07 175
0.08 201
0.09 226
0.1 251
0.15 378
0.2 507
0.25 637
0.3 768
0.35 900
0.4 1033
0.45 1168
0.5 1304

Relative risk reduction Deaths prevented (×1000)
0.001 0.3
0.005 1.7
0.01 3.5
0.02 7.0
0.03 10

0.04 14
0.05 18
0.06 21
0.07 25
0.08 28
0.09 32
0.1 35
0.15 53
0.2 71
0.25 89
0.3 108
0.35 126
0.4 145
0.45 164
0.5 183

Relative risk reduction Life years gained (×1000)
0.001 7
0.005 37
0.01 74
0.02 149
0.03 224
0.04 299
0.05 374
0.06 449
0.07 524
0.08 600
0.09 675
0.1 751
0.15 1132
0.2 1516
0.25 1903
0.3 2294
0.35 2689
0.4 3088
0.45 3490
0.5 3895

Relative risk reduction QALYs gained (×1000)
0.001 10
0.005 49
0.01 98
0.02 197
0.03 295
0.04 394
0.05 493
0.06 592
0.07 692
0.08 791
0.09 891
0.1 990
0.15 1492
0.2 1997
0.25 2507
0.3 3021
0.35 3540
0.4 4062

0.45 4589
0.5 5121

Relative risk reduction Total savings (£m)
0.001 26
0.005 132
0.01 265
0.02 530
0.03 796
0.04 1063
0.05 1330
0.06 1597
0.07 1865
0.08 2133
0.09 2402
0.1 2671
0.15 4024
0.2 5389
0.25 6766
0.3 8155
0.35 9557
0.4 10 971
0.45 12 397
0.5 13 836

Relative risk reduction Annual equivalent savings (£m)
0.001 3
0.005 15
0.01 31
0.02 62
0.03 93
0.04 123
0.05 154
0.06 186
0.07 217
0.08 248
0.09 279
0.1 310
0.15 467
0.2 626
0.25 786
0.3 947
0.35 1110
0.4 1275
0.45 1440
0.5 1607

Discounted outcomes for intervention with given percentage reduction in systolic blood pressure sustained over 10 years
Percentage reduction in systolic blood pressure Cases prevented (×1000)
0.5 8
1 16
1.5 24
2 32
2.5 40
3 48
3.5 57

4 65
4.5 73
5 81

Percentage reduction in systolic blood pressure Deaths prevented (×1000)
0.5 1.1
1 2.2
1.5 3.3
2 4.4
2.5 5.5
3 6.7
3.5 7.8
4 8.9
4.5 10.0
5 11.2

Percentage reduction in systolic blood pressure Life years gained (×1000)
0.5 24
1 48
1.5 72
2 96
2.5 121
3 145
3.5 169
4 194
4.5 219
5 243

Percentage reduction in systolic blood pressure QALYs gained (×1000)
0.5 33
1 65
1.5 98
2 131
2.5 164
3 197
3.5 230
4 263
4.5 296
5 330

Percentage reduction in systolic blood pressure Total savings (£m)
0.5 86
1 173
1.5 260
2 347
2.5 435
3 522
3.5 610
4 699
4.5 787
5 876

Percentage reduction in systolic blood pressure Annual equivalent savings (£m)
0.5 10
1 20
1.5 30
2 40

2.5 50
3 61
3.5 71
4 81
4.5 91
5 102

Discounted outcomes for intervention with given percentage reduction in cholesterol concentration sustained over 10 years

Percentage reduction in cholesterol Cases prevented (×1000)
0.5 6
1 13
1.5 19
2 25
2.5 32
3 38
3.5 45
4 51
4.5 58
5 64

Percentage reduction in cholesterol Deaths prevented (×1000)
0.5 0.9
1 1.7
1.5 2.6
2 3.5
2.5 4.4
3 5.3
3.5 6.1
4 7.0
4.5 7.9
5 8.8

Percentage reduction in cholesterol Life years gained (×1000)
0.5 19
1 38
1.5 57
2 76
2.5 95
3 114
3.5 134
4 153
4.5 172
5 192

Percentage reduction in cholesterol QALYs gained (×1000)
0.5 26
1 51
1.5 77
2 103
2.5 129
3 155
3.5 181
4 208
4.5 234
5 260

Percentage reduction in cholesterol Total savings (£m)
0.5 68
1 136
1.5 205
2 274
2.5 343
3 412
3.5 481
4 551
4.5 621
5 691

Percentage reduction in cholesterol Annual equivalent savings (£m)
0.5 8
1 16
1.5 24
2 32
2.5 40
3 48
3.5 56
4 64
4.5 72
5 80

Discounted estimates of total population effects from reduction of 3 g/day in salt intake sustained over 10 years, by age and sex
Age groups (years) Cases prevented (×1000)
Men:
40-49 4.4
50-59 4.9
60-69 4.8
70-79 3.1
Women:
40-49 4.0
50-59 3.8
60-69 3.9
70-79 3.2
Totals 32.2

Age groups (years) Deaths prevented (×1000)
Men:
40-49 0.51
50-59 0.71
60-69 0.74
70-79 0.45
Women:
40-49 0.39
50-59 0.51
60-69 0.64
70-79 0.48
Totals 4.43

Age groups (years) Life years gained (×1000)
Men:
40-49 12
50-59 16

60-69 15
70-79 7
Women:
40-49 11
50-59 13
60-69 14
70-79 9
Totals 96

Age groups (years) QALYs gained (×1000)
Men:
40-49 21
50-59 21
60-69 17
70-79 8
Women:
40-49 19
50-59 18
60-69 16
70-79 10
Totals 131

Age groups (years) Total savings (£m)
Men:
40-49 47
50-59 53
60-69 49
70-79 28
Women:
40-49 48
50-59 46
60-69 45
70-79 31
Totals 347

Age groups (years) Annual equivalent savings (£m)
Men:
40-49 5
50-59 6
60-69 6
70-79 3
Women:
40-49 6
50-59 5
60-69 5
70-79 4
Totals 40

Discounted estimates of total population effects from intervention based on legislation against trans fats sustained over 10 years, by age and sex
Age groups (years) Cases prevented(×1000)
Men:
40-49 23
50-59 30
60-69 33
70-79 23
Women:

40-49 19
50-59 20
60-69 23
70-79 21
Totals 191

Age groups (years) Deaths prevented (×1000)
Men:
40-49 2.7
50-59 4.3
60-69 5.1
70-79 3.3
Women:
40-49 1.9
50-59 2.7
60-69 3.7
70-79 3.1
Totals 26.8

Age groups (years) Life years gained (×1000)
Men:
40-49 64
50-59 96
60-69 100
70-79 51
Women:
40-49 53
50-59 68
60-69 82
70-79 58
Totals 571

Age groups (years) QALYs gained (×1000)
Men:
40-49 107
50-59 129
60-69 119
70-79 57
Women:
40-49 92
50-59 94
60-69 95
70-79 61
Totals 754

Age groups (years) Total savings (£m)
Men:
40-49 243
50-59 322
60-69 335
70-79 200
Women:
40-49 234
50-59 239
60-69 261
70-79 199
Totals 2033

Age groups (years) Annual equivalent savings (£m)
Men:
40-49 28
50-59 37
60-69 39
70-79 23
Women:
40-49 27
50-59 28
60-69 30
70-79 23
Totals 235

Sensitivity analysis
Savings occurred even when the background risk was reduced by 5% or 50%

Trends, Limitations, Comments and Source of Funding

Significant trends
A programme across the entire population of England and Wales (about 50 million people) that reduced cardiovascular events by just 1% would result in savings to the health service worth at least £30m (€34m; $48m) a year compared with no additional intervention. Reducing mean cholesterol concentrations or blood pressure levels in the population by 5% (as already achieved by similar interventions in some other countries) would result in annual savings worth at least £80m to £100m. Legislation or other measures to reduce dietary salt intake by 3 g/day (current mean intake approximately 8.5 g/day) would prevent approximately 30 000 cardiovascular events, with savings worth at least £40m a year. Legislation to reduce intake of industrial trans fatty acid by approximately 0.5% of total energy content might gain around 570 000 life years and generate NHS savings worth at least £230m a year.

Reducing salt intake by 3 g/day might reduce mean population systolic blood pressure by approximately 2.5 mm Hg.23 This would equate to a 2% decrease in the risk reduction model. This would prevent approximately 4450 deaths from cardiovascular disease, with total discounted savings overall of approximately £347m over a decade

Banning industrial trans fats would reduce the relative risk of death from cardiovascular

Reported limitations
Reviewer
XXX

Author
made no attempt to consider recurrent events or subsequent deaths; 10 year time frame for prevention of cases; limited to people aged between 40 and 79 years at the time of the intervention; assumed relatively uniform effects across age and risk groups; the counterfactual (no intervention) implicitly assumes that the population risk of cardiovascular disease would remain constant; lacks a full probabilistic sensitivity analysis

Source of funding
PB and LA were funded by NICE. KMcP, AB, and SC were all members of the NICE Programme Development Group on cardiovascular disease prevention in populations. However, the conclusions do not necessarily reflect official NICE views. West Midlands Health Technology Assessment Collaboration (WMHTAC) and Peninsula Technology Appraisal Group (PenTAG) were funded to provide support to the NICE Centre for Public Health Excellence (CPHE).

disease by approximately 6%. Applying these benefits to the entire England and Wales population would prevent approximately 2700 deaths annually and thus gain 570 000 life years, saving the equivalent of approximately £235m a year. An intervention costing up to £230m a year would therefore still be cost saving if it achieved the desired reduction in trans fats. **General comments** No comment	

Economic studies not included but presented for information

Barton GR, Goodall M, Bower P et al. (2012) Increasing heart-health lifestyles in deprived communities: economic evaluation of lay health trainers. Journal of Evaluation in Clinical Practice 18(4): 835-840.

Rationale, aims and objectives: Cardiovascular disease (CVD) often arises from modifiable lifestyle factors. Health care professionals may lack the skills and resources to sustain behaviour change, lay 'health trainers' (LHT) offer a potential alternative. We sought to assess the cost-effectiveness of using a LHT to improve heart-health lifestyles in deprived communities.

Methods: Participants in this randomized trial were aged ≥18 years with at least one risk factor for CVD (hypertension, raised cholesterol, diabetes, BMI>30 or current smoker). Both groups received health promotion literature. LHT were also able to provide intervention participants with information, advice and support aimed at changing beliefs and behaviour. Costs and quality-adjusted life year (QALY) changes were estimated over 6 months. The cost-utility [incremental cost-effectiveness ratio (ICER)] of LHT was calculated and assessed in relation to the cost-effectiveness threshold of £20 000–30 000 per QALY. The probability of LHT being cost-effective was also calculated.

Results: Seventy-two participants were randomized to a LHT, with 38 controls. The mean cost of the LHT intervention was £151. On average, other health and social service costs fell by £21 for controls and £75 for intervention participants giving a LHT mean overall incremental cost of £98. The mean QALY gains were 0.022 and 0.028, respectively. The ICER for LHT was £14 480, yet there was a 61% chance of making the wrong decision at a £20 000/QALY threshold.

Conclusion: LHT provision was estimated to be cost-effective for people at risk of CVD. However, a large level of uncertainty was associated with that decision.

APPENDIX A.18 – Evidence table DISADVANTAGED MINORITIES Included Primary Studies

Authors: Anderssen E, Hostmark A, Holme I, Anderssen S.
Year: 2013
Citation: Journal of Immigrant and Minority Health 15(1): 101-110
Country of study: Norway
Aim of study: Increase the physical activity level in a group of Pakistani immigrant men, and to see whether any increase was associated with reduced serum glucose and insulin concentrations.
Study design: RCT
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Men living in Oslo with a Pakistani background (either born in Pakistan or having had both parents born in Pakistan) in the 25–60 year age group, who were not physically active on a regular basis

Number of people
126

Locality
Oslo, Norway

Recruitment strategy
Brief oral presentation concerning the project at six mosques and at various Muslim festivals in Oslo.

Response rate
126/182

Characteristics of population
mean (SD)
Intervention group
Age (years) 35.7 (6.1); Weight (kg) 83.7 (12); Height (cm) 174 (6.2); BMI (kg m-2) 27.1 (3.2); Waist circumference (cm) 98 (9); Total PA (CPM) 328 (138); Inactive time (h day-1) 8.4 (1.6)

Control group
Age (years) 39.7 (9.2); Weight (kg) 84.1 (14.4); Height (cm) 174 (6.2); BMI (kg m-2) 27.4 (4.2); Waist circumference (cm) 99 (11); Total PA (CPM) 281 (118); Inactive time (h day-1) 8.9 (1.5)

Excluded populations
See opp.

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Structured group exercise, group lectures, individual counselling sessions and phone call

Setting
In community and exercise facilities

Delivery
Structured presentations and sessions

Length of follow-up
5 months

Method of allocation
Random computerised list

Measurement of exposure
Not reported

Comparator
Control

Outcomes and Analysis

Outcomes PA habits and diabetes	**Outcome measurement** Venous blood samples and oral glucose test; habitual PA was assessed with an MTI Actigraph accelerometer **Analysis strategy** Repeated measures ANCOVA was used for analysing mean changes within each group and for testing differences between mean changes in the two groups. **Confounders** Adjusted for age and baseline differences
Results **Intervention group** Weight (kg) -1.7 (0.2) BMI (kg m-2) -0.5 (0.1) Waist circumference (cm) -1.9 (0.4) Total PA level (CPM) 65 (12) Inactive time (min day-1) -13 (11) MVPA (min day-1) 13 (2) Peak VO2 (mL kg-1 min-1) 7.3 (0.4) HbA1c (%) 0.06 (0.02) Glucose (mmol/L) -0.14 (0.05) Glucose-2 h (mmol/L) -0.6 (0.2)	**Results** **Control group** Weight (kg) 0.1 (0.3) BMI (kg m-2) 0.3 (0.1) Waist circumference (cm) 1.7 (0.4) Total PA level (CPM) 19 (13) Inactive time (min day-1) -14 (15) MVPA (min day-1) 4 (2) Peak VO2 (mL kg-1 min-1)b 3.7 (0.8) HbA1c (%) 0.04 (0.03) Glucose (mmol/L) -0.06 (0.1) Glucose-2 h (mmol/L) -0.6 (0.3)

Results – Group difference

BMI (kg m-2) -0.2 (-1.5–0.9)
Waist circumference (cm) -1.1 (-4.6–2.3)
Total PA (CPM)a 46 (3–89)
Inactive time (h day-1) -0.5 (-1.03–0.04)
Moderate,vigorous and very vigorous intensity physical activity (min day-1) 6.4 (-0.4–13)
HbA1c (%) -0.1 (-0.3–0.1)
Glucose (mmol/L) -0.1 (-0.5–0.1
Glucose-2 h (mmol/L) -1.2 (-2.3 to -0.1)

Multivariate analyses (n = 102)
b coefficient (±95 % CI); t value; R^2; P
Change total PA (CPM) -1.4 (-2.4 to -0.4); -3.0; 0.10; 0.003
Change inactive time (min day-1) 1.6 (0.72–2.5); 3.7; 0.13; <0.001

Trends, Limitations, Comments and Source of Funding

Significant trends There was a mean difference in PA between the two groups of 49 counts per minute per	**Reported limitations** Reviewer Did not ask when the participants performed

day, representing a 15 % (95 % CI = 8.7–21.2; P = 0.01) higher increase in total PA level in the intervention group than in the control group. **General comments** No comment	their last exercise session; no economic evaluation <u>Author</u> No comment **Source of funding** Norwegian ExtraFoundation for Health and Rehabilitation through EXTRA funds.

Authors: Begh RA, Aveyard P, Upton P et al
Year: 2011
Citation: Trials 12(1): 197
Country of study: UK
Aim of study: Compare the effectiveness of Pakistani and Bangladeshi smoking cessation outreach workers with standard care to improve access to and the success of English smoking cessation services
Study design: Exploratory Phase II cluster randomised controlled trial
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Pakistani and Bangladeshi residents

Number of people
271 intervention
169 control
524 external control

Locality
UK

Recruitment strategy
Approach people on main roads and side streets, signposting the stop smoking services

Response rate
Not reported

Characteristics
Intervention
Age in years mean (SD) 35.8 (12.6); Ethnicity n (%) Bangladeshi 8 (15.4), Pakistani 44 (84.6); Marital status n (%) Single 18 (34.6), Separated 1 (1.9), Married living with partner 28 (53.8), Unknown 5 (9.6); Employment In paid employment 18 (34.6), Unemployed 24 (46.2), Pensioner 0 (0), Full time student 5 (9.6), Unknown 5 (9.6); Type of Work n (%), Manual 29 (55.8), Clerical secretarial 4 (7.7), Managerial professional 6 (11.5), Not worked 5 (9.6), Unknown 8 (15.4); Highest Education n (%) None 14 (26.9), GCSE or equivalent 16 (30.8), A-level or equivalent 8 (15.4), Degree or equivalent 5 (9.6), Other 3 (5.8), Unknown 6 (11.5); Age of starting smoking in years mean (SD) 17.6 (6.5); Cigarettes per day mean (SD) 15 (10); Number past quit attempts mean (SD) 1 (1); Maximum length of previous quit attempt in days, median (range) 21 (1-336)

Combined control
Age in years mean (SD) 34.3 (10.4); Ethnicity n (%) Bangladeshi 26 (37.7), Pakistani 43 (62.3); Marital status n (%) Single 25 (36.2), Separated 2 (2.9), Married living with partner 42 (60.9), Unknown 0 (0); Employment In paid employment 38 (55.1), Unemployed 24 (34.8), Pensioner 1 (1.4), Full time student 6 (8.7), Unknown 0 (0); Type of Work n (%) Manual 46 (66.7), Clerical secretarial 3 (4.3), Managerial professional 9 (13.0), Not worked 7 (10.1), Unknown 4 (5.8); Highest Education n (%) None 21 (30.4), GCSE or equivalent 22 (31.9), A-level or equivalent 12 (17.4), Degree or equivalent 8 (11.6), Other 5 (7.2), Unknown 1 (1.4); Age of starting smoking in years mean (SD) 17.7 (5.0); Cigarettes per day mean (SD) 17 (7); Number past quit attempts mean (SD) 1 (1); Maximum length of previous quit attempt in days, median (range) 21 (1-672)

Excluded populations
Not reported

Low risk/high risk population

	<u>Low risk population</u> Control 58/1000 <u>High risk population</u> Intervention 63/1000 External control areas 80/1000
Intervention and Comparison	
Intervention Community based stop smoking advisors **Setting** Community **Delivery** 'Street outreach' **Length of follow-up** Six month	**Method of allocation** Census lower layer super output areas were used as the unit of allocation. Permuted blocks of four to randomise **Measurement of exposure** Outreach workers kept a copy of referral records and checked on clinic attendance **Comparator** Outreach workers with standard care
Outcomes and Analysis	
Outcomes Smoking cessation **Economic analysis** • Perspective of the NHS as payer; assessed the costs of the intervention, with benefits and costs discounted at 3.5%. • Calculated the estimated total costs and quality adjusted life years (QALYs) gained from the programme as a whole. • Costs such as the salary costs of the outreach workers included as fixed costs, as they did not change with the number of smokers recruited, while costs such as additional treatment costs were multiplied by the number of people treated. • Modelled from the short-term abstinence rate the projected long-term abstinence rate using data from the evaluation of NHS SSS [6] & studies with long-term follow up [41] to produce the number of lifetime abstainers. • Assumed no health benefit from anything other than lifetime abstinence and we calculated an estimate of the QALYs gained using a previously developed	**Outcome measurement** Self-report **Analysis strategy** Multilevel logistic regression model and X^2 tests **Confounders** Adjusted for quit proportion achieved in the seven months prior to the intervention starting

model [42]. • As quit rates are generally the primary driver of cost-effectiveness estimates [43], we used the 95% confidence interval of the rate ratio for abstinence as the only sensitivity analysis of cost-effectiveness.	
Results **Intervention group**	**Results** **Control group**
Adherence to treatments Intervention vs control RR (95%CI) Session 1 0.98 (0.94-1.02) Session 2 1.22 (0.56-2.66) Session 3 1.28 (0.59-2.78) Session 4 0.94 (0.52-1.70) Session 5 - Intervention vs external control RR (95%CI) Session 1 1.00 (0.95-1.05) Session 2 0.89 (0.61-1.30) Session 3 0.99 (0.63-1.56) Session 4 1.00 (0.57-1.76) Session 5 1.00 (0.60-1.66) Intervention vs combined control RR (95%CI) Session 1 1.00 (0.95-1.04) Session 2 0.95 (0.65-1.39) Session 3 1.08 (0.69-1.68) Session 4 0.97 (0.59-1.61) Session 5 1.50 (0.76-2.98) **Attendance at weekly clinics** Intervention vs control RR (95%CI) Session 1 1 Session 2 0.92 (0.40-2.14) Session 3 0.80 (0.34-1.90) Session 4 0.49 (0.19-1.29) Session 5 0.62 (0.17-2.19) Intervention vs external control RR (95%CI) Session 1 1 Session 2 0.90 (0.50-1.61) Session 3 1.47 (0.69-3.14) Session 4 1.02 (0.41-2.51) Session 5 1.02 (0.35-2.96) Intervention vs combined control RR (95%CI) Session 1 1	**Before** **After**

Session 2 0.90 (0.52-1.57) Session 3 1.23 (0.63-2.39) Session 4 0.82 (0.37-1.82) Session 5 0.88 (0.34-2.33)	

Results – Economic analysis

The total cost of the intervention to achieve this was £124,000; an estimated cost per QALY gained of £8,500. Applying the upper limit of the 95% confidence interval gave an estimated cost/QALY gained of £2,000. Apply- ing the lower limit for the rate ratio for increased use resulted in an estimated cost/QALY gained of over £100,000.

Trends, Limitations, Comments and Source of Funding

Significant trends

More Pakistani and Bangladeshi men made quit attempts with NHS services in intervention areas compared with control areas

General comments

The total cost of the intervention was £124,000; an estimated cost per quality-adjusted life year (QALY) gained of £8,500.

The number of smokers achieving abstinence as a proportion of all those trying to quit in the intervention areas was lower than in the control areas; retention in the behavioural support programme was somewhat lower for outreach workers than for typical SSS providers

Reported limitations

Author

Imprecisely estimated rate of uptake; clinically relevant 30% change in the number of abstinent smokers, but, as might be expected from a pilot trial, this was not statistically significant; sample size in the study precludes definitive conclusions

Reviewer

Source of funding

National Prevention Research Initiative [grant number G0501288] with support from the following organisations: British Heart Foundation; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Health & Social Care Research & Development Office for Northern Ireland; Medical Research Council; The Wellcome Trust; Welsh Assembly Government; and World Cancer Research Fund. Service support funding was provided by the Midlands General Practice Research Consortium (MidRec)

Authors: Gaston MH, Porter GK, Thomas VG
Year: 2007
Citation: Journal of the National Medical Association 99(4): 428
Country of study: USA
Aim of study: To evaluate the effectiveness of Prime Time Sister Circles
Study design: Pre-test and post-test
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
African-American women aged >35

Number of people
134

Locality
Illinois; Washington, DC; Florida; and Maryland

Recruitment strategy
Recruitment from sites intervention was delivered

Response rate
Not reported at baseline, 77.7% at six months and 88.1% at 12 months.

Characteristics of population
Mean Age 54.4 years; SD=9.46; Age (Years) 35-44 18.0, 45-55 36.1, 56 45.9; Children Yes 79.9; Education Level High school or less 2.3, High school diploma 4.5, Some college/technical 26.5; College graduate 66.7; Marital Status Widowed 11.2, Divorced 20.1, Separated 5.2, Married 42.5, Not married, with live-in partner 3.7; Single, no live-in partner 17.2; Employment Status Employed 50.7, Retired 18.7, Not employed 4.5; Personal Yearly Income <$20,000 8.7, $20,001-30,000 15.9, $30,001-40,000 15.1, $40,001-50,000 15.1, >$50,001 45.2

Excluded populations
Not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Educational workshop and a "sister-to-sister" support structure

Setting
Four churches, a state health education centre, a mental health centre, a community centre, a hospital, a feminist bookstore, a predominantly African-American college and a social club

Delivery
workshop conducted by the mid-life African-American female co-leaders of the project

Length of follow-up
12 months

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Comparison group received an educational book but did not receive a curriculum, facilitator, expert consultants or stipend.

Outcomes and Analysis

Outcomes	**Outcome measurement**

Perception of overall health, self-care, Nutrition and eating patterns	Self-report questionnaire **Analysis strategy** T tests **Confounders** Unadjusted
Results **Intervention group**	**Results** **Control group**
Before Not reported **After** Percent Reported Change "a Lot" Utilized stress management strategies 66.0% Prioritized their health before care of others 65.3% Incorporated healthy eating habits 78.4% Engaged in regular exercise 58.5% Changed diet to prevent disease 100.0%	**Before** Not reported **After** Not reported
Results – Group difference	
Trends, Limitations, Comments and Source of Funding	
Significant trends Statistically significant increase in the women's involvement in physical activity at 12 months. A significant.10-week difference was found in the women's diet, with them reporting eating more nutritious foods **General comments**	**Reported limitations** <u>Author</u> Small number of comparison groups and sample size; non-random recruitment and assignment to the intervention and comparison groups; participants were mostly college-educated, middle-income women; self-report data <u>Reviewer</u> Does not report baseline measures; does not report intervention and comparison group data separately **Source of funding** The Ford Foundation and the Office of Policy & Planning, of the School of Medicine, University of Maryland.

Authors: Goyder E, Hind D, Breckon J et al.

Year: 2014

Citation: Health Technology Assessment 18(13).

Country of study: International

Aim of study: To determine whether objectively measured physical activity is increased in those receiving physical activity 'booster' consultations delivered in a motivational interviewing style, either face to face or by telephone.

Study design: Three-arm, parallel-group, pragmatic, superiority randomised controlled trial with nested qualitative research fidelity and geographical information systems and health economic substudies.

Quality score: (++, + or -): ++

Study (eligible and selected) population

Primary data OR modelling
Primary data

Eligible population
Previously sedentary people, aged 40–64 years, living in deprived areas of Sheffield, UK, who had increased their physical activity levels after receiving a brief intervention

Number of people
282

Locality
Deprived areas of Sheffield, UK.

Recruitment strategy
Letters

Response rate
282/70,388

Characteristics of population
Gender, n (%) Male 130 (46.1), Female 152 (53.9); Employment status, n (%) Part-time 52 (18.4), Full-time 93 (33.0), Not employed 134 (47.5), Missing 3 (1.1); Ethnicity, n (%) White British 246 (87.2), Other 33 (11.7), Missing 3 (1.1); Marital status, n (%) Single 45 (16.0), Married 151 (53.5), Co-habiting 20 (7.1), Divorced/separated 55 (19.5), Widowed 11 (3.9); Stage of change, n (%) Contemplation 12 (4.3), Preparation 125 (44.3), Action 91 (32.3), Maintenance 50 (17.7), Missing 4 (1.4); Age (years) n (%) 282 (100.0), Mean (SD) 54.6 (7.3), Median (IQR) 55.3 (48.8 to 61.4), Min. to max. 40.4 to 65.5; Weight (kg) n (%) 282 (100.0), Mean (SD) 85.2 (18.7), Median (IQR) 82.9 (72.5 to 96.6), Min. to max. 46.9 to 160.0; BMI (kg/m2), n (%) 281 (99.6), Mean (SD) 30.3 (5.9), Median (IQR) 29.8 (26.3 to 33.0), Min. to max. 17.1 to 53.4

Excluded populations
Already meeting activity guidelines, if limited by chronic ill-health, if unable or unwilling to participate.

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Motivational interviewing

Setting
Community

Delivery

Method of allocation
Block size of 200 with no stratification

Measurement of exposure
'Behaviour counts' were recorded, which included giving information, MI adherent behaviours (e.g. asking permission, affirming,

DVD and information sheet **Length of follow-up** 6 month	emphasising personal control), MI non-adherent behaviours (e.g. advising, confronting, directing), open compared with closed questions and simple and complex reflections. The calculations for MITI were based on existing standards, **Comparator** Face to face or by telephone
Outcomes and Analysis	
Clinical Outcomes (used in CE/CU) Total energy expenditure (TEE) per day in kcal **Service Use measures** Not reported **Costing** The interventions will be costed, as will the consequences for the use of health and social services in general. **Discounting** Discounting QALY gains at a rate of 3.5% per annum.	**Outcome measurement** Actiheart device (CamNtech Ltd, Cambridge, UK). Chest-worn device that records heart rate, interbeat interval and physical activity. It calculates and measures activity energy expenditure. **Perspective** NHS **Analysis strategy (including key sensitivity analyses)** Intention-to-treat **Confounders** Adjusted for age, gender, BMI, total minutes of physical activity at 3 months and 1 week before randomisation, and HRQoL (SF-12v2 plus 4 total score).
Results **Intervention group** Mean (SD) Multiple imputation (≥ 4 days) (n = 55); 2235.2 (395.5); Regression imputation (≥ 4 days) (n = 52) 2281.7 (379.8); Complete cases (n = 39) 2315.5 (726.2); Complete cases (n = 38); 2217.5 (395.5); Multiple imputation (≥ 1 days) (n = 61) 2215.9 (395.5); Per protocol (n = 55) 2308.2 (646.3); Per protocol (n = 54) 2239.1 (397.1)	**Results** **Control group** Mean (SD) Multiple imputation (≥ 4 days) ; (n = 36); 2163.0 (298.9); Regression imputation (≥ 4 days) (n = 34); 2202.0 (371.3); Complete cases (n = 21); 2118.1 (298.9); Complete cases (n = 21); 2118.1 (298.9); Multiple imputation (≥ 1 days) (n = 37); 2168.4 (298.9); Per protocol (n = 36) 2177.2 (390.7); Per protocol (n = 36) 2177.2 (390.7)
Results – CE & ICER (for basecase and sensitivity analyses) **Sensitivity analysis: difference in mean TEE per day between the booster intervention group (mini plus full) and the control group at 9 months** Adjusted Mean difference 95% CI); Multiple imputation (≥ 4 days); 18.1 (−102.9 to 139.1); Regression imputation (≥ 4 days) 13.9 (−80.1 to 107.9); Complete cases 118.6 (−152.7 to 389.9); Complete cases 31.7 (−88.7 to 152.1); Multiple imputation (≥ 1 days) 14.5 (−105.6 to 134.6); Per protocol 51.5 (−137.2 to 240.2); Per protocol −7.1 (−115.8 to 101.6)	

p-value
Multiple imputation (≥ 4 days) 0.766
Regression imputation (≥ 4 days) 0.769
Complete cases 0.384
Complete cases 0.599
Multiple imputation (≥ 1 days) 0.811
Per protocol 0.589
Per protocol 0.897

Long-term physical activity scenarios assumed
Control
Scenario A
Extra years lived Mean (SE) 26.73 (0.02)
QALYs accrued Mean (SE) 12.75 (0.01)

Scenario B
Extra years lived Mean (SE) 26.73 (0.02)
QALYs accrued Mean (SE) 12.75 (0.01)

Scenario C
Extra years lived Mean (SE) 26.90 (0.02)
QALYs accrued Mean (SE) 12.81 (0.01)

Mini booster
Scenario A
Extra years lived Mean (SE) 26.71 (0.02)
QALYs accrued Mean (SE) 12.73 (0.01)

Scenario B
Extra years lived Mean (SE) 26.82 (0.02)
QALYs accrued Mean (SE) 12.78 (0.01)

Scenario C
Extra years lived Mean (SE) 26.14 (0.02)
QALYs accrued Mean (SE) 12.52 (0.01)
Full booster
Scenario A
Extra years lived Mean (SE) 26.58 (0.02)
QALYs accrued Mean (SE) 12.69 (0.01)
Scenario B
Extra years lived Mean (SE) 26.67 (0.02)
QALYs accrued Mean (SE) 12.72 (0.01)
Scenario C
Extra years lived Mean (SE) 26.18 (0.02)
QALYs accrued Mean (SE) 12.53 (0.01)

Shift in physical activity quintile
Quintiles moved between
Mean utility gain (SE) Maximum acceptable intervention cost (£)

1 (most sedentary) to 2	0.122 (0.0119)	2430.70
2 to 3	0.046 (0.0102)	914.36
3 to 4	0.043 (0.0094)	853.83
4 to 5 (most physically active)	0.032 (0.0088)	649.66

Trends, Limitations, Comments and Source of Funding

Significant trends

The mean difference in TEE per day between baseline and 3 months favoured the control arm over the combined booster arm but this was not statistically significant (–39 kcal, 95% confidence interval −173 to 95, p = 0.57).

General comments

No comment

Reported limitations

Reviewer

No comment

Author

Neither the process evaluation survey nor the topic guide for the interviews was piloted; interviews were conducted by those who delivered the intervention; economic model does not directly consider the relationship between physical activity levels and morbidity risks;

Source of funding

HTA programme as project number 07/25/02

APPENDIX A.19 – DISADVANTAGED MINORITIES Included Systematic Reviews

Authors: Chapman J, Qureshi N, Kai J
Year: 2013
Citation: British Journal of General Practice 63(607): e104-114
Country of study: Not reported
Aim of study: Effectiveness of physical activity and dietary interventions in South Asian populations
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
South Asians

Number of people
From 13 to 201

Locality
Not reported

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Only one study reported sample age range (13–81 years)

Excluded populations
Various inc. those received diabetes education, those planning a holiday during study, pregnant women, those with a knee/hip replacement

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Various inc. screening, education, exercise classes

Setting
Community, practices and health clinics

Delivery
Various inc. link workers, dieticians, fitness instructors, health visitors

Length of follow-up
From 1 month to 17 months

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Not reported

Outcomes and Analysis

Outcomes
Changes to anthropometric measures, blood pressure, and/or blood biochemistry

Outcome measurement
Combined self-report and objective anthropometric and physiological measures

Analysis strategy
Not reported

	Confounders No studies adjusted for confounding in analyses
Results **Intervention group**	**Results** **Control group**
Not reported	Not reported
Results – Group difference All studies measuring changes in weight demonstrated a reduction in kilogrammes from baseline to follow-up, ranging from a 0.9% reduction over 6–12 months to 3.4% at 17 months. Waist girth in centimetres showed small percentage decreases of 0.6 and 2.1 and reductions in body and abdominal fat were also found. Males and females reported significant improvements in salt intake and consumption of fried meat snacks following a CHD-prevention service. 49% of participants reported taking more moderate exercise	
Trends, Limitations, Comments and Source of Funding	
Significant trends Physical activity and dietary interventions with South Asian populations show modest promise but, given the paucity of controlled evaluations or use of objective measures, outcomes are difficult to interpret **General comments**	**Reported limitations** <u>Reviewer</u> Unclear reporting of analyses. Self-reporting outcomes and exposures <u>Author</u> None identified **Source of funding** This review was funded by a National Institute for Health Research Collaboration in Applied Health Research and Care (Nottinghamshire, Derbyshire and Lincolnshire) grant.

Authors: Cleland CL, Tully MA, Kee F et al
Year: 2012
Citation: Preventive Medicine 54(6): 371-380.
Country of study: International
Aim of study: Assess the effectiveness of physical activity interventions in socio-economically disadvantaged communities
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Socio-economically disadvantaged communities

Number of people
Not reported

Locality
Not reported

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Aged 18 - 75

Excluded populations
Included children but results are not reported

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Individual and group targeted interventions such as exercise vouchers, education, counselling and pedometers

Setting
Not reported

Delivery
Face to face, by telephone or a combination of both

Length of follow-up
Between 7 weeks and 24 months

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Usual care or control group

Outcomes and Analysis

Outcomes
Physical activity

Outcome measurement
Various inc. recall, questionnaires, accelerometer

Analysis strategy
Attempted to calculate a Cohen's d effect size for each intervention

Confounders
Not reported

Results Intervention group Not reported	Results Control group Not reported

Results – Group difference

Two of the 12 interventions that targeted adults showed a moderate effect on PA. Each study is reported separately.

Individually targeted interventions

Lowther et al. (2002) Cohen's da: at 4 weeks FA: 0.33 (95% CI −0.84, 0.21); EC: 0.10 (95% CI−0.39, 0.59) 3months FA: 0.27 (95% CI−0.79, 0.26); EC: 0.35 (95% CI −0.16, 0.84) 6months FA: 0.42 (95% CI 1.19, 0.41); EC: 0.69 (95% CI−0.03, 1.35) One year FA 0.27 (95% CI−1.04, 0.54); EC: 0.43 (95% CI−0.27, 1.08)

Fahrenwald et al. (2004) Cohen's d: 2.1 (95% CI 1.37, 2.71) Increased moderate PA (Intervention: 89 min per week; Control: 1 min per week)

Emmons et al. (2005) No significant difference between or within groups

Black et al. (2010) Cohen's d: 11months, 0.03 (95% CI −0.26, 0.32); 24months, 0.10 (95% CI−0.42, 0.17) Decreased log PA counts (Intervention: 0.04 at 11 months; 0.07 at 24months; control: 0.08 at 11 months; 0.06 at 24 months)

Group interventions targeting adults

Reijneveld et al. (2003) No significant within or between group differences

Kim et al. (2004) Intervention group improved PA (p≤0.001) (no control group)

Staten et al. (2004) No significant difference between groups MVPA increased in all groups: PC+HE: 22.6min per week, p≤0.05; PC+HE+CHW 22.8 min per week, p≤0.01 PC: 15.1 min per week, p≤0.001

Kolbe-Alexander et al. (2006) Significantly greater increase in reported energy expenditure in intervention group than controls (pb0.001)

Stewart et al. (2006) Non-significant increased PA (0.8 h per week) in intervention groups (no control group)

White et al. (2006) No control group; no differences between intervention groups, minutes spent walking per 'active' day decreased

Yancey et al. (2006) Significant difference between groups at 2months (pb0.05);marginal at 12months (p=0.058) Intervention group: self-rated PA level increased among participants at 2months (pb0.001); 6 months (pb0.05); but not at 12 months Control: no increase

Clarke et al. (2007) Significant increase in percentage taking >10,000 steps per day (pb0.05) (from 11.8% to 46.2% at 8 weeks); energy expenditure increased (pb0.001) by 224 kcal/day (No comparative control group data)

Speck et al. (2007) Cohen's d: 0.47 (95% CI 0.01, 0.91) (number of steps); 0.06 (95% CI −0.50, 0.39) (MET score per day) Intervention: non-significant changes (decreased steps per day (5791.3 to 5369.6); increased MET score (42.9 to 48.8) Control: decreased steps per day 5314.6 to 4094.9 (pb0.05); non-significant increase in MET score per day 49.2 to 49.8

Hovell et al. (2008) Significantly greater increase in vigorous PA and walking in intervention group than controls at 6months; Vigorous activity at 12months significantly greater in intervention group Difference in percentage achieving ACSM PA guidelines (intervention group increased from 19.1% to 63.2%; control group, 13.6% to 16.7%) at 6 months intervention: increased vigorous activity and walking (pb0.001) at 6months. Subsequent decrease in vigorous activity (p≤0.01) and walking (p≤0.011) at 12 months but remained higher than baseline Control: increased vigorous activity (p≤0.001) and walking (pb0.05) at 6months; not at 12months

Keyserling et al. (2008) Intervention: significantly increased self-reported moderate (p=0.001) and vigorous activity (p=0.003) at 6 and 12 months compared with controls No significant difference between groups in accelerometer outcomes

Resnick et al. (2008) Cohen's d: 0.01 (95% CI −0.13, 0.67) Intervention: spent significantly (p<0.05) more time in exercise than those in the control group at 12 weeks

Community interventions

Jenum et al. (2006) Between group's comparison: greater reduction in proportion of inactive people in intervention group (6.9%) Intervention group: reduced proportion reporting no heavy activity (40.5% to 32.4%); number categorised as 'active' increased by 8.1% ($p<0.05$) Control: no significant changes in PA

Cochrane and Davey (2008) Significantly more of intervention group than controls reported increased level of PA ($p\leq0.001$) (30.6% of intervention group reported beingmore physically active after one year)

Brown and Werner (2007) Intervention: participants using the rail increased (pb0.05) from 50% to 68.75%; self-reported rail rides were significantly related to higher level of moderate activity ($p<0.01$) (no control group)

Wendel-Vos et al. (2009) Significant differences between groups: intervention group women walked 2.2 h per week more ($p\leq0.05$) and reported more leisure time PA (2.1 h per week) ($p\leq0.05$) compared with controls after 4 years

Hoelscher et al. (2010) No between group significant differences Intervention: increased number of days per week played outdoors (0.3, pb0.05), days played sports activity (0.3, $p\leq0.01$) and days participated in organised PA (0.2, $p\leq0.05$) Control: significant difference in number of days per week played outdoors (0.2, $p\leq0.05$) and number days participated in organised PA (0.3, $p\leq0.01$)

Trends, Limitations, Comments and Source of Funding

Significant trends

Found that group-based interventions were effective for adults; evidence for the effectiveness of interventions targeting individuals was insufficient; limited evidence suggested that community-wide interventions produced small changes in PA.

General comments

Reported limitations

Reviewer

Heterogeneity of interventions; presents little detail on study methodology, participants, analysis and duration

Author

Non-validated measurements, lack of detail regarding sampling and high attrition rates; small sample sizes (<150 participants) and are of relatively short duration (<6 months).

Source of funding

This work was carried out as part of the PARC Study, which is funded by the National Prevention Research Initiative. CLC conducted the review as part of a PhD funded by the Department of Employment and Learning Northern Ireland (DEL). MAT, FK and MEC are cofounded by the Centre of Excellence for Public Health (Northern Ireland), a UKCRC Public Health Research Centre of Excellence. Funding from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council, Research and Development Office for the Northern Ireland Health and Social Services, and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged.

Authors: Cleland, V, Granados A, Crawford D
Year: 2013
Citation: Obesity Reviews 14(3): 197-212
Country of study: International
Aim of study: Effectiveness of interventions to promote physical activity among socioeconomically disadvantaged women
Study design: Systematic review and meta-analysis.
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Socioeconomically disadvantaged healthy women (18–64 years)

Number of people
6,339

Locality
International

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Age from 25.1 to 59.

Excluded populations
Men

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Intervention: any intervention (individually, socially, environmentally or policy targeted) focused on increasing physical activity in any setting.

Setting
Various inc. home, church, community, face to face and telephony

Delivery
Group or individual, no details provided on who delivered the intervention

Length of follow-up
From 6 weeks to 6 years (median = 5 months).

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Any control group

Outcomes and Analysis

Outcomes
“physical activity outcomes”

Outcome measurement
Self-report questionnaire, one study used objective measure

Analysis strategy
Meta-analysis

	Confounders Not reported
Results **Intervention group** **Albright et al. (2005)** G0: Pre = 33.7 (SD: 2.2) 12 m = 33.5 (SD: 1.5) G1: Pre = 33.2 (SD: 1.7), 12 m = 33.2 (SD: 3.1) **Baranowski et al. (1990)** G0: Pre = 235.5 (SD: 16.1), 14 weeks = 248.0 (SD: 29.4) G1: Pre = 241.4 (SD: 22.8), 14 weeks = 247.8 (SD: 46.6) **Brown et al. (1996)** G0: Pre = 103.5 (SD: 11.5), 12 weeks = 98.7 (SD: 14.9) G1: Pre = 114.2 (SD: 19.0), 12 weeks = 98.5 (SD: 13.9) **Chang et al. (2010)** G0: Pre = 27.3 (SD: 29.9), 42 weeks = 36.0 (SD: 29.3) G1: Pre = 29.8 (SD: 26.7), 42 weeks Post = 53.2 (SD: 30.2) **Fahrenwald et al. (2004)** G0: Pre = 32.59 (SD: 0.38), 10 weeks (change) = -0.17 (SD: 0.41) G1: Pre = 32.52 (SD: 0.39), 10 weeks (change): 0.46 (SD: 0.45) **Fjeldsoe et al. (2010)** G0: Pre = 84.0 (SE: 26.0), 13 weeks = 159.8 (SE: 29.3) G1: Pre = 164.3 (SE: 25.4), 13 weeks = 149.8 (SE: 25.0) **Hovell et al. (2008)** G0: Pre = 13.6%, 12 m = 15.2% G1: Pre = 19.1%, 12 m = 38.2% **Jacobs et al. (2004)** G0: Pre = 12.68 (SD:5.96); 12 m = 12.98 (SD: 6.96) G1: Pre = 12.84 (SD: 6.51); 12 m = 12.86(SD: 6.69) **Lucumi et al. (2006)** G0: Pre = 5.3, 7 m = 5.3 G1: Pre = 27.8, 7 m = 33.3 **Lupton et al. (2002)** G0: Pre = 81.1%; 6 years = 83.2% G1: Pre = 76.5%; **Lupton et al. (2003)** G0: Pre = 81.2%, 6 years = 80.9% G1: Pre = 73.0%, 6 years = 80.9%	**Results** **Control group**

Olvera et al. (2010) G0: Pre = 1.2 (SD: 1.5), 12 weeks = 1.2 (SD: 0.9) G1: Pre = 1.4 (SD: 0.9), 12 weeks = 2.1 (SD: 1.6) **Opdenacker et al. (2008)** G0: Pre = 1,664,013 (SD: 521,275), 6 m = 1,501,413 (SD: 594,714) G1: Pre = 1,702,474 (SD: 618,907), 6 m = 1,827,888 (SD: 687,279) **Shirazi et al. (2007)** G0: Pre = 73.9 (SD:131.2), 12 weeks = 78.9 (SD: 136.2) G1: Pre = 54.1 (SD:131.5) 12 weeks = 191.4 (SD: 231.4) **Speck et al. (2007)** G0: Pre = 5,314.6 (SD: 2,862.5) 23 weeks = 4,094.9 (SD: 2,735.9) G1: Pre = 5,791.3 (SD: 2,995.4) 23 weeks = 5,369.6 (SD: 2,786.5) **Stoddard et al. (2004)** G0: Pre = 45.8%, 12 m = 52.0% G1: Pre = 36.4%, 12 m = 54.5% **Watson et al. (2005)** G0: Pre = 22.9, 6 m = 35.4 G1: Pre = 33.3, 6 m = 43.3 **Wendel-Vos et al. (2009)** G0: Pre = 18.3 (SD: 12.8) 5 years = 17.4 (SD: 12.4) G1: Pre = 15.4 (SD: 11.7) 5 years = 17.2 (SD: 12.9) **Williams et al. (2005)** G0: 6 weeks = 31% G1: 6 weeks = 81%	
Results – Group difference Because of substantial statistical heterogeneity (X^2 = 53.61, df = 18, P < 0.0001, I^2 = 66%), an overall pooled effect is not reported. Subgroup analyses demonstrated that studies using group and those using group in combination with individual delivery modes had similar effect sizes of SMD 0.40 (95% CI 0.14–0.67) and 0.32 (95% CI 0.05–0.59), respectively. Studies with a group delivery component had a standardised mean difference of 0.38 greater than either individual or community-based delivery.	
Trends, Limitations, Comments and Source of Funding	
Significant trends Programs with a group delivery mode significantly increase physical activity among women experiencing disadvantage **General comments**	**Reported limitations** <u>Reviewer</u> 14/19 studies had a high risk of bias <u>Author</u> Self-reported physical activity measures;

	studies did not account for clustering in their study design; had to calculate SMDs and SEs from dichotomous data; substantial clinical, methodological and statistical heterogeneity; **Source of funding** V.C. is supported by a National Health and Medical Research Council Public Health Training (Postdoctoral) Fellowship. A.G. is supported by a National Health and Medical Research Council Strategic Award. T.W. is supported by a National Health and Medical Research Council/Primary Health Care Research, Evaluation and Development Career Development Fellowship. K.B. is supported by a National Health and Medical Research Council Senior Research Fellowship. D.C. is supported by a Victorian Health Promotion Foundation Senior Research Fellowship.

Authors: Coles E, Themessl-Huber M, Freeman R
Year: 2012
Citation: Health Education Research 27(4): 624-644
Country of study: International
Aim of study: Investigating community-based health and health promotion for homeless people
Study design: Mixed-methods review
Quality score: (++, + or -): ++

Study (eligible and selected) population

Eligible population
Homeless people

Number of people
1,897

Locality
Developed industrialized countries

Recruitment strategy
Various inc. locating programme at shelters, and by rapport between staff and participants

Response rate
Not reported

Characteristics of population
16 to 61 years.

Excluded populations
Non-industrialized countries and target populations who are not homeless

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Various inc. oral health promotion interventions, smoking cessation programmes, chronic disease programmes

Setting
Community setting to include hostels, shelters, drop-in centres, food banks, churches, centres for homelessness, kerbside

Delivery
Not reported

Length of follow-up
Not reported

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
Control group received usual care or alternative intervention group

Outcomes and Analysis

Outcomes
Various inc. abstinence, physical health status, trust in physician, self-efficacy, intention to use service, sexual risk taking

Outcome measurement
Self-report and service utilisation

Analysis strategy
Thematic analysis

Confounders

	One study adjusted for health status
Results **Intervention group** **Goldade et al.** Importance of reminding participants of follow-up visits via effective communications to promote **Okuyemi et al.** Majority of participants attended 60% of intervention sessions, 68% of participants took part in week 26 follow-up. **Lashley** 279 residents received oral health education. 203 residents received oral health screening. 218 residents received dental treatment. 18 residents completed exit questionnaire.	**Results** **Control group**

Results – Group difference

Mares and Rosenheck CICH clients receive more mental health services and substance abuse treatment, more case management and more outpatient treatment services than comparison group. CICH clients housed an average of 52% more days than comparison group participants.

Padgett et al. Housing First participants have lower rates of substance use and are less likely to leave the programme.

Rew et al. Increased self-reported knowledge between intervention and control groups. Males report more sexual risk-taking behaviours. Females score higher on cognitive and behavioural outcomes. Findings support gender-specific interventions for increased engagement

Okuyemi et al. Abstinence and quit rates higher in group receiving NRT in combination with MI addressing smoking and other barriers to quitting. Evidence of beneficial role of MI in changing addictive behaviours and engagement with smoking cessation programme.

Bradford et al. Participants receiving intervention more likely to engage with CMHC appointment (but not 2nd/3rd appointments). Substantial effect on engagement with the substance misuse programme.

Trends, Limitations, Comments and Source of Funding

Significant trends All seven intervention studies reported positive effects in participants' engagement **General comments**	**Reported limitations** Reviewer XXX Author small sample sizes, sample selection from single sites or geographic locations; losses to follow-up; self-reporting biases were evident; **Source of funding** This work was supported by the Scottish Government Health Department [grant number 121.804497].

Authors: Conn VS, Phillips LJ, Ruppar TM
Year: 2012
Citation: Journal of Health Care for the Poor & Underserved 23(1): 59-80
Country of study: USA
Aim of study: Physical activity interventions with healthy minority adults
Study design: Systematic review and meta-analysis
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
Minority adults.

Number of people
21,151

Locality
USA

Recruitment strategy
Not reported

Response rate
Not reported

Characteristics of population
Percentage female 100; Percentage African-American 100; Percentage Hispanic 0; Percent European-American 0; Mean age (years) 44; body mass index=25–29.9),

Excluded populations
Children and youth younger than 18 years. Participants with acute or chronic mental (e.g., schizophrenia, clinical depression, drug abuse) or physical (e.g., hypertension, diabetes, cardiovascular diseases) illnesses

Low risk/high risk population
Not reported

Intervention and Comparison

Intervention
Supervised, planned, structured, and repetitive physical activity focused on improving or maintaining physical fitness. Minutes of supervised exercise per session 38.5; Frequency per week of supervised physical activity 3; Total number of supervised exercise sessions 33

Setting
Not reported

Delivery
Twenty-five intervention delivery sites

Length of follow-up
Not reported

Method of allocation
Not reported

Measurement of exposure
Not reported

Comparator
"Any type of comparison"

Outcomes and Analysis

Outcomes
Fitness, Anthropometric outcomes, diabetes risk, mood

Outcome measurement
Self-report questionnaire

Analysis strategy
Meta-analysis

Confounders
Not reported

Results **Intervention group**	**Results** **Control group**
Estimates for supervised physical activity eS Fitness Treatment group pre- vs. post-test .584 Anthropometric outcomes Treatment group pre- vs. post-test .104 Diabetes risk Treatment group pre- vs. post-test -.064 Mood Treatment group pre- vs. post-test .410 P(eS) Fitness Treatment group pre- vs. post-test <.001 Anthropometric outcomes Treatment group pre- vs. post-test .010 Diabetes risk Treatment group pre- vs. post-test .793 Mood Treatment group pre- vs. post-test .021 95% Ci Fitness Treatment group pre- vs. post-test (.431, .737) Anthropometric outcomes Treatment group pre- vs. post-test (.025, .182) Diabetes risk Treatment group pre- vs. post-test (-.539, .412) Mood Treatment group pre- vs. post-test (.063, .757) Estimates for motivational and education physical activity eS, p (eS), (95% CI) Physical activity behaviour Treatment group pre- vs. post-test .312, <.001 (.237, .386) Anthropometric outcomes Treatment group pre- vs. post-test .070, .001 (.027, .112) Diabetes risk Treatment group pre- vs. post-test .041, .225 (-.025, .108) Quality of life Treatment group pre- vs. post-test .464, .108 (-.102, 1.031)	Estimates for supervised physical activity eS Fitness Control group pre- vs. post-test .073 Anthropometric outcomes Control group pre- vs. post-test -.036 Diabetes risk Control group pre- vs. post-test — Mood Control group pre- vs. post-test .119 P(eS) Fitness Control group pre- vs. post-test .519 Anthropometric outcomes Control group pre- vs. post-test .563 Diabetes risk Control group pre- vs. post-test — Mood Control group pre- vs. post-test .308 95% Ci Fitness Control group pre- vs. post-test (-.149, .294) Anthropometric outcomes Control group pre- vs. post-test (-.156, .085) Diabetes risk Control group pre- vs. post-test (—) Mood Control group pre- vs. post-test (-.110, .348) Estimates for motivational and education physical activity eS, p (eS), (95% CI) Physical activity behaviour Control group pre- vs. post-test .053, .251 (-.037, .142) Anthropometric outcomes Control group pre- vs. post-test -.069, .195 (-.173, .035) Diabetes risk Control group pre- vs. post-test -.521, .414 (-1.771, .729) Quality of life Control group pre- vs. post-test — , — (—)
Results – Group difference Supervised exercise significantly improved fitness (ES=.571–.584). Interventions designed to motivate minority adults to increase physical activity changed subsequent physical activity	

behaviour (ES = .172–.312) and anthropometric outcomes (ES=.070–.124).

Estimates for supervised physical activity
eS
Fitness
Treatment vs. control groups at post-test .571
Anthropometric outcomes
Treatment vs. control groups at post-test .041
Diabetes risk
Treatment vs. control groups at post-test —
Mood
Treatment vs. control groups at post-test .198

P(eS)
Fitness
Treatment vs. control groups at post-test .012
Anthropometric outcomes
Treatment vs. control groups at post-test .643
Diabetes risk
Treatment vs. control groups at post-test —
Mood
Treatment vs. control groups at post-test .365

95% Ci
Fitness
Treatment vs. control groups at post-test (.127, 1.015)
Anthropometric outcomes
Treatment vs. control groups at post-test (-.132, .214)
Diabetes risk
Treatment vs. control groups at post-test (-)
Mood
Treatment vs. control groups at post-test (-.231, .627)

Estimates for motivational and education physical activity
eS, p (eS), (95% CI)
Physical activity behaviour
Treatment vs. control groups at post-test .172, .024 (.023, .321)
Anthropometric outcomes
Treatment vs. control groups at post-test .124, .077 (-.014, .262)
Diabetes risk
Treatment vs. control groups at post-test -.024, .899 (-.393, .345)
Quality of life
Treatment vs. control groups at post-test —, — (—)

Trends, Limitations, Comments and Source of Funding

Significant trends

Interventions effectively increased PA behaviour as documented for both 2-group (ES=.172) and treatment-group pre-post (ES=.312) comparisons. Anthropometric outcomes improved significantly in the treatment group pre-post comparison, but the magnitude of the effect (ES=.070) is small and probably not clinically meaningful. The quality of life outcome ES was moderate sized (ES=.464) but did not achieve statistical significance

Reported limitations

Reviewer

No comment

Author

Intervention content and delivery with minority populations were inconsistently reported; intervention dose were inconsistently reported

Source of funding

Financial support provided by a grant from the

General comments	National Institutes of Health (R01NR009656) to Vicki Conn, principal investigator.

Authors: Ickes MJ, Sharma M

Year: 2012
Citation: Journal of Environmental & Public Health 156435
Country of study: US
Aim of study: A systematic review of physical activity interventions in Hispanic adults.
Study design: Systematic review
Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Studies were included if the participants included >35% Hispanic or Latino population (over 18 years). Hispanics or Latinos were defined as persons of Cuba, Mexico, Puerto Rico, South or Central-America, or other Spanish culture or origin, regardless of race.

Number of people
Three of the interventions were very small (n <20, six were small (n= 20–75), five were medium (n=75–150), five were large (n=150–300), and one intervention was classified with very large sample size (n= 869).

Locality
All studies conducted in the US. Interventions were limited to those published in English.

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
Nine of the interventions included a 100% Hispanic population while the others ranged from 70–80% Hispanics (*n* = 6) and 40–50% (*n* = 4).

The age of participants in the interventions ranged from 18 to 95 years, although 85% (*n* = 17) targeted middle-aged adults. Half of the interventions (*n* = 10) specifically targeted females.

Excluded populations
Exclusion criteria were articles in languages other than English and case studies.

Low risk/high risk population
Several of the interventions recruited specific populations including low income (*n* = 6), sedentary (*n* = 4), obese (*n* = 3) those with diabetes (*n* = 3) and individuals at risk for cardiovascular disease (*n* = 1).

Intervention and Comparison

Intervention
Physical activity interventions with the goal of obesity prevention. All intervention studies were eligible for inclusion, except case studies.

20 intervention studies were included. 65% of included studies (*n* =13) were RCTs. Two of the interventions were quasi-experimental which did not randomize the participants, yet still had a control or comparison group. A non-experimental design was used in four of the interventions in which control and/or comparison groups were not delineated. One of the interventions used a qualitative non-experimental design.

Method of allocation
Studies did not have to be RCTs. 65% of included studies (*n* =13) were RCTs. Two of the interventions were quasi-experimental which did not randomize the participants, yet still had a control or comparison group. A non-experimental design was used in four of the interventions in which control and/or comparison groups were not delineated. One of the interventions used a qualitative non-experimental design.

Method of allocation concealment for RCTs not reported for individual studies.

Measurement of exposure

Theory was widely incorporated into the interventions, with 75% (*n* = 15) reporting the use of some theoretical framework. Community-based settings (*n* = 14), clinical settings (*n* = 2), family and home-based (*n* = 3), and faith-based settings (*n* = 1) were also represented. Duration of the interventions ranged from one to three sessions (*n* = 2) to twelve months (*n* = 2). The duration of 90% of the interventions lasted less than one year; 1.5 to 2 months (*n* = 6), three to four months (*n* = 6) six months (*n* =3) and 9 months (*n* = 1). Duration within sessions also varied with 20-30-minute phone calls to 90-minute educational and group-led exercise sessions. Culturally appropriate messages were incorporated into 45% of the interventions, including the use of focus groups to assist in the design and implementation of culturally relevant materials.	N/A **Comparator** Not reported for all individual studies but were generally less intensive counselling, social support or phone contact, with less PA emphasis.
Outcomes and Analysis	
Outcomes Outcomes reported in individual studies varied and did not appear to be specifically specified in the design of the systematic review. Outcomes meeting inclusion criteria of NICE review included: behaviour change relating to PA (reported in 90% of studies), level, amount and frequency of PA, number of participants reaching recommended levels, type of PA; BMI, waist to hip ratio, body fat; total energy expenditure. Other outcomes:- Physical fitness, cognitive and behavioural processes of change, lipids, knowledge and social support, self efficacy and motivation, glycemic control, medications, levels of depressive symptoms and stress.	**Outcome measurement** Self-reported via logs and checklists (n=9 studies), 7 day recall (n=6), pedometers (n=1), accelerometers (n=2). BMI was measured in 55% (n=11) interventions. Other measures included clinical tests related to diabetes and/or CVD (n=9), other anthropometric measures (n=6), social support questionnaires (n=6), measures of acculturation (n=2), stage of change/motivation (n=2), fitness testing (n=4), physical activity attitudes/knowledge/awareness (n=4), self-efficacy for PA (n=2) and psychological well-being (n=2). **Analysis strategy** No statistical analysis or meta-analyses were conducted. The existing analysis reported in the reviewed articles was extracted and reported in a systematic format. **Confounders** Not reported
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

Physical activity (PA)

In interventions that measured PA as an outcome, 72% (*n* = 13) indicated an improvement. Five interventions reported an increase in minutes walking and/or associated METS. Three interventions reported an increase in individuals meeting recommended physical activity levels. Two interventions indicated an increase in MVPA and one an increase in VPA.

Two of the interventions reported a significant decrease in BMI at follow-up. Only 25% (*n* = 5) of the interventions conducted a follow-up measure; two at 2 months, one at 6 months, and two at 12 months. There was insufficient data to make conclusions about sustainability of behaviour change.

Interventions that included staff from the same ethnic group of the population reportedly improved recruitment in one study. One study reported that participants responded favourably when receiving the intervention in Spanish and appreciated information addressing culture-specific barriers to PA for Latinos.

Social support increased the likelihood of participation in two of the interventions.

Trends, Limitations, Comments and Source of Funding

Significant trends

General comments

The authors provided a number of recommendations for improving interventions among Hispanic populations:-the importance of choosing activities that are appealing and fun as well as culturally relevant. Interventions among Hispanic populations should build on their sense of culture and incorporate social support .Building in educational opportunities as well as the ability for participants to enhance self-management skills resulted in higher PA levels.

Reported limitations

Reviewer

Author

This is a narrative review and not a quantitative meta-analysis. Interventions included were limited to those published in English.

Source of funding

Not reported.

Authors: Osei-Assibey G, Kyrou I, Adi Y et al

Year: 2010

Citation: Obesity Reviews 11(11): 769-776.

Country of study: US

Aim of study: Systematic review of dietary and lifestyle interventions for weight management in adults from minority ethnic/non-White groups

Study design: Systematic review

Quality score: (++, + or -): +

Study (eligible and selected) population

Eligible population
Studies were included if at least 50% of the participants were non-White minority adults (aged >18 yrs) who were overweight or obese at baseline.

Number of people

Locality
Searches for studies were not limited by country but all 19 included studies were conducted in the US.

Recruitment strategy

Response rate

Characteristics of population
Of 19 included studies, 14 involved African–Americans, one non-White Hispanics, one Japanese Americans and three in both African–Americans and non-White Hispanics.

Mean age 45-59 (in studies in overweight populations)

Excluded populations
Studies designed specifically to deal with eating disorders such as anorexia nervosa and bulimia nervosa were excluded.

Low risk/high risk population
N/A

Intervention and Comparison

Nineteen studies met the inclusion criteria.

Studies were included if:-
(i) At least 50% of the participants were non-White minority adults (aged _ 18 years). For studies with <50% non-White minorities, authors would be contacted for subgroup analysis on non-White minorities;
(ii) Interventions were RCTs involving only dietary and lifestyle changes (dietary, physical activity or behaviour modification or any of these combinations);
(iii) At least 6-month duration and
(iv) The primary outcome measure was change in weight/body mass index (BMI) between baseline and intervention end-point.

The review aimed to include studies in overweight as well as obese participants but in 17 of the 19 included studies mean baseline BMI was >30kg/m^2 so were in obese groups.

Method of allocation
Randomisation – only RCTs included.

Measurement of exposure
Not reported

Comparator
Varies across studies but generally usual care or less intervention or less intensive intervention.

See results section for control groups of individual studies in overweight populations.

So when reporting results we have included separate analysis of 1) the studies that were in overweight participants and 2) the combined analysis and conclusions from the overall review which includes people who were overweight and/or obese at baseline.	
Outcomes and Analysis	
Outcomes Weight or BMI change between baseline and endpoint.	**Outcome measurement** Not reported for individual studies **Analysis strategy** No meta-analysis conducted – narrative synthesis **Confounders** Note that majority of included studies in obese populations. However data for individual studies in overweight populations has also been reported separately (in this review and below).
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

The review aimed to include studies in overweight as well as obese participants but in most of the included studies mean baseline BMI was >30kg/m^2 so were in obese groups.

Nineteen studies were included but only 2 were in overweight, BMI 25-30 kg/m^2 (rather than obese) populations:

The overall conclusions of the review (narrative synthesis) and the conclusions of the individual studies in overweight people are reported below.

Overall conclusions (overweight and obese included)

Most of the included dietary and lifestyle interventions achieved positive weight management results in people from minority ethnic groups.

1) There is some evidence that group/family based interventions are effective in African Americans compared to individual interventions; 2) that low fat diets are effective in Black and Hispanic populations 3) that nutrition education and cookery classes with provision of fruit and vegetables are effective in African Americans; 4) there is some evidence that web based tailored weight management programmes (healthy eating and PA) are more effective than web based information only.

Interventions in overweight people

Interventions in people with pre-diabetes or diabetes

One study (Liao et al 2009) in people with impaired glucose tolerance . Significant weight loss was achieved in intervention group (-1.8 +/- 0.5 vs 0.7 +.- 0.6 kg, p= 0.002). Intervention was dietary advice based on AHA step 2 diet plus endurance exercise. Control group followed AHA step 1 diet plus stretching exercise.

Low fat diet vs general dietary info

One study (Hall et al 2003). Intervention group received dietary advice to reduce fat intake to < 20% E, control group received a pamphlet on general dietary guidelines. Both groups lost weight but difference between groups not stat sig.

Peer educator intervention

One study aimed at weight gain prevention (mean BMI 33, but prevention intervention) (Kennedy et al 2009). Nutrition education and cookery classes delivered by peer educators to African American women and provision of fruit and veg. Significant weight loss in the intervention group compared to control (-2.0 +/-3.2 vs 1.1 +/- 2.0 kg).

Web based tailored weight management programme vs web based information only

One study (Rothert et al, mean BMI 32 but prevention/management intervention). Significantly greater weight loss in web based weight management programme (healthy eating and PA) compared with information only group -1.21 +/-0.1 vs -0.48 +/- 0.2 kg (p=0.007).

Trends, Limitations, Comments and Source of Funding

Significant trends

General comments

As the Ossei-Assibey review aimed to include studies in both overweight and obese participants, and only overweight participants were included in the review for NICE, both the overall results of the review and the results of individual studies in overweight participants have been included.

Reported limitations

Reviewer

Author

Significant drawbacks were noted for several of these studies, such as small sample size, high attrition rates and lack of follow-up data. Better quality and long-term trials are required in order to investigate in detail the effectiveness of lifestyle changes for weight management in these populations.

Source of funding

Not reported

Authors: Webb MS, Rodríguez-Esquivel D, Baker EA
Year: 2010
Citation: American Journal of Health Promotion 25(2): 109-118
Country of study: US
Aim of study: Systematic review of smoking cessation interventions among Hispanics in the United States
Study design: Systematic reviews
Quality score: (++, + or -): -

Study (eligible and selected) population

Eligible population
Healthy Hispanic adults living in the US

Number of people
Not reported for individual studies or meta-analysis

Locality
US

Recruitment strategy
Not reported for individual studies

Response rate
Not reported for individual studies

Characteristics of population
The age range of included studies was 35-44 (mean 40.70 SD 3.21).

Excluded populations
Non- Hispanic adults, non US studies

Pregnant women, medical patients, adolescents, or non-U.S. smokers were excluded, studies without a control group were excluded from meta-analysis.

Low risk/high risk population
N/A

Intervention and Comparison

Smoking cessation interventions in healthy Hispanic adults living in the US.

Interventions consisted of self-help, nicotine replacement therapy, and community-based interventions, as well as individual, group, and telephone counselling.

Method of allocation
Any intervention eligible for inclusion but studies included in meta-analysis had to be RCTs.
Methods of randomisation or allocation concealment not reported for individual studies.

Measurement of exposure
N/A

Comparator
No control group for some studies. Details of control group for individual studies reported in results section.

Outcomes and Analysis

Outcomes
Smoking abstinence, quit rates or current smoking rates.

Outcome measurement
Self-reported and biochemically verified

Analysis strategy
Meta-analysis of 5 RCTs and narrative synthesis of 12 studies.

	Confounders Authors report for some studies there were differences in intensity and frequency of contact between intervention and control groups.
Results **Intervention group** See below	**Results** **Control group** See below

Results – Group difference

12 studies were included in the systematic review and 5 RCTs in the meta-analysis.

From meta-analysis of 5 studies, there was evidence for the efficacy of smoking cessation interventions at the end of treatment (odds ratio, 1.54; 95% confidence interval, 1.09-2.16), which was attenuated in the longer term.

Self-help: Two studies examined self-help smoking cessation. One trial examined a Spanish language mood management and written smoking cessation messages delivered immediately or delayed (3 months). There was greater 7-day point prevalence abstinence for the immediate intervention compared to the delayed group at 3 months (22.5% vs 10.8%, however results were not significant based on biochemical confirmation of smoking status. Another study examined the effect of self-help materials, including an incentive postcard in a quasi-experimental trial (no control group). Respondents reported abstinence rates of 21% at 3 months and 14% at 14 months of which 8% were biochemically verified.

Nicotine-replacement therapy (NRT): Two studies included: One was a double-blind RCT in which smokers were randomly assigned to receive 10 weeks of NRT or placebo patches. All participants received additional behavioural support by telephone and clinic visits. Biochemically confirmed abstinence rates were greater for the nicotine patch compared to placebo (63% vs 35%) at 6 weeks and 10 weeks (46% vs 35%). In another descriptive quasi-experimental trial, smokers interested in quitting were provided with nicotine patches, lozenges, gum or buproprion. Based on self-report, 63% of participants reported smoking cessation at 8 to 12 weeks and 44% were abstinent at 6 months.

Individual counselling: Two studies examined individual counselling for smoking cessation. One RCT examined culturally specific individual counselling delivered during home visits by community health advisors. Biochemically confirmed abstinence rates were greater for the intervention (19%) compared to the control (7%). However, there were differences in intensity and frequency between arms of the study. Another study examined brief individual counselling based on motivational interviewing and NRT. Less acculturated Hispanics were more likely to quit smoking compared to bicultural Hispanics and non-Hispanic white groups at 3 months (34% vs 20% vs 24%) and 6 months (21% vs 9% vs 18%).

Group counselling: Two studies examined group counselling smoking cessation interventions. One RCT tested a culturally specific group based cessation intervention (weekly 2 hour sessions, story therapy, a buddy system, maintenance self-help materials plus supportive telephone calls) versus a self-help control (self-help materials and a bimonthly telephone call). There were no significant differences between groups at 6 and 12 month follow up. Another study used group counselling based on cognitive behavioural therapy. A non-controlled intervention consisted of 6 group counselling sessions conducted in Spanish and NRT. At the end of treatment 14% (biochemically confirmed) had quit with 18% and 13% self-reported cessation rates at 3 and 6 month follow up.

Telephone counselling: One trial tested a telephone based behavioural intervention. Callers to

the National Cancer Information service received either enhanced counselling (4 telephone contacts) or standard counselling (one telephone contact plus self-help materials). The calls consisted of practical counselling (identification of triggers to smoke and strategies for coping), supportive counseling, and strategies to increase social support from significant others. Motivational enhancement and a culturally tailored approach were also used. The enhanced programme produced greater 7 day point prevalence abstinence (27.4%) compared with the standard condition (20.5%) at the 3 month follow up.

Community based interventions: Three studies used community based interventions to promote smoking cessation. One study compared a comprehensive intervention (cessation counselling, media campaign and community network with a media only campaign or no intervention. There were no statistically significant differences in smoking results across the three follow-up assessments, which occurred over 4 years. Biochemically confirmed smoking cessation rates were also low. Another non-controlled community study found that exposure to a campaign involving widely distributed self-help materials, a media campaign and outreach by community health workers was unrelated to smoking cessation. However smokers exposed to the campaign were more likely to make an attempt to quit. In another trial in which 20 communities were randomised to either a community cancer prevention intervention or no intervention there were no differences in current smoking (15.7%) between the intervention and control communities (13.6%). However, the smoking cessation intervention was a minor part of the overall intervention.

Trends, Limitations, Comments and Source of Funding

Significant trends **General comments**	**Reported limitations** Reviewer Author Short follow up periods for some studies, lack of RCTs, small sample sizes, self-report data for some studies. Participants in most of the studies were Mexican American which limits generalizability to other US Hispanic populations. **Source of funding** Not reported

Systematic reviews not included but presented for information

Fitzgibbon ML, Tussing-Humphreys LM, Porter JS, Martin IK, Odoms-Young A, Sharp LK. (2012). Weight loss and African-American women: a systematic review of the behavioural weight loss intervention literature. Obesity Reviews 13(3): 193-213

The excess burden of obesity among African–American women is well documented. However, the behavioural weight loss intervention literature often does not report results by ethnic group or gender. The purpose of this article is to conduct a systematic review of all behavioural weight loss intervention trials published between 1990 and 2010 that included and reported results separately for African– American women. The criteria for inclusion included (i) participants age >18 years; (ii) a behavioural weight loss intervention; (iii) weight as an outcome variable; (iv) inclusion of African–American women; and (v) weight loss results reported separately by ethnicity and gender. The literature search identified 25 studies that met inclusion criteria. Our findings suggest that more intensive randomized behavioural weight loss trials with medically at-risk populations yield better results. Well-designed and more intensive multi-site trials with medically at-risk populations currently offer the most promising results for African–American women. Still, African–American women lose less weight than other subgroups in behavioural weight loss interventions. It is now critical to expand on individual-level approaches and incorporate the biological, social and environmental factors that influence obesity. This will help enable the adoption of healthier behaviours for this group of women disproportionately affected by obesity.

APPENDIX A.20 Interventions Bibliography

3.3 PHYSICAL ACTIVITY

Included Primary Studies

*Disadvantaged or minority groups

1. *****Anderssen E, Hostmark A, Holme I et al. (2013) Intervention effects on physical activity and insulin levels in men of Pakistani origin living in Oslo: A randomised controlled trial. Journal of Immigrant and Minority Health 15:101-110.
2. Anderssen SA, Carroll S, Urdal P et al. (2007) Combined diet and exercise intervention reverses the metabolic syndrome in middle-aged males: results from the Oslo Diet and Exercise Study. Scandinavian Journal of Medicine & Science in Sports 17(6): 687-695.
3. Arbour KP, Ginis KAM. (2004) Helping middle-aged women translate physical activity intentions into action: combining the theory of planned behavior and implementation intentions. Journal of Applied Biobehavioral Research 9(3): 172-187.
4. Bowen DJ, Fesinmeyer MD, Yasui Y et al. (2006) Randomized trial of exercise in sedentary middle aged women: effects on quality of life. International Journal of Behavioral Nutrition and Physical Activity 3(1): 34.
5. Cussler EC, Teixeira PJ, Going SB et al. (2008) Maintenance of weight loss in overweight middle-aged women through the internet. Obesity 16(5): 1052-1060.
6. Elavsky S. (2010) Longitudinal examination of exercise and self-esteem in middle-aged women. Journal of Sport & Exercise Psychology 32(6): 862.
7. Ferney SL, Marshall AL, Eakin EG et al. (2009) Randomized trial of a neighborhood environment-focused physical activity website intervention. Preventive Medicine 48(2): 144-150.
8. Gaston M, Porter G, Thomas V. (2007) Prime Time Sister Circle: Evaluating a gender-specific, culturally relevant health intervention to decrease major risk factors in mid-life African-American Women. Journal of the Medical Association 99(4): 428-438.
9. Hageman PA, Walker SN, Pullen CH. (2005) Tailored versus standard Internet-delivered interventions to promote physical activity in older women. Journal of Geriatric Physical Therapy 28(1): 28-33.
10. Hardcastle SJ, Taylor AH, Bailey MP et al. (2013) Effectiveness of a motivational interviewing intervention on weight loss, physical activity and cardiovascular disease risk factors: a randomised controlled trial with a 12-month post-intervention follow-up. International Journal of Behavioral Nutrition and Physical Activity 10(1): 40.
11. Hötting K, Reich B, Holzschneider K et al. (2012) Differential cognitive effects of cycling versus stretching/coordination training in middle-aged adults. Health Psychology 31(2): 145.
12. Kamada M, Kitayuguchi J, Inoue S et al. (2013) A community-wide campaign to promote physical activity in middle-aged and elderly people: a cluster randomized controlled trial. International Journal of Behavioral Nutrition and Physical Activity 10(1): 44.
13. King AC, Ahn DK, Oliveira BM et al. (2008) Promoting physical activity through hand-held computer technology. American Journal of Preventive Medicine 34(2): 138-142.

14. King AC, Hekler EB, Grieco LA et al. (2013) Harnessing different motivational frames via mobile phones to promote daily physical activity and reduce sedentary behavior in aging adults. PLoS One 8(4): e62613.

15. Maiorana A, O'Driscoll G, Dembo L et al. (2001) Exercise training, vascular function, and functional capacity in middle-aged subjects. Medicine and Science in Sports and Exercise 33(12): 2022-2028.

16. Moustaka FC, Vlachopoulos SP, Kabitsis C et al. (2012) Effects of an autonomy-supportive exercise instructing style on exercise motivation, psychological well-being, and exercise attendance in middle-age women. Journal of Physical Activity & Health 9(1).

17. Palumbo MV, Wu G, Shaner-McRae H et al. (2012) Tai Chi for older nurses: a workplace wellness pilot study. Applied Nursing Research 25(1): 54-9.

18. Pratley RE, Hagberg JM, Dengel DR et al. (2000) Aerobic exercise training-induced reductions in abdominal fat and glucose-stimulated insulin responses in middle-aged and older men. Journal of the American Geriatrics Society 48(9): 1055-61.

19. Ramos-Jiménez A, Hernández-Torres RP, Wall-Medrano A et al. (2009) Cardiovascular and metabolic effects of intensive Hatha Yoga training in middle-aged and older women from northern Mexico. International Journal of Yoga 2(2): 49.

20. Sheeran P, Harris P, Vaughan J et al. (2013). Gone exercising: Mental contrasting promotes physical activity among overweight, middle-aged, low-SES fishermen. Health Psychology 32(7): 802.

21. Stadler G, Oettinge G, Gollwitzer PM. (2009) Physical activity in women effects of a self-regulation intervention. American Journal of Preventive Medicine 36(1): 29-34.

22. Ueda M. (2004) A 12-week structured education and exercise program improved climacteric symptoms in middle-aged women. Journal of Physiological Anthropology and Applied Human Science 23: 143-148.

23. Yoshikawa T, Miyazaki A, Fujimoto S. (2009) Decrease in serum levels of advanced glycation end-products by short-term lifestyle modification in non-diabetic middle-aged females. Medical Science Monitor 15(6): PH65-73.

Included Systematic Reviews

Specifically targeted at mid-life:

1. Bolam KA, van Uffelen JG, Taaffe DR. (2013) The effect of physical exercise on bone density in middle-aged and older men: a systematic review. Osteoporosis International 24(11): 2749-62.

2. Cavill JL, Jancey JM, Howat P. (2012) Review and recommendations for online physical activity and nutrition programmes targeted at over 40s. Global Health Promotion 19(2): 44-53.

3. Ferreira ML, Sherrington C, Smith K et al. (2012) Physical activity improves strength, balance and endurance in adults aged 40-65 years: a systematic review. Journal of Physiotherapy 58(3): 145-156.

4. Hobbs N, Godfrey A, Lara J et al. (2013) Are behavioral interventions effective in increasing physical activity at 12 to 36 months in adults aged 55 to 70 years? A systematic review and meta-analysis. BMC Medicine 19;11:75.

Systematic Reviews in which included studies are mainly in mid-life:

5. Abioye AI, Hajifathalian K, Danaei G. (2013) Do mass media campaigns improve physical

activity? A systematic review and meta-analysis. Archives of Public Health 71(1): 20.

6. Conn VS, Hafdahl AR, Mehr DR. (2011) Interventions to increase physical activity among healthy adults: meta-analysis of outcomes. American Journal of Public Health 101(4): 751-758.
7. Davies CA, Spence JC, Vandelanotte C et al. (2012) Meta-analysis of internet-delivered interventions to increase physical activity levels. International Journal of Behavioral Nutrition & Physical Activity 30(9): 52.
8. Foster C, Richards J, Thorogood M et al. (2013) Remote and web 2.0 interventions for promoting physical activity (Review). The Cochrane Library (9): CD010395.
9. Foster C, Richards J, Thorogood M et al. (2013) Face-to-face interventions for promoting physical activity (Review). The Cochrane Library (9): CD010392.
10. Foster C, Richards J, Thorogood M et al. (2013) Face-to-face versus remote and web 2.0 interventions for promoting physical activity. The Cochrane Library (9): CD010393.
11. Leavy JE, Bull FC, Rosenberg M et al. (2011) Physical activity mass media campaigns and their evaluation: a systematic review of the literature 2003-2010. Health Education Research 26(6): 1060-1085.

Systematic Reviews in disadvantaged groups:

12. *Chapman J, Qureshi N, Kai J. (2013) Effectiveness of physical activity and dietary interventions in South Asian populations: a systematic review. British Journal of General Practice 63(607): e104-114.
13. *Cleland CL, Tully MA, Kee F et al. (2012) The effectiveness of physical activity interventions in socio-economically disadvantaged communities: a systematic review. Preventive Medicine 54(6): 371-380.
14. *Cleland, V, Granados A, Crawford D et al. (2013) Effectiveness of interventions to promote physical activity among socioeconomically disadvantaged women: a systematic review and meta-analysis. Obesity Reviews 14(3): 197-212.
15. *Conn VS, Phillips LJ, Ruppar TM et al. (2012) Physical activity interventions with healthy minority adults: meta-analysis of behavior and health outcomes. Journal of Health Care for the Poor & Underserved 23(1): 59-80.
16. *Ickes MJ, Sharma M. (2012) A systematic review of physical activity interventions in Hispanic adults. Journal of Environmental & Public Health 156435.

Systematic Reviews of cost-effectiveness:

17. Wu S, Cohen D, Shi Y et al. (2011) Economic analysis of physical activity interventions. American Journal of Preventive Medicine 40(2): 149-158.

Included Economic Studies

Primary studies:

1. Annemans L, Lamotte M, Clarys P et al. (2007) Health economic evaluation of controlled and maintained physical exercise in the prevention of cardiovascular and other prosperity diseases. European Journal of Cardiovascular Prevention & Rehabilitation 14(6): 815-824.
2. Anokye NK, Trueman P, Green C et al. (2011) The cost-effectiveness of exercise referral schemes. BMC Public Health 11(1): 954.

3. Dalziel K, Segal L, Elley CR. (2006) Cost utility analysis of physical activity counselling in general practice. Australian and New Zealand Journal of Public Health 30(1): 57-63.

4. *****Goyder E, Hind D, Breckon J et al. (2014) A randomised controlled trial and cost-effectiveness evaluation of 'booster' interventions to sustain increases in physical activity in middle-aged adults in deprived urban neighbourhoods. Health Technology Assessment 18(13).

3.4 DIET & NUTRITION

Included Primary Studies

1. Hjerkinn EM, Sandvik L, Hjermann I et al. (2004) Effect of diet intervention on long-term mortality in healthy middle-aged men with combined hyperlipidaemia. Journal of Internal Medicine 255(1): 68-73.

2. Turner LW, Wallace LS, Hunt SB et al. (2003) Changes in behavior and behavioral intentions among middle-age women: Results from an osteoporosis prevention program. Psychological Reports 93(2): 521-526.

3. Wright JL, Sherriff JL, Dhaliwal SS et al. (2011) Tailored, iterative, printed dietary feedback is as effective as group education in improving dietary behaviours: results from a randomised control trial in middle-aged adults with cardiovascular risk factors. International Journal of Behavioral Nutrition and Physical Activity 8: 43.

Included Systematic Reviews

1. Esposito K, Kastorini CM, Panagiotakos DB et al. (2011) Mediterranean diet and weight loss: meta-analysis of randomized controlled trials. Metabolic Syndrome & Related Disorders 9(1): 1-12.

2. Hopper I, Billah B, Skiba M et al. (2011) Prevention of diabetes and reduction in major cardiovascular events in studies of subjects with prediabetes: meta-analysis of randomised controlled clinical trials. European Journal of Cardiovascular Prevention & Rehabilitation 18(6): 813-823.

3. Rees K, Hartley L, Flowers N et al. (2013) 'Mediterranean' dietary pattern for the primary prevention of cardiovascular disease. Cochrane Database of Systematic Reviews (8): CD009825.

4. Rees K, Dyakova M, Wilson N et al. (2013) Dietary advice for reducing cardiovascular risk. Cochrane Database of Systematic Reviews (3): CD002128.

Included Economic Studies

1. Bós AM, Howard BV, Beresford SA et al. (2011) Cost-effectiveness analysis of a low-fat diet in the prevention of breast and ovarian cancer. Journal of the American Dietetic Association 111(1): 56-66.

3.5 SMOKING

Included Primary Studies

1. Begh RA, Aveyard P, Upton P et al. (2011) Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers. Trials 12(1): 197.
2. Brown J, Michie S, Geraghty AW et al. (2012) A pilot study of StopAdvisor: a theory-based interactive internet-based smoking cessation intervention aimed across the social spectrum. Addictive Behaviors 37(12): 1365-1370.
3. Hall S, Bishop AJ, Marteau TM. (2003) Increasing readiness to stop smoking in women undergoing cervical screening: Evaluation of two leaflets. Nicotine and Tobacco Research 5(6): 821-826.
4. Hall SM, Humfleet G, Muñoz RF et al. (2009) Extended treatment of older cigarette smokers. Addiction 104(6): 1043-1052.
5. Halpin HA, McMenamin SB, Rideout J et al. (2006) The costs and effectiveness of different benefit designs for treating tobacco dependence: results from a randomized trial. Journal Information 43(1).
6. Hollis JF, McAfee TA, Fellows JL et al. (2007) The effectiveness and cost effectiveness of telephone counselling and the nicotine patch in a state tobacco quitline. Tobacco Control 16(Suppl 1): i53-i59.
7. McDermott MS, Marteau TM, Hajek P. (2011) Effects of a brief cognitive intervention aimed at communicating the negative reinforcement explanation for smoking on relevant cognitions and urges to smoke. Journal of Smoking Cessation 6(2): 112-118.
8. Vogt F, Marteau TM. (2012) Perceived effectiveness of stop smoking interventions: Impact of presenting evidence using numbers, visual displays, and different timeframes. Nicotine and Tobacco Research 14(2): 200-208.

Included Systematic Reviews

1. Lindson-Hawley N, Aveyard P, Hughes JR. (2010) Reduction versus abrupt cessation in smokers who want to quit. Cochrane Database of Systematic Reviews (3): CD008033.

2. Webb MS, Rodríguez-Esquivel D, Baker EA. (2010) Smoking cessation interventions among Hispanics in the United States: A systematic review and mini meta-analysis. American Journal of Health Promotion 25(2): 109-118.

Excluded Systematic Reviews

1. Rooke S, Thorsteinsson E, Karpin A, Copeland J, Allsop D. (2010). Computer-delivered interventions for alcohol and tobacco use: a meta-analysis. Addiction 105(8): 1381-139.

2. Zbikowski SM, Magnusson B, Pockey JR et al. (2012) A review of smoking cessation interventions for smokers aged 50 and older. Maturitas 71(2): 131-141.

Included Economic Studies

1. Smith MW, An LC, Fu SS et al. (2011) Cost-effectiveness of an intensive telephone-based intervention for smoking cessation. Journal of Telemedicine and Telecare 17(8): 437-440.

Excluded Economic Studies

1. Rasmussen S. (2013) The cost effectiveness of telephone counseling to aid smoking cessation in Denmark: A modelling study. Scandinavian Journal of Public Health 41(1): 4-10.

3.6 ALCOHOL

Included Primary Studies

1. Blankers M, Nabitz U, Smit F et al. (2011) Economic evaluation of internet-based interventions for harmful alcohol use alongside a pragmatic randomized controlled trial. Journal of Medical Internet Research 14(5): e134-e134.
2. Boon B, Risselada A, Huiberts A et al. (2011) Curbing alcohol use in male adults through computer generated personalized advice: randomized controlled trial. Journal of Medical Internet Research 13(2): e43.
3. Lock CA, Kaner E, Heather N et al. (2006) Effectiveness of nurse-led brief alcohol intervention: a cluster randomized controlled trial. Journal of Advanced Nursing 54(4): 426–439.
4. Williams EC, Achtmeyer CE, Kivlahan DR et al. (2010) Evaluation of an electronic clinical reminder to facilitate brief alcohol-counseling interventions in primary care. Journal of Studies on Alcohol and Drugs 71(5): 720.

Excluded Systematic Reviews

1. Bryden A, Roberts B, McKee M et al. (2012) A systematic review of the influence on alcohol use of community level availability and marketing of alcohol. Health & Place 18(2): 349-357.
2. Bryden A, Roberts B, Petticrew M et al. (2013) A systematic review of the influence of community level social factors on alcohol use. Health and Place 21: 70-85.
3. Khadjesari Z, Murray E, Hewitt C et al. (2011) Can stand-alone computer-based interventions reduce alcohol consumption? A systematic review. Addiction 106(2): 267-282.
4. Rooke S, Thorsteinsson E, Karpin A et al. (2010) Computer-delivered interventions for alcohol and tobacco use: a meta-analysis. Addiction 105(8): 1381-1390.
5. White A, Kavanagh D, Stallman H et al. (2010) Online alcohol interventions: a systematic review. Journal of Medical Internet Research 12(5): e62.
6. Hyman Z. (2006) Brief interventions for high-risk drinkers. Journal of Clinical Nursing 15(11): 1383-1396.
7. Vasilaki EI, Hosier SG, Cox WM. (2006) The efficacy of motivational interviewing as a brief intervention for excessive drinking: a meta-analytic review. Alcohol & Alcoholism 41(3): 328-335.
8. Whitlock EP, Polen MR, Green CA et al. (2004) Behavioral counseling interventions in primary care to reduce risky/harmful alcohol use by adults: a summary of the evidence for the US Preventive Services Task Force. Annals of Internal Medicine 140(7): 557-568+I564.
9. Ballesteros J, Duffy JC, Querejeta I et al. (2004) Efficacy of brief interventions for hazardous drinkers in primary care: Systematic review and meta-analyses. Alcoholism-Clinical and Experimental Research 28(4): 608-618.
10. Ballesteros J, González-Pinto A, Querejeta I et al. (2004) Brief interventions for hazardous drinkers delivered in primary care are equally effective in men and women. Addiction 99(1): 103-108.
11. D'Onofrio G, Degutis LC. (2002) Preventive care in the emergency department:

screening and brief intervention for alcohol problems in the emergency department: a systematic review. Academic Emergency Medicine 9(6): 627-638.

Included Economic Studies

1. Blankers M, Nabitz U, Smit F et al. (2012) Economic evaluation of internet-based interventions for harmful alcohol use alongside a pragmatic randomized controlled trial. Journal of Medical Internet Research 14(5): 71-83.

Excluded Economic Studies

1. Tariq L, van den Berg M, Hoogenveen RT et al. (2009) Cost-effectiveness of an opportunistic screening programme and brief intervention for excessive alcohol use in primary care PLoS One 4(5), e5696.
2. Månsdotter AM, Rydberg MK, Wallin E et al. (2007) A cost-effectiveness analysis of alcohol prevention targeting licensed premises. European Journal of Public Health 17(6): 618-623.
3. Barrett B, Byford S, Crawford MJ et al. (2006) Cost-effectiveness of screening and referral to an alcohol health worker in alcohol misusing patients attending an accident and emergency department: a decision-making approach. Drug and Alcohol Dependence 81(1): 47-54.
4. Mortimer D, Segal L. (2005) Economic evaluation of interventions for problem drinking and alcohol dependence: Cost per QALY estimates. Alcohol and Alcoholism 40(6): 549-555.
5. Fleming MF, Mundt MP, French MT et al. (2002) Brief physician advice for problem drinkers: long-term efficacy and benefit-cost analysis. Alcoholism: Clinical and Experimental Research 26(1): 36-43.

3.7 WEIGHT MANAGEMENT

Included Primary Studies

1. Maiorana A, O'Driscoll G, Dembo L et al. (2001) Exercise training, vascular function, and functional capacity in middle-aged subjects. Medicine and Science in Sports and Exercise 33(12): 2022-2028.
2. Lee HJ, Kang KJ, Park SH et al. (2012) Effect of integrated personalized health care system on middle-aged and elderly women's health. Healthcare Informatics Research 18(3): 199-207.

Included Systematic Reviews

1. Ali MK, Echouffo-Tcheugui JB, Williamson DF. (2012) How effective were lifestyle interventions in real-world settings that were modeled on the Diabetes Prevention Program? Health Affairs 31(1): 67-75.
2. Armstrong MJ, Mottershead TA, Ronksley PE et al. (2011) Motivational interviewing to improve weight loss in overweight and/or obese patients: a systematic review and meta-analysis of randomized controlled trials. Obesity Reviews 12(9): 709-723.

3. Osei-Assibey G, Kyrou I, Adi Y et al. (2010) Dietary and lifestyle interventions for weight management in adults from minority ethnic/non-White groups: a systematic review. Obesity Reviews 11(11): 769-776.
4. Rioux J, Ritenbaugh C. (2013) Narrative review of yoga intervention clinical trials including weight-related outcomes. Alternative Therapies in Health & Medicine 19(3).

3.8 MULTIPLE COMPONENT

Included Primary Studies

1. Gaston MH, Porter GK, Thomas VG. (2007) Prime Time Sister Circles: evaluating a gender-specific, culturally relevant health intervention to decrease major risk factors in mid-life African-American women. Journal of the National Medical Association 99(4): 428.
2. Lakerveld J, Bot SD, Chinapaw MJ et al. (2013) Motivational interviewing and problem solving treatment to reduce type 2 diabetes and cardiovascular disease risk in real life: a randomized controlled trial. International Journal of Behavioral Nutrition and Physical Activity 10(1): 47.
3. Lee WK, Bang HJ. (2010) The effects of mindfulness-based group intervention on the mental health of middle-aged Korean women in community. Stress and Health 26(4): 341-348.

Included Systematic Reviews

1. Aalbers T, Baars MA, Rikkert MG. (2011) Characteristics of effective Internet-mediated interventions to change lifestyle in people aged 50 and older: a systematic review. Ageing Research Reviews 10(4): 487-497.
2. Ebrahim S, Taylor F, Ward K et al. (2011) Multiple risk factor interventions for primary prevention of coronary heart disease. Cochrane Database of Systematic Reviews (1): CD001561.
3. Hopper I, Billah B, Skiba M et al. (2011) Prevention of diabetes and reduction in major cardiovascular events in studies of subjects with prediabetes: meta-analysis of randomised controlled clinical trials. European Journal of Cardiovascular Prevention & Rehabilitation 18(6): 813-823.

Systematic Reviews in disadvantaged groups:

4. Osei-Assibey G, Kyrou I, Adi Y et al. (2010) Dietary and lifestyle interventions for weight management in adults from minority ethnic/non-White groups: a systematic review. Obesity Reviews 11(11): 769-776.
5. Coles E, Themessl-Huber M, Freeman R. (2012) Investigating community-based health and health promotion for homeless people: a mixed methods review. Health Education Research 27(4): 624-644.

Systematic Reviews of cost effectiveness:

6. Bertram MY, Lim SS, Barendregt JJ et al. (2010) Assessing the cost-effectiveness of drug and lifestyle intervention following opportunistic screening for pre-diabetes in primary care. Diabetologia 53(5): 875-881.

Included Economic Studies (since 2000)

1. Barton P, Andronis L, Briggs A et al. (2011) Effectiveness and cost effectiveness of cardiovascular disease prevention in whole populations: modelling study. BMJ 343: d4044.

Excluded Economic Studies (since 2000)

1. Barton GR, Goodall M, Bower P et al. (2012) Increasing heart-health lifestyles in deprived communities: economic evaluation of lay health trainers. Journal of Evaluation in Clinical Practice 18(4): 835-840.

3.9 DISADVANTAGED MINORITIES

Included Primary Studies

1. Anderssen E, Hostmark A, Holme I et al. (2013) Intervention effects on physical activity and insulin levels in men of Pakistani origin living in Oslo: A randomised controlled trial. Journal of Immigrant and Minority Health 15(1): 101-110.
2. Begh RA, Aveyard P, Upton P et al. (2011) Promoting smoking cessation in Pakistani and Bangladeshi men in the UK: pilot cluster randomised controlled trial of trained community outreach workers. Trials 12(1): 197.
3. Gaston M, Porter G, Thomas V. (2007) Prime Time Sister Circle: Evaluating a gender-specific, culturally relevant health intervention to decrease major risk factors in mid-life African-American Women. Journal of the Medical Association 99(4): 428-438.
4. Goyder E, Hind D, Breckon J et al. (2014) A randomised controlled trial and cost-effectiveness evaluation of 'booster' interventions to sustain increases in physical activity in middle-aged adults in deprived urban neighbourhoods. Health Technology Assessment 18(13).

Included Systematic Reviews

1. Chapman J, Qureshi N, Kai J. (2013) Effectiveness of physical activity and dietary interventions in South Asian populations: a systematic review. British Journal of General Practice 63(607): e104-114.
2. Cleland CL, Tully MA, Kee F et al. (2012) The effectiveness of physical activity interventions in socio-economically disadvantaged communities: a systematic review. Preventive Medicine 54(6): 371-380.
3. Cleland, V, Granados A, Crawford D et al. (2013) Effectiveness of interventions to promote physical activity among socioeconomically disadvantaged women: a systematic review and meta-analysis. Obesity Reviews 14(3): 197-212.
4. Coles E, Themessl-Huber M, Freeman R. (2012) Investigating community-based health and health promotion for homeless people: a mixed methods review. Health Education Research 27(4): 624-644.
5. Conn VS, Phillips LJ, Ruppar TM et al. (2012) Physical activity interventions with healthy minority adults: meta-analysis of behavior and health outcomes. Journal of Health Care

for the Poor & Underserved 23(1): 59-80.

6. Ickes MJ, Sharma M. (2012) A systematic review of physical activity interventions in Hispanic adults. Journal Of Environmental & Public Health 2012: 156435.
7. Osei-Assibey G, Kyrou I, Adi Y et al. (2010) Dietary and lifestyle interventions for weight management in adults from minority ethnic/non-white groups: a systematic review. Obesity Reviews 11(11): 769-776.
8. Webb MS, Rodríguez-Esquivel D, Baker EA. (2010) Smoking cessation interventions among Hispanics in the United States: A systematic review and mini meta-analysis. American Journal of Health Promotion 25(2): 109-118.

Excluded Systematic Reviews

1. Fitzgibbon ML, Tussing-Humphreys LM, Porter JS et al. (2012) Weight loss and African-American women: a systematic review of the behavioural weight loss intervention literature. Obesity Reviews 13(3): 193-213.