Appendix G: Study characteristics extraction tables

Notes:

- n= in content column reflects number randomised in each trial arm; number analysed reported in review Evidence Statements
- Follow-up points reflect author reported follow-up; post-intervention follow-up reported in review Evidence Statements and used in sensitivity analyses.

Sexual health

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW-UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
Cortes-Bordoy et al, 2010 **Country** Spain **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=278. 76% of women who participated in the study were included ('evaluable' and information regarding delivery of leaflet available) and data on these women was presented in the paper **Selection/recruitment criteria** Adult women with vulvoperineal (genital) warts attending gynaecological outpatient clinics of 39 acute-care hospitals (a random sample of hospitals). HIV positive women were excluded. **Participant characteristics (non-excluded women)** **Mean age** 30.2 years **Gender** 100% female (inclusion criteria) **SES:** Not reported **Ethnicity** Not reported **Sexual orientation** 96.2% heterosexual; 0.5% homosexual; 2.4% bisexual	**Setting**: Gynaecology outpatient clinics. Leaflet provided to the intervention group was to be read at home. **Provider**: Gynaecologist **Mode of delivery**: Leaflet delivered and explained face-to-face by a gynaecologist (individual level)	**Comparison** Included women: N= 114 Behaviour change leaflet vs. N= 97 no treatment **Type**: Brief **Focus**: Risky sexual behaviour	**Intensity**: Leaflet given to the intervention group at initial visit. 5 visits over 12 months were required for the treatment and monitoring of genital warts	**Target behaviour outcome(s)** Number of partners and condom use over the previous 3 months **Prioritised main outcome:** % patients reporting condom use over the previous3 months **How was it measured:** Self-report to gynaecologist	**Duration of follow-up:** 12 months from randomisation and delivery of the intervention. 76% of the initial population were included.	3 months (during intervention) Intervention: 83.2% Control: 75.8% p=0.250	12months (end of intervention) Intervention: 65.4% Control: 69.3% p=0.752	**Adverse effects:** Not reported **Inequality issues**: Not reported
Crosby et al, 2009 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 266 **Selection/recruitment criteria** Men aged between 18 and 29 years old newly diagnosed with an STD and self-identifying as African American attending a public STD clinic located in a southern US city. Men reporting to be HIV positive were excluded. Men had to report use of a male condom at least once in the previous 3 months for sexual intercourse with a woman. **Participant characteristics** **Mean age** 23.2 years **Gender** 100% male (inclusion criteria) **Ethnicity** Self-identifying as African American was an inclusion criterion **SES** Not reported **Sexual orientation** Not reported, although self-report of sexual intercourse with a women during the previous 3 months an inclusion criterion	**Setting**: Clinic **Provider**: Lay health advisor **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 141 Focus on the future behaviour change intervention vs. N= 125 Usual Care **Type**: Extended **Focus**: Men's quality, correctness, and consistency of condom use	**Intensity**: 1session of 45 to 50 minutes	**Target behaviour outcome(s)** Number of female sexual partners in the previous 3 months; condom use during the last act of penetrative (penile-vaginal or penile-anal) sexual intercourse with a female partner in the previous 3 months; proficiency in using condoms as determined through direct observation of men's ability to apply condoms to a stationary, life-size, rubber penile model. (Primary outcome was STD diagnosis) **Prioritised main outcome:** Number of unprotected	**Duration of follow-up:** 3 months post intervention (74.1%) 6 months (medical records review, for STD diagnosis, all participants)	3 months Mean (SD) Intervention 12.3 (25.8) Control 29.4 (79.3) p=0.045 Adjusted mean difference estimate with multiple imputation -11.9; 95% CI -31.3 to 7.5	NA	**Adverse effects:** Not reported **Inequality issues**: Findings applicable to African American male population

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW-UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
	Other 30.2% had a net monthly income of >$1,000				acts of intercourse in the previous 3 months **How was it measured:** Self-administered questionnaire; directly observed condom-application skills assessment				
Dermen and Thomas, 2011 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=154 **Selection/recruitment criteria** Heavy-drinking students aged between 18 and 30 years old at behaviour risk for infection with HIV and other sexually transmitted diseases recruited from colleges and universities. Heavy drinking was defined as consuming at least 5 (men) or 4 (women) drinks at least once in the past 2 weeks. Students with a score of 20 or more on the Short-Form Alcohol Dependence Data Questionnaire, and those receiving counselling for drinking, were excluded. Students had to report 7 or more occurrences of unprotected heterosexual intercourse in the past 90 days and having 2 or more sex partner in the past 90 days, or having a partner who had other partners in the past 24 months but who had not been tested for HIV during the past 12 months. **Participant characteristics** **Mean Age** 20.7 years **Gender** 40.9% male, 59.1% female **Ethnicity** 86.4% While; 5.2% Hispanic; 3.9% African American; 3.9% Asian American; 0.6% American Indian **SES** Not reported **Sexual orientation** 98.7% Heterosexual; 1.3% Bisexual. Being either heterosexual or bisexual was an inclusion criterion	**Setting**: Not reported **Provider**: Counsellor of the same gender as the participant **Mode of delivery**: Face-to-face (individual level). Participants in intervention groups were provided with a personal feedback report, an explanatory booklet, a decisional balance sheet (if completed), a change plan worksheet (if completed), a booklet describing strategies and sources of support for reducing risk behaviour, and a handwritten note from the counsellor.	**Comparison** Intervention 1 N= 39 Behaviour change intervention focussing on reducing alcohol risk behaviour (ALC) vs. Intervention 2 N= 39 Behaviour change intervention focussing on reducing HIV risk behaviour (HIV) vs. Intervention 3 N= 36 Behaviour change intervention focussing on reducing alcohol and HIV risk behaviour (H&A) vs. N= 40 No intervention **Type**: Multi-session **Focus**: Alcohol risk behaviour; HIV risk behaviour; both alcohol and HIV risk behaviour	**Intensity**: 2 sessions over 5 weeks (all interventions). The first sessions were 45 minutes long (intervention 1 and 2) or 60 minutes long (intervention 3). The second sessions were 30 minutes long (intervention 1 and 2) or 45 minutes long (intervention 3)	**Target behaviour outcome(s):** Occurrences of unprotected sex, number of partners (HIV risk outcomes) **Prioritised main outcome:** Number of unprotected intercourse acts in past 3 month (HIV risk outcome) **How was it measured:** Modified TLFB interview with same gender counsellor (face-to-face). For participants who had moved out of the area, assessments were completed by telephone or by mail.	**Duration of follow-up:** 3 months (95% follow-up), 6 months (94% follow-up), 9 months (92% follow-up), 12 months (91% follow-up), 15 months (91% follow-up) following randomisation	<u>3 months</u> Mean (SD) Intervention 1: 26.7 (25.4) Intervention 2: 19.1 (25.4) Intervention 3: 22.1 (19.3) Control: 30.4 (32.7)	<u>15 months</u> Mean (SD) Intervention 1: 16.7 (17.8) Intervention 2: 15.4 (18.8) Intervention 3: 11.7 (13.0) Control: 17.6 (20.6) ANOVA Participants who received the HIV only intervention (intervention 2) engaged in unprotected sex less frequently during follow-upp=0.042, whereas outcomes of those in the combined and alcohol conditions did not differ p=0.801	**Adverse effects:** Not reported **Inequality issues:** Not reported **Other:** Baseline levels of number of drinking days in past 90 days; number of drinks per drinking day and number of sexual partners was not equal between groups Results for alcohol behaviour outcomes are described in the extraction table for alcohol.
Gilbert et al, 2008 **Country** USA **Design** RCT **Internal**	**Number randomised** N=476 Risky drinking was reported by 182 participants; unprotected anal or vaginal intercourse was reported by 284 participants. **Selection/recruitment criteria** Adults HIV positive for 3 months or longer reporting substance use or	**Setting**: Outpatient HIV clinics **Provider**: “Video doctor” **Mode of delivery**: “Video doctor” delivered via laptop computer 1 hour prior to a regularly scheduled medical appointment; and printed educational	**Comparison** N= 243 Positive choice behaviour change intervention vs. N= 233 Usual care **Type**:	**Intensity**: 2 sessions (24 minutes in length on average) over 3 months	**Target behaviour outcome(s):** Unprotected anal or vaginal sex, cessation of illicit drug use, and risky drinking **Prioritised main outcome:** Any unprotected sex 3	**Duration of follow-up:** 3 months (78%) and 6 months (83%) post randomisation	<u>3 months</u> Intervention 104/143 (73%) Control 117/141 (83%) RR 0.88, 95% CI 0.773 to 0.993	<u>6 months</u> Intervention 88/143 (62%) Control 108/141 (77%) RR 0.80, 95% CI 0.686 to 0.941	**Adverse effects:** There were 2 incidences of perceived breaches of confidentiality, both successfully resolved. 5

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validity ++ **External validity** ++	sexual risks (drug use defined as use of 10 illicit drugs in the past month; risky alcohol use was defined as exceeding the US National Institute on Alcoholism and Alcohol Abuse's recommended number of drinks per week or 3 or more binge drinking episodes within previous 3 months; sexual risk was defined as anal or vaginal intercourse without a condom in the past 3 months) **Participant characteristics** **Mean age** 44.1 years **Gender** 79% male, 21% female **Ethnicity** 13% Hispanic/Latino; 50% Black or African American; 29% White; 8% other or multiple races **SES** Not reported **Sexual orientation** 51% MSM or MSM/W **HIV status** HIV infection an inclusion criterion	worksheet printed at end of "video doctor" session	Multi-session **Focus**: Illicit drug use, risky alcohol drinking, and anal or vaginal intercourse without a condom		months after randomisation (among participants reporting behaviour at baseline) **How was it measured:** Computer-administered assessment (self-report)		p=0.039 (not significant with Bonferroni correction)	p=0.007 (significant with Bonferroni correction)	study participants died during the data collection period. Investigations found that the deaths were due to HIV and not associated with participation in the trial. **Inequality issues:** Preplanned subgroup analyses by participants' gender, race/ethnicity, hepatitis-C co-infection, HIV viral load, source of HIV infection, or sex partners' HIV status did not differ from aggregate results. Participants' previous treatment for alcohol or drug abuse did not affect substance use outcomes. Findings applicable to Black/African-American population.
Golin et al, 2012 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=492 **Selection and recruitment criteria** Sexually active HIV positive adults receiving HIV treatment at one of the 3 HIV clinics involved in the study. **Participant characteristics** **Mean age** 42.6 years **Gender** 65.2% men; 34.8% women **Ethnicity** 71.11% Black/African-American; 20.49% White, non-Hispanic; 8.40% other **SES** Not reported **Sexual orientation** 38.30% MSM; 26.92% MSW; 33.33% WSM; 1.45%	**Setting:** HIV clinic **Provider:** Counsellor (Masters degree in Social work, counselling, or health behaviour and health education) **Mode of delivery:** Face-to-face or via telephone (for participants who reported difficulty travelling) (individual level)	**Comparison** N=248 SafeTalk safer sex behavioural change intervention vs. N=242 New Leaf (attention control; nutrition and physical activity counselling program) **Type:** Multi-session	**Intensity:** Monthly for 4 months	**Target behaviour outcome(s):** Transmission risk behaviour (unprotected vaginal or anal sex with a HIV-negative or unknown serostatus partner) in the previous 3 months **Prioritised main outcome:** The number of unprotected vaginal or anal intercourse in the previous 3 months	**Duration of follow-up:** 4 months (84% follow-up), 8 months (76% follow-up) and 12 months (63% follow-up) post enrolment	4 months Mean (SD) Intervention: 1.68 (6.22) Control: 3.66 (29.60) (difference between groups not significant, p value not reported)	12 months Mean (SD) Intervention: 1.30 (7.10) Control: 2.31 (16.12) (difference between groups not significant, p value not reported)	**Adverse effects:** Not reported **Inequality issues**: Findings applicable to Black/African American population

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	WSW ; 57.47% straight/heterosexual; 32.21% gay/homosexual; 8.00% bisexual; 4.42% other/not sure **HIV status** HIV infection an inclusion criterion **Other** 57.54% income $10,000 or less; 34.48% income between $10,001 and $40,000; 7.97% income more than $40,000		**Focus:** Risky sexual behaviour		**How was it measured:** Audio computer-assisted self interview (ACASI)				
Ingersoll et al, 2005 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=228 **Selection/recruitment criteria** Female students aged between 18 and 24 years old at risk for alcohol exposed pregnancy recruited from one university. Risk for alcohol exposed pregnancy as defined as having sexual intercourse with a man in the past 90 days while using contraception ineffectively (no use, incorrect use of an effective method, or use of an ineffective method only); and drinking at risk levels (engaging in at least one binge [5 or more standard drinks per occasion] in the past 90 days or consuming an average of 8 standard drinks per week) **Participant characteristics** **Mean age** 20.5 years **Gender** 100% females (inclusion criteria) **Ethnicity** 70% Caucasian; 16% African American; 6% Asian; 2% Latina; 4% Other; 1% Pacific Islander **SES** Not reported **Sexual orientation** Not reported	**Setting**: Not reported **Provider**: Counsellor **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 114 Birth Control and Alcohol Awareness: Negotiating Choices Effectively (BALANCE) behaviour change intervention vs. N= 114 Information only (informational pamphlet about women's health) **Type**: Extended **Focus**: Risk of alcohol-exposed pregnancy	**Intensity**: 1 session of 60 to 75 minutes	**Target behaviour outcome(s):** Alcohol exposed pregnancy risk **Prioritised main outcome:** % of correct use of an effective contraceptive method **How was it measured:** Mailed questionnaire (self-report)	**Duration of follow-up:** 1 month (93% follow-up)	<u>1 month</u> Intervention: 63.7% Control: 47.6% p<0.03	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported **Other:** Results for alcohol behaviour outcomes are described in the extraction table for alcohol.
Koblin et al, 2010 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=283 **Selection/recruitment criteria** Participants self-identifying as male and as African-American, black, Caribbean black or multi-ethnic black; reporting 2 or more sexual partners and unprotected anal intercourse with a man during the previous 3 months **Participant characteristics** **Mean age** 39.3 years **Gender** 100% male (inclusion criteria) **Ethnicity** Identifying as black was an inclusion criterion. 8.5% additionally identified as Latino. **SES** Not reported **Sexual orientation** 67.5% gay; 26.9% bisexual; 5.7% other **HIV status** 62.5% HIV positive **Other** 61.8% annual income less than $10,000; 25.4% income between $10,000 and $29,999; 12.7% income	**Setting**: Not reported **Provider**: Teams of trained facilitators **Mode of delivery**: Face-to-face (group level)	**Comparison** N=142 Behavioural change intervention vs. N=141 No intervention **Type**: Multi-session **Focus**: Risky sexual behaviour	**Intensity**: 5 sessions of 2 hours over 2 weeks	**Target behaviour outcome(s):** Occurrence of unprotected insertive or receptive anal intercourse and unknown or serodiscordant unprotected insertive or receptive anal intercourse with most recent partner and any partner **Prioritised main outcome:** Unprotected insertive anal intercourse with any partner during previous 3 months **How was it measured:** Computer-administered questionnaire (self-	**Duration of follow-up:** 3 months post completion of the intervention (90.1% of the invention group and 92.2% of the control group)	<u>3 months</u> Intervention: 39.4% Control: 36.2% p=0.51	NA	**Adverse effects:** Not reported **Inequality issues**: Findings applicable to Black male population who report having intercourse with a man

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	more than $30,000				report)				
Langston et al, 2010 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=250 (28 participants had no procedure performed) **Selection/recruitment criteria** Adult women with no desire to become pregnant right away seeking a first trimester procedure for a spontaneous or induced abortion **Participant characteristics** **Mean age:** 26.1 years **Gender** 100% female (inclusion criteria) **Ethnicity** 97.5% Hispanic **SES** Not reported **Sexual orientation** Not reported	**Setting**: Private practice (clinic) setting **Provider**: Trained research coordinator **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 114 Behaviour change intervention using a version of the WHO 2005 Decision-Making Tool for Family Planning Clients and Providers vs. N= 108 Usual care **Type**: Brief (author report) **Focus**: Initiation and continuation of effective contraception	**Intensity**: 1 session, length of time not reported	**Target behaviour outcome(s):** Proportion of participants choosing a very effective contraceptive method **Prioritised main outcome:** Use of a very effective or effective contraception method **How was it measured:** Self report via telephone call from a research coordinator	**Duration of follow-up:** 3 months after enrolment (84%), 6 months for a subgroup (59%)	<u>3 months</u> Adjusted odds ratio with the intervention AOR 1.59, 95% CI 0.77 to 3.28	<u>6 months</u> Continuation at 6 months of an effective or very-effective method Intervention: 67% Usual care: 68% (OR 0.95, 95% CI 0.45 to 2.02)	**Adverse effects:** Not reported **Inequality issues**: Findings applicable to females of Hispanic ethnicity.
Mansergh et al, 2010 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=1,206 (study included a nonrandomised control group who received standard care, N=480) **Selection/recruitment criteria** Out of treatment substance-using men who have sex with men recruited from the community. Men were eligible if they reported being drunk or “buzzed” on alcohol 2 or more times, or high on noninjection drugs at least once, during or 2h before anal sex in the past 6 months; and having at least one unprotected anal sex episode with a male partner whose HIV serostatus was unknown or different from their own. **Participant characteristics** **Age** 10% aged between 18 and 24 years; 27% aged between 25 and 34 years; 42% aged between 35 and 44	**Setting**: Centres for Disease Control and Prevention (CDC), National Centre for Health Statistics (NCHS), Division of HIV/AIDs Prevention (DHAP), Prevention Research Branch; Health Research Association; New York Blood Centre and New York Academy of Medicine; Chicago & Howard Brown Health Centre; Public Health Foundation Enterprises (PHFE) Management Solutions, Inc. and San Francisco Department of Public Health AIDS Office **Provider**: Trained and experienced facilitators (defined as having experience counselling and facilitating groups and having experience working with populations targeted in this study) **Mode of delivery**: Face-to-face (group level)	**Comparison** N= 599 Cognitive-behavioural change intervention vs. N= 507 Attention control (videos and discussion of men who have sex with men community issues unrelated to substance use, sexual risk, and HIV/AIDS **Type**: Multi-session **Focus**: Sexual risk	**Intensity**: 6 weekly sessions of 2hours	**Target behaviour outcome(s):** Unprotected anal sex; unprotected anal sex with a discordant partner; alcohol use soon before or during unprotected anal sex; alcohol use during or before unprotected anal sex with a discordant partner; drug use soon before or during unprotected anal sex; drug use soon before or during unprotected anal sex with a discordant partner during most recent anal sex encounter with a nonprimary partner	**Duration of follow-up:** 3 months (88% follow-up), 6 months (88% follow-up), 12 months (89% follow-up) after the final group session	<u>3 months</u> Intervention: 43% Control: 44% AOR 0.93, 95% CI 0.70 to 1.22	<u>12 months</u> Intervention: 40% Control: 38% AOR 1.14, 95% CI 0.86 to 1.51	**Adverse effects:** Not reported **Inequality issues:** Results may be applicable to minority ethnic groups as the majority of participants were black or Hispanic/Latino **Other:** This study included a non-randomised third group who received usual care. This

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	years; 21% aged 45 years old or older **Gender** 100% male (inclusion criteria) **Ethnicity** 33% Black; 18% Hispanic/Latino; 39% White; 10% other **SES** Not reported **Sexual orientation** 84% Gay/homosexual; 16% Bisexual/other		behaviour		**Prioritised main outcome:** Unprotected anal sex in most recent event with most recent non-primary partner **How was it measured:** Audio computer-assisted self-interview (ACASI)				group is not described further here.
Petersen et al, 2007 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=764 **Selection/recruitment criteria** Women visiting primary care facilities aged between 16 and 44 years who were at risk of unintended pregnancy (nor pregnant, not planning a pregnancy, not using an IUD and neither they nor their partners were sterilized) **Participant characteristics** **Age** 41% aged between 16 and 25; 59% aged between 26 and 44 **Gender** 100% female (inclusion criteria) **Ethnicity** 62% white; 27% black; 10% other **SES** Not reported **Sexual orientation** Not reported	**Setting**: 3 primary care facilities **Provider**: Experienced health educators **Mode of delivery**: First session was delivered face-to-face. Booster session 2 months later conducted face-to-face or by telephone	**Comparison** N= 380 Women's Reproductive Assessment Program vs. N= 384 Attention control (counselling on preventative health care) **Type**: Multi-session **Focus**: Use of contraceptives	**Intensity**: 2 sessions over 2 months	**Target behaviour outcome(s):** Improvement in the level of women's contraceptive use, or maintenance of a high level of use **Prioritised main outcome:** Maintaining a high level of or improving contraceptive use **How was it measured:** Self-administered questionnaire	**Duration of follow-up:** 2 months (85%), 8 months (91%) and 12 months (87%) post randomisation	2 months (end of intervention) Intervention: 72% Control: 66% (difference between groups not significant, p value not reported)	12 months (10 months post intervention) Intervention: 64% Control: 60% (difference between groups not significant, p value not reported)	**Adverse effects:** During the 12 months of follow-up, 10% of participants became pregnant, 1% were diagnosed with chlamydia and 8% had another STD diagnosed. There were no significant differences between the intervention and control groups. **Inequality issues:** Black women reported an improvement in contraceptive use or maintenance of a high level of use at 2 month follow-up with the intervention (72% with intervention vs. 55% with control; p<0.05). This difference was maintained at 12 months (60% vs. 54%, p value not reported).

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Schunmann and Glasier, 2006 **Country** UK **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=613 **Selection/recruitment criteria** Women presenting to the abortion clinic of a hospital. Women undergoing termination of foetal abnormality or who, in the opinion of the nursing staff, were too distressed to be approached were excluded. **Participant characteristics** **Mean age** 24 years **Gender** 100% female (inclusion criteria) **Ethnicity** Not reported **SES** Deprivation category calculated from the postal codes of each individual's residential address: 3.8% category 1 (least deprived); 12.4% category 2; 20.2% category 3; 29.9% category 4; 23.5% category 5; 3.6% category 6; 1.3% category 7 (most deprived) **Sexual orientation** Not reported	**Setting**: Abortion Clinic at a hospital **Provider**: Doctor with specialist training in contraception. Enhanced care was provided by referring doctors or the hospital. **Mode of delivery**: Face-to face (individual level). The first session with a doctor with specialist training in contraception was generally delivered pre-operatively before surgical termination of pregnancy or whilst in the ward undergoing medical termination of pregnancy. A few women undergoing surgical abortion were interviewed post-operatively if there was no time before the procedure. 2 weeks and 12 weeks follow-upappointments with GP/referring doctor or at the hospital were arranged for women receiving the intervention.	**Comparison** N= 316 specialised contraceptive advice and enhanced provision behaviour change intervention vs. N= 297 Usual care **Type**: Multi-session **Focus**: Contraceptive use	**Intensity**: 1 session of 15 to 20 minutes with a doctor with specialist training in contraception. Follow-up appointments 2 weeks and 12 weeks after the abortion at GP/referring doctor or at the hospital	**Target behaviour outcome(s):** **Contraceptive uptake and continuation 16 weeks after termination of pregnancy** **Prioritised main outcome:** Contraceptive use at 16 weeks **How was it measured:** Questionnaire (according to stated preference at time of recruitment, self-administered if mailed or interviewer administered if telephoned). Subsequent abortions assessed by review of hospital records 2 years later	**Duration of follow-up:** 16 weeks (61.5% follow-up). Case notes review at 2 years (available for 93.0% participants)	<u>16 weeks</u> Intervention: 88% Control: 89% (not significantly different, p value not reported)	NA	**Adverse effects:** After 2 years, 14.6% of the intervention group and 10% of the control group had experienced at least one further unintended pregnancy which ended in abortion. The difference between the 2 groups was not statistically significant (chi-squared tests for trend p=0.267; linear-by-linear association p=0.122) **Inequality issues:** Not reported
Tross et al, 2008 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=515 **Selection/recruitment criteria** Adult women participating in drug treatment reporting one or more unprotected vaginal or anal sex occasion with a male partner in the previous 6 months **Participant characteristics** **Age** 54.2% aged 40 years or less **Gender** 100% female (inclusion criteria) **Ethnicity** 57.9% white; 24.3% Black/African American; 8.9% Hispanic/Latina; 8.9% mixed or other **SES** Not reported **Sexual orientation** Not reported, although self-report of sexual intercourse with a man during the previous 6 months an inclusion criterion	**Setting**: 12 community-based outpatient substance abuse treatment programs (affiliated with the National Institute on Drug Abuse Clinical Trials Network, 7 methadone maintenance and 5 outpatient psychosocial treatment programs) **Provider**: Pair of female counsellors **Mode of delivery**: Face-to-face (group level)	**Comparison** N= 250 Safer sex skills building behaviour change intervention vs. N= 265 Usual care (standard HIV/STD education) **Type**: Multi-session **Focus**: Risky sexual behaviour	**Intensity**: 5 sessions of 90 minutes	**Target behaviour outcome(s):** Unprotected vaginal or anal sex occasions **Prioritised main outcome** Number of unprotected vaginal or anal sex occasions in the previous 3 months **How was it measured:** Audio computer-assisted self-interview	**Duration of follow-up:** 3 months (66%) and 6 months (64%) post-intervention	<u>3 months</u> Intervention: 15.08 Control: 17.33 (not significantly different, p value not reported)	<u>6 months:</u> Intervention: 13.96 Control: 24.14 p<0.0377 Effect size (standard difference between predicted means) of 0.42	**Adverse effects:** There were a total of 52 serious adverse events (26 in each group). None of the adverse events were determined to be study related. **Inequality issues**: Not reported

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Wolitski et al, 2005 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=811 randomised and eligible for follow-up(attended first session) **Selection/recruitment criteria** Self-identifying adult HIV positive gay and bisexual men recruited from the community who reported sex in the past year with one or more male partners whose HIV status was seronegative or unknown to the participant **Participant characteristics** **Mean age** 41 years **Gender** 100% male (inclusion criteria) **Ethnicity** 23.1% African American or black; 1.1% Asian or Pacific Islander; 17.4% Hispanic or Latino; 50.6% White or Caucasian; 1.1% Native American; 6.7% mixed race/ethnicity, other **SES** Not reported **Sexual orientation** 87.5% homosexual; 11.4% bisexual; 0.4% straight, heterosexual; 0.7% none of the above, not sure **Other** 33.9% annual income less than $10,000; 23.9% income between $10,000 and $19,999; 19.7% income between $20,000 and $39,999; 17.4% income between $40,000 and $74,999; 5.2% annual income more than $75,000	**Setting**: Community (outside of a medical or social service setting) **Provider**: 2 HIV-seropositive gay or bisexual peer facilitators **Mode of delivery**: Face-to-face (group level)	**Comparison** N= 413 Seropositive Urban Men's Intervention, a peer-led behavioural intervention vs. N= 398 Usual care **Type**: Multi-session **Focus**: Transmission risk behaviour and serostatus disclosure	**Intensity**: 6 sessions of 3 hours over 6 weeks	**Target behaviour outcome(s):** Reduce unprotected insertive anal intercourse, unprotected receptive anal intercourse and unprotected insertive oral intercourse with HIV-seronegative or unknown-status partners; increase condom use during insertive anal intercourse with HIV-seronegative or unknown-status partners; increase disclosure of HIV status to sex partners **Prioritised main outcome:** Unprotected anal intercourse with HIV seronegative or unknown status partner over past 3 months **How was it measured:** Audio computer-assisted self-interview (ACASI)	**Duration of follow-up:** 3 months (85% follow-up), 6 months (90% follow-up) after the last session (intervention or control)	<u>3 months</u> Intervention: 31.3% Control: 26.5% AOR 0.74, 95% CI 0.51 to 1.06	<u>6 months</u> Intervention: 30.5% Control: 26.5% AOR 0.78, 95% CI 0.54 to 1.11	**Adverse effects:** There were no significant differences in sexually transmitted infections between intervention groups at either baseline or 6 month follow-upassessments **Inequality issues:** Not reported
Dilley et al, 2007 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=305 **Selection/recruitment criteria** Adult HIV-negative men who have sex with men voluntarily presenting for anonymous HIV testing who reported at least one episode of unprotected anal intercourse in the previous 12 months with a nonconcordant (unknown or known positive HIV serostatus) and nonprimary (neither husband, domestic partner, nor boyfriend for more than 3 months) male partner **Participant characteristics** **Mean age** 35.5 years **Gender** 100% male (inclusion criteria) **Ethnicity** 1.3% American Indian/Alaskan Native; 7.2% Asian; 7.5% Black/African-American; 64.3% white; 11.8% Latino; 1.3% Native Hawaiian/Pacific Islander; 3.9% More than 1 race or ethnicity; 2.6% other **SES** 16.1% <$15,000 annual household income; 32.8% $15,000 to 44,999; 28.2% $45,000 to 74,999; 22.0% $75,000 or more annual household income; 0.3% not reported **Sexual orientation** Not reported	**Setting**: Publicly funded HIV counselling and testing venues **Provider**: Paraprofessionals (bachelor's level trained and California certified HIV test counsellors with a minimum of 1 year of HIV test counselling experience) **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 147 Personalised cognitive counselling behaviour change intervention vs. N= 158 Usual care **Type**: Extended **Focus**: Risky sexual behaviour	**Intensity**: 1 session of 50 minutes	**Target behaviour outcome(s):** Unprotected anal intercourse with any nonprimary partner of nonconcordant HIV serostatus **Prioritised main outcome:** Number of episodes of unprotected anal intercourse with any nonprimary partner of nonconcordant HIV serostatus within the previous 3 months **How was it measured:** Audio computer-assisted self-interview (ACASI)	**Duration of follow-up:** 6 months, and 12 months (87.9% follow-up)	NA	<u>6 months</u> Intervention: 1.9 Control: 4.3 p=0.029 <u>12 months</u> Intervention: 1.9 Control: 2.2 p=0.756	**Adverse effects:** Not reported **Inequality issues:** Not reported

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Harvey et al, 2009 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 301 couples Data presented for the 212 couples who were intact (still together) at 3 months follow-up **Selection/recruitment criteria** Women aged between 18 and 25 years old and their male partners (aged 18 years or older) who reported having sex without a condom at least once in the past 3 months and met at least one of the following criteria: engaged in risky behaviour (e.g. had another partner in the past year, ever used intravenous drugs); knew or thought their partners were at risk (e.g. had a sexually transmitted disease); or thought thy or their partners would have sex with someone else in the next year while they were still together. Women who reported being HIV positive were excluded. Women were recruited using active and passive methods from clinics and the community **Participant characteristics** **Mean age** Not reported **Gender** 212 women, 212 men (couples) **Ethnicity** 55% women and 56% men Hispanic; 27% women and 26% of men non-Hispanic White; 11% of women and 10% of men African American; 7% of women and 8% of men other race/ethnicity **SES** Not reported **Sexual orientation** Being part of a heterosexual couple an inclusion criterion	**Setting**: Not reported **Provider**: Male and female facilitator (with experience of providing services to the target population) and a facilitator assistant **Mode of delivery**: Face-to-face (group level: up to 12 other couples)	**Comparison** N= Not reported Behaviour change intervention vs. N= Not reported Usual care **Type**: Multi-session **Focus**: Consistency of condom use	**Intensity**: 3 weekly sessions of 2.5 hours	**Target behaviour outcome(s):** Consistency of condom use for vaginal sex with a main partner **Prioritised main outcome:** Proportion of vaginal sex with a main partner in which a condom was used in the previous 90 days **How was it measured:** Interviews (for women and men at 3 months, for women only at 6 months) face-to face with interviewer of the same gender using audio computer-assisted interviewing (CASI). For the most sensitive sexual and risk behaviour questions, participants were given the option of entering their responses directly into the computer	**Duration of follow-up:** 3 months (follow-upof 83% of women and 79% of men) and 6 months (follow-upof 78% of women)	3 months (based on information from 212 intact couples) Intervention: 0.38 Control: 0.35 Condition x Time not significant, p value not reported	6 months (based on information from 178 intact couples) Intervention: 0.34 Control: 0.37 Condition x Time not significant, p value not reported	**Adverse effects:** Not reported **Inequality issues:** Findings applicable to women and men of Hispanic ethnicity.
Healthy Living Project, 2007 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 936 **Selection/recruitment criteria** HIV-Positive adults considered to be at risk of transmitting HIV due to reporting at least 1 act of unprotected vaginal or anal intercourse in the previous 3 months with any partner of HIV negative or unknown serostatus or unprotected intercourse with at least 1 HIV-infected partner other than a primary relationship (e.g. a 1-time partner). Participants were recruited from community agencies and medical clinics **Participant characteristics** **Mean age** 39.8 years **Gender** 79% male, 21% female **Ethnicity** 32% White, 45% African American; 15% Hispanic; 8% Other **SES** Not reported	**Setting**: Not reported **Provider**: Facilitators (included community-based service providers, social workers, counsellors, and doctoral-level therapists) **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 467 cognitive behaviour change intervention vs. N= 469 Wait list control **Type**: Multi-session **Focus**: Transmission risk behaviour	**Intensity**: 15 sessions of 90 minutes over 15 months	**Target behaviour outcome(s):** Transmission risk behaviour including unprotected sexual intercourse, reduction in number of sexual partners and increase in clean needle use **Prioritised main outcome:** Number of unprotected sexual risk acts with persons of HIV negative or unknown status during the previous 3 months **How was it measured:** Audio computer-assisted self-interviewing (ACASI)	**Duration of follow-up:** 5 months (86.0% follow-up), 10 months (82.4%), 15 months (80.1%), 20 months (76.4%), 25 months (76.9%) post randomisation		15 months (end of intervention) There was a 23% reduction in unprotected sex acts with partners whose HIV status was negative or unknown in the intervention group relative to the control group p=0.080 (not significant) 25 months (10 months post intervention)	**Adverse effects:** Not reported **Inequality issues:** Predominantly male population. Analysis of a subgroup (currently and formerly homeless adults living with HIV) is presented in another publication. Findings may be applicable to African

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	Sexual orientation 72% MSM				and computer –assisted personal interviewing (CAPI) (self-report)			There were no differences between groups months , p=0.57 Overall, a significant difference in mean unprotected sex acts with partners whose HIV status was negative or unknown between the intervention and control arms over 5 to 25 months p=0.007. The greatest reduction occurred at the 20-month follow-up, with a 36% reduction in the intervention group compared with the control group	Americans and Hispanic patients **Other:** Baseline characteristics were well balanced between the treatment and control arms except for: transmission risk acts in the last 3 months (individuals in the intervention group reported significantly more); unprotected sex acts (the intervention group reported significantly more) and ethnicity (the intervention group had more African Americans and fewer Latinos/ Hispanics). Researchers used propensity score adjustment to account for this.
Mausbach et al, 2007 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised** N= 451 **Selection/recruitment criteria** Adult HIV negative heterosexual methamphetamine users reporting unprotected sex with at least one opposite sex partner during the previous 2 months. Participants were recruited from the community, venues known to be meeting places of methamphetamine users, snowball sampling techniques, referrals and brochures placed at health clinics, health service agencies and community organisations. **Participant characteristics** **Mean age** 36.5 years **Gender** 67.6% male, 32.4% female **Ethnicity** 49.4% White; 26.8% African American; 12.9% Hispanic/Latino; 1.8%	**Setting**: Drop in centre that offered free coffee and day shelter **Provider**: Counsellors (Educated to Master's level, with previous experience with HIV prevention and substance abuse counselling) **Mode of delivery**: Face-to face (individual level)	**Comparison** N= 149 Fast-Lane safer sex behavioural intervention (Intervention 1) vs. N= 152 Fast-Lane safer sex behavioural intervention with boosters (Intervention 2) vs. N= 150 Attention control (diet and exercise attention	**Intensity**: Intervention 1 (Fast Lane): 4 weekly 90 minute sessions Intervention 2 (Fast Lane plus booster): 4 weekly 90 minute sessions and 4 90minute monthly "booster" sessions at 7, 8, 9 and 10 months post baseline	**Target behaviour outcome(s):** Increased protected sex, decreased unprotected sex, increase in percentage of safer sex behaviours **Prioritised main outcome:** Unprotected sex acts during previous 2 months **How was it measured:** Audio-computer use self-interview (ACASI)	**Duration of follow-up:** 6 months (60.5%), 12 months (48.1%) and 18 months (45.9%) post baseline	NA	<u>6 months</u> Intervention 1: Participants in the Fast Lane condition showed significant reductions in unprotected sex (significant Time x Intervention interaction, p=0.005) Intervention 2: Participants in the Fast Lane plus booster condition showed no significant reduction in	**Adverse effects:** Not reported **Inequality issues:** The effectiveness of the intervention did not vary with gender.

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	Asian/Pacific Islander; 2.2% Native American; 6.9% other **SES** Not reported **Sexual orientation** Being heterosexual was an inclusion criterion		control) **Type**: Multi-session for both interventions **Focus**: Risky sexual behaviour (unsafe sex within the context of methamphetamine use)					unprotected sex (no significant Time x Intervention interaction, p=0.808) <u>18 months</u> Intervention 1: Participants in the Fast Lane condition showed no significant reductions in unprotected sex (no significant Time x Intervention interaction, p=0.261) Intervention 2: Participants in the Fast Lane plus booster condition showed no significant reduction in unprotected sex (no significant Time x Intervention interaction, p=0.808)	
McKirnan et al, 2010 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N= 317 **Selection/recruitment criteria** HIV-positive men enrolled in primary care at one of the clinics involved in the study reporting men who have sex with men sexual activity during the previous year **Participant characteristics** 4 patients died during the study and their characteristics were excluded **Mean age** 42 years **Gender** 100% male (inclusion criteria) **Ethnicity** 31% African American; 17% Latino; 47% White; 5% Asian/Other **SES** Not reported **Sexual orientation** 90% “gay” **Other** 30% <$10,000 income; 27% $10,000 to $20,000; 25% $21,000 to $40,000; 18% >$40,000 income	**Setting**: Primary care (a well-established gay/lesbian health centre, a public clinic and a private medical centre) **Provider**: HIV-positive men who have sex with men “peer advocates” **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 166 Treatment Advocacy Program behaviour change intervention vs. N= 151 Usual care/Waiting list **Type**: Multi-session **Focus**: Transmission risk behaviour	**Intensity**: 4 sessions of 60 to 90 minutes over 8 weeks and 6 and 12 month coping follow-up counselling sessions	**Target behaviour outcome(s):** Unprotected anal intercourse with HIV-negative or HIV-unknown partners; unprotected anal intercourse and number of anal sex partners **Prioritised main outcome:** Unprotected anal intercourse over previous 6 months **How was it measured:** Audio computer-assisted self-interviewing (ACASI) (self-report)	**Duration of follow-up:** 6 months (80%), 12 months (92%) after randomisation	<u>6 months</u> Intervention (n=131 analysed, data for all 3 assessments) Control (n=120 analysed, data for all 3 assessments) Intervention significantly better at 6 months p=0.045	<u>12 months</u> Intervention (n=131 analysed, data for all 3 assessments) Control (n=120 analysed, data for all 3 assessments) Intervention not significantly better at 12 months (no statistically significant interaction of time by group in the 3-wave repeated measures analysis [baseline-6 months-12 months], p=0.10)	**Adverse effects:** Not reported **Inequality issues:** Not reported

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Patterson et al, 2003 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=387 Only participants who completed all 4 assessments were included in the analyses (N=212) **Selection/recruitment criteria** Adult HIV positive individuals who reported in engaging in unprotected sex (oral, anal or vaginal) with HIV- or partners of unknown serostatus during the previous 4 months recruited from the community **Participant characteristics** **Mean age** 37.4 years **Gender** 91% male, 9% female **Ethnicity** 65% non-Hispanic White; 15% African American; 12% Hispanic; and 8% of other ethnicity **SES** Not reported **Sexual orientation** 85% gay or bisexual	**Setting**: Study project offices, located in an off-campus facility near the central business district of San Diego. **Provider**: Counsellors **Mode of delivery**: One-to-one (individual level)	**Comparison** Only participants who completed all 4 assessments and who were included in the analyses are included in the numbers below N= 51 Single session targeting one behaviour change domain (condom use, negotiation or disclosure (intervention 1) vs. N= 47 Single comprehensive session targeting all 3 behaviour change domains (intervention 2) vs. N= 57 Three session comprehensive intervention targeting all 3 behaviour change domains (intervention 3) vs. N= 57 Attention control (3 sessions focussed on diet and exercise) **Type**: Intervention 1 & 2: Extended Intervention 3: Multi-session **Focus**: Sexual/transmission risk behaviour	**Intensity**: Intervention 1 & 2: 1 session of 90 minute Intervention 3: 3 sessions of 90 minutes	**Target behaviour outcome(s):** Unprotected vaginal, anal or oral sex **Prioritised main outcome:** Number of unprotected vaginal, anal or oral sex acts during the 12 month study **How was it measured:** Self-report to counsellor	**Duration of follow-up:** 4 months (79% follow-upof those randomised), 8 months (73% follow-up) and 12 months (69% follow-up) post intervention	NA	12 months Repeated measure ANOVA for unprotected sex acts including participants with complete follow-updata Significant Trials x Group interaction, $F(9,624) = 1.86$ $p<0.05$ Follow-up simple effects tests showed that the nature of the interaction was that the comprehensive-with-booster intervention group reported more unprotected sex acts than the other 3 groups at the 8-month follow-up When using imputation to replace missing values Trials x Group interaction $F(9,1143) = 1.73$ $p=0.07$	**Adverse effects:** Not reported **Inequality issues:** Not reported

Alcohol

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Burke et al, 2008 **Country** Australia **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=241 **Selection/recruitment criteria** Overweight patients aged 40 to 70 years who were hypertensive Recruited by media advertising, detail described elsewhere (Burke et al, 2005) **Participant characteristics** **Mean age** 56.2 **Gender** 44.4% male, 55.6% female **Ethnicity** Not reported **SES** Not reported	**Setting:** Not reported **Provider:** Not reported **Mode of delivery:** Face-to-face (group level)	**Comparison** N= 123 Lifestyle programme vs. N= 118 Usual care **Type:** Multi-session **Focus:** Lifestyle modification for overweight hypertensive patients	**Intensity:** 4 month programme	**Target behaviour outcome(s)** Lifestyle modification **Prioritised main outcome:** Grammes of alcohol consumption in the past week **Measured:** Retrospective diary	**Duration of follow-up:** 4 months (84.6% follow-up), 1 year (80% follow-up), 3 years (58.1% follow-up)	Previously assessed at 4 months and one year (Burke et al, 2005)	3 years (36 months) Intervention: 16.1 (95% CI 12.9 to 19.3) Control: 13.0 (95% CI 9.1 to 16.8) (difference between groups not significant, p value not reported)	**Adverse effects:** Not reported **Inequality issues:** Not reported **Other:** Results for sexual health behaviour outcomes are described in the extraction table for sexual health.
Carey et al, 2006 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=509 **Selection/recruitment criteria** University students **Participant characteristics** **Mean age** 19 **Gender** 35% male , 65% female **Ethnicity** 89% white **SES** Not reported	**Setting**: University **Provider**: Psychology graduate students **Mode of delivery**: Face-to-face	**Comparison** Intervention 1 N=89 TLFB Intervention 2 N=87 TLFB/basic brief motivational intervention (BMI+TLFB) Intervention 3 N=86 TLFB enhanced brief motivational intervention (EBMI+TLFB) Intervention 4 N=85 basic brief motivational intervention (BMI) Intervention 5 N=81 enhanced brief motivational intervention vs. N=81 No intervention **Type**: Brief **Focus**: Heavy dinking	**Intensity**: 1 session, duration not reported	**Target behaviour outcome(s):** Alcohol intake **Prioritised main outcome:** Drinks per week **Measured**: Self-reported drinking behaviour	**Duration of follow-up:** 1 month (97% follow-up), 6 months (77% follow-up), 12 months (78% follow-up)	1 month Intervention 1 (TLFB): 16.0 Intervention 2(TLFB, basic brief motivational interviewing): 13.3 Intervention 3 (TLFB, enhanced brief motivational intervention): 13.1 Intervention 4 (basic brief motivational intervention): 13.7 Intervention 5 (enhanced brief motivational intervention): 13.8 Control: 16.4 No p-value reported	6 months Intervention (TLFB): 15.9 Intervention 2 (TLFB, basic brief motivational intervention): 13.8 Intervention 3 (TLFB, enhanced brief motivational intervention): 14.6 Intervention 4 (basic brief motivational intervention): 14.0 Intervention 5 (enhanced brief motivational intervention): 17.6 Control: 17.4 No p-value reported 12 months: Intervention 1 (TLFB): 16.2 Intervention 2 (TLFB, basic	**Adverse effects:** Not reported **Inequality issues:** Not reported

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								brief motivational intervention): 14.5 Intervention 3 (TLFB, enhanced brief motivational intervention): 116.5 Intervention 4 (basic brief motivational intervention): 12.8 Intervention 5 (enhanced brief motivational intervention): 15.6 Control: 15.0 No p-value reported.	
Chang et al, 2005 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised** N=304 **Selection/recruitment criteria** Pregnant women **Participant characteristics** **Median age** 30.7 to 32 **Gender** 100% female **Ethnicity** 7.6% African American, 78.6% White, 13.8% other **SES** Median annual income: $55,000, median years of education: 16 to 16.3 years	**Setting**: Clinic **Provider**: Nurse or doctor **Mode of delivery**: Face-to-face (individual level)	**Comparison** N=152 Brief intervention with partners vs. N=152 Assessment only **Type**: Brief **Focus**: Alcohol consumption during pregnancy	**Intensity**: 1 session for 25minutes.	**Target behaviour outcome(s):** Alcohol intake **Prioritised main outcome:** Drinks per day **Measured**: Self-reported days drinking (as % of all days) using TLFB	**Duration of follow-up:** Median 23 weeks (95% follow-up)	Median 23 weeks Intervention: 1.9% Control: 2.0%	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Chang et al, 2011 **Country** US **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised** N=511 **Selection/recruitment criteria** Women with diabetes, hypertension, infertility or osteoporosis who were T-ACE alcohol screen positive and/or typically consumed more than 7 drinks per week or more than 2 drinks at a time. Recruited from outpatient care and advertisements on the subway, newspapers, online. **Participant characteristics** **Mean age** 45 **Gender** 100% female **Ethnicity** 75.5% white, 21.8% black, 5.4% Hispanic, 2% Asian, 0.7% Pacific Islander	**Setting**: Hospital outpatient (OP) **Provider**: Physicians **Mode of delivery**: Face-to-face (individual level)	**Comparison** N=249 Brief intervention vs. N=262 Assessment only **Type**: Brief **Focus**: Risky alcohol consumption	**Intensity**: 1 session of 30 minutes	**Target behaviour outcome(s):** Risky alcohol consumption **Prioritised main outcome:** Drinks per drinking day in the past 90 days **Measured**: TLFB	**Duration of follow-up:** 12 months (96% follow-up) (Intervention group assessed at 3, 6 and 12 months Assessment only group assessed at 12 months only)	NA	12 months Intervention: 2.0, mean change -0.31 (SD 1.4) Control: 1.9, mean change -0.18 (SD 1.4) Mean difference in change: -0.06, 95% CI 0.3 to 0.18, p=0.63	**Adverse effects:** Not reported **Inequality issues:** Brief intervention was ‘less helpful’ among Hispanic women.

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	SES Employed 66.2%, Education (<bachelor of arts including high school) 37.8%								
Collins and Carey, 2005 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=131 **Selection/recruitment criteria** University students **Participant characteristics** **Mean age** Not reported **Gender** Not reported **Ethnicity** Not reported **SES** Not reported	**Setting**: University **Provider**: Psychologist **Mode of delivery**: Face-to-face and computer	**Comparison** N=Not reported in-person decisional balance (IDB) vs. N=Not reported written decisional balance (WDB) vs. N=Not reported Assessment only **Type**: Brief **Focus**: Heavy drinking	**Intensity**: 1 session for 30 minutes.	**Target behaviour outcome(s):** Alcohol intake **Prioritised main outcome:** Drinks during the previous 2 weeks **Measured**: Self-reported drinking behaviour during the previous 2 weeks using the Daily Drink Assessment	**Duration of follow-up:** 2 weeks (98% follow-up), 6 months (64% follow-up), 12 months (78% follow-up)	<u>2 weeks</u> No data provided, intervention not a significant predictor of drinking outcomes.	<u>6 months</u> No data provided. Intervention not a significant predictor of drinking outcomes.	**Adverse effects:** Not reported **Inequality issues:** Not reported
Curry et al, 2003 **Country** US **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=307 **Selection/recruitment criteria** Patients identified as having at risk drinking patterns Recruited from scheduled appointments to see 1 of 23 participating primary care physicians **Participant characteristics** **Mean age** 47 **Gender** 65% male, 35% female **Ethnicity** 80% Caucasian **SES** 67% reported household incomes greater than $35,000 per year, 80% employed full or part time**,** 90% post high school education, 52% married or living as married	**Setting:** Urban health clinic (Group Health Cooperative, a consumer governed health maintenance organisation) **Provider:** Primary care physicians who received training in delivery intervention (Face-to-face session), graduate level clinical psychology student (telephone follow-up) **Mode of delivery:** Face-to-face (individual level) and telephone	**Comparison** N= 151 Multi-component intervention vs. N= 156 Usual care **Type:** Multi-session **Focus:** Drinking patterns including alcohol consumption	**Intensity:** 1 session of 1 to 5 minutes and 3 follow-up phone calls (average length 14 minutes) over a 3 month period (first call within 1 to 2 weeks following initial session; second call within 4 weeks of first call; third call within 4 weeks of second call).	**Target behaviour outcome(s)** Drinking patterns including alcohol consumption **Prioritised main outcome:** Any risky drinking pattern (chronic drinking, binge drinking, drink driving) **Measured:** Modified Cahalan questions assessed drinking quantity and frequency. Retrospective 1-week drinking diary used as additional measure of alcohol consumption to assess number of standardised drinks consumed per week. Binge drinking assessed using single question. Drinking and driving assessed using standardised question.	**Duration of follow-up:** 3 months 82.4% follow-up), 12 months (72% follow-up)	<u>3 months</u> Intervention: 42%, p=0.002 Control: 58% Drinks per week: Intervention: 8.6, p=0.06 Control: 10.3	<u>12 months</u> Intervention: 43%, p=0.012 Control: 57% Drinks per week: Intervention: 10.6, p=0.33 Control: 10.6	**Adverse effects:** Not reported **Inequality issues:** Not reported

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW-UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
Daeppen et al, 2007 **Country** Switzerland **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=987 **Selection/recruitment criteria** Injured, hazardous drinking ED patients **Participant characteristics** **Mean age** 36.7 **Gender** 78.2% male, 21.8% female **Ethnicity** Not reported **SES** Not reported	**Setting**: Hospital ED **Provider**: Masters level psychologists or ED nurse **Mode of delivery**: Face-to-face (individual level)	**Comparison** N=310 Brief alcohol intervention (BAI) vs. N=342 Screening and assessment vs. N=335 Screening only **Type**: Brief **Focus**: Risky drinking	**Intensity**: 1 session of 10 to15 minutes	**Target behaviour outcome(s):** Risky drinking **Prioritised main outcome:** Total number of drinks over 7 days **Measured**: Self-reported via telephone interview	**Duration of follow-up:** 12 months (78% follow-up)	NA	<u>12 months</u> Mean (SD) BAI: 13.4 (12.8) Screening and Assessment:13.3 (14.7) Screening only: 10.9 (14.2) No significant differences between groups	**Adverse effects:** Not reported **Inequality issues:** No significant differences found across gender or age groups.
Dent et al, 2008 **Country** Australia **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=468 **Selection/recruitment criteria** ED patients **Participant characteristics** **Median age** 34-36 **Gender** 78% male, 22% female **Ethnicity** Not reported **SES** Not reported	**Setting**: Hospital ED and clinic **Provider**: Doctor or nurse **Mode of delivery**: Face-to-face (individual level)	**Comparison** Intervention 1: N=159 Brief intervention (BI) in ED vs. Intervention 2: N=148 post-discharge motivational interview (MI) vs. N=161 Usual care (Control) **Type**: BI: Brief MI: Extended **Focus**: Alcohol consumption	**Intensity**: Intervention 1: 1 session for median 5 minutes Intervention 2: 1 session median 45 minutes	**Target behaviour outcome(s):** Alcohol consumption **Prioritised main outcome:** Most drinks per day **Measured**: Self-reported	**Duration of follow-up:** 3 months (54% follow-up	<u>1 month</u> Median and IQR, p-value vs. control Intervention 1 (BI): 10.75 (7 to 18), NS Intervention 2 (MI): 10.5 (6 to 18), p<0.001 Control: 8 (4.5 to 13.5), p<0.05 <u>3 months</u> Intervention 1 (BI): 9 (6 to 18) Intervention 2 (MI): 10.3 (6 to 17.5), NS Control: 9 (5 to 13.5), p<0.05	NA	**Adverse effects:** Not reported **Inequality issues:** Not Reported
Dermen and Thomas, 2011 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=154 **Selection/recruitment criteria** Heavy-drinking students aged between 18 and 30 years old at behaviour risk for infection with HIV and other sexually transmitted diseases recruited from colleges and universities. Heavy drinking was defined as consuming at least 5 (men) or 4 (women) drinks at least once in the past 2 weeks. Students with a score of 20 or more on the Short-Form Alcohol Dependence Data Questionnaire, and those receiving counselling for drinking, were excluded. Students had to report 7 or more	**Setting**: Not reported **Provider**: Counsellor of the same gender as the participant **Mode of delivery**: Face-to-face (individual level). Participants in intervention groups were provided with a personal feedback report, an explanatory booklet, a decisional balance sheet (if completed), a change plan worksheet (if completed), a booklet describing strategies and sources of support for reducing risk behaviour, and a handwritten note from the counsellor.	**Comparison** Intervention 1: N= 39 Behaviour change intervention focussing on reducing alcohol risk behaviour (intervention 1) vs. Intervention 2: N= 39 Behaviour change intervention focussing on reducing HIV risk behaviour	**Intensity**: 2 sessions over 5 weeks (all interventions). The first sessions were 45 minutes long (intervention 1 and 2) or 60 minutes long (intervention 3). The second sessions were 30 minutes long (intervention 1 and 2) or 45 minutes long (intervention 3)	**Target behaviour outcome(s):** Drinking days, drinks per day (alcohol outcomes) **Prioritised main outcome** Drinks per drinking day (Alcohol risk outcome) within the previous 3 months **How was it measured:** modified TLFB interview with same gender counsellor, face-to-face.	**Duration of follow-up:** 3 months (95% follow-up), 6 months (94% follow-up), 9 months (92% follow-up), 12 months (91% follow-up), 15 months (91% follow-up) following randomisation	<u>3 months</u> Mean (SD) Intervention 1: 5.2 (2.9) Intervention 2: 6.3 (3.9) Intervention 3: 5.3 (2.8) Control: 5.0 (2.4)	<u>15 months</u> Mean (SD) Intervention 1: 4.0 (2.1) Intervention 2: 6.1 (4.3) Intervention 3: 5.2 (2.6) Control: 5.1 (2.9) ANOVA Alcohol condition	**Adverse effects:** Not reported **Inequality issues:** Not reported **Other:** Baseline levels of number of drinking days in past 90 days; number of drinks per drinking day and number of

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	occurrences of unprotected heterosexual intercourse in the past 90 days and having 2 or more sex partner in the past 90 days, or having a partner who had other partners in the past 24 months but who had not been tested for HIV during the past 12 months. **Participant characteristics** **Mean Age** 20.7 years **Gender** 40.9% male, 59.1% female **Ethnicity** 86.4% While; 5.2% Hispanic; 3.9% African American; 3.9% Asian American; 0.6% American Indian **SES** Not reported **Sexual orientation** 98.7% Heterosexual; 1.3% Bisexual. Being either heterosexual or bisexual was an inclusion criterion		(intervention 2) vs. Intervention 4: N= 36 Behaviour change intervention focussing on reducing alcohol and HIV risk behaviour (intervention 3) vs. N= 40 No intervention **Type**: Multi-session for all 3 interventions **Focus**: Alcohol risk behaviour; HIV risk behaviour; both alcohol and HIV risk behaviour		For participants who had moved out of the area, assessments were completed by telephone or by mail. Collateral assessments of drinking were obtained by telephone administered TLFB from friends, significant others, roommates, siblings and cousins. Participants who were missing outcome data from any follow-up point were dropped from outcome analyses. N=140 participants were analysed			participants drank significantly fewer drinks per drinking day than did control condition participants (p=0.010), whereas outcomes of combined (intervention 3) and HIV participants (intervention 2) did not differ (p=0.662)	sexual partners was not equal between groups
Emmen et al, 2005 **Country** The Netherlands **Design** RCT **Internal validity** **++** **External validity** **+**	**Number randomised** N=123 **Selection/recruitment criteria** Patients who visited an outpatient clinic for general internal medicine and were identified as problem drinkers or whom physicians suspected of having drinking problems **Participant characteristics** **Mean age** 48.9 **Gender** 75.6% male, 24.4% female **Ethnicity** Not reported **SES** 56.1% employed, 47.2% higher education	**Setting:** University hospital **Provider:** 7 psychologists trained to perform the intervention **Mode of delivery:** Face-to-face (individual level) and on paper (feedback).	**Comparison** N= 61 Brief psychosocial intervention vs. N= 62 Usual care **Type:** Multi-session **Focus:** Change in alcohol consumption	**Intensity:** 1 session of 90 minutes delivered shortly after the baseline assessment followed by a second session of 60 minutes delivered 1 to 2 weeks after the first session.	**Target behaviour outcome(s)** Change in alcohol consumption **Prioritised main outcome:** Alcohol consumption (Laboratory indicator of alcohol consumption Serum carbohydrate-deficient transferring; CDT) **Measured:** Serum carbohydrate-deficient transferrin	**Duration of follow-up:** 6 months (91.1% follow-up)	NA	<u>6 months</u> Units per day (U/day) Intervention: 3.35 (SD 2.15) Control: 2.86 (SD 2.45) Change in U/day: Intervention: 0.81 (SD 2.0), p not significant (p value not reported) Control: 0.84 (SD 2.61) % CDT Intervention: 2.52 (1.04), p not significant (p value not reported) Control: 2.35 (SD 0.77) No differences were found between the intervention and	**Adverse effects:** Not reported **Inequality issues:** Not reported

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW-UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
								control groups.	
Feldman et al, 2011 **Country** Switzerland **Design** RCT **Internal validity** **++** **External validity** **++**	**Number randomised** N=112 **Selection and recruitment** People receiving treatment for opioid or cocaine dependence with excessive drinking or alcohol dependence Recruited from outpatient clinics **Participant characteristics** **Mean age** 34.5 **Gender** 73.2% male, 26.8% female **Ethnicity** Not reported **SES** Not reported **Other** 43.7% heavy drinkers, 56.3% alcohol dependence Considered heterogeneous sample	**Setting:** University Hospital outpatient (OP) **Provider:** Multidisciplinary team (psychiatrists, psychologists, nurses and social workers) **Mode of delivery:** Face-to-face (individual level)	**Comparison** N= 52 Brief intervention vs. N= 60 Usual care **Type:** Single brief intervention **Focus:** Alcohol abuse and dependence	**Intensity:** 1 session of 16 minutes (SD 4.7 minutes) delivered 2 to 3 weeks following screening	**Target behaviour outcome(s)** Alcohol abuse and dependence **Prioritised main outcome:** Glasses of alcohol per week **Measured:** First question of the AUDIT score	**Duration of follow-up:** 3 months (53.6% follow-up, 9 months (59.1% follow-up)	<u>3 months</u> Intervention: 13 (SD 19.5) Control: 15.4 (SD 17.6) (significant decrease in alcohol consumption, p value not reported)	<u>9 months</u> Intervention: 16.4 (SD 20.7) drinks per week Control: 14.7 (SD 17.5) drinks per week (difference between groups not significant, p value not reported)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Field et al, 2009 **Country** US **Design** RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N=1493 **Selection/recruitment criteria** Injured patients (intentional or unintentional) presenting at a trauma centre considered at risk drinkers who identified as white, black or Hispanic. Recruited from a level 1 urban trauma centre over 2 years **Participant characteristics** **Mean age** Not reported **Gender** 82.5% male, 17.5% female **Ethnicity** 44.7% white, 36.0% Hispanic, 19.3% black **SES** 37.3% some high school, 69.4% employed for wages, 5.8% no income, 19.5% <$10,000 income level, 41.6% $10,000 to <$30,000 income level. Employment: 38.8% some high school	**Setting:** Level 1 urban trauma centre **Provider:** Clinicians (Masters level or degree and certified in brief intervention following training) **Mode of delivery:** Face-to-face (individual level)	**Comparison** N= 737 Brief motivational intervention vs. N= 756 Usual care Further analysed as: N=326 White brief motivational intervention N=342 White usual care N= 148 Black brief motivational intervention N=140 Black usual care N=263 Hispanic brief motivational intervention N=274 Hispanic usual care **Type:** Unclear **Focus:** Change in drinking outcomes	**Intensity:** Not reported	**Target behaviour outcome(s)** Change in drinking outcomes **Prioritised main outcome:** Change in weekly alcohol volume consumed **Measured:** Graduated frequency	**Duration of follow-up:** 6 months (77% follow-up), 12 months (66% follow-up) (Hispanics were less likely to complete a 6 month follow-up)	<u>6 months</u> White brief motivational intervention: -5.0 (26.3) White usual care: -5.1 (21.7) p>0.50 Black brief motivational intervention: -4.5 (18.5) Black usual care: -4.0 (21.8) p>0.50 Hispanic motivational intervention: -9.4 (24.2) Hispanic usual care: -8.0 (19.4) p=0.09	<u>12 months</u> White brief motivational intervention: -4.6 (26.6) White usual care: -3.7 (20.3), p>0.50 Black brief motivational intervention: -3.0 (20.3) Black usual care: -3.5 (19.4), p>0.50 Hispanic brief motivational intervention: -8.9 (SD 26.2) Hispanic usual care: -5.7 (17.9), p=0.01	**Adverse effects:** Not reported **Inequality issues:** Intervention effect was significant among Hispanics at 6 and 12 months but not significant for whites or blacks at either time point.
Fleming et al, 2008 **Country** US **Design** RCT **Internal**	**Number randomised** N=235 **Selection/recruitment criteria** Postpartum women identified as high risk drinkers Recruited from regularly scheduled appointments for postpartum care **Participant characteristics**	**Setting:** Offices of 34 obstetrical primary care practice clinics including a diverse sample of rural, urban and small communities. **Provider:** Trained outpatient obstetrical nurses (90% of delivery) or obstetricians **Mode of delivery:**	**Comparison** N= 122 Brief intervention vs. N= 113 Usual care **Type:** Multi-session	**Intensity:** 2 sessions of 15 minutes (1 month apart) and 2 follow-upphone calls (2 weeks after each Face-to-face visit). Total of 4 contacts over 8 weeks.	**Target behaviour outcome(s):** Reduced alcohol consumption and related consequences **Prioritised main outcome:** Number of drinks in the past 28 days	**Duration of follow-up:** 6 months (87% follow-up)	NA	<u>6 months</u> Intervention: 19.8 (SD 19.2) drinks in past 28 days, p=0.013 Control: 27.1 (SD 22.1) drinks in past 28 days	**Adverse effects:** Not reported **Inequality issues:** Not reported

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validity **++** **External validity** **++**	**Median age** 28 **Gender** 100% women **Ethnicity** 81.7% Caucasian, 7.2% Native American, 6.8% African American, 2.5% Hispanic, 0.9% Asian, 0.9% Other **SES** 12.8% less than high school educated 53.2% tobacco use, 17.9% marijuana use	Face-to-face (individual level) and telephone follow-up	**Focus:** Reduced alcohol consumption and related consequences among women during the postpartum period		**Measured:** TLFB				
Fleming et al, 2010 **Country** US and Canada **Design** RCT **Internal validity** **++** **External validity** **+**	**Number randomised** N=986 **Selection/recruitment criteria** College students identified as high risk drinkers Recruited from scheduled appointments to see their primary care clinicians **Participant characteristics** **Mean age** 21 **Gender** 49.1% male, 50.9% female **Ethnicity** 90.7% non-Hispanic white **SES** Not reported 46% tobacco use	**Setting:** 5 college health clinics based at 5 universities (including 2 sites located in rural areas) **Provider:** Primary care providers trained in intervention delivery; 13 physicians (91% of delivery of interventions); 3 nurse practitioners; 1 physician assistant **Mode of delivery:** Face-to-face (individual level)**,** telephone or email follow-up.	**Comparison** N=493 Brief intervention vs. N=493 Usual care **Type:** Multi-session **Focus:** Reduced alcohol consumption and related harm	**Intensity:** 2 sessions of 15 minutes (1 month apart) and 2 follow-upphone calls or emails (2 weeks after the first visit and 1 month after the second visit)	**Target behaviour outcome(s):** Reduced alcohol consumption and related harm **Prioritised main outcome:** Number of drinks in the past 28 days **Measured:** TLFB	**Duration of follow-up:** 6 and/or 12 months (96% follow-up), 6 and 12 months (88% follow-up)	<u>6 months</u> Intervention: 52.9 (SD 42.5) average drinks in the past 28 days, p value not reported Control: 57.2 (SD 39.6) average drinks in the past 28 days, p value not reported	<u>12 months</u> Intervention: 51.7 (SD 40.1) average drinks in the past 28 days, p=0.018 % change from baseline to 12 months: 27.2% Control: 54.7 (SD 40.3) average drinks in the past 28 days, % change from baseline to 12 months: 21.0%	**Adverse effects:** Significant reductions in alcohol related self reported harm in favour of the intervention are reported **Inequality issues:** Not reported
Gilbert et al, 2008 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=476 Risky drinking was reported by 182 participants; unprotected anal or vaginal intercourse was reported by 284 participants. **Selection/recruitment criteria** Adults HIV positive for 3 months or longer reporting substance use or sexual risks (drug use defined as use of 10 illicit drugs in the past month; risky alcohol use was defined as exceeding the US National Institute on Alcoholism and Alcohol Abuse's recommended number of drinks per week or 3 or more binge drinking episodes within previous 3 months; sexual risk was defined as anal or vaginal intercourse without a condom in the past 3 months) **Participant characteristics** **Mean age** 44.1 years **Gender** 79% male21% female **Ethnicity** 13% Hispanic/Latino; 50% Black or African American; 29% white; 8% other or multiple races **SES** Not reported **Sexual orientation** 51% MSM or MSM/W **HIV status** HIV infection an inclusion criterion	**Setting**: Outpatient HIV clinics **Provider**: "Video doctor" **Mode of delivery**: "Video doctor" delivered via laptop computer 1 hour prior to a regularly scheduled medical appointment; and printed educational worksheet printed at end of "video doctor" session	**Comparison** N= 243 Positive choice behaviour change intervention vs. N= 233 Usual care **Type**: Multi-session **Focus**: Illicit drug use, risky alcohol drinking, and anal or vaginal intercourse without a condom	**Intensity**: 2 sessions (24 minutes in length on average) over 3 months	**Target behaviour outcome(s):** Cessation of illicit drug use, risky drinking, and unprotected anal or vaginal sex **Prioritised main outcome:** Any ongoing risky drinking **How was it measured:** Computer-administered assessment (self-report)	**Duration of follow-up:** 3 months (78%) and 6 months (83%) post randomisation	<u>3 months</u> Intervention 48/92 (52%) Control 56/90 (62%) Relative risk 0.84, 95% CI 0.651 to 1.080 p=0.172 (not significant)	<u>6 months</u> Intervention 47/92 (51%) Control 53/90 (59%) Relative risk 0.87, 95% CI 0.666 to 1.130 p=0.291 (not significant)	**Adverse effects:** There were 2 incidences of perceived breaches of confidentiality, both successfully resolved. 5 study participants died during the data collection period. Investigations found that the deaths were due to HIV and not associated with participation in the trial. **Inequality issues:** Preplanned subgroup analyses by participants' gender, race/ethnicity, hepatitis-C co-

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									infection, HIV viral load, source of HIV infection, or sex partners' HIV status did not differ from aggregate results. Participants' previous treatment for alcohol or drug abuse did not affect substance use outcomes. Findings relevant to Black/African-American populations
Holloway et al, 2007 **Country** UK **Design** Cluster RCT **Internal validity** + **External validity** ++	**Number randomised** N=215 **Selection/recruitment criteria** Hospital patients **Participant characteristics** **Mean age** 44-46 **Gender** 85% male, 15% female **Ethnicity** Not reported **SES** Carstairs >4 (relatively deprived) 63%	**Setting**: Hospital **Provider**: Mental health nurse (SEE) or media only (SHB) **Mode of delivery**: Face-to-face (SEE) or printed booklet (SHB)	**Comparison** Intervention 1 N=70 self-efficacy enhancement (SEE) vs. Intervention 2 N=69 self-help booklet (SHB) vs. N=76 Usual care **Type**: Intervention 1: Brief Intervention 2: Not reported **Focus**: Alcohol consumption	**Intensity**: Intervention 1: 1 session, of 20 minutes Intervention 2: Not reported	**Target behaviour outcome(s):** Alcohol consumption **Prioritised main outcome:** Change in weekly alcohol consumption **Measured**: Self-reported	**Duration of follow-up:** 6 months (80% follow-up)	NA	<u>6 months</u> Mean change from baseline (SD) Intervention 1: -15.1 (24.76) Intervention 2: -13.9 (21.54) Control: -4.7 (10.68) Mean change difference vs. control: Intervention 1: -10.1 (-16.1 to -4.1) p=0.001 Intervention 2: -10.0 (-16.0 to -3.9) p=0.001	**Adverse effects:** Not reported **Inequality issues:** Not reported

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Ingersoll et al, 2005 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=228 **Selection/recruitment criteria** Female students aged between 18 and 24 years old at risk for alcohol exposed pregnancy recruited from one university. Risk for alcohol exposed pregnancy as defined as having sexual intercourse with a man in the past 90 days while using contraception ineffectively (no use, incorrect use of an effective method, or use of an ineffective method only); and drinking at risk levels (engaging in at least one binge [5 or more standard drinks per occasion] in the past 90 days or consuming an average of 8 standard drinks per week) **Participant characteristics** **Mean age** 20.5 years **Gender** 100% female (inclusion criteria) **Ethnicity** 70% Caucasian; 16% African American; 6% Asian; 2% Latina; 4% Other; 1% Pacific Islander **SES** Not reported **Sexual orientation** Not reported	**Setting**: Not reported **Provider**: Counsellor **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 114 Birth Control and Alcohol Awareness: Negotiating Choices Effectively (BALANCE) behaviour change intervention vs. N= 114 Information only (informational pamphlet about women's health) **Type**: Extended **Focus**: Risk of alcohol-exposed pregnancy	**Intensity**: 1 session of 60 to 75 minutes	**Target behaviour outcome(s):** Alcohol exposed pregnancy risk **Prioritised main outcome:** Number of standard drinks per week **How was it measured:** Mailed questionnaire (self-report)	**Duration of follow-up:** 1 month (93% follow-up)	<u>1 month</u> Mean (SD) Intervention: 9.5 (14.7) Control: 11.4 (10.7) Not significant, p value not reported	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported **Other:** Results for sexual health behaviour outcomes are described in the extraction table for sexual health.
Juarez et al, 2006 **Country** US **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=122 (89 analysed) **Selection/recruitment criteria** College students identified as having at least one heavy drinking episode Recruited from introductory and advanced psychology classes at a large South-western university **Participant characteristics** **Mean age**19.43 **Gender** 47.5 % male, 52.5% female **Ethnicity** 56.6% White/non-Hispanic, 30.3% Hispanic **SES** Not reported 80.3% freshman or sophomores	**Setting:** University **Provider:** Motivational interview sessions provided by 7 master's level clinical psychology graduate students who were trained in MI. **Mode of delivery:** Face-to-face for motivational interviewing sessions (individual level). Remote delivery of mailed paper feedback.	**Comparison** Intervention 1 N= 15 Motivational interviewing only (MI) Intervention 2 N= 20 Mailed feedback only (MF) Intervention 3 N= 15 Motivational interviewing including feedback (MI+F) Intervention 4 N= 18 Motivational interviewing + mailed feedback (MI+MF) vs. Control N= 21 Assessment only **Type:** Intervention 1: Extended Intervention 2: Brief Intervention 3 : Multi-session Intervention 4: Multi-	**Intensity:** Intervention 1: 1 session of 40 to 60 minutes Intervention 2: Students received mailed feedback 1 to 2 weeks after baseline assessment Intervention 3: 1 session of 60 to 80 minutes. Students received feedback during extended session. Intervention 4: 1 session was 40 to 60 minutes. Students received mailed feedback 1 week after session	**Target behaviour outcome(s)** Frequency and quantity of alcohol consumption **Prioritised main outcome:** Drinks per day in the past 2 months **Measured:** Modified TLFB	**Duration of follow-up:** 2 months (73% follow-up)	<u>2 months</u> Intervention 1 (Motivational interviewing only): 0.59 (SD 0.52) drinks per day Intervention 2 (mailed feedback only): 0.80 (SD 0.64) drinks per day Intervention 3 (Motivational interviewing including feedback): 1.20 (SD 1.56) drinks per day Intervention 4 (Motivational interviewing + mailed feedback): 0.57 (SD 0.50) drinks per day Control (assessment only): 0.87 (SD 0.69) drinks per	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported.

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			session **Focus:** Frequency and quantity of alcohol consumption				day Group by time interaction was not significant for drinks per day		
Koelewijn-van Loon et al, 2009 **Country** The Netherlands **Design** Cluster RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N=25 practices, 615 patients (589 analysed) **Selection/recruitment criteria** **Practices:** Practices that employed a practice nurse and used electronic patient records. Recruited by letter. **Patients:** Patients eligible for cardiovascular risk management as per the national guideline for risk management - included diabetes, smoker >50 for men and >55 for women (patients with existing cardiovascular disease were excluded). Recruited by nurses and general practitioners. **Participant characteristics** **Mean age** 57 (of 589 analysed) **Gender** 44.8% male, 55.2% female (of 589 analysed) **Ethnicity** Not reported **SES** 23.6% high SES, 40.1% intermediate SES, 36.4% (of 589 analysed)	**Setting:** 25 primary care practices **Provider:** Practice nurses trained in intervention delivery **Mode of delivery:** Face-to-face (individual level) and telephone (follow-up).	**Comparison** N= 13 practices, Nurse led cardiovascular risk management vs. N= 12 practices, Usual care **Type:** Multi-session **Focus:** Lifestyle change	**Intensity:** 2 sessions of 15 to 20 minutes (Face-to-face) and 10 minute follow-upphone call	**Target behaviour outcome(s):** Alcohol intake above nationally recommended levels **Prioritised main outcome:** Drinking above the nationally recommended level **Measured:** 2-item questionnaire about frequency and quantity of alcohol use resulting in a score of drinking above the national recommendation (males <3 alcohol units per day, <2 alcohol units per day for females)	**Duration of follow-up:** 12 months (79.3% follow-up)	NA	<u>12 months</u> Intervention: 24 (SD 9.9) people above the nationally recommended level, p=0.75 Control: 24 (SD 10.8) people above the nationally recommended level OR 4.67 for intervention group (95% CI 0.54 to 40.61)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Kulesza et al, 2010 **Country** US **Design** RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N=114 **Selection/recruitment criteria** Undergraduate college students identified as heavy drinkers Recruited from the university's psychology subject pool **Participant characteristics** **Mean age** 20 **Gender** 28.1% male, 71.9% female **Ethnicity** 84.2% Caucasian **SES** Not reported	**Setting:** University **Provider:** Clinical graduate students trained in motivational interviewing (MI) **Mode of delivery:** Face-to-face (individual level)	**Comparison** Intervention 1 N= 39 'Brief Alcohol Screening and Intervention for College Students' (BASICS) brief intervention of 10 minutes (10M) Intervention 2 N= 35 'Brief Alcohol Screening and Intervention for College Students' (BASICS) brief intervention of 50 minutes (50M) vs. Control N= 40 Waitlist control of 6 weeks	**Intensity:** Intervention 1: 1 session of 10 minutes delivered 2 weeks after baseline assessment Intervention 2: 1 session of 50 minutes delivered 2 weeks after baseline assessment	**Target behaviour outcome(s)** Reduced alcohol consumption and alcohol related problems **Prioritised main outcome:** Drinks consumed and hours spent drinking each day of the week over the past month **Measured:** DDQ	**Duration of follow-up:** 1 month (100% follow-up)	<u>1 month</u> Intervention 1: 9.9 (SD 7.2) drinks per week, p=0.03 for comparison with control group, effect size compared to control d=0.02 Intervention 2: 12.1 (SD 8.1)drinks per week, p value not reported, effect size compared to control d=0.18 Control: 13.9 (SD 7.6) drinks per week	NA	**Adverse effects:** Not reported **Inequality issues:** Predominantly female study population

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW-UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
			(assessment only) **Type:** Intervention 1:Brief Intervention 2: Extended **Focus:** Reduced alcohol consumption and alcohol related problems among high risk college drinkers						
Lane et al, 2008 **Country** Australia **Design** RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N=184 **Selection/recruitment criteria** Sexual health clinic patients identified as hazardous or harmful drinkers Recruited from sexual health clinics (including one male clinic) in 2 city locations from 4 to 5 clinic sessions per week **Participant characteristics** Not reported for the randomised sample. **Mean age** 34 (from the 511 patients that provided demographical data) **Gender** 74% male, 26% female (from the 511 patients that provided demographical data) **Ethnicity** Not reported **SES** Not reported	**Setting:** Sexual health clinic **Provider:** 2 nurse practitioners trained in intervention delivery **Mode of delivery:** Face-to-face (individual level)	**Comparison** N=87 Drink-less brief intervention vs. N=97 No intervention **Type:** Brief **Focus:** Risky alcohol consumption	**Intensity:** 1 session of 5 to 10 minutes	**Target behaviour outcome(s)** Risky alcohol consumption **Prioritised main outcome:** AUDIT-C score **Measured:** AUDIT-C score (the first 3 questions of AUDIT)	**Duration of follow-up:** 3 months (72.3% follow-up)	<u>3 months</u> Intervention: Significant reduction in AUDIT-C score. Difference in AUDIT-C score from baseline by downward change in mean: 0.8 (95% CI 0.18 to 1.4), p=0.01 Difference in AUDIT-C score from baseline by downward change in mean: 0.4 (95% CI -0.06 to 0.8), p=0.08	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Lau-Barraco et al, 2008 **Country** US **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N=336 (217 analysed) **Selection/recruitment criteria** College students identified as having heavy episodic drinking occasions Recruited from undergraduate psychology courses **Participant characteristics** **Mean age** 19.88 **Gender** 43.3% male, 56.7% female **Ethnicity** 76% Caucasian, 13.4% Hispanic **SES** Not reported 40.6% freshman, 21.7% sophomores, 28.1% juniors, 9.2% seniors	**Setting:** University (Intervention 1: simulated bar; Intervention 2: university campus computer laboratory). **Provider:** Same-gender advanced undergraduate research assistant trained in intervention delivery **Mode of delivery:** Face-to-face (group level)	**Comparison** Intervention 1 N= Experiential expectancy challenge (gender specific) (EEC) Control 1 N= Education only (EDU) vs. Control 2 N= Attention control **Type:** Intervention 1: Extended Control 1: Extended **Focus:** Reduced alcohol consumption	**Intensity:** 1 session of 90 to 120 minutes (interventions 1 and 2)	**Target behaviour outcome(s):** Reduced alcohol consumption **Prioritised main outcome:** Average standard drinks per week in the past 30 days **Measured:** TLFB	**Duration of follow-up:** 1 month (91% follow-up[217 of 336])	<u>1 month</u> Intervention 1: 8.20 (SD 7.05) drinks per week, p<0.05 Control 1: 8.60 ((SD8.96) drinks per week, p value not reported Control 2: 9.84 (SD 9.02) drinks per week, p value not reported	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

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Lewis et al, 2007 **Country** US **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N=245 **Selection/recruitment criteria** Freshman college students enrolled in a first-year orientation course from a mid-sized university who reported drinking to a dangerous level. Recruited via telephone and email (approximately half of the class participated in screening, not all students were present when screening took place) **Participant characteristics** **Mean age** 18.53 **Gender** 47.8% male, 52.2% female **Ethnicity** Caucasian 99.6% **SES** Not reported	**Setting:** University, controlled laboratory setting **Provider:** Electronic media only **Mode of delivery:** Computer delivered (interventions 1 and 2)	**Comparison** Intervention 1 N=82 Gender-specific personalised normative feedback (PNF) (GSF) Intervention 2 N=75 Gender-non-specific PNF (GNSF) vs. Control N= 88 Assessment only **Type:** Unclear **Focus:** Reduced alcohol consumption among high risk freshman college students	**Intensity:** 1 session delivered at baseline assessment	**Target behaviour outcome(s)** Reduced alcohol consumption **Prioritised main outcome:** Drinks per week in the past month **Measured:** Modified DDQ	**Duration of follow-up:** 3 months (93.9% follow-up), 5 months (85.3% follow-up)	<u>3 months</u> Not reported <u>5 months</u> Intervention 1 (gender specific PNF): 7.97 (SE 0.83) drinks per week, p value not reported Intervention 2 (gender non-specific PNF): 8.41 (SE 0.82) drinks per week. Not considered significant, p value not reported Control (assessment only): 11.02 (SE 0.76) drinks per week	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Lock et al, 2006 **Country** UK **Design** Cluster RCT **Internal validity** **++** **External validity** **++**	**Number randomised** N=40 practices, 127 patients **Selection/recruitment criteria** **Practices:** General practices from 5 health authority areas in the North-east of England Nurses were recruited via telephone by 2 research assistants Mean number of patients per cluster: 3 **Patients:** Patients were recruited at presentation to primary care who were screened and identified as at risk drinkers by the trial nurses **Cluster characteristics** **Mean age:** 46 (nurse) **Gender:** 100% female 55% urban practices, 17.5% rural practices, 27.5% mixed (urban/rural) practices. 80% group practice type, 20% solo practice type **Participant characteristics** **Mean age** 44.1 **Gender** 50% male **Ethnicity** Not reported **SES** 2.7% unskilled (occupation), 5.4% unemployed, 2.7% primary school, 6.3% some secondary/high school, 46.8% completed secondary / high school,	**Setting:** General practice (primary health care) **Provider:** Nurses trained in intervention delivery **Mode of delivery:** Face-to-face (individual level)	**Comparison** N= 21 practices,67 patients: Brief intervention vs. N= 19 practices, 60 patients: Usual care **Type:** Brief **Focus:** Reduced excessive alcohol consumption among patients in primary health care	**Intensity:** 1 session of 5 to 10 minutes	**Target behaviour outcome(s):** Reduced excessive alcohol consumption **Prioritised main outcome:** Units consumed in the past week **Measured:** TLFB	**Duration of follow-up:** 6 months (56% follow-up), 12 months (61% follow-up)	<u>6 months</u> Intervention: 15.80 (SD 12.31) units per week Control: 24.96 (SD 40.10) units per week Difference in units per week: -9.16, 95% CI -24.26 to 5.94, p=0.22	<u>12 months</u> Intervention: 16.08 (SD 22.84) units per week Control: 19.60 (SD 23.57) units per week Difference in units per week: -3.52, 95% CI -19.84 to 12.80, p=0.65	**Adverse effects:** Not reported **Inequality issues:** Not reported

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	20.7% technical or trade certificate, 23.4% university, CAE, tertiary education								
Mastroleo et al, 2010 **Country** US **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=238 **Selection/recruitment criteria** First-semester first year college students from a large rural university identified as heavy drinkers Recruited randomly from university student database of student information (volunteers) **Participant characteristics** **Mean age** 18.1 **Gender** 52% male, 48% female **Ethnicity** 92.4% white, 3.4% Asian, 1.7% multiracial, 0.42% Native Hawaiian or other Pacific Islander, 0.4% African American, 1.7% other, 12% Hispanic/Latino **SES** Not reported	**Setting:** University **Provider:** Trained undergraduate peer counsellors **Mode of delivery:** Face-to-face (individual level)	**Comparison** Intervention 1 N= 74 'Brief Alcohol Screening and Intervention for College Students' (BASICS) with EEA (supervision*) Intervention 2 N= 82 'Brief Alcohol Screening and Intervention for College Students' (BASICS) with CPA (no supervision*) vs. Control N= 82 Assessment only *Supervision was of the peer counsellor not of the student. **Type:** Extended **Focus:** Risky alcohol consumption	**Intensity:** 1 session of 50 minutes (BASICS) delivered within 2 weeks of completing the baseline assessment	**Target behaviour outcome(s)** Risky alcohol consumption **Prioritised main outcome:** Weekly sum of total daily drinking over the past month **Measured:** Modified DDQ	**Duration of follow-up:** 3 months (84% follow-up)	<u>3 months</u> Intervention 1: EEA: 11.57 (SD 8.05) weekly sum of daily drinks Intervention 2: CPA: 11.42 (SD 6.69) weekly sum of daily drinks Control: 14.54 (SD 11.93) weekly sum of daily drinks p<0.05 No differences found between intervention groups (EEA and CPA)	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Mello et al, 2008 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=285 **Selection/recruitment criteria** Injured ED patients **Participant characteristics** **Mean age** 29.5 **Gender** 61% male , 39% female **Ethnicity** 72.4% white, 86.9% non-Hispanic **SES** Employed 74.5%	**Setting**: Hospital ED **Provider**: Master's- or doctoral-level certified motivational interview staff **Mode of delivery**: Telephone	**Comparison** N=140 Brief motivational interview with booster session vs. N=145 Usual care **Type**: Multi-session **Focus**: Alcohol-related risky behaviours	**Intensity**: 1 session for 30 minutes plus 1 session for 15 minutes over 3 weeks	**Target behaviour outcome(s):** Alcohol-related risky behaviours **Prioritised main outcome:** Impaired driving **Measured**: Self-reported on the Impaired Driving Scale (IDS)	**Duration of follow-up:** 3 months (95% follow-up)	<u>3 months</u> Mean change on IDS: Intervention: -1.4 (-3.0 to +0.2) Control: 2.0% 1.0 (-0.9 to +2.9) Overall effect size 0.31	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

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Moore et al, 2010 **Country** US **Design** RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N=631 **Selection/recruitment criteria** Older adults over the age of 55 years identified as at risk drinkers (e.g. drinking 3 drinks 4 or more times per week) Recruited from a list of patients scheduled to see a participating PCP in the following week **Participant characteristics** **Mean age** 68.4 **Gender** 71% male, 29% female **Ethnicity** 87% white non-Hispanic, 9% Hispanic/Latino, 3% other **SES:** Education: 23% high school or less, 31% some college, 46% college degree or more. Employment status: 74% retired or homemaker, 26% working full- or part-time	**Setting:** 3 community based primary care practices (independent provider organisation [63%], large group model health maintenance organisation [21%] and university-affiliated ambulatory care system [16%]) **Provider:** Primary care providers (PCP; initial intervention) and health educator (telephone follow-up) **Mode of delivery:** Face-to-face (individual level) for delivery of intervention at baseline visit followed by remote delivery (telephone) follow-up	**Comparison** N=310 Multi-faceted intervention (oral and written advice) vs. N=321 Usual care **Type:** Multi-session **Focus:** Risky alcohol consumption	**Intensity:** 1 session delivered at baseline when seeing the PCP followed by telephone contact at weeks 2, 4 and 8.	**Target behaviour outcome(s):** Risky alcohol consumption **Prioritised main outcome:** Number of drinks in past week **Measured:** CARET and TLFB (using the time-frame since prior assessment)	**Duration of follow-up:** 3 months (88% follow-up), 12 months (83% follow-up)	<u>3 months</u> Intervention: 8.93 (SD 7.3) drinks in past 7 days Control: 10.73 (SD 8.0) drinks in past 7 days Reduced alcohol consumption from baseline observed, significance and p value not reported	<u>12 months</u> Intervention: 9.39 (SD 8.0) drinks in past 7 days Control: 10.70 (SD 8.4) drinks in past 7 days Between group difference: 1.31 drinks, reported as smaller than expected 1.8 to 2.0 drink difference. Reported as statistically significant, p value not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Neighbors et al, 2006 **Country** US **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N=214 **Selection/recruitment criteria** College students enrolled in introductory and lower division psychology courses at a medium sized Midwestern university who reported at least one heavy drinking episode in the past month Recruited from a voluntary mass testing screening session **Participant characteristics** **Mean age** 19.67 **Gender** 44.4 % male, 55.6% female **Ethnicity** 98.04% Caucasian, 1.96% other **SES** Not reported **Other** 59.8% freshman, 25.0% sophomores, 9.3% juniors, 5.88 seniors	**Setting:** University campus laboratory **Provider:** Electronic media only **Mode of delivery:** Computer delivery	**Comparison** N= 108 Computer delivered personalised normative feedback (PNF) vs. N= 106 Assessment only **Type:** Brief **Focus:** Reduced weekly drinking and negative consequences among heavy College drinkers	**Intensity:** 1 session delivered immediately after baseline assessment**.** Intervention was viewed on screen for 1 to 2 minutes and a print out of the personalised feedback was given to each participant	**Target behaviour outcome(s):** Reduced weekly drinking **Prioritised main outcome:** Drinks per week in the past 3 months [sic, despite it being 2 month follow-up] **Measured:** DDQ	**Duration of follow-up:** 2 months (86.45% follow-up)	<u>2 months</u> Intervention: 10.70 (SD 9.14) average drinks per week, p<0.05 Control: 11.56 (SD 10.68) average drinks per week	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Neighbors et al, 2010 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=818 **Selection/recruitment criteria** First year university students **Participant characteristics** **Mean age** 18 **Gende**r 42% male, 58% female, **Ethnicity** 65.3% Caucasian, 24.2% Asian/Pacific Islander, 4.2% Hispanic, 1.5% African American, 0.49% Native American/American Indian, 4.4% other **SES** Not reported	**Setting**: University **Provider**: Electronic media only **Mode of delivery**: Computer	**Comparison** Intervention 1 N=163 gender-specific feedback (GSF) at baseline vs. Intervention 2 N=164 gender-specific feedback (GSF) throughout vs. Intervention 3 N=164 gender-non-	**Intensity**: 'Very brief' single intervention or 'very brief' biannual intervention	**Target behaviour outcome(s):** Alcohol consumption **Prioritised main outcome:** Change in weekly alcohol consumption **Measured**: DDQ	**Duration of follow-up:** 6 months (92% follow-up), 12 months (87% follow-up), 18 months (84% follow-up), 24 months (81% follow-up)	NA	No extractable data (graph of ES and 95% CI for drinks per week, or beta-values from hierarchical generalised linear model)	**Adverse effects:** Not reported **Inequality issues:** Not reported

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			specific feedback (GNSF) at baseline vs. Intervention 4 N=163 gender-non-specific feedback (GNSF) throughout vs. N=164 Attention control **Type**: Intervention 1 & 4: Unclear Intervention 2, 3 and 5: Multi-session **Focus**: Alcohol consumption						
Neumann et al, 2006 **Country** Germany **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=1,139 **Selection/recruitment criteria** Injured ED patients **Participant characteristics** **Mean age** 30.5 **Gender** 79% male, 21% female **Ethnicity** Not reported **SES** 63% employed , 54.5% high school degree	**Setting**: Hospital ED **Provider**: Nurse and lay person support **Mode of delivery**: Computer	**Comparison** N=561 Computer feedback vs. N=575 Usual care **Type**: Unclear **Focus**: At risk drinking	**Intensity**: 1 session prior to ED discharge, duration of session not reported	**Target behaviour outcome(s):** Alcohol intake **Prioritised main outcome:** % change in **a**lcohol intake (grammes per day) from baseline **Measured**: Alcohol Use Disorders Identification Test (AUDIT)	**Duration of follow-up:** 6 months (63% follow-up), 12 months (58% follow-up)	<u>6 months</u> Intervention: 36% reduction from baseline Control: 20% reduction from baseline p=0.006	<u>12 months</u> Intervention: 23% reduction from baseline Control: 11% reduction from baseline p=0.023	**Adverse effects:** Not reported **Inequality issues:** Not reported
Ockene et al, 2009 **Country** US **Design** Cluster RCT **Internal validity** **++** **External validity** **++**	**Number randomised** N=530 **Selection/recruitment criteria** Men and women identified as high risk drinkers Recruited from scheduled appointments to see their primary care provider **Participant characteristics** **Mean age** 43.8 **Gender** 64.7% male, 35.3% female **Ethnicity** 94.5% white, 7.1% Hispanic **SES** 8.6% less than high school educated	**Setting:** 4 primary care internal medicine practices **Provider:** Physician and nurse practitioners trained to deliver the intervention **Mode of delivery:** Face-to-face (individual level)	**Comparison** N= 274 Special intervention vs. N= 256 Usual care **Type:** Brief **Focus:** Reduced alcohol consumption among high risk drinkers	**Intensity:** 1 session of 5 to 10 minutes	**Target behaviour outcome(s)** Reduced alcohol consumption among high risk drinkers **Prioritised main outcome:** Drinks in past week **Measured:** TLFB	**Duration of follow-up:** 12 months (84.3% follow-up), 48 months (62.8% follow-up)	NA	<u>12 months</u> Ratio of intervention to control using results of random effects: 0.83 (95% CI 0.81 to 1.12) <u>48 months</u> No significant differences in drinks per week, binges per month. Ratio of intervention to control using results of random	**Adverse effects:** Non-significant 4% increase in intervention group compared to usual care. **Inequality issues:** Not reported

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								effects: 1.07 (95% CI 0.90 to 1.26)	
O'Connor and Whaley, 2007 **Country** USA **Design** Cluster RCT **Internal validity** + **External validity** +	**Number randomised** N=345 **Selection/recruitment criteria** Currently drinking pregnant low income women **Participant characteristics** **Mean age** 28 **Gender** 100% female **Ethnicity** 7 to10% White, 17 to23% Black, 69 to 71% Hispanic, 2 to 5% Other **SES** 67% annual income <$15,000	**Setting**: Clinic **Provider**: Nutritionist **Mode of delivery**: Face-to-face	**Comparison** N=183 Brief intervention vs. N=162 Assessment only **Type**: Multi-session **Focus**: Alcohol consumption during pregnancy	**Intensity**: Repeated sessions lasting 10 to15 minutes throughout pregnancy	**Target behaviour outcome(s):** Alcohol consumption during pregnancy **Prioritised main outcome:** Alcohol abstinence during the third trimester **Measured**: Self-reported via Health Interview for Women questionnaire	**Duration of follow-up:** 17 weeks (74% follow-up)	NA	3rd trimester Abstinence OR Brief intervention vs. Assessment only: OR 5.39 (95% CI 1.59 to18.25)	**Adverse effects:** Not reported **Inequality issues:** Results relevant to low income women
Smeulders et al, 2009 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=317 **Selection/recruitment criteria** Patients with diagnosed congestive heart failure (CHF) for 6 months who received information about the study and were eligible after being admitted at least once to hospital based on cardiac decompensation Recruited from 6 hospitals in The Netherlands **Participant characteristics** **Mean age** 66.7 **Gender** 72.6% male, 27.4% female **Ethnicity** Not reported **SES** 89% not employed, 66% middle education level, 67.2% not living alone	**Setting:** Intervention: Hospital Usual care: (outpatient clinic) **Provider:** Intervention was delivered by a cardiac nurse specialist (professional leader) and a CHF patient (peer leader) both trained in intervention delivery**.** Usual care was delivered by a Cardiologist and/or nurse specialist. **Mode of delivery:** Face-to-face (group sessions), telephone (with co-participants)	**Comparison** N= 186 Chronic disease self management programme (CDSMP) + usual care vs. N= 131 Usual care **Type:** Multi-session **Focus:** Health behaviour and healthcare utilisation among patients with CHF	**Intensity:** 6 weekly group sessions of 2.5 hours each	**Target behaviour outcome(s)** Health behaviour and healthcare utilisation **Prioritised main outcome:** Drinks per week **Measured:** By asking the patient how much they drank alcoholic beverages at baseline and each follow-up	**Duration of follow-up:** 6 months (86.4% follow-up), 12 months (83.6% follow-up)	NA	6 months Intervention:3.3 (SD 6.6) drinks per week, p=0.122 Control: 3.9 (SD 6.6) drinks per week (unadjusted means) 12 months Intervention: 3.2 (SD 5.8) drinks per week, p=0.639 Control: 3.7 (SD 6.2) drinks per week (unadjusted means)	**Adverse effects:** Not reported **Inequality issues:** Not reported

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW-UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
Walters et al, 2009 **Country** US **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised** N=279 **Selection/recruitment criteria** College psychology students identified as heavy drinkers Recruited from medium sized private university using invitation emails, brief presentations and flyers **Participant characteristics** **Mean age** 19.8 **Gender** 35.8% male, 64.2% female **Ethnicity** 84.6% white **SES** Not reported **Other** 41.2% freshman, 21.1% sophomores, 21.9% juniors, 15.8% seniors	**Setting:** University **Provider:** Face-to-face sessions delivered by 2 trained PhD level counsellors and 5 trained clinical psychology doctoral students. Electronic media for computer delivered feedback. **Mode of delivery:** Intervention 1 (web feedback): computer Intervention 2 (motivational interview only): Face-to-face (individual level) Intervention 3 (motivational interview with feedback): Face-to-face (individual level) and computer	**Comparison** Intervention 1 N= 67 Web feedback only (WEB) vs. Intervention 2 N= 70 Motivational interview only (MI) vs. Intervention 3 N= 73 Motivational interview with feedback (MI+F) vs. Control N= 69 Assessment only **Type:** Intervention 1: unclear Intervention 2 and 3: Extended **Focus:** Reduced risky drinking	**Intensity:** Intervention 1: not reported Intervention 2: mean duration of 40 minutes Intervention 3: mean duration of 50 minutes	**Target behaviour outcome(s)** Reduced risky drinking **Prioritised main outcome:** Drinks per week in the past month **Measured:** DDQ	**Duration of follow-up:** 3 months (90% follow-up), 6 months (86% follow-up)	<u>3 months</u> Intervention 1 (web feedback only): 13.48 (SD 14.67) drinks per week, p=0.39 Intervention 2 (motivational interview only): 13.17 (SD 13.33) drinks per week, p=0.13 Intervention 3 (motivational interview with feedback): 11.69 (SD 12.7) drinks per week, p=0.046 Control (Assessment only): 11.97 (SD 11.80) drinks per week	<u>6 months</u> Intervention 1 (web feedback only): 12.07 (SD 12.31) drinks per week, p=0.80 Intervention 2 (motivational interview only): 11.59 (SD 9.55) drinks per week, p=0.88 Intervention 3 (motivational interview with feedback): 10.19 (SD 8.71) drinks per week, p=0.009 Control (Assessment only): 12.92 (14.16) drinks per week	**Adverse effects:** There were no adverse events reported in any of the intervention groups **Inequality issues:** Not reported
Wood et al, 2007 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised** N=355 **Selection/recruitment criteria** University students **Participant characteristics** **Mean age** 20.9 **Gender** 47.5% male , 52.5% female **Ethnicity** 89.5% White **SES** Not reported	**Setting**: University **Provider**: Graduate student **Mode of delivery**: Face-to-face	**Comparison** Intervention 1 N=84* Brief motivational interview vs. Intervention 2 N=84* Alcohol expectancy challenge (AEC) vs. Intervention 3 N=84* brief motivational interview and AEC vs. N=83* Assessment only **Type**: Intervention 1: Extended	**Intensity**: Intervention 1: 45 to 60 minutes Intervention 2: 90 minutes	**Target behaviour outcome(s):** Alcohol consumption **Prioritised main outcome:** 30 day alcohol consumption **Measured**: Self-reported on TLFB	**Duration of follow-up:** 1 month (82.4% follow-up), 3 months (75.5% follow-up), 6 months (72.5% follow-up)	No extractable data (graph of number of drinking over the past 30 days for 1 and 3 month follow-up. No p-values or 95% CIs for within or between group comparisons	No extractable data (graph of number of drinking over the past 30 days for 6 month follow-up. No p-values or 95% CIs for within or between group comparisons	**Adverse effects:** Not reported **Inequality issues:** Not reported

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW-UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
			Intervention 2: Extended Intervention 3: Multi-session **Focus**: Alcohol consumption *n= Not reported; estimated across groups based on factorial design						
Woodall et al, 2007 **Country** US **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N=305 **Selection/recruitment criteria** Court defined first time offenders convicted of driving while intoxicated (DWI) and sentenced to the DWI jail/treatment program were recruited from a region with a predominantly Native American population. Recruited from the San Juan County DWI (SJC-DWI) treatment program. **Participant characteristics** **Mean age** 27.1 **Gender** 86.9% male, 13.1% female **Ethnicity** 76.7% Native American, 13.8% Anglo, 7.9% Hispanic or other **SES** 11.8 years of education 27.6% identified as having anti-social personality disorder (ASPD) on the Diagnostic Interview Schedule (DIS)	**Setting:** Incarceration inpatient (during 28 days of incarceration) and outpatient follow-up **Provider:** Counsellors trained in motivational interviewing before and during the study period **Mode of delivery:** Face-to-face (individual level). Monitoring phase included group sessions.	**Comparison** N= 177 Motivational interviewing vs. N= 128 No intervention (28 days of incarceration only) **Type:** Multi-session **Focus:** Frequency of drinking and driving among first time incarcerated offenders	**Intensity:** Intensity not described. Intervention delivered during 28 days of incarceration including outpatient follow-up. Participants were incarcerated for 28 days and received post discharge monitoring for 3 to 12 months (average length of 6 months)	**Target behaviour outcome(s)** Frequency of drinking and driving among first time incarcerated offenders **Prioritised main outcome:** Change in number of drinks in past 90 days from baseline (averaged across follow-up) **Measured:** Form 90 (to estimate alcohol consumption in terms of standard ethyl-alcohol consumption [SEC] units as a measure of a standard drink); TLFB (to assess drinking over previous 90 days).	**Duration of follow-up:** 24 months (80% follow-up)	NA	<u>12 months</u> Intervention-control difference in amount of change from intake to follow-upwas significant at for all 3 follow-upperiods, $p<0.05$ <u>24 months</u> Intervention: 110.3 drinks per 90 days (improvement from intake to the average of the post treatment assessments for total SECs), effect size $d=0.328$, $p<0.05$ Control: 26.9 drinks per 90 days	**Adverse effects:** Not reported **Inequality issues:** Intervention was found to be effective in primarily Native American sample

Smoking

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
An et al, 2006 **REFID** 5234 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=837 **Selection / Recruitment criteria:** Daily smokers that visited Veterans Affairs medical centres who were willing to set a quit date in the next 30 days **Participant characteristics:** **Mean age** 57.2 **Gender** 89.7% Male, 10.3% Female **Ethnicity** White 94.3% **SES** Not reported **Other:** Graduates 14.3% *Income ($)* <10,000 14.3% 10,000–20,000 27.8% 20,001-40,000 36.4% 40,001-60,000 13.9% >60,001 6.6%	**Setting**: Telephone **Provider**: Counselors **Mode of delivery**: Remote (Telephone)	**Comparison:** N=418 Telephone care vs. N=420 Usual care **Type**: Multi-session **Focus**: Smoking cessation through encouragement of use of pharmacologic therapy	**Intensity**: -7 calls over a 2-month period - Additional calls given at the discretion of the counselor - Counselling continued for up to 3 quit attempts during 12 months after enrollment	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Self-reported sustained abstinence for 6 months **Measured:** Telephone survey (independent of telephone counselling)	**Duration of follow-up:** 3 months (99.2% follow-up) 12 months (98.1% follow-up)	<u>3-months</u> *7-day point-prevalence abstinence*: Intervention = 39.6% Control = 10.1% OR = 5.84 (95% CI 4.02 to 8.50) p<0.001	<u>12 months</u> *7-day point-prevalence abstinence*: Intervention: 21.6% Control: 15.0% OR 1.57 (95% CI 1.09 to 2.24) p=0.01 *6-month sustained abstinence*: Intervention: 13.0% Control: 4.1% OR 3.50 (95% CI 1.99 to 6.15) p<0.01	**Adverse effects:** Not reported **Inequality issues:** Not reported
Anthonisen et al, 2005 **REFID** 5781 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=5887 **Selection / Recruitment criteria:** Smokers 35 to 60 years old who did not consider themselves ill but had evidence of mild to moderate airway obstruction **Participant characteristics:** **Mean age** 48.5 **Gender** Men 63.1%, Women 36.9% **Ethnicity** White 95.7% **SES** Not reported **Other:** Married 70.7% Mean length of education 13.6 years	**Setting**: Clinical centres **Provider**: Physician and counselors **Mode of delivery**: Face-to-face	**Comparison:** N=1,961 Behaviour modification + Nicotine gum + Ipratropium N=1,962 Behaviour modification + Nicotine gum + Placebo inhaler vs. N=1964 Usual care **Type:** Multi-session **Focus**: Physician message and group counselling Smoking cessation	**Intensity**: One strong physician message, 12 two-hour group sessions (behaviour modification & nicotine gum).	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** All-cause mortality **Measured:** Biannual telephone contacts over 10 years and 1 clinic visit 11 to 12 years after the original study	**Duration of follow-up:** 10 years (75% follow-up)		<u>5 years</u> ***Smoking status*** *Sustained quitters:* Interventions: 21.7% Control: 5.4% *Intermittent quitters* Interventions: 29.3% Control: 23.3% *Continuing smokers*: Intervention: 49.0% Control: 71.3%	**Adverse effects:** Not reported **Inequality issues:** Not reported

Armitage et al, 2008 **REFID** 3117 **Country** UK **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=350 **Selection / Recruitment criteria:** Workers of a company who currently smoked **Participant characteristics:** **Mean age** 36 **Gender** Male 49.4%, Female 50.6% **Ethnicity** Not reported **SES** Not reported **Other:** No formal qualification 14% End of education at ≤18 years of age 50.8%	**Setting**: Not reported **Provider**: Research group **Mode of delivery**: Paper (questionnaire, print-outs, plans)	**Comparison:** N=115 Experimental condition vs. N=120 Active control vs. N=115 Passive control **Type**: Brief **Focus**: Stages of change to reduce smoking	**Intensity**: - Questionnaire - Plan to quit - Form an implementation intention	**Target behaviour outcome(s):** Smoking reduction **Prioritised main outcome:** Self-reported smoking cessation **Measured:** Self-report	**Duration of follow-up:** 2 months (80.9% follow-up)	<u>2 months</u> Experimental: 12.2% Active control: 1.67% Passive control: 0.87% Significance not reported	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Baker et al, 2006 **REFID** 4904 **Country** Australia **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=298 **Selection / Recruitment criteria:** Adults with a diagnosed non-acute psychotic disorder who smoke at least 15 cigarettes per day **Participant characteristics:** **Mean age** 37.2 **Gender** Male 52.3%, Female 47.7% **Ethnicity** Not reported **SES** Not reported **Other:** Receiving welfare support 95.6% Not completed high school 64.8% Diagnosis of schizophrenia / schizoaffective disorder 56.7%	**Setting**: Research center or a nearby community clinic **Provider**: Trained therapist **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=147 MI + CBT + NRT vs. N=151 Usual care **Type**: Multi-session **Focus**: Integrated psychological intervention (MI/CBT) and nicotine replacement therapy to increase smoking cessation in people with a psychotic disorder	**Intensity**: Eight 1-hr sessions of MI & CBT, and NRT **Adherence**: - 47.6% attended all 8 sessions - 28.6% attended 5 to 7 sessions - 23.8% attended < 5 sessions	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically verified continuous abstinence from quit date to 12 months (CO) **Measured:** Self-report confirmed with CO test	**Duration of follow-up:** 3 months (84.6% follow-up) 6 months (81.9% follow-up) 12 months (82.9% follow-up)	NA	<u>6 months</u> Intervention:5.4% Control: 2.0% OR 2.84 99% CI 0.48 to 16.67 <u>12 months</u> Intervention: 3.4% Control: 0.7% OR 5.28 99% CI 0.31 to 90.20	**Adverse effects:** No evidence of deterioration or improvement in symptoms or functioning associated with treatments **Inequality issues:** Not reported
Bernstein et al, 2011 **REFID** 783 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=338 **Selection / Recruitment criteria:** Adult patients (≥21 years old) about to be discharged from emergency department who smoked at least 100 cigarettes in lifetime and at least 10 cigarettes daily **Participant characteristics:** **Mean age** 40.2 **Gender** Male 48.2%, Female 51.8% **Ethnicity** White 9.8%, African American 22.5%, Hispanic 61.5%, Other 6.2% **SES** Not reported	**Setting**: An emergency department (ED) of an academic medical center in an urban area **Provider**: Peer educators trained in tobacco treatment **Mode of delivery**: Face-to-face; brochure; telephone calls	**Comparison:** N=170 Enhanced care vs. N=168 Usual care **Type**: Multi session **Focus**: ED-based smoking cessation	**Intensity**: - Pamphlet & Brochure given initially - One motivational interview (10 to 15 minutes) - One telephone call 3 days after ED visit - 6-wk course of nicotine patches	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed abstinence in past 7 days (cotinine/CO) **Measured:** Self-report verified by salivary cotinine and CO test	**Duration of follow-up:** 3 months (82.8% follow-up)	<u>3 months</u> Intervention: 14.7% Control: 13.2% p=0.68	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

Bock et al, 2008 **REFID** 3183 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=543 **Selection / Recruitment criteria:** Adult smokers who presented to the emergency department with chest pain and who were admitted to an observation unit for 24hr observation to rule out myocardial infarction **Participant characteristics:** **Mean age** 47.7 **Gender** Male 52.9%, Female 47.1% **Ethnicity** White 69.1%, Black 12.4%, Hispanic 9.8%, Other 8.5% **SES** Not reported **Other:** Mean education level 11.9 years Married / Living with partner 48.6% Divorced / Separated / Widowed 30.2% Never married 21.2%	**Setting**: Hospitals **Provider**: Trained research counselors **Mode of delivery**: Face-to-face (individual level) and telephone calls	**Comparison:** N=271 Tailored intervention vs. N=272 Usual care **Type**: Multi-session **Focus**: Tailored intervention using motivational interviewing for smoking cessation in chest pain patients	**Intensity**: - One 30-mins counselling session - 2 brief telephone follow-ups at 2 and 4 weeks after initial visit - Nicotine patches given to those who decided to quit - 2 further brief telephone calls on quit day and 7 days after	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Biochemically confirmed abstinence in past 7 days (cotinine) **Measured:** Self-report confirmed with saliva cotinine test	**Duration of follow-up:** 6 months (53.8% follow-up)	NA	<u>6 months</u> Intervention: 21.7% Control:18.8% Difference: 7.1% p=0.54	**Adverse effects:** Not reported **Inequality issues:** Not reported
Borrelli et al, 2005 **REFID** 5390 **Country** USA **Design** cRCT **Internal validity** + **External validity** +	**Number randomised:** N=273 **Selection / Recruitment criteria:** Adult patients who are either unable to visit their physician or who require frequent daily care that smoke at least 3 cigarettes per day **Participant characteristics:** **Mean age** 57.2 **Gender** Male 46%, Female 54% **Ethnicity** Caucasian 83%, 12.2% African-American, 2.2% Hispanic, 1.4% American Indian, 0.7% Cape Verdian **SES** Not reported **Other:** ≤ High school education : 41% Unemployed: 91% Annual income <US$10,000: 60%; $10,000 to $24,000: 24%	**Setting**: Home **Provider**: Home health care nurses **Mode of delivery**: Face-to-face (individual level) with remote (phone) follow up	**Comparison:** N=129 Motivational Enhancement (ME) intervention vs. N=144 Usual care **Type**: Multi-session **Focus**: Home health care nurses-delivered MI & CO feedback for smoking cessation in high risk smokers	**Intensity**: Three home visits + One 5-min follow-up telephone call	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Exhaled CO verified continuous abstinence at 12 months **Measured:** Self-report and CO assessments	**Duration of follow-up:** End of treatment (89.5% follow-up) 2 months (87.0% follow-up) 6 months (80.4% follow-up) 12 months (70.5% follow-up)	NA	*Continuous abstinence*: <u>6 months</u> Intervention: 6.1% Control 3.6% OR 1.7 95% CI 0.4 to 6.3 <u>12 months</u> Intervention: 11.8% Control: 5.2% OR 2.4 95% CI 0.7 to 7.6	**Adverse effects:** Not reported **Inequality issues:** Not reported
Carpenter et al, 2004 **REFID** 6043 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=616 **Selection / Recruitment criteria:** Adult smokers not interested in quitting who smoked at least 10 cigarettes per day **Participant characteristics:** **Mean age** 39.3 **Gender** Male 30%, Female 70% **Ethnicity** Caucasian 88.7% **SES** Not reported **Other:** Married 50.3% Employed 67% Graduated from high school 85.3%	**Setting**: Home **Provider**: Research group **Mode of delivery**: Telephone and post	**Comparison:** N=212 Reduction counselling + NRT + brief advice vs. N=197 Motivational advice + brief advice vs. N=207 No intervention **Type**: Multi-session	**Intensity**: - Counselling calls at Week 0, 3 and 6 - NRT offered for reduction group at Week 0 and 3 by telephone - Telephone advice to quit given at Week 6 - Follow-up calls at Week 12 and 24	**Target behaviour outcome(s):** Smoking reduction **Prioritised main outcome:** Self-reported 7 day point prevalence at 6 months **Measured:** Self-report	**Duration of follow-up:** Not reported	NA	<u>6 months</u> 7-day point prevalence abstinence: Reduction intervention: 18% Motivation intervention: 23% Control intervention: 4% Reduction vs	**Adverse effects:** Of the total NRT users, 14.6% reported an adverse event; adverse events were of varied degrees **Inequality issues:** Not reported

			Focus: Smoking reduction using NRT and motivational advice					Control OR 4.5 95% CI 2.1 to 9.6 Motivation vs Control OR 6.3 95% CI 3.0 to 13.3	
Chouinard et al, 2005 **REFID** 5562 **Country** Canada **Design** cRCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=168 **Selection / Recruitment criteria:** Adult smokers hospitalised for a CVD **Participant characteristics:** **Mean age** 55.9 **Gender** Men 73.8%, Women 26.8% **Ethnicity** Not reported **Other:** Married 73.8% Employed 35.7% Retired 38.7% Unemployed 25.6% *Income* <$14,999 18.1% $15,000-59,999 65.0% >$60,000 16.9%	**Setting**: Hospital inpatient environment **Provider**: Nurse **Mode of delivery**: Face-to-face (individual level, but in 46.4% the interviews, spouses accompanied the participant) and telephone	**Comparison:** Intervention 1 N=56 Inpatient counselling + telephone follow-ups vs. Intervention 2 N=56 Inpatient counselling only vs. N=56 Usual care **Type**: Multi-session **Focus**: Smoking cessation and/or relapse-prevention	**Intensity**: One 1hr counselling, followed by 6 telephone follow-up calls in first 2 months after discharge	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed sustained cessation for 6 months (CO) **Measured:** Self-report, but if declared non-smoking, this was validated using CO test	**Duration of follow-up:** 2 months (80.4% follow-up) 6 months (66.7% follow-up)	<u>2 months</u> *Continuous abstinence*: Intervention 1: 42.6% Intervention 2: 29.6% Usual care: 21.8% $X^2 = 5.57$ p=0.06	<u>6 months</u> Continuous abstinence: Intervention 1: 24.5% Intervention 2: 24.5% Usual care: 12.7% p=0.21	**Adverse effects:** Not reported **Inequality issues:** Not reported
de Vries et al, 2006 **REFID** 4972 **Country** Netherlands **Design** cRCT **Internal validity** + **External validity** ++	**Number randomised:** N=318 **Selection / Recruitment criteria:** Pregnant women (approx. 12 weeks gestation) who had not been pregnant more than twice and smoked at least one cigarette per day **Participant characteristics:** **Mean age** 28.5 **Gender** 0% male, 100% female **Ethnicity** Not reported **SES** Not reported **Other:** With paid job 66.8% With steady partner 98.3% <u>Level of education</u> Low 54.4% Medium 31.0% High 14.7%	**Setting**: Midwifery practice **Provider**: Midwives **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=141 Midwife health counselling vs. N=177 Usual care **Type**: Multi session **Focus**: Midwife-delivered counselling for smoking cessation, abstinence and relapse prevention in pregnant women	**Intensity**: Two face-to-face counselling sessions (about 10 minutes each) as part of prenatal visits: at 3-month and 8 month into pregnancy	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically verified continuous abstinence from 6 weeks post-intervention to 6 weeks post-partum (CO) → It was not CO but it was urine cotinine → Section 3.6 indicates that only 7 valid urine samples were available at 6 weeks post-partum and that biochemical validation results were unusable due to problems experienced in their transportation… **Measured:** Self-report	**Duration of follow-up:** 6 weeks post-intervention (94.3% follow-up) 6 weeks post-partum (87.1% follow-up)	*Continuous abstinence (reporting 7-day abstinence at both 6 weeks post-intervention and 6 weeks post-partum)*: Intervention: 12% Control: 3% OR = 6.25, 95% CI 1.16 to 33.61 p=0.033	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

Dornelas et al, 2006 **REFID** 4863 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=105 **Selection / Recruitment criteria:** Pregnant women 18 years or older and 30 weeks gestation or less, who were current smokers and had low-income **Participant characteristics:** **Mean age** 26.1 **Gender** 0% male, 100% female **Ethnicity** Hispanic 66%, Caucasian 17%, African American 11%, Other 6% **SES** Described as low-income **Other:** Unemployed 61% Less than high school 54% Unmarried 60%	**Setting**: Prenatal clinic in a non-profit tertiary care community hospital **Provider**: Masters-prepared mental health counselors **Mode of delivery**: Face-to-face (individual level), followed by telephone calls	**Comparison:** N=53 Counselling vs. N=52 Usual care **Type**: Multi session **Focus**: Smoking cessation through psychotherapy	**Intensity**: One 90-min psychotherapy session, followed by bi-monthly prenatal telephone calls, and monthly telephone calls after delivery	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Biochemically confirmed abstinence in past 7 days (CO) **Measured:** Self-report confirmed with a CO reading	**Duration of follow-up:** End of pregnancy (100% follow-up) 6 months post-partum (82% follow-up)	<u>End of pregnancy</u> Intervention: 28.3% Control: 9.6% p=0.015	<u>6-months</u> Intervention: 9.4% Control: 3.8% p=0.251	**Adverse effects:** Not reported **Inequality issues:** Not reported
El-Mohandes et al, 2011 **REFID** 491 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=500 **Selection / Recruitment criteria:** Adult African-American pregnant women of <29wk gestation residing in Washington DC, who had smoked a puff of a cigarette or more in the 6 months preceding pregnancy **Participant characteristics:** **Mean age** 26.9 **Gender** 0% male, 100% female **Ethnicity** Not reported **SES** Urban American-Africans living in communities with high poverty rates **Other:** Mean no. of previous live births 2.2 Actively smoking at baseline 39%	**Setting**: Prenatal care sites **Provider**: Not reported **Mode of delivery**: Face-to-face	**Comparison:** N=521 CBT vs. N=523 Usual care **Type**: Multi session **Focus**: Cognitive behavioural therapy for smoking cessation and relapse prevention	**Intensity**: 8 prenatal + 2 postnatal sessions of approx. 35 minutes each	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Smoking postpartum **Measured:** Self-report	**Duration of follow-up:** Before delivery (79.2% follow-up) 8-10 weeks after delivery (76.8% follow-up)	NA	<u>Smoking 8-10 weeks postpartum</u> OR 0.45 (0.25 to 0.80)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Free et al, 2011 **REFID** 919 **Country** UK **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=5792 (5800 initially randomised but 8 excluded for multiple randomisations) **Selection / Recruitment criteria:** Smokers aged 16 years or older with a mobile phone who were willing to make an attempt to quit smoking in the next month **Participant characteristics:** **Mean age** 36.9 **Gender** Male 55%, Female 45% **Ethnicity** White 89%, Black 4%, Asian 4%, Other 3.1% **SES** Not reported **Other:** *Employment type* Manual 31% Non-manual 44% Student/Unemployed 25% *Age education stopped* ≤16 years 44% ≥16 years 56%	**Setting**: Mobile phone **Provider**: Research group **Mode of delivery**: Text messages	**Comparison:** N=2911 Smoking cessation text messages vs. N=2881 Attention control text messages irrelevant to smoking cessation **Type**: Multi-session **Focus**: Automated smoking cessation delivered via mobile phone text messaging	**Intensity**: 5 text messages per day for first 5 weeks, 3 per week for following 26 weeks	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed sustained cessation from quit date to 6 months (cotinine/CO) **Measured:** Self-report verified by postal salivary-cotinine testing sample (CO testing also available)	**Duration of follow-up:** 6 months (95.4% follow-up) 542 out of 666 (81.4%) participants selected for biochemical assessment had their sample analysed	NA	<u>6 months</u> Intervention: 10.7% Control: 4.9% RR 2.20 95% CI 1.80 to 2.68 p<0.0001	**Adverse effects:** Not reported **Inequality issues:** Not reported

Giannuzzi et al. 2006 **REFID** 10871 **Country** Italy **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=3,241 **Selection/recruitment criteria** Patients with recent MI **Participant characteristics** **Age range** 57.9 **Gender** 86.3% male **Ethnicity** Not reported **SES** Not reported	**Setting:** Clinic **Provider:** Cardiac rehabilitation team **Mode of delivery:** Face-to-face	**Comparison** N= 1,620 intervention vs. N= 1,621 Usual care **Type:** Multi-session **Focus:** Education and behaviour intervention for secondary prevention of MI (diet, physical activity and smoking)	**Intensity:** 1 cardiac rehabilitation session each month for months 1 to 6, followed by one session every six months for 3 years; each session lasted approximately 30 minutes of supervised exercise, 1 hour of lifestyle and risk factor counselling, and 30 minutes of prevention reinforcement.	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % smoking cessation among smokers **Measured:** Self-report	**Duration of follow up** 36 months (95.2% primary outcomes – non-behavioural)	NA	6 months Intervention: 80.2% Control: 75.1% p=0.02 36 months Reported as non-significant at p=0.60; % cessation not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Glasgow et al, 2009 **REFID** 2993 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=320 **Selection / Recruitment criteria:** Adults who smoke 10 or more cigarettes per day who are scheduled for an outpatient surgery or diagnostic procedure **Participant characteristics:** **Mean age** 55 **Gender** Male 27.5%, Female 72.5% **Ethnicity** Latino 5.1%, White majority **SES** Not reported	**Setting**: Hospital / Home **Provider**: Telephone counselors **Mode of delivery**: Telephone and post (newsletters)	**Comparison:** N=200 Intervention vs. N=191 Control **Type**: Multi-session **Focus**: Maintenance of smoking reduction	**Intensity**: - 4 telephone counselling sessions - 4 individually tailored newsletters - 1 targeted newsletter	**Target behaviour outcome(s):** Smoking reduction **Prioritised main outcome:** Quit (not further defined) **Measured:** Self-report	**Duration of follow-up:** 3 months (75.9% follow-up) 12 months (72.2% follow-up)	3 months Intervention: 1 person Control: 2 people	12 months Intervention: 11 people Control: 7 people	**Adverse effects:** Not reported **Inequality issues:** Not reported
Gordon et al, 2010a **REFID** 1713 **Country** USA **Design** Cluster RCT **Internal validity** + **External validity** ++	**Number randomised** N=68 clusters; n=2,160 individuals **Selection/recruitment criteria** Dental patients **Participant characteristics** **Age range** Not reported **Gender** 40% male **Ethnicity** 81% white **SES** Not reported	**Setting:** Clinic **Provider:** Dentist **Mode of delivery:** Face-to-face	**Comparison** N=545 5As intervention N=601 3As intervention vs. N=405 Usual care **Type:** Brief **Focus:** Smoking cessation	**Intensity:** 1 brief session (length of intervention not described) during routine dental visit	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % reporting continuous abstinence, month 3 to 12 **Measured:** Self-report	**Duration of follow up** 3 months (77.5% follow up) 12 months (71.8% follow up)	3 months 5As: 6.6% 3As: 5.0% Combined: 5.8% Control:4.9% p=NS (value not reported)	9 month *continuous abstinence* 5As: 3.3% 3As: 3.0% Combined: 3.2% Control: 1.5% P=NS (value not reported) 12 point abstinence 5As 13.2% 3As 10.8% Combined:	**Adverse effects:** Not reported **Inequality issues:** Not reported

								12.0% Control: 7.6% p<0.01 for combined vs. control	
Gordon et al, 2010b **REFID** 1832 **Country** USA **Design** cRCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=2549 **Selection / Recruitment criteria:** Dental patients 18 years and older who were seen for a non-emergency visit to the clinic and who indicated current tobacco use **Participant characteristics:** **Mean age** 40.5 **Gender** 42.8% Male, 57.2% female **Ethnicity** 45.8% Non-Hispanic African American, 32.2% Non-Hispanic White, 15.8% Hispanic, 6.2% Other ethnicity **SES** Not reported	**Setting**: Federally funded community health centre dental clinics **Provider**: Dentists, dental hygienists and dental assistants **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=1,434 5As intervention vs. N=1,203 Usual care **Type**: Brief **Focus**: Smoking cessation through 5As	**Intensity**: Not indicated, described as brief	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Self-reported sustained abstinence for at least 6 months **Measured:** Follow-up survey by post / a phone call if survey not returned by post	**Duration of follow-up:** 6 weeks (85% follow-up) 7.5 months (71% follow-up)	NA	<u>7.5 months</u> *Prolonged abstinence (no tobacco use 6-months post-enrollment plus a 6-wk grace period)* Intervention: 5.3% Control: 1.9% p<0.01 *Point prevalence (no tobacco use in past 7 days)* Intervention: 11.3% Control: 6.8% p<0.05	**Adverse effects:** Not reported **Inequality issues:** (i) Non-Hispanic participants were more likely to complete a 7.5 month assessment than Hispanic participants (p<0.001). (ii) The intervention was effective for non-Hispanic African Americans and non-Hispanic Whites but not for Hispanics.
Groenveld et al, 2011 **REFID** 461 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=816 **Selection/recruitment criteria** Male construction workers with elevated CVD risk (10 year Framingham Risk Score greater than moderate) **Participant characteristics** **Age range** 18 to 65 **Gender** 100.0% male **Ethnicity** Not reported **SES** Not reported	**Setting:** Occupational **Provider:** Physician or nurse **Mode of delivery:** Face-to-face with telephone follow-up	**Comparison** N= 288 intervention vs. N= 307 Usual care **Type:** Multi-session **Focus:** Lifestyle modification for CVD risk	**Intensity:** 3 face-to-face session lasting 45 to 60 minutes, followed by 4 telephone sessions lasting 15 to 30 minutes; intervention over 6 months	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % smoking among baseline smoking subgroup **Measured:** Self-report	**Duration of follow up** 6 months (79.0% follow up) 12 months (72.9% follow up)	NA	<u>6 months</u> Intervention: 68.7% Control: 86.6% OR 0.3 95% CI: 0.1 to 0.7 p<0.05 <u>12 months</u> Intervention: 76.3 Control: 80.5% OR 0.8 95% CI: 0.4 to 1.6 p=NS	**Adverse effects:** Not reported **Inequality issues:** Not reported

Hall et al, 2009 **REFID** 2685 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=402 **Selection / Recruitment criteria:** Aged 50 years or older who smoke 10 or more cigarettes per day **Participant characteristics:** **Mean age** 56.7 **Gender** 60% Male, 40% Female **Ethnicity** Caucasian 76.9%, Other ethnicity 23.1% **SES** Not reported **Other:** Graduates 52.4% Non-graduates 47.6% Married / living with partner 42.5% Separated/Divorced/Widowed 39.7%	**Setting**: Free-standing, smoking treatment research clinic **Provider**: Clinic counselors / therapists **Mode of delivery**: Face-to-face (Initial group counselling sessions followed by individual sessions in the extended part of the interventions)	**Comparison:** N=99 Extended cognitive nicotine replacement therapy (NRT) N=99 Extended cognitive behavioural therapy (CBT) N=104 Extended NRT + Extended CBT vs. N=200 Standard (brief) treatment **Type**: Multi-session **Focus**: Smoking cessation through CBT	**Intensity**: - All participants began with standard treatment lasting 12 weeks. - Extended NRT: up to 52 weeks - Extended CBT: 11 sessions between Wk10 and Wk52. - E-NRT & E-CBT combined: parallel administration, as above (NRT use was re-enforced by counselor)	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Biochemically confirmed abstinence in past 7 days (CO/anatabine/anabasine) **Measured:** (i) Self-report (ii) Expired air CO levels (iii) Anatabine / Anabasine levels (iv) Cotinine could also be used → All combined	**Duration of follow-up:** 12 weeks (96.5% follow-up) 24 weeks (95.8% follow-up) 52 weeks (92.3% follow-up) 64 weeks (90.3% follow-up) 104 weeks (85.3% follow-up)	<u>12 weeks</u> E-NRT: 63% E-CBT: 64% E-combined: 66% ST: 63%	<u>24 weeks</u> E-NRT: 56% E-CBT: 58% E-combined: 59% ST: 54% <u>52 weeks</u> E-NRT: 41% E-CBT: 55% E-combined:48% ST: 33% p-value not reported <u>64 weeks</u> E-NRT: 46% E-CBT: 55% E-combined: 51% ST: 34% p-value not reported <u>104 weeks</u> E-NRT: 40% E-CBT: 55% E-combined: 45% ST: 36% p-value not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Harting et al, 2006 **REFID** 5200 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N1,270 **Selection/recruitment criteria** Patients at high risk of a CV event **Participant characteristics** **Mean age** 61.1 **Gender** 68.9% male **Ethnicity** Not reported **SES** Not reported	**Setting:** Cardiology outpatient clinic **Provider:** Nurse **Mode of delivery:** Face-to-face, with telephone follow-up	**Comparison** N= 600 intervention (of whom, 160 smokers) vs. N= 607 Usual care (of whom, 160 smokers) **Type:** Multi-session **Focus:** Cardiovascular risk behaviours (smoking, physical activity)	**Intensity:** Average of 2.76 sessions (range 1 to 9) lasting an average of 90 minutes (range 15 to 330); average duration 87 days (range 1 to 616).	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % of baseline smokers still smoking at follow-up **Measured:** Self-report	**Duration of follow up** 4 months (92% follow up) 18 months (81.3% follow up)	<u>4 months</u> Intervention vs. control: OR 0.57 (0.33 to 0.97)	<u>18 months</u> Intervention vs. control: OR Not reported; reported as non-significant	**Adverse effects:** Not reported **Inequality issues:** Not reported

Hiberink et al, 2011 **REFID** 1185 **Country** The Netherlands **Design** Cluster RCT **Internal validity** + **External validity** ++	**Number randomised** N=68 clusters; n= 753 individuals **Selection/recruitment criteria** Smokers with COPD **Participant characteristics** **Mean age range** 58.0 to 60.7 **Gender** 46.5 to 55.4% male **Ethnicity** Not reported **SES** Not reported	**Setting:** Clinic **Provider:** GP **Mode of delivery:** Face-to-face, one-on-one and telephone follow-up	**Comparison** N=21 clusters, 243 individuals Counselling plus NRT vs. N=25 clusters, 276 individuals Counselling plus NRT and bupropion-SR vs. N=22 clusters, 148 individuals Usual care **Type:** Multi-session **Focus:** Smoking cessation	**Intensity:** 1 to 2+ face-to-face sessions with a GP, and supporting print, video and follow-up telephone calls over 6 months; intensity of intervention varied depending on individual intention to quit smoking; information of session/call length not reported	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** Point prevalence abstinence **Measured:** Biochemically verified	**Duration of follow up** 12 months (80.8% follow up)	NA	<u>12 months</u> Counselling plus NRT: 7.4% Counselling plus NRT and bupropion: 7.6% Combined interventions: 7.5% Control: 3.4% Counselling plus NRT vs. Counselling, NRT plus bupropion: OR 1.0 (0.5 to 2.0) p=0.931 Combined interventions vs. Control OR 2.3 (0.9 to 6.0) p=0.083	**Adverse effects:** Not reported **Inequality issues:** Not reported
Hovell et al, 2009 **REFID** 2330 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=150 **Selection / Recruitment criteria:** Mothers who exposed their children younger than 4 years to 10 or more cigarettes per week **Participant characteristics:** **Mother's mean age** 30.1 years **Gender** 0% male, 100% female **Mothers' ethnicity** Non-Hispanic White 68.1%, Hispanic 12%, Black 10.7%, Other 9.2% **SES** Not reported **Other:** Child's mean age 23.3 months Single parent family 25.5% Employed mothers 26.5%	**Setting**: "WIC families who smoke: a behavioural counselling study", San Diego State University **Provider**: Research group staff **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=76 SHSe and smoking cessation counselling vs. N=74 Usual care **Type**: Multi session **Focus**: Smoking cessation through tailored counselling	**Intensity**: 14 bi-weekly counselling sessions over 6 months; 10 in-person at home + 4 by telephone; 23 minutes per session (mean)	**Target behaviour outcome(s):** Smoking cessation for mothers **Prioritised main outcome:** No. of cigarettes smoked per week **Measured:** Reported at counselling sessions	**Duration of follow-up:** 6 months (86.7% post-intervention) 12 months (80.7% follow-up) 18 months (86.7% follow-up)	NA	<u>6 months</u> No. of cigarettes per week: Intervention: 58.5 (95% CI 47.5 to 69.6) Control: 88.8 (95% CI 78.6 to 99.1) Mean difference = 30.3 <u>12 months</u> *No. of cigarettes per week*: Intervention: 69.8 (95% CI 58.7 to 80.9) Control: 90.8 (95% CI 77.5 to 104.1)	**Adverse effects:** Not reported **Inequality issues:** WIC is a service available to low income women and their children; Low-income families experienced significant life challenges which the researchers believe may have amounted to difficulties in attending counselling sessions and quitting smoking or reducing children's SHSe.

								Mean difference = 21.0 <u>18 months</u> Intervention: 77.9 (95% CI 64.2 to 91.6) Control: 92.9 (95% CI 80.6 to 105.2) Mean difference = 15.0	
Hyman et al, 2007 **REFID** 4495 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=289 **Selection/recruitment criteria** Currently smoking African Americans with hypertension **Participant characteristics** **Mean age** 53 (range 45 to 64) **Gender** 32.7% male **Ethnicity** 100% African American **SES** Not reported	**Setting:** Clinic **Provider:** Health educator **Mode of delivery:** Face-to-face, with telephone follow-up and supplementary take-home printed materials	**Comparison** N= 92 simultaneous intervention N=96 sequential intervention vs. N= 93 Usual care **Type:** Multi-session **Focus:** Modifiable lifestyle hypertension risk factors (smoking, diet, physical activity)	**Intensity:** 1 brief in clinic session followed by 7 telephone counselling sessions up to 15 minutes in length every 2 to 4 weeks thereafter, for 20 weeks.	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % of followed-up smokers still smoking at follow-up **Measured:** Cotinine verified	**Duration of follow up** 6 months (88.2% follow up) 12 months (80.6% follow up) 18 months (79.6% follow up)	NA	<u>6 months</u> Simultaneous: 87.8% Sequential: 83.3% Usual care: 93.6% p for trend=0.20 <u>18 months</u> Simultaneous: 79.7% Sequential: 83.1% Usual care: 89.9% p for trend=0.21	**Adverse effects:** Not reported **Inequality issues:** Trial included African American hypertensive participants only
Joseph et al, 2008 **REFID** 11072 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=152 **Selection / Recruitment criteria:** Patients aged 18 to 80 with heart disease who smoked at least 15 cigarettes per day that did not intend to stop smoking in the next 30 days **Participant characteristics:** **Mean age** 57.9 **Gender** Male 88.8%, Female 11.2% **Ethnicity** White 88.8% **SES** Not reported **Other:** Income <$30,000 58.6% Employed 38.8% Married 48.0%	**Setting**: University affiliated Veterans Affairs Medical Center **Provider**: Experienced tobacco cessation counselors **Mode of delivery**: Face-to-face (individual level) followed by telephone calls	**Comparison:** N=78 Smoking reduction vs. N=74 Usual care **Type**: Multi-session **Focus**: CVD Smoking reduction	**Intensity**: i) In-person visit ii) In-person visits at Week 1, Week 2, Month 1 and Month 3 iii) Telephone calls at Month 2, Month 4, Month 6, Month 12 and Month 18	**Target behaviour outcome(s):** Smoking reduction **Prioritised main outcome:** Self-reported abstinence at 18 month **Measured:** Self-report	**Duration of follow-up:** Month 1 (82.4-88.5% follow-up) Month 3 (79.7-82.1% follow-up) Month 6 (75.7%-82.1% follow-up) Month 12 (69.2-70.3% follow-up) Month 18 (64.1-68.5%	*Changes in cigarettes per day from baseline*	*Changes in cigarettes per day from baseline* <u>6 months</u> Intervention: -11.2 Control: -7.8 p=0.202 12 months Intervention: -9.5 Control: -5.3	**Adverse effects:** N **Inequality issues:** Not reported

						follow-up)		p=0.088 <u>18 months</u> Intervention: -9.7 Control: -8.6 p=0.694	
Joseph et al, 2011 **REFID** 683 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=443 **Selection / Recruitment criteria:** Adults aged 18 to 80 with a history of smoking ≥5 cigarettes per day and interested in making a quit attempt in the next 14 days **Participant characteristics:** **Mean age** 42.2 **Gender** Male 39.5%, Female 60.3% **Ethnicity** White 94.5%, Black 3.7%, Other 1.8% **SES** Not reported **Other:** *Annual income ($)* <19,000 11.1% 20,000-39,999 36.8% 40,000-59,999 35.9% >60,000 13.8%	**Setting**: Telephone **Provider**: Tobacco-cessation counselors **Mode of delivery**: Remote (Telephone)	**Comparison:** N=222 Longitudinal care vs. N=221 Usual care **Type**: Multi-session **Focus**: Longitudinal smoking reduction, cessation, abstinence and relapse prevention based on chronic disease management principles of care	**Intensity**: - NRT for 1 year (intervention group) *Initially* 30-60 minutes telephone call, 5 times over 4 weeks for both groups *Longitudinally,* Protocol for intervention group depended on whether participant quit, reduced or continued smoking	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported 6-month sustained abstinence **Measured:** Self-report	**Duration of follow-up:** 18 months after initial quit date (91.6% follow-up)	NA	<u>6 months sustained abstinence</u> Intervention:30.2% Control: 23.5% OR 1.74 95% CI 1.08 to 2.80 p=0.02	**Adverse effects:** Not reported **Inequality issues:** Not reported
Katz et al, 2004 **REFID** 6171 **Country** USA **Design** cRCT **Internal validity** + **External validity** ++	**Number randomised:** N=1141 **Selection / Recruitment criteria:** Adult patients who smoked at least one cigarette per day **Participant characteristics:** **Mean age** 42.7 **Gender** Male 45.5%, Female 54.5% **Ethnicity** Not reported **SES** Not reported **Other:** Mean years of education 12.5	**Setting**: Community-based Clinics **Provider**: Nurses and Medical Assistants **Mode of delivery**: Telephone	**Comparison:** N=642 Intervention vs. N=499 Usual care **Type**: Multi-session **Focus**: Effectiveness of a guideline on smoking cessation	**Intensity**: - Nicotine patches - One telephone counselling before and one after the quit date - Additional counselling sessions offered depending on the participant's situation	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported quit rate at 6 months **Measured:** Self-report	**Duration of follow-up:** 6 months (93.7% follow-up)		<u>6 months</u> Abstinence over prior 7 days: Intervention: 15%, 95% CI 13 to 18 Control 10%, 95% CI 7 to 12 p=0.009 Continuous abstinence (abstinence at both 2 and 6 months): Intervention: 11., 95% CI 8 to 13 Control: 4%, 95% CI 2 to 5 p<0.001	**Adverse effects:** Not reported **Inequality issues:** Not reported

Koelewijn van Loon et al, 2009 **REFID** 2310 **Country** The Netherlands **Design** Cluster RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N=25 practices, 615 patients (589 analysed) **Selection/recruitment criteria** **Practices:** Practices that employed a practice nurse and used electronic patient records. Recruited by letter. **Patients:** Patients eligible for cardiovascular risk management as per the national guideline for risk management (patients with existing cardiovascular disease were excluded). Recruited by nurses and general practitioners. **Participant characteristics** **Mean age** 57 (of 589 analysed) **Gender** 44.8% male (of 589 analysed) **Ethnicity** Not reported **SES** 23.6% high SES, 40.1% intermediate SES, 36.4% (of 589 analysed)	**Setting:** General practice **Provider:** Practice nurses trained in intervention delivery **Mode of delivery:** Face-to-face (individual level) and telephone (follow up).	**Comparison** N= 13 practices, Nurse led cardiovascular risk management Vs. N= 12 practices, Usual care **Type:** Multi-session **Focus:** Lifestyle change	**Intensity:** 2 sessions of 15 to 20 minutes (face-to-face) and 10 minute follow up phone call	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % of participants smoking **Measured:** 2-item questionnaire to assess smoking status (yes/no)	**Duration of follow up** 12 months (79.3% follow up)	No other time points assessed	<u>12 months</u> Intervention: 68 (27.3) Control: 40 (17.5) P=0.011 favouring control compared to intervention Intervention vs. Control: OR 3.14 (0.61 to 19.22) indicating an increased risk of smoking with intervention compared to control	**Adverse effects:** Not reported **Inequality issues:** Not reported
Kotz et al, 2009 **REFID** 2800 **Country** Netherlands **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=296 **Selection / Recruitment criteria:** Current smokers aged 35 to 70 years who were interested in quitting, and who had no prior diagnosis of COPD but were detected with mild-to-moderate airflow limitation **Participant characteristics:** **Mean age** 53.9 **Gender** 61.7% Male, 38.3% Female **Ethnicity** Not reported **SES** Not reported	**Setting**: Maastricht University **Provider**: Respiratory nurse **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=116 High-intensity confrontational counselling vs. N=112 Medium-intensity non-confrontational counselling (Control 1) vs. N=68 Low-intensity usual care (Control 2) **Type:** Multi-session **Focus**: Smoking cessation through confrontational counselling	**Intensity**: - 40 minutes individual counselling twice before target quite date and twice after - On target quite date, 5 minutes telephone counselling - Spirometry used additionally for confrontational counselling	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Biochemically confirmed sustained abstinence from week 5 to 52 after quit date (cotinine) **Measured:** Urine cotinine-validated abstinence from smoking at all three follow-up visits at 5, 26 and 52 weeks.	**Duration of follow-up:** 52 weeks (98.7% follow-up) - *All after the target quit date*	<u>Up to 5 weeks</u> Intervention: 50.9% Control 1: 39.3% Control 2: 17.6% *Intervention vs. Control 1* OR 1.6 95% CI 0.95 to 2.70 p=0.08 *Intervention vs. Control 2* OR 4.83 95% CI 2.35 to 9.94 p<0.001 *C1 vs. C2* OR 3.02 95% CI 1.46 to 6.26 p=0.003	<u>5 to 26 weeks</u> Intervention:30 .2% Control 1:23.2% Control 2: 11.8% *Intervention vs. Control 1* OR 1.43 95% CI 0.79 to 2.58 p=0.236 *Intervention vs. Control 2* OR 3.24 95% CI 1.40 to 7.49 p=0.006 *C1 vs. C2* OR 2.27 95% CI 0.96 to 5.35 p=0.062 <u>26 to 52 weeks</u> Intervention: 11.2% Control 1: 11.6%	**Adverse effects:** Not reported **Inequality issues:** Not reported

								Control 2: 5.9% *Intervention vs. Control 1* OR 0.96 95% CI 0.43 to 2.18 p=0.961 *Intervention vs. Control 2* OR 2.02 95% CI 0.63 to 6.46 p<0.236 *C1 vs. C2* OR = 2.10 (95% CI 0.66 to 6.73), p=0.211	
Lacasse et al, 2008 **REFID** 3382 **Country** Canada **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=196 **Selection / Recruitment criteria:** "Hospitalised smokers" → (a) Current smokers aged ≤70 (b) Anticipated duration of hospitalization ≥36hrs (c) Patients in contemplation, preparation or action state of change **Participant characteristics:** **Mean age** 52 **Gender** 66% Male, 34% Female **Ethnicity** Not reported **SES** Not reported	**Setting**: University-affiliated cardio-pulmonary tertiary care centre **Provider**: Physicians and counselors **Mode of delivery**: Face-to-face assessments and main interventions (individual level); pharmacological adjunct (if indicated)	**Comparison:** N=99 Education & psychological support (of which N=18 also received nicotine replacement therapy) vs. N=97 Usual care **Type:** Multi-session **Focus**: Smoking cessation through 5As	**Intensity**: 1st intervention = 20 minutes 2nd intervention (possible) = 15 minutes	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Biochemically confirmed point prevalence abstinence (cotinine) **Measured:** At 6-month follow-up = self-reported abstinence At 1-year follow-up = abstinence validated by urinary cotinine assay and self-reported abstinence	**Duration of follow-up:** 6 months (92% follow-up) 12 months (87% follow-up)	NA	<u>6 months</u> Self-reported Intervention: 32.2% Control: 30.0% Mean difference +2.2% 95% CI -4.0 to +8.5% <u>12 months</u> Self-reported Intervention: 35.3% Control: 31.4% Mean difference +3.9% (95% CI -2.9 to +10.6%) *Cotinine-validated*: Intervention 32.6% Control 34.7% Mean difference -2.1% (95% CI -11.1 to +6.9%)	**Adverse effects:** Not reported **Inequality issues:** Not reported

Lawrence et al, 2003 **REFID** 6524 **Country** UK **Design** cRCT **Internal validity** + **External validity** +	**Number randomised:** N=918 **Selection / Recruitment criteria:** Pregnant women aged 16 or over who were current smokers at booking **Participant characteristics:** **Mean age** = 26.1 **Gender** 0% male, 100% female **Ethnicity** White = 88.8%, Black = 1.9% Indian/Pakistani = 0.5%, Mixed = 1.5%, Don't know = 7.3% **SES** Not reported **Other:** *Weekly income (£)* <100 = 21.0% 100 - 400 = 57.3% >400 = 11.0% Don't know = 10.7% *Education* Degree = 1.5% A-levels = 10.2% O-levels = 30.6% None = 22.2% Other = 13.0% Don't know = 22.4% *Partner* Has partner = 86.4% No partner = 8.2% Don't know = 5.4%	**Setting**: Antenatal clinics **Provider**: Midwives **Mode of delivery**: Face-to-face (individual level); manuals; computer	**Comparison:** N=289 Usual care (Arm A) vs. N=305 Manuals (Arm B) vs. N=324 Computer (Arm C) **Type**: Multi session **Focus**: Stages of change Smoking cessation	**Intensity**: *Manuals* Self-help (i.e. read in their own time), but had three*, 15-mins sessions with midwives for guidance & discussion *Computer* Women worked alone using the 20-mins programme, three* times during pregnancy *The three stages of gestation T1: < 20 weeks T2: 23 – 25 weeks T3: 28 – 30 weeks	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Cotinine confirmed sustained quit from 30 weeks gestation to 10 days post-natal **Measured:** Self-report confirmed by urinary cotinine	**Duration of follow-up:** 10 days post-natal (71.1% follow-up)	10 days post-natal *Sustained quit since 20weeks gestation* Arm A = 2.4% Arm B = 3.8% OR = 1.57 (95% CI 0.46 to 5.30) Arm C = 4.1% OR = 1.72 (95% CI 0.53 to 5.59) X^2 = 0.8 p=0.66	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Malchodi al, 2003 **REFID** 6601 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=142 **Selection / Recruitment criteria:** Pregnant smokers of <20wk gestation aged 18 years or older, who intended to carry to term **Participant characteristics:** **Mean age** 25.5 **Gender** 0% male, 100% female **Ethnicity** Hispanic 63%, White 23.5%, Black 12.5%, Other 1% **SES** Not reported **Other:** Mean gravida 3 Unemployed 61.5% >12th grade 10% Single 92.3%	**Setting**: Large urban obstetric clinic **Provider**: Peer counselors (non-smoking female community outreach workers with same socio-environmental and cultural qualities as participants) **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=67 Peer counselling vs. N=75 Usual care **Type**: Multi-session **Focus**: Smoking cessation and reduction in pregnancy	**Intensity**: 8 contacts planned (median = 6); mean length per session = 45 minutes	**Target behaviour outcome(s):** Smoking cessation and reduction **Prioritised main outcome:** Cotinine confirmed abstinence at 36 weeks gestation **Measured:** Self-report confirmed with both CO level and urinary cotinine	**Duration of follow-up:** 36 weeks gestation	36 weeks gestation (mean baseline gestation unknown) *Change in no. of cigarettes per day*: Intervention :-9.1 Control: -4.5 p=0.03 *Quit rate*: Intervention: 24% Control: 21% p=0.84	NA	**Adverse effects:** Not directly related to the intervention itself; infant birth weight inversely correlated with number of cigarettes smoked per day at end of pregnancy and CO level **Inequality issues:** Not reported

McBride et al, 2004 **REFID** 5988 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=583 **Selection/recruitment criteria** Currently smoking or recently quit women ≤20 weeks pregnant receiving prenatal care at Womack Army Medical Center, Fort Bragg, NC USA **Participant characteristics** **Mean Age** 24 **Gender** 0% male **Ethnicity** 77% white **SES** Not reported	**Setting:** Clinic **Provider:** Health advisor **Mode of delivery:** Face-to-Face with telephone counselling follow-up	**Comparison** N=192 Women Only (WO) intervention N=193 Partner Assisted (PA) intervention vs. N=198 Usual care **Type:** Multi-session **Focus:** Smoking cessation and relapse prevention	**Intensity:** Single brief session followed by 6 monthly counselling calls to the women (WO condition) or the women and a separate call to the partner (physical activity condition); (length of intervention not described; calls completed by 4 months postpartum	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % continuously abstinent (28 weeks pregnant to 12 months postpartum) Among entire sample; Relapse prevention among baseline recent quitters (n=315 at baseline) **Measured:** Biochemically confirmed abstinence	**Duration of follow up** 28 weeks pregnant (81% follow up) 2 months postpartum (77% follow up) 6 months postpartum (79% follow up) 12 months postpartum (76% follow up)	<u>28 weeks pregnant</u> WO: 59% PA: 61% Control: 60% P=NS at 0.025 Relapse prevention (percentage abstinent at 28 weeks pregnant) WO: 29% PA: 37% Control: 36% P=NS at 0.025 <u>2 months postpartum</u> WO: 37% PA: 42% Control: 38% P=NS at 0.025	<u>6 months postpartum</u> WO: 36% PA: 37% Control: 33% P=NS at 0.025 12 months postpartum WO: 32% PA: 35% Control: 15% P=NS at 0.025 Sustained abstinence WO: 20% PA: 21% Control: 15% P=NS at 0.025	**Adverse effects:** Not reported **Inequality issues:** Not reported
McClure et al, 2005 **REFID** 3834 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=275 **Selection/recruitment criteria** Female smokers with an elevated cervical cancer risk (evaluated by abnormal pap exam or colposcopy) **Participant characteristics** **Mean age** 32.7 **Gender** 0% male, 100% female **Ethnicity** 82% white, 5% black, 4% Asian/Pacific Islander, 2% Hispanic, 7% other **SES** Not reported	**Setting:** NA **Provider:** Female smoking cessation counsellors **Mode of delivery:** Telephone	**Comparison** N=138 Motivationally enhanced phone counselling vs. N=137 Usual care **Type:** Multi-session **Focus:** Smoking cessation	**Intensity:** Up to 4 counselling calls (mean length 16 minutes) over 6 months; length of calls not reported	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** Repeated 7 day point prevalent abstinence (%) at 6 and 12 months **Measured:** CO verified at 12 months, self-report at all other time points	**Duration of follow up** Not reported	NA	<u>6 months</u> Intervention: 19.6% Control: 12.4% OR: 2.08 (1.04 to 4.12) <u>12 months</u> Intervention: 18.1% Control: 19.7% OR: 0.90 (0.49 to 1.67) Repeated abstinence at 6 and 12 months Intervention: 10.9% Control: 10.2% OR: 1.08 (0.49 to 2.36)	**Adverse effects:** Not reported **Inequality issues:** Not reported

Mohiuddin et al, 2006 **REFID** 4698 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=209 **Selection / Recruitment criteria:** Hospitalized smokers aged 30 to 75 years with a diagnosis of acute coronary syndrome or decompensated heart failure **Participant characteristics:** **Mean age** 54.0 to 55.5 years **Gender** 63% Male, 37% Female **Ethnicity** 77% White, 19% black, 4% other **SES** Not reported	**Setting**: Coronary care unit, university-affiliated teaching hospital **Provider**: Tobacco cessation counsellor **Mode of delivery**: Face-to-face (mainly group sessions but individual sessions arranged if necessary)	**Comparison:** N=109 Intensive intervention vs. N=100 Usual care **Type:** Multi-session **Focus**: Smoking cessation through behaviour modification	**Intensity**: Weekly 60-mins session for a min. for 3 months	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Biochemically confirmed abstinence over 3 months (CO) **Measured:** CO level	**Duration of follow-up:** Not reported *It is mentioned that 9 patients were lost to follow-up, but it is unclear as to which follow-up visit the authors are referring to, or whether this is the total number of patients lost to follow-up.	*Sustained abstinence* <u>3 months</u> Intervention: 69% Control:15% p<0.0001	*Sustained abstinence* <u>6 months</u> Intervention: 55% Control: 13% p<0.0001 <u>12 months</u> Intervention: 39% Control :11% p<0.0001 <u>24 months</u> Intervention: 33% Control 9% p<0.0001	**Adverse effects:** <u>Over 2 years</u> Hospitalisation Intervention = 25/109 (23%) Control = 41/100 (41%) Hospitalisation due to CV causes: Intervention = 20/25 (80%) Control = 37/41 (90%) Death Intervention = 3/109 (2.8%) Control = 12/100 (12%) **Inequality issues:** Not reported
Molyneux et al, 2003 **REFID** 6520 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=274 **Selection / Recruitment criteria:** Adult medical and surgical inpatients who were current smokers at the time of admission **Participant characteristics:** **Mean age** 49.4 **Gender** Male 59.5, Female 40.5% **Ethnicity** White 95.9%, Black 3.7% Other 0.4% **SES** Not reported	**Setting**: Hospital **Provider**: Research doctor/nurse trained in smoking cessation counselling **Mode of delivery**: Face-to-face (individual level)	**Comparison:** Intervention 1 N=91 NRT + counselling vs. Intervention 2 N=91 Counselling only vs. N=92 Usual care **Type**: Brief **Focus**: Smoking abstinence	**Intensity**: - One 20 minutes counselling session - 6wk course of NRT	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Exhaled CO verified continuous abstinence at 12 months **Measured:** Self-report validated by CO level	**Duration of follow-up:** At discharge (91.6% follow-up) At 3 months (62.4% follow-up) At 12 months (40.9% follow-up)	<u>At discharge</u> *Point prevalence abstinence*: Intervention 1: 54.9% Intervention 2: 42.9% Control: 37.0% p=0.04 <u>3 months</u> *Point prevalence abstinence*: Intervention 1: 16.5% Intervention 2: 9.9% Control: 10.9% p-value ot reported *Continuous abstinence*: Intervention 1 16.5% Intervention 2: 7.7% Control: 10.9%	<u>12 months</u> *Point prevalence abstinence*: Interventionv1: 6.5% Intervention 2: 5.5% Control: 7.6% p=0.03 *Continuous abstinence*: Intervention 1: 11.0% Intervention 2: 4.4% Control: 7.6% p-value not reported	**Adverse effects:** 89 AEs recorded in 65 patients; no sig. difference found between treatment groups; 5 cases were considered to be related to NRT **Inequality issues:** Not reported

							p-value NR		
Muniz et al, 2010 **REFID** 8775 **Country** Spain **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=1,757 **Selection/recruitment criteria** Patients recently discharged following acute coronary syndrome hospitalisation **Participant characteristics** **Age range** 63 **Gender** 76% male **Ethnicity** Not reported **SES** Not reported	**Setting:** Hospital **Provider:** Physician **Mode of delivery:** Face-to-face (individual level)	**Comparison** N= 867 intervention vs. N= 890 Usual care **Type:** Multi-session **Focus:** Lifestyle risk factors for CVD secondary prevention	**Intensity:** 2 face-to-face sessions lasting 30 to 40 minutes each, over two months	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % smoking cessation among smokers **Measured:** Self-report	**Duration of follow up:** 6 months (85.9% follow up)	NA	<u>6 months</u> Intervention: 76.3% Control: 71.0% OR 1.25 95% CI: 0.81 to 1.94 p=0.309	**Adverse effects:** Not reported **Inequality issues:** Not reported
Neuner et al, 2009 **REFID** 2547 **Country** Germany **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=1044 **Selection / Recruitment criteria:** All patients aged ≥18years treated in the emergency department (ED) who reported a min. of 1 cigarette smoked per day during last 7 days **Participant characteristics:** **Mean age** 30 **Gender** 60.7% Male, 39.3% Female **Ethnicity** Not reported **SES** Not reported	**Setting**: Emergency department of an inner city university hospital **Provider**: Senior researchers **Mode of delivery**: Face-to-face with remote (phone) follow-up	**Comparison:** N=515 ED-initiated tobacco control (ETC) intervention vs. N=529 Usual care **Type**: Multi-session **Focus**: Smoking cessation through 5As, 5Rs or behavioural support	**Intensity**: 1 on-site counselling + up to 4 telephone booster follow-up sessions ETC median time = 30 minutes	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Self-reported abstinence in last 7 days **Measured:** Via telephone booster follow-up sessions	**Duration of follow-up:** 12 months (65.6% follow-up)	NA	<u>12 months</u> Intervention: 14.2% Control:1.3% Mean difference 2.9% AOR 1.31 95% CI 0.91 to 1.89 p=0.15	**Adverse effects:** Not reported **Inequality issues:** Not reported
Nollen et al, 2007 **REFID** 4210 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=500 **Selection / Recruitment criteria:** Self-identified African American over the age of 18 who wanted to quit smoking in the next 6 months or 30 days, and currently smoking more than 10 cigarettes per day **Participant characteristics:** **Mean age** 43.0 **Gender** Male 40.8%, Female 60.2% **Ethnicity** 100% African American **SES** Not reported **Other:** ≤ High school diploma 54.8% Monthly income ≤ $1,200 65.2% Married / Living with partner 22.7% Employed 46.6%	**Setting**: Research site **Provider**: Research group **Mode of delivery**: Videotape; face-to-face; telephone calls	**Comparison:** N=250 Culturally targeted intervention (+ nicotine patches) vs. N=250 Usual care (+ nicotine patches) **Type**: Multi-session **Focus**: Culturally targeted intervention for smoking cessation	**Intensity**: - 4 weeks of nicotine patches - One viewing of the videotape (40-mins long) before quit date & read written guide - Verbal instruction given on quit date - Reminder phone calls at Week 1 and 3 - Further 2weeks supply of nicotine patches at Week 4 - Final phone call at Month 6	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed abstinence in past 7 days **Measured:** Self-report confirmed with CO test	**Duration of follow-up:** Week 4 (66.6% follow-up) Month 6 (65.6% follow-up)	NA	<u>6 months</u> (end of intervention) Intervention: 18.0% Control: 14.4% p=0.27	**Adverse effects:** No significant difference between groups for adverse skin reactions (reported as adverse effect of transdermal patches) up to week, p=0.18. 79.8 reported no skin reactions, 15.7% reported mild reactions, 1.2% reported moderate reactions, <1% reported severe reactions **Inequality issues:** Findings applicable to African American women

Ondersma et al, 2012 **REFID** 229 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=110 **Selection / Recruitment criteria:** Adult pregnant women of ≤27wk gestation and reporting smoking in the past week **Participant characteristics:** **Mean age** 27.9 **Gender** 100% female **Ethnicity** Black 81.8% **SES** Almost exclusively low-income black women in an urban setting **Other:** >20wk gestation 36%	**Setting**: Prenatal care clinics **Provider**: Interactive computer software **Mode of delivery**: Remote (Computer)	**Comparison:** N=26 CD-5As N=28 CM-Lite N=30 CD-5As + CM-Lite vs. N=26 Usual care **Type**: Brief **Focus**: Computer delivered short-term reduction of smoking in pregnancy 5As Contingency management (CM)	**Intensity**: One session per programme	**Target behaviour outcome(s):** Smoking reduction **Prioritised main outcome:** Biochemically confirmed abstinence in past 7 days (CO) **Measured:** Self-report confirmed with CO test	**Duration of follow-up:** 10 weeks post-intervention (85.4% follow-up)	<u>10 weeks</u> *7-day point prevalence*: Control: 8.7% CD-5As: 30.4% AOR 5.7 95% CI 0.9 to 34.3 CM-Lite 9.1% AOR 0.5 95% CI 0.1 to 6.7 Combined 19.2% AOR 2.8 95% CI 0.5 to 16.9	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Pbert et al, 2004 **REFID** 6128 **Country** USA **Design** cRCT **Internal validity** ++ **External validity** +	**Number randomised:** N=601 **Selection / Recruitment criteria:** Women receiving prenatal care, having ≥2 months before due date, and being a current smoker or spontaneously quit smoking after learning of pregnancy **Participant characteristics:** **Mean age** 25.7 **Mean gestational age** 16.1 weeks **Gender** 0% male, 100% female **Ethnicity** White 48.3%, Black 18.5%, Hispanic 17.5%, Other 7.0% **SES** a federal assistance programme for low income women **Other:** Not working 63.7% < High school 49.9% Not married / not living with partner 59.2% Current smokers 65.2% Spontaneous quitters 26.3%	**Setting**: WIC centres **Provider**: Existing healthcare providers **Mode of delivery**: Face-to-face	**Comparison:** N=309 Special intervention vs. N=300 Usual care **Type**: Multi session **Focus**: 4As for smoking cessation and abstinence	**Intensity**: Not reported	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Self-reported continued abstinence at 1 month postpartum among previously abstinent women **Measured:** Self-report and saliva cotinine assay	**Duration of follow-up:** At 9 month of pregnancy, before delivery (77.9% follow-up) 1 month after delivery (67.2% follow-up) 3 months after delivery (45.8% follow-up) 6 months after delivery (46.8% follow-up)	*Proportions of quitters who were smoking at baseline*: <u>1 month postpartum</u> Intervention: 26% Control = 11% OR = 3.01 p = 0.04 <u>3 month postpartum</u> Intervention: 10% Control: 5% OR = 1.91 p = 0.65	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Pisinger et al, 2010 **REFID** 2076 **Country** Denmark **Design** cRCT **Internal validity** + **External**	**Number randomised:** N=1,518 **Selection / Recruitment criteria:** Smokers registered at general practice **Participant characteristics:** **Mean age** 48.0 **Gender** Male 37.4%, Female 62.6% **Ethnicity** Not reported **SES** Not reported **Other:** Unemployed 38.4% Employed 61.6%	**Setting**: General practice **Provider**: General practitioners (GP) **Mode of delivery**: Face-to-face (group counselling) Internet	**Comparison:** N=600 Group counselling (Group A) vs. N=476 Internet-based programme (Group B) vs. N=442 Usual care (Group C) **Type**:	**Intensity**: Internet – 13 sessions over 6 months, similar to the national model for smoking cessation group counselling.	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed abstinence at 1year (cotinine) **Measured:** Self-report confirmed with urine cotinine test	**Duration of follow-up:** 1 year (50.1% follow-up)	NA	<u>12 months</u> Group A: 3.5% Group B: 2.5% Group C: 2.7% No additional effect of the two interventions found in cluster analyses, in terms of self-reported 1	**Adverse effects:** Not reported **Inequality issues:** Not reported

validity ++			Multi-session **Focus**: Smoking cessation interventions in general practice					year abstinence: Vs. Group C: Group A OR 1.05 95% CI 0.6 to 1.8 Group B OR 0.91 95% CI 0.6 to §.4)	
Rabius et al, 2004 **REFID** 6005 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=3522 **Selection / Recruitment criteria:** Adult current daily smokers who called the helpline number to enquire about smoking cessation and those who were willing to attempt quitting within 2 weeks **Participant characteristics:** **Mean age** younger 21.9, older 43.8 **Gender** male 33%, female 67% **Ethnicity** White/Anglo 72 – 73% in both age groups **SES** Not reported	**Setting**: American Cancer Society smoking cessation helpline **Provider**: Helpline counselors **Mode of delivery**: Telephone and mail	**Comparison:** N=(not reported) Telephone counselling + Self-help book vs. N=(not reported) Self-help book only **Type**: Multi-session **Focus**: Motivational interview Smoking abstinence	**Intensity**: Up to 5 telephone counselling sessions	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Self-reported 48hr abstinence at 3 months **Measured:** Self-report by telephone interview	**Duration of follow-up:** 3 months after quit date (52% follow-up in 18-25 year olds, 66% follow-up in >25 year olds) 6 months after quit date (64% follow-up in 18-25 year olds, 85% follow-up in >25 year olds)	3 months *48hr abstinence*: [18-25 year olds] Intervention: 19.6% Control: 9.3% p<0.005 [>25 year olds] Intervention: 15.1% Control: 9.6% p<0.001	6 months (of those who reported abstinence at 3 months) [18-25 year olds] Intervention: 9.8% Control 3.2% p<0.005 [>25 year olds] Intervention: 7.7% Control: 4.1% p<0.005	**Adverse effects:** Not reported **Inequality issues:** Not reported
Ratner et al, 2004 **REFID** 6144 **Country** Canada **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=237 **Selection / Recruitment criteria:** All patients admitted for pre-surgical assessment who identified themselves as current smokers **Participant characteristics:** **Mean age** 49.8 **Gender** Male 48.1%, Female 51.9% **Ethnicity** Not reported **SES** Not reported **Other:** *Annual income ($)* <29,000 30.8% 30,000-49,999 21.0% 50,000-69,999 16.1% >70,000 32.2%	**Setting**: Preadmission clinic of a large, urban teaching hospital **Provider**: Registered nurses **Mode of delivery**: Face-to-face and telephone	**Comparison:** N=117 Intervention vs. N=120 Usual care **Type**: Multi-session **Focus**: Smoking cessation for elective-surgical patients	**Intensity**: One 15-min counselling session pre-surgery; one post-operative progress review; 10 telephone counselling sessions over 16 weeks after discharge	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported and biochemically confirmed abstinence over 12 months **Measured:** Self-report verified by urine cotinine measurement	**Duration of follow-up:** 6 months (85.2% follow-up) 12 months (84.5% follow-up)	NA	12 months Intervention: 18.8% Control: 19.2% OR 0.92 95% CI 0.47 to 1.78	**Adverse effects:** Not reported **Inequality issues:** Not reported

Reid et al, 2008 **REFID** 3480 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=225 **Selection / Recruitment criteria:** Patients in treatment for drug/alcohol dependence who smoked at least 10 cigarettes per day and were interested in quitting **Participant characteristics:** **Mean age** 41.3 **Gender** Male 52%, Female 48% **Ethnicity** White 39.5%, Black 25.0%, Hispanic 32.5%, Other 3% **SES** Mostly methadone users **Other:** Employed/Student 36.5% Mean length of education 11.7 years	**Setting**: 7 community-based outpatient substance abuse treatment programs **Provider**: Trained counselors **Mode of delivery**: Face-to-face (group level)	**Comparison:** N=153 Cessation programme vs. N=72 Usual care **Type**: Multi-session **Focus**: Group counselling for smoking cessation in substance abusers	**Intensity**: - Total of 9 group counselling sessions (from 1 week before quit date through to 6 weeks after quit date) - NRT from quit date to end of Week 8	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed abstinence in past 7 days (CO) **Measured:** Self-report confirmed with CO test	**Duration of follow-up:** Week 13 & Week 26 after randomisation Percentages of follow-ups are not shown!	<u>13 weeks</u> Intervention: 5.5% Control: 0% p=0.065	<u>26 weeks</u> Intervention: 5.7% Control: 5.2% p=0.963	**Adverse effects:** Not reported **Inequality issues:** Not reported
Rigotti et al, 2006 **REFID** 5076 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=442 **Selection / Recruitment criteria:** Adult pregnant women at ≤26 weeks gestation who had smoked at least one cigarette in last 7 days, willing to consider altering their smoking during pregnancy **Participant characteristics:** **Mean age** 28.5 **Gender** 0% male, 100% female **Ethnicity** Non-Hispanic White 87.3% **SES** Not reported **Other:** Employed in past year 88.9% Mean years of education 13.1	**Setting**: Telephone counselling **Provider**: Trained counselor **Mode of delivery**: Remote (Telephone)	**Comparison:** N=220 Tailored telephone counselling vs. N=222 Usual care **Type**: Multi session **Focus**: Proactive pregnancy-tailored telephone counselling for smoking cessation	**Intensity**: Max. 90-mins telephone counselling session (mean no. of sessions = 4) during pregnancy, followed by max. 15-mins (mean no. of sessions = 1) telephone counselling over 2 months post-partum	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically verified sustained abstinence at end of pregnancy and 3 months post-partum **Measured:** Self-report verified by saliva cotinine test	**Duration of follow-up:** End of pregnancy (69.7% follow-up) 3 months post-partum (66.3% follow-up)	*Sustained abstinence (7-day point prevalence at both end of pregnancy and 3 months postpartum)* Intervention 4.8% Control 3.3% OR =1.46 95% CI 0.54 to 3.90 p=0.47	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Rodriguez-Artalejo et al, 2003 **REFID** 6561 **Country** Spain **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=217 **Selection / Recruitment criteria:** Currently smoking employees of 3 worksites aged 20 to 63 years who were motivated to quit and not contraindicated for nicotine patches **Participant characteristics:** **Mean age** 43.2 **Gender** Male 86.2%, Female 13.8% **Ethnicity** Not reported **SES** Not reported **Other:** Manual workers 54.6% *Education level* No formal education 23.9% Primary 17.0% Secondary 36.1% University 23.1%	**Setting**: Workplace **Provider**: Occupational health physician **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=115 Graded intervention (grade depending on nicotine dependence) vs. N=103 Usual care **Type**: Multi session **Focus**: Counselling for Smoking abstinence	**Intensity**: One 5 – 8 minutes counselling session, brochure given, further three contacts of 2 – 3 minutes after quit date More specifically, the intensity of the intervention was graded depending on the participant's nicotine dependence (Fagerström test score) Grade I: counselling only Grade II: counselling + nicotine patches (14mg/day then 7mg/day) Grade III: counselling + nicotine patches (21mg/day then 14mg/day then 7mg/day)	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed continuous abstinence at 12 months (CO) **Measured:** Self-report confirmed by CO test	**Duration of follow-up:** 2 days 15 days 3 months 12 months All except for one participant who died of lung cancer gave info at all four follow-up points	NA	<u>12 months</u> Intervention: 20.2% Control: 8.7% OR 2.58 95% CI 1.13 to 5.90 p=0.025	**Adverse effects:** Participants kept a daily record of possible adverse events accompanying the therapy - Except for general tobacco withdrawal symptoms and some weight gain no serious adverse events were observed **Inequality issues:** Not reported

Ruger et al, 2008 **REFID** 3586 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=302 **Selection / Recruitment criteria:** Pregnant women of < 28 weeks gestation receiving prenatal care, and currently smoking or recently quit (within 3 months of baseline) **Participant characteristics:** **Mean age** 26 **Gender** 0% male, 100% female **Ethnicity** White 67.2%, Black 17.2%, Hispanic 9.6%, Other 6.0% **SES** Low-income women **Other:** Married 20.2% *Education level* < High school 32.5% Completed high school 41.1% Post-secondary 26.2%	**Setting**: Home **Provider**: Public health nurses **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=156 Motivational interviewing vs. N=146 Usual care **Type**: Multi session **Focus**: Motivational interviewing for smoking cessation and relapse prevention in low income pregnant women	**Intensity**: 3 home visits of 1 hour per session + self-help manuals	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed abstinence in past 30 days (cotinine) **Measured:** Self-report verified by saliva cotinine test	**Duration of follow-up:** 1 month post-partum (% follow-up) 6 months post-partum (% follow-up)		<u>6 months</u> % who quit (were smokers @ baseline): Intervention: 6.4% Control: 8.0% % who remained as non-smokers (had quit pre-baseline): Intervention: 8.2% Control: 5% p=0.055	**Adverse effects:** Not reported **Inequality issues:** Not reported
Sadr Azodi et al, 2009 **REFID** 2827 **Country** Sweden **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=117 **Selection / Recruitment criteria:** Active daily smokers aged 18 to 79 years old, scheduled to undergo elective orthopaedic and general surgery **Participant characteristics:** **Median age** 55 to 57.5 **Gender** 46.2% Male, 53.8% Female **Ethnicity** Not reported **SES** Not reported **Other:** University level education 19.7% Employment 54.0% Married / Have partner 53.8%	**Setting**: University affiliated hospitals **Provider**: Nurse **Mode of delivery**: Face-to-face (individual level) or telephone counselling	**Comparison:** N=55 Perioperative smoking cessation intervention vs. N=62 Usual care **Type**: Multi session **Focus**: Smoking cessation through counselling before and after operation	**Intensity**: Min. of 3 weekly sessions pre-operation and 4 weekly sessions post-operation	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported smoking cessation at 12 months post-surgery **Measured:** During intervention sessions by face-to-face or by telephone. Post-operatively, patients answered a self-administered structured questionnaire.	**Duration of follow-up:** 4 weeks after surgery (100% follow-up) 1 year after surgery (100% follow-up)	<u>4 weeks*</u> Intervention: 36% Control: 2% p<0.001 *Successful short-term abstinence was recorded only if participants reported no use of cigarettes at least 3 weeks before surgery and if the CO measured 2 – 3 weeks post-operatively was ≤10ppm.	<u>12 months</u> Intervention:33 % Control: 15% p=0.02	**Adverse effects:** Not reported **Inequality issues:** Not reported
Sallit et al, 2007 **REFID** 2555 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=216 **Selection/recruitment criteria** Female weight concerned smokers **Participant characteristics** **Age range** 21 to 59, means 33 to 36 **Gender** 0.0% male **Ethnicity** Intervention: 77% white, 9% Hispanic, 7% African American, 7% other; Control: 67% white, 19% Hispanic, 10% African American, 3% Other **SES** Not reported **Other:** Intervention 3%, Control 9% Annual household income $0 to 19,999	**Setting:** Community **Provider:** PhD dietician professor **Mode of delivery:** Face-to-face	**Comparison** N= 70 intervention vs. N= 58 Assessment only **Type:** Multi-session **Focus:** Weight control programme for dietary and smoking behaviours	**Intensity:** 1 hour once a week for 12 weeks.	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** Mean number of cigarettes smoked per day **Measured:** Self-report	**Duration of follow up** 9 months (59.2% follow up)	<u>Post intervention</u> Mean (SD) Intervention 12.66 (6.95) Control 15.76 (6.72) <u>3 month</u> Mean (SD) Intervention: 11.33 (7.32) Control: 15.95 (6.98)	<u>9 months</u> Mean (SD) Intervention: 14.07 (8.41) Change from baseline: -4.9, p<0.001 Control: 17.09 (8.04) Change from baseline NS	**Adverse effects:** Not reported **Inequality issues:** Not reported

Schumann et al, 2008 **REFID** 3728 **Country** Germany **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=611 **Selection / Recruitment criteria:** Adults aged 20 to 79 years living in a defined (rural) area who were current smokers at the time of a previously undertaken general population survey (i.e. may include past smokers at the time of this present study) **Participant characteristics:** **Mean age** 44.5 **Gender** Male 53.4%, Female 46.6% **Ethnicity** Not reported **SES** Not reported **Other:** *Length of school education* < 10 years 25.9% 10 years 53.0% > 10 years 19.0%	**Setting**: Home / General population **Provider**: Research group **Mode of delivery**: Remote (Post)	**Comparison:** N=302 Computer-tailored intervention vs. N=309 No intervention **Type**: Multi-session **Focus**: Transtheoretical model (TTM) based computer-tailored smoking cessation	**Intensity**: Up to 6 questionnaires; up to 3 computer-generated individualised feedback letters; self-help booklets	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported abstinence in past 7 days **Measured:** Self-report	**Duration of follow-up:** 6 months (82.5% follow-up) 12 months (75.0% follow-up) 18 months (72.2% follow-up) 24 months (71.4% follow-up)	NA	7-day point prevalence abstinence <u>6 months</u> Intervention: 19.6% Control: 17.4% Difference 2.2% Significance Not reported *Effect of intervention compared with control with the full longitudinal data incorporated in the logistic repeated-measures model (where non-respondents counted as smokers):* *AOR 0.98 95% CI 0.64 to 1.44* <u>12 months</u> Intervention: 27.5% Control: 22.2% Difference 5.3% Significance Not reported <u>18 months</u> Intervention: 27.4% Control 23.3% Difference 4.1% Significance Not reported <u>24 months</u> Intervention: 31.8% Control: 29.5%	**Adverse effects:** Not reported **Inequality issues:** Not reported

								Difference 2.3% Significance ot reported	
Segan et al, 2011 **REFID** 1145 **Country** Australia **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=698 (second randomisation – which was more focal/relevant than the first randomisation) **Selection / Recruitment criteria:** Recent ex-smokers who quit for more than 7 days and completed the baseline assessment **Participant characteristics:** **Mean age** 37 **Gender** Male 46%, Female 54% **Ethnicity** Not reported **SES** Not reported **Other:** Employed 73%	**Setting**: Quitline (Australia) **Provider**: Trained counselor **Mode of delivery**: Telephone	**Comparison:** N=352 Extended callback counselling vs. N=346 Usual care **Type**: Multi-session **Focus**: Extended callback counselling for smoking relapse prevention	**Intensity**: 4 to 6 calls 1 to 3 months after quitting; additional calls provided if any crisis occurred; additional calls also scheduled for end of medication	**Target behaviour outcome(s):** Smoking relapse prevention **Prioritised main outcome:** Self-reported continuous abstinence since baseline **Measured:** Self-report	**Duration of follow-up:** 4 months (74.5% follow-up) 12 months (58.6% follow-up)	<u>4 months</u> Intervention: 47.4% Control: 47.7% p=0.95	<u>12 months</u> Intervention: 19.0% Control: 19.7% p=0.84	**Adverse effects:** Not reported **Inequality issues:** Not reported
Simmons et al, 2007 **REFID** 4541 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=215 **Selection / Recruitment criteria:** University students aged 18 to 24 who smoke 5 or more cigarettes per week **Participant characteristics:** **Mean age** 20.2 **Gender** Not reported **Ethnicity** Caucasian 83% **SES** Not reported	**Setting**: University **Provider**: Research group **Mode of delivery**: Face-to-face (group discussions)	**Comparison:** N=72 Experiential smoking intervention (exp-smoke) vs. N=71 Experiential nutrition intervention (exp-nutrition) vs. N=72 Standard didactic smoking intervention (standard) **Type**: Extended **Focus**: Use of dissonance-enhancing behaviour to increase motivation for smoking cessation	**Intensity**: - One group discussion, videotaped and played back for participants	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported abstinence in past 7 days **Measured:** Self-report	**Duration of follow-up:** 1 month (99.5% follow-up – all except one person)	<u>1 month</u> *7-day point prevalence abstinence* Exp-smoke: 9.9% Standard: 12.5% Exp-nutrition: 1.4% *Experimental smoking intervention vs. Standard care* No quit significant rate difference p=0.616	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

Sivarajan Froelicher et al, 2004 **REFID** 6257 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=277 **Selection / Recruitment criteria:** Female smokers hospitalised with a diagnosis of CVD or peripheral vascular disease **Participant characteristics:** **Mean age** 61 **Gender** 100% female **Ethnicity** White 76% **SES** Not reported **Other:** Separated / Divorced / Widowed 55% Graduates 19% Employed 38% Retired 38% Homemaker 9% Other 15% <u>Annual household income ($):</u> <19,000 35% 20,000-34,999 16% 35,000-69,000 23% >70,000 8% Don't know / refused to say 17%	**Setting**: Hospitals **Provider**: Nurses **Mode of delivery**: Face-to-face; multimedia aids; telephone calls	**Comparison:** N= 142 Intervention vs. N=135 Usual care **Type**: Multi-session **Focus**: CBT Smoking relapse prevention	**Intensity**: One 30-45 minutes individualised counselling session; multimedia aids given to participant before discharge; up to five 5-10 minutes telephone calls over 1.5 months after discharge Women in the intervention group who resumed smoking in the first 90 days of enrollment were offered an additional counselling appointment with a nurse at home or over telephone	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed point prevalence abstinence (cotinine) **Measured:** Self-report validated by cotinine test at 6 and 12 months. Self-report only for follow-ups at 24 and 30 months	**Duration of follow-up:** 6 months (91.3% follow-up) 12 months (88.8% follow-up) 24 months (78.3% follow-up) 30 months (78.0% follow-up)	NA	<u>6 months</u> Intervention: 51.5% Control: 40.8% Difference10.7 % 95% CI -3.1 to 24.5% p=0.15 <u>12 months</u> Intervention: 47.6% Control: 41.7% Difference 5.9% 95% CI -7.5 to 19.3% p=0.40 <u>24 months</u> Intervention: 48.5% Control: 46.2% Difference 2.3% 95% CI -12.0 to 16.6% p=0.77 <u>30 months</u> Intervention: 50.0% Control: 50.0% Difference 0.0% 95% CI -14.7 to 14.7% p=1.00	**Adverse effects:** Not reported **Inequality issues:** Not reported

Smeulders et al, 2009 **REFID** 10068 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=317 **Selection/recruitment criteria** Patients with diagnosed congestive heart failure (CHF) for 6 months who received information about the study and were eligible after being admitted at least once to hospital based on cardiac decompensation Recruited from 6 hospitals in The Netherlands **Participant characteristics** **Mean age** 66.7 **Gender** 72.6% male **Ethnicity** Not reported **SES** Not reported **Other:** 89% not employed, 66% middle education level, 67.2% not living alone	**Setting:** Hospital Usual care (outpatient clinic) **Provider:** Intervention was delivered by a cardiac nurse specialist (professional leader) and a CHF patient (peer leader) both trained in intervention delivery**.** Usual care was delivered by a Cardiologist and/or nurse specialist. **Mode of delivery:** Face-to-face (group sessions), telephone (with co-participants)	**Comparison** N= 186 Chronic disease self-management programme (CDSMP) + usual care vs. N= 131 Usual care **Type:** Multi-session **Focus:** Health behaviour and healthcare utilisation among patients with CHF	**Intensity:** 6 weekly group sessions of 2.5 hours each	**Target behaviour outcome(s)** Health behaviour and healthcare utilisation **Prioritised main outcome for meta-regression:** Mean number of cigarettes per week **Measured:** Self-report	**Duration of follow up** 6 months (86.4% follow up) 12 months (83.6% follow up)	Unadjusted mean (SD) <u>Baseline</u> Intervention: 10.2 (29.6) Control: 13.5 (40.7) p=0.587	Unadjusted mean (SD) <u>6 months</u> Intervention: 9.6 (28.8) Control: 8.4 (25.1) p=0.902 <u>12 months</u> Intervention: 10.0 (29.8) Control: 9.7 (27.9) p=0.878	**Adverse effects:** Not reported **Inequality issues:** Not reported
Stotts et al, 2009 **REFID** 2575 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=360 **Selection / Recruitment criteria:** Pregnant smokers between 16 and 26 weeks of gestation **Participant characteristics:** **Mean age** 25.1years **Mean gestational age** 22.4weeks **Gender** 0% male, 100% female **Ethnicity** Caucasian 57.3%, African American 38.7%, Hispanic 22.0% Other 4.03% **SES** Not reported **Other:** *Income*: <$15,000 per year 54.0% >$15,000 per year 46%	**Setting**: University Clinical Research Center, Memorial Hermann Hospital, Texas **Provider**: - Nurses provided Best Practice (BP) - Sonographers provided BP and ultrasound feedback (US) - Masters-level counselors provided motivational interview (MI) **Mode of delivery**: Face-to-face (individual level), remote (Letter, Telephone)	**Comparison:** N=120 BP + US N=120 MI + US vs. N=120 Best Practice **Type**: BP+US: Extended MI: multi-session **Focus**: (i) Smoking cessation at end of pregnancy (ii) Ultrasound feedback to investigate adverse effects on foetus	**Intensity**: US Approx. 30 minutes MI One 45 – 50 minutes face-to-face session, followed by a personalised letter 1 week later; One telephone counselling 2 weeks after first MI session BP = 10 to 15 minutes advised	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed smoking cessation at end of pregnancy **Measured:** (I) Saliva cotinine-validated self-reported smoking status (ii) Ultrasound feedback	**Duration of follow-up:** End of pregnancy (95.6% follow-up)	<u>End of pregnancy</u> BP + US: 14.2% MI + US 18.3% BP only: 10.8% p=0.30	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Sutton et al, 2007 **REFID** 4521 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=1,508 **Selection / Recruitment criteria:** Non-pregnant adult current smokers or recent ex-smokers (quit in last 14 days) who were first-time callers to Quitline **Participant characteristics:** **Mean age** 38.1 **Gender** Male 34.1%, Female 65.9% **Ethnicity** Not reported **SES** Not reported	**Setting**: UK Quitline **Provider**: Research group **Mode of delivery**: Post	**Comparison:** N=765 Tailored letter vs. N=743 Usual care **Type**: Brief **Focus**: Individually tailored letter as an adjunct to telephone counselling and generic self-help materials for smoking cessation	**Intensity**: One letter	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported sustained abstinence for at least 3 months **Measured:** Self-report	**Duration of follow-up:** 6 months (77.5% follow-up)	NA	6 months 3 months sustained abstinence: Intervention: 14.5% Control: 13.7% OR 1.07 95% CI 0.79 to 1.43 p=0.663	**Adverse effects:** Not reported **Inequality issues:** Not reported

Swartz et al, 2006 **REFID** 5300 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=351 **Selection / Recruitment criteria:** Workers aged 18 years or older, currently smoking daily, intending to quit in next 30 days, with access to internet **Participant characteristics:** **Age** 18-25 years old 7% 26-39 years old 38% 40-55 years old 48% Over 55 years old 6% **Gender** 48% Male, 52% Female **Ethnicity** White 83.5%, African American 6.7%, Hispanic 4.3%, Other 5.5% **SES** Not reported	**Setting**: Internet **Provider**: Website **Mode of delivery**: Computer	**Comparison:** N=171 Treatment vs. N=180 Waiting list **Type**: Multi-session **Focus**: Smoking cessation through tailored motivational website	**Intensity**: Depended on individual	**Target behaviour outcome(s):** Smoking abstinence **Prioritised main outcome:** Self-reported abstinence in past 7 days **Measured:** Self-report via website	**Duration of follow-up:** 90 days (56.1% follow-up)	<u>90 days</u> Intervention: 24.1% Control: 8.2% p =0.002 OR 3.57 95% CI 1.54 to 8.27	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Tappin et al, 2005 **REFID** 4013 **Country** UK **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=762 **Selection / Recruitment criteria:** Pregnant women who were regular smokers at antenatal booking **Participant characteristics:** **Mean age** 26.7 **Mean gestation** 13.4weeks **Gender** 0% male, 100% female **Ethnicity** Not reported **SES** Deprivation category: 1-3 (least deprived) 8.7% 4-5 20.0% 6-7 (most deprived) 71.3%	**Setting**: At the participating mothers' home **Provider**: Midwives **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=351 Intervention vs. N=411 Usual care **Type**: Multi-session **Focus**: Smoking reduction or cessation through motivational interviewing at home	**Intensity**: 2 to 5 additional home visits, approx. 30 minutes per session	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Biochemically confirmed cessation (cotinine) **Measured:** Self-report + Cotinine measurement	**Duration of follow-up:** Late pregnancy (Blood and saliva samples obtained from 92.0% of the women)	<u>Late pregnancy</u> "Quit" = self-report + cotinine <13.7ng/ml serum or <14.2 ng/ml saliva "Cut down" = Self-report of smoking halved + cotinine conc. halved *Self-report & cotinine combined*: "Quit" Intervention: 4.8% Control: 4.6% RR = 1.05 (95% CI 0.55 to 1.98) "Cut down" Intervention: 4.3% Control: 6.3%		**Adverse effects:** Yes, Adverse events were recorded but none were attributable to the intervention. **Inequality issues:** The study took place in an area of severe deprivation

							RR = 0.68 (95% CI 0.36 to 1.25)		
Thomsen et al, 2010 **REFID** 1526 **Country** Denmark **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=130 **Selection / Recruitment criteria:** Adult female patients due to undergo breast cancer surgery who smoke daily **Participant characteristics:** **Median age** 56.5 to 57.5 **Gender** 0% male, 100% female **Ethnicity** Not reported **SES** Not reported	**Setting**: Hospitals **Provider**: Smoking cessation counselor **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=65 Brief intervention vs. N=65 Usual care **Type**: Extended **Focus**: Smoking cessation intervention shortly before breast cancer surgery	**Intensity**: One 45-90 minutes long counselling session (NRT also offered during perioperative period)	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported 12 month sustained abstinence **Measured:** Self-report	**Duration of follow-up:** 12 months post-operation (86.9% follow-up)	NA	<u>12 months</u> Intervention: 13% Control: 9% RR 1.48 (95% CI 0.50 to 4.38)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Toll et al, 2010 **REFID** 2178 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised:** N=2032 **Selection / Recruitment criteria:** Smokers who called the New York State Smokers' Quitline between Mar 2008 and Jun 2008 **Participant characteristics:** **Mean age** 46.7 **Gender** 43.3% Male, 56.7% Female **Ethnicity** Not reported **SES** Not reported	**Setting**: New York State Smokers' Quitline **Provider**: Quitline counselors **Mode of delivery**: Telephone	**Comparison:** N=810 Gain-framed messages vs. N=1,222 Standard care messages **Type**: Brief **Focus**: Smoking cessation through gain-frame messages	**Intensity**: Mean length of call in intervention group = 14 minutes 30 seconds vs. Mean length of call in control group = 12 minutes 8 seconds	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported abstinence in past 7 days **Measured:** Telephone interview	**Duration of follow-up:** 2 weeks (50.5% follow-up) 3 months (63.3% follow-up)	<u>3 months</u> Intervention: 28.4% Control: 26.6% OR 1.1 95% CI 0.9 to 1.4 p=0.48	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Unrod et al, 2007 **REFID** 4632 **Country** USA	**Number randomised:** N=518 (patients) N=70 (physicians) **Selection / Recruitment criteria:** Adult patients of the participating physicians who have smoked in the past 7 days and to have smoked more than 100 cigarettes in their lifetime	**Setting**: Primary care **Provider**: Participating physicians **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=270 Group of patients whose physicians were trained in smoking cessation counselling vs.	**Intensity**: - Initial computerised patient assessment of 5-10 minutes long, producing individualised report - Medical visit with their physician - Second assessment	**Target behaviour outcome(s):** Implementation of smoking cessation guideline and improvement in smoking behaviour **Prioritised main**	**Duration of follow-up:** 6 months (90% follow-up)	NA	<u>6 months</u> Intervention: 12% Control: 8% p=0.078	**Adverse effects:** Not reported **Inequality issues:** Not reported

Design cRCT **Internal validity** + **External validity** ++	**Participant characteristics:** **Mean age** 43.2 **Gender** Male 39%, Female 61% **Ethnicity** Caucasian 62%, African American 20%, Other 18%, Hispanic 17% **SES** Not reported		N=248 Group of patients whose physicians were **not** trained in smoking cessation counselling **Type**: Brief **Focus**: Computer-tailored intervention to increase physician adherence to the Smoking Cessation Clinical Guideline (5As) and smoking behaviours of the patients	of patient to review physician performance	**outcome:** Self-reported abstinence in past 7 days (biochemically checked in 35%) **Measured:** Self-report and saliva cotinine for some quitters				
Vale et al, 2003 **REFID** 19175 **Country** Australia **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=792 **Selection/recruitment criteria** Patients hospitalised for CABG, PCI, acute MI or unstable angina, coronary angiography with planned revascularisation. **Participant characteristics** **Mean age** 58 **Gender** 77.0% male **Ethnicity** Not reported **SES** Not reported	**Setting:** Recruited from hospital, delivered via telephone and mail **Provider:** Dietician or nurse **Mode of delivery:** Remote (telephone)	**Comparison** N= 398 COACH programme vs. N= 394 Usual care **Type:** Multi-session **Focus:** Coronary risk factors	**Intensity:** 5 telephone coaching sessions, median call length 20-30 minutes; duration 24 weeks	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** Number of self-reported baseline smokers who quit since hospital discharge **Measured:** Cotinine verified	**Duration of follow up** 6 months (85.7% follow up)	NA	<u>6 months</u> Intervention: 53 of 106 baseline smokers quit (50%) Control: 41 of 97 baseline smokers quit (42%) p=0.27	**Adverse effects:** Not reported **Inequality issues:** Not reported
Vestford Heartcare Study Group, 2003 **REFID** 6338 **Country** Norway **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=197 **Selection/recruitment criteria** Patients hospitalised for CABG, acute MI or unstable angina, or treated in an out-patient clinic with PCI. **Participant characteristics** **Mean age** 55 **Gender** 82.2% male **Ethnicity** Not reported **SES** Not reported	**Setting:** Cardiac rehabilitation clinic **Provider:** Physician, nutritionist, physiotherapist and nurse **Mode of delivery:** Face-to-face (individual and group)	**Comparison** N= 98 intervention (of whom, 49 smokers) vs. N= 99 Usual care (of whom, 42 smokers) **Type:** Multi-session **Focus:** Multidisciplinary lifestyle cardiac rehabilitation, plus physical exercise	**Intensity:** 2 hour education sessions for six weeks; followed by twice weekly group meetings for 9 weeks; Followed by group meetings every third month for two years.	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % of baseline smokers quit at follow-up **Measured:** Not reported	**Duration of follow up** 12 months (84% follow up)	NA	<u>6 months</u> Intervention: 55% of 49 baseline smokers quit Control: 33% of 42 baseline smokers quit p<0.05 <u>12 months</u> Intervention: 45% of 49 baseline smokers quit Control: 23% of 42 baseline	**Adverse effects:** Not reported **Inequality issues:** Not reported

								smokers quit p<0.05	
Vidrine et al, 2012 **REFID** 110 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** n=474 **Selection and recruitment** HIV positive individuals **Participant characteristics** **Mean age** 44.8 **Gender** 70% male, 30% female **Ethnicity** 12% Caucasian, 77% African-American, 9% Latino, 2% Other 79% unemployed **SES** Not reported	**Setting**: Clinic **Provider**: Not reported **Mode of delivery**: Remote (Telephone)	**Comparison** N=236 Cell phone intervention Vs. N=238 usual care **Type**: Multi-session **Focus**: Smoking cessation	**Intensity**: 11 sessions over 12 weeks, session length not reported	**Target behaviour outcome(s)** Smoking cessation **Prioritised main outcome:** Validated 24 hour abstinence **Measured:** Exhaled CO	**Duration of follow up** 12 weeks (% follow up not reported)	<u>3 month abstinence</u> OR 4.23 2.14 to 8.36 p<0.0001	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Willemsen et al, 2006 **REFID** 5256 **Country** Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=1014 **Selection / Recruitment criteria:** Current smokers who intended to quit smoking within the next 6 months **Participant characteristics:** **Mode age range** 35-44 **Gender** Male 53.8%, Female 46.2% **Ethnicity** Not reported **SES** Highest quarter 16.0%, 2nd quarter 39.0%, 3rd quarter 20.4%, Lowest quarter 24.7%	**Setting**: Home **Provider**: Research group **Mode of delivery**: Post	**Comparison:** N=500 Decision aid vs. N=514 No intervention **Type**: Brief **Focus**: Decision aid to motivate smoking cessation	**Intensity**: One postal delivery of a decision aid kit comprising of various components	**Target behaviour outcome(s):** Smoking cessation **Prioritised main outcome:** Self-reported sustained abstinence from quit to 6 months **Measured:** Self-report	**Duration of follow-up:** 2 weeks after receipt of decision aid (90.4% follow-up) 6 months after receipt of decision aid (88.2% follow-up)	NA	<u>6 months</u> Continuous abstinence Intervention: 5.0% Control: 5.1% Difference 0.1% p-value NS	**Adverse effects:** Not reported **Inequality issues:** Not reported

Wood et al, 2008 **REFID** 3456 **Country** France, Italy, Poland, Spain, Sweden, Denmark, the Netherlands and the UK **Design** Cluster RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=24 clusters (6,858 individuals) **Selection/recruitment criteria** Hospitalised CHD patients or GP patients at risk for CHD **Participant characteristics** **Mean age** 61-63 (range of means) **Gender** 70%% male (CHD) 50-57% (CHD risk) **Ethnicity** Not reported **SES** Not reported	**Setting:** Clinic **Provider:** Nurse, dietician and physiotherapist (for hospital based intervention with CHD patients); nurse and GP (for GP based intervention for patients at risk for CHD) **Mode of delivery:** Face-to-face (individual and group, included partners)	**Comparison Hospital/CHD** N=6 hospitals (1,589 patients) intervention vs. N=6 hospitals (1,499 patients) Usual care **GP/CHD risk** N=6 GPs (1,189 patients) intervention vs. N=6 GPs (1,128 patients) Usual care **Type:** Multi-session **Focus:** Modifiable lifestyle CHD risk factors (smoking, diet, physical activity)	**Intensity:** **Hospital -** Smoking, diet and physical activity assessment followed by 1 group workshop and supervised exercise class per week for 8 weeks. Length per session not reported. GP - Smoking, diet and physical activity assessment followed by 1 group workshop per week; open ended duration. Length per session not reported.	**Target behaviour outcome(s)** Smoking **Prioritised main outcome for meta-regression:** % cessation among 623 baseline smokers **Measured:** Validated CO concentration	**Duration of follow up** 12 months (73.3% follow up)	NA	12 months Hospital Intervention: 58% Usual care: 47% Difference 10.4% (-0.3 to +21.2) p=0.06) GP Intervention: 73% Usual care: 72% Difference 0.8% (-13.1 to +14.7) p=0.89	**Adverse effects:** Not reported **Inequality issues:** Not reported
SMOKING STUDIES WITH MISSING OR UNUSABLE DATA NOT INCLUDED IN META-REGRESSION OR NARRATIVE REVIEW									
Carmody et al, 2012 **REFID** 71 **Country** USA **Design** RCT **Internal validity** **++** **External validity** **+**	**Number randomised:** N=162 **Selection/recruitment criteria:** Us Veterans in Drug and Alcohol Treatment programmes **Participant characteristics:** **Mean age** 50 **Gender** 97% male, 3% female **Ethnicity** 48% Caucasian, 37% African-America **SES** 83% annual income below US$21,000 **Other** Employment: 81% unemployed, 26% homeless	**Setting:** Clinic **Provider:** Not reported **Mode of delivery:** Face-to-face (individual level)	**Comparison:** N=82 CBT vs. N=80 Usual care **Type:** Intensive intervention **Focus:** Smoking cessation	**Intensity:** 16 sessions over 26 weeks, session length not reported	**Target behaviour outcome(s)** Smoking cessation **Prioritised main outcome for meta-regression:** Validated 7-day point prevalence **Measured:** Self-reported no smoking and CO level <10ppm	**Duration of follow up** 12 weeks (75% follow up) 26 weeks (73% follow up) 38 weeks (67% follow up) 52 weeks (69% follow up)	Graphical evidenced only; no p values reported	Graphical evidenced only; no p values reported	**Adverse effects:** Not reported **Inequality issues:** Intervention was found to be more effective in people with a history of mood disorders

Ferguson et al, 2012 **REFID** 359 **Country** UK **Design** RCT **Internal validity** **++** **External validity** **++**	**Number randomised:** N=2591 **Selection/recruitment criteria:** Non-pregnant smokers aged 16 or older, residing in England who called the national Quitline between Feb 2009 to Feb 2010 and agreed to set a quit date **Participant characteristics:** **Median age** 38 **Gender** 43.9% male, 52.3% female, 3.8% missing **Ethnicity** Not reported **SES** Not reported	**Setting:** National Quitline, England **Provider:** Quitline counselors **Mode of delivery:** Interventions: multiple telephone calls Standard care: support material provided via e-mail letter or text message; telephone contact also offered	**Comparison:** Intervention 1 N=648 Standard support + Proactive support vs. Intervention 2 N=648 Standard support + Proactive support + Nicotine replacement therapy vs. Intervention 3 N=647 Standard support + Nicotine replacement therapy Vs. N=648 Standard support (Control) **Type:** Intensive **Focus:** Smoking cessation through motivational interviewing	**Intensity:** Intervention 1: 6 telephone interactions with advisors; Intervention 2 & 3: Nicotine replacement therapy = Free nicotine patches offered initially, which could be redeemed by a telephone call. Control: several messages of support at regular intervals	**Target behaviour outcome(s)** Smoking abstinence **Prioritised main outcome for meta-regression:** Biochemically sustained abstinence from quit date to 6 months (CO) **Measured:** At 1 month = self-reported cessation At 6 months = self-reported and CO-validated cessation	**Duration of follow up** 1 month (65% follow-up) 6 months (56% follow-up)	NA	<u>6 months</u> *CO-validated*: Standard care (SC) = 8.3% Proactive support (PS) = 7.7% AOR = 0.97 (95% CI 0.72 to 1.30) p=0.84 With NRT = 6.6% Without NRT = 9.4% AOR = 0.65 (95% CI 0.48 to 0.88) p=0.005	**Adverse effects:** Not reported **Inequality issues:** Not reported

Diet

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
Burke et al, 2008 **REFID** 3635 **Country** Australia **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 241 **Selection/recruitment criteria** Adults aged 40 to 70 years with BMI >25kg/m2 and treated with one1 or 2 antihypertensive drugs for at least 3 months Recruited by advertisement (volunteer) **Participant characteristics** **Mean age** 56.2 **Gender** 44.4% male, 55.6% female **Ethnicity** Not reported **SES** Not reported	**Setting**: Clinical trials centre **Provider**: Dietician or program co-ordinator **Mode of delivery**: Face-to-face (primarily group, with individual outcome measurement); remote (telephone, paper materials)	**Comparison** N= 123 Lifestyle program (Activity, Diet, and Blood Pressure Trial; ADAPT) Vs. N= 118 Usual care **Type**: Multi-session **Focus**: Decreased CV risk and lifestyle change	**Intensity**: 4 month intervention period (dose and frequency not reported) + 6 follow up sessions over the first year	**Target behaviour outcome(s)** Diet (and physical activity and alcohol) **Prioritised main outcome:** % participants consuming at least five servings of fruit and vegetables per day **Measured**: Self-reported diet records from household measures	**Duration of follow up** 4 months (84.2% follow-up) – reported elsewhere 12 months (79.7% follow-up) – reported elsewhere 36 months (58.1% follow-up)	Not reported	<u>36 months</u> Intervention: 469% Control: 37% p=0.147	**Adverse effects:** Not reported **Inequality issues:** Not reported
Clark et al., 2004 **REFID** 6036 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=100 **Selection/recruitment criteria** Overweight individuals with Type 2 Diabetes **Participant characteristics** **Mean age** 59.5 **Gender** 42% female, 58% male **Ethnicity** Not reported **SES** Not reported	**Setting**: Clinic (diabetes centre) **Provider**: Not reported **Mode of delivery**: Face-to-face (individual) with remote (telephone) follow-up	**Comparison** N=265 intervention Vs. N=257 Usual care **Type**: Multi-session **Focus**: Lifestyle intervention to reduce the amount of fat consumed and increase the amount of physical activity	**Intensity**: 2 face-to-face session lasting 30 minutes, followed by 3 follow-up phone calls lasting 10 minutes; intervention duration 12 weeks	**Target behaviour outcome(s)** Diet (and physical activity) **Prioritised main outcome:** Fat consumption **Measured**: Self-report using the Block fat screener (lower scores better)	**Duration of follow up** 6 months (99% follow up) 12 months (94% follow up)	<u>3 months</u> Mean score (SD) Intervention: 23.6 (14.13) Significant reduction from baseline (p<0.001) Control: 26.03 (18.78) Mean difference, 95% CI/p-values not reported	<u>12 months</u> Mean score (SD) Intervention: 20.97 (12.97) Significant reduction from baseline (p<0.001) Control: 31.24 (23.14) Mean difference, 95% CI/p-values not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Eakin et al, 2007 **REFID** 20579 **Country** USA **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N= 200 **Selection/recruitment criteria** Adults aged 30 years and older with greater than 1 or more chronic conditions (hypertension, chronic pain, hypercholesterolemia, depression, type 2 diabetes, osteoarthritis, obesity, chronic lung disease, heart disease, osteoporosis, hepatitis, history of cancer, previous stroke, multiple sclerosis) Recruited from an urban community health centre in the Denver metro area. Letters sent by clinic providers and recruitment calls made by research assistants.	**Setting**: An urban community health centre clinic or the patients home (setting based on participant preference) **Provider**: Experienced health educator trained in intervention delivery; printed materials **Mode of delivery**: Face-to-face (individual level), telephone, and printed materials.	**Comparison** N= 101 Lifestyle intervention vs. N= 99 Usual care **Type**: Multi-session **Focus**: Changes in dietary behaviour and physical activity	**Intensity**: 2 sessions face-to-face of 60 to 90 minutes (3 months apart), 3 follow up phone calls (at 2 and 6 weeks after the initial visit and 2 weeks after the second visit) and 3 tailored newsletters. (6 month intervention period)	**Target behaviour outcome(s)** Diet (and physical activity) **Prioritised main outcome:** Low fat and high fibre eating patterns **Measured**: Self-report using Kristal Fat and Fibre Behaviour Questionnaire (FFB) (lower scores better)	**Duration of follow up** 6 weeks (68.5% follow-up) 6 months (81% follow-up).	<u>6 weeks</u> Mean score (SE) Intervention: 2.25 (0.06) Significant reduction from baseline (p<0.05) Control: 2.42 (0.05) Mean difference, 95% CI/p-values not reported	<u>6 months</u> mean score (SE) Intervention: 2.24 (0.05) Significant reduction from baseline (p<0.05) Control: 2.43 (0.05) Mean difference, 95% CI/p-values not reported	**Adverse effects:** Not reported **Inequality issues:** None reported

	Participant characteristics **Mean age** 49.5 **Gender** 21.5% male, 78.5% female **Ethnicity** 75% Hispanic/Latino, 15% Anglo, 9% other Language: 66.5% Spanish, 33.5% English **SES** Not reported **Other:** Yearly household income: 34% less than US$10,000; 47.5% US$10,000 to $30,000; 13% greater than US$30,000 Education: 68% elementary/some high school, 15% high school graduate, 16.5% some college/college graduate								
Eakin et al, 2010 **REFID** 1467 **Country** Australia **Design** Cluster RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N= 434 **Selection/recruitment criteria** Patients older than 30 years with type 2 diabetes or hypertension Recruited from 10 primary care practices in a socioeconomically disadvantaged community bordering Brisbane **Participant characteristics** **Mean age** 58.2 **Gender** 38.9% male, 61.1% female **Ethnicity** 91% Caucasian **SES** Considered a socioeconomically disadvantaged community **Other:** Education: 44.9% more than high school graduate 36.2% retired	**Setting**: Remote (telephone delivery) **Provider**: Counsellors with Bachelor orMasters degree in with public health/health promotion or the allied health sciences (nutrition or exercise) trained in intervention delivery; mailed materials **Mode of delivery**: Telephone, printed materials	**Comparison** N= 228 Telephone counselling (5 practices) vs. N= 206 Usual care (5 practices) **Type**: Multi-session **Focus**: Increased physical activity levels and improve diet	**Intensity**: 4 month intervention phase (10 telephone calls of 20 minutes; weekly for the first 3 weeks then fortnightly until 4 months) + 8 month maintenance phase (8 telephone calls of 20 minutes delivered monthly). 12 month intervention period.	**Target behaviour outcome(s)** Diet (and physical activity) **Prioritised main outcome:** Servings per day of vegetables **Measured**: Self-reported using Australian National Nutritional Survey	**Duration of follow up** 12 months (78.6% follow-up) 18 months (72.6% follow-up)	Not reported	18 months mean (SE) Intervention: 0.77 (0.21) Significant increase from baseline (p<0.001) Control: 0.18 (0.21) NS change from baseline Mean difference: 0.59 (-0.01 to +1.17), p=0.051	**Adverse effects:** Not reported **Inequality issues:** Yes, trial results applicable to low SES groups.
Ellingsen et al, 2006 **REFID** 5252 **Country** Norway **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N= 1,232 (558 survivors were re-assessed) **Selection/recruitment criteria** Healthy men aged 40 to 49 years with elevated serum total cholesterol or a high coronary risk score. All subjects had normal electrocardiogram at rest, were free of chest pain at exercise testing and were free of diseases in the cardiovascular system, hypertension, diabetes mellitus, cancer, disabling or psychopathological conditions and alcoholism. Recruited from 16,302 screened men (65% of all men aged 40 to 49 years in Oslo, Norway). **Participant characteristics** **Mean age** 45.3 **Gender** 100% male, 0% female **Ethnicity** Not reported **SES** Not reported	**Setting**: Not reported **Provider**: Dietician and lead investigator trained in intervention delivery **Mode of delivery**: Face-to-face (individual and group level)	**Comparison** N= 604 Counselling vs. N= 628 No intervention **Type**: Multi-session **Focus**: Long-term maintenance of lifestyle change	**Intensity**: 1 session every 6 months for 5 years	**Target behaviour outcome(s)** Long-term maintenance of lifestyle change (Diet) **Prioritised main outcome:** Fat intake quality score **Measured**: Self-reported using quantitative food frequency questionnaire (FFQ) (low scores indicate high-coronary risk diet)	**Duration of follow up** 20 years (45.3% follow-up). 26.1% of the study population died.	Not reported	20 years mean (SD) Intervention: 29.2 (7.9) Control: 26.7 (6.8) Mean difference in change scores (baseline to 20y): 1.7 (0.3 to 3.1), p=0.06	**Adverse effects:** Not reported **Inequality issues:** Not reported

Giannuzzi et al, 2008 **REFID** 10871 **Country** Italy **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 3,241 **Selection/recruitment criteria** Patients younger than 75 years who had a recent MI (within <3 months) and had completed a cardiac rehabilitation program lasting approximately 1 month **Participant characteristics** **Mean age** 57.9 **Gender** 86.3% male, 13.7% female **Ethnicity** Not reported **SES** Not reported **Other:** 33.1% more than 5 years education 42.9% retired	**Setting**: 78 cardiac rehabilitation centres across Italy **Provider**: Cardiac rehabilitation team (specialist cardiac nurse, physiotherapist, cardiologist). A clinical psychologist and occupational therapist were recruited when needed. **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 1,620 Multifactorial educational and behavioural intervention vs. N= 1,621 Usual care **Type**: Multi-session **Focus**: CV events (CV mortality, non-fatal MI, non-fatal stroke, hospitalisation for angina pectoris and revascularisation procedures)	**Intensity**: Monthly sessions from 0 to 6 months and then 1 session every 6 months up to 3 years consisting of 30 minutes of exercise, 1hour of counselling and 30 minutes of reinforcement	**Target behaviour outcome(s)** Diet (and physical activity, smoking) **Prioritised main outcome:** Mediterranean diet compliance **Measured**: Self-report using brief questionnaire designed for study; scores ranged from 6 to 24, with higher scores indicating better diet. Score of 19.0 indicates a Mediterranean like diet.	**Duration of follow up** 6 months (96.3% follow-up) 36 months (90.5% follow-up)	NA	% patients with score >19.0 <u>6 months</u> Mediterranean diet score (mean (SD) Intervention: 19.1 (2.2) Control: 18.6 (2.3) Between group p<0.001) % patients with score >19.0 Intervention: 64.5% Control: 54.8% Mean Difference: p<0.001 <u>12 months</u> Intervention: 64.5% Control: 57.2% Mean Difference: p<0.001 <u>24 months</u> Intervention: 63.8% Control: 58.8% Mean Difference: p=01 <u>36 months</u> Intervention: 64.4% Control: 56.1% Mean Difference: p<0.001	**Adverse effects:** Intervention decreased the absolute risk of overall CV events compared to the control, although this was not significant **Inequality issues:** None reported

Glasgow et al, 2006 **REFID** 4829 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 335 **Selection/recruitment criteria** Adults aged 25 years and older with diagnosed type 2 diabetes residing in Denver, Colorado metropolitan area Recruited from lists provided by 42 physicians (20% from mixed payer settings, and the remainder employed by Kaiser Permanente) **Participant characteristics** **Mean age** 61.5 **Gender** 50.0% male, 50.0% female **Ethnicity** 17.9% Hispanic, 76.7% white **SES** Not reported **Other:** Education: 35% with college degree Annual income (US$): 28% <$30,000; 64% <US$50,000; 50.8% >$50,000	**Setting**: Central clinic or medical office not too far from the patient's home (external to the patient's primary care setting). **Provider**: Health educators with varying educational backgrounds trained in motivational interviewing (no formal training and little or no experience in diabetes); electronic media **Mode of delivery**: Face-to-face, computer, mailed paper materials, telephone	**Comparison** N= 174 Tailored self-management Vs. N= 161 Computer-aided enhanced usual care **Type**: Multi-session **Focus**: Dietary behaviours	**Intensity**: Not clear. Appears to be 1 session incorporating computer assisted component and a face-to-face component followed by mailed materials and 1 follow up phone call of 10 to 15 minutes 5 weeks following the first session.	**Target behaviour outcome(s)** Changes in dietary behaviours **Prioritised main outcome:** Daily fat consumption **Measured**: Self-report using Block fat screener	**Duration of follow up** 2 months (89.9% follow-up)	<u>2 months</u> mean (SD) Intervention: 22.4 (15.2) Control: 28.5 (17.8) Between condition ANCOVA, treatment effect p=0.006	NA	**Adverse effects:** Not reported **Inequality issues:** None reported
Groenveld et al, 2011 **REFID** 461 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 573 (433 analysed) **Selection/recruitment criteria** Male construction workers aged 18 to 65 years employed at (>400) companies throughout The Netherlands who had attended a voluntary health screening at the occupational health service and were identified as at risk for CVD. **Participant characteristics** **Mean age** 47.4 **Gender** 100% male, 0.0% female **Ethnicity** Not reported **SES** Not reported **Other:** 32.7% smokers 31.1% blue-collar workers 69.9% white-collar workers	**Setting**: Not reported for face-to-face sessions; remote (telephone) **Provider**: Occupational physician or occupational nurse **Mode of delivery**: Face-to-face (individual level), telephone	**Comparison** N= 293 Lifestyle intervention vs. N= 280 Usual care **Type**: Multi-session **Focus**: Changes in physical activity, diet and smoking	**Intensity**: 3 face-to-face sessions of 45 to 60 minutes and 4 telephone calls of 15 to 30 minutes over 6 months	**Target behaviour outcome(s)** Diet (and physical activity, smoking) **Prioritised main outcome:** Vegetable consumption (spoons per week) **Measured** Self-report using the Short Questionnaire for Measuring Fruit and Vegetables Intake	**Duration of follow up** 6 months (84.6% follow-up) 12 months (81.3% follow-up)	NA	<u>6 months</u> mean (SD) Intervention: 18.0 (9.2) Control: 17.3 (8.3) Mean Difference: 0.7 95% CI and p-value not reported <u>12 months</u> mean (SD) Intervention: 17.5 (8.8) Control: 7.7 (8.8) Mean Difference: 9.8 95% CI and p-value not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported

Guelinckx et al, 2010 **REFID** 2177 **Country** Belgium **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=195 **Selection / Recruitment criteria:** Obese (BMI > 29.0) white pregnant women consecutively attending the prenatal clinic before 15wk gestation **Participant characteristics:** **Mean age** 28.7 **Gender** 100% female **Ethnicity** 100% white **SES** Not reported **Other:** Mean BMI (pre-pregnancy) 33.7	**Setting**: Prenatal clinic of a university hospital **Provider**: Active intervention was provided by a trained nutritionist **Mode of delivery**: - Brochure for passive intervention group and active intervention group - In addition, face-to-face group counselling sessions for the active intervention group	**Comparison:** N=65 Active intervention vs. N=65 Passive intervention vs. N=65 Usual care **Type**: - Brief for passive intervention group - Multi-session for active intervention group **Focus**: Lifestyle intervention using brochure or active education to improve lifestyle and reduce gestational weight gain in obese pregnant women	**Intensity**: - Brochure only for passive intervention group - In addition to brochure, three 1hr group educational sessions for active intervention group at 15, 20 and 32 week of pregnancy	**Target behaviour outcome(s):** Diet (and physical activity) **Prioritised main outcome:** Fruit intake **Measured**: Self-reported using dietary records, checked by nutritionist	**Duration of follow-up:** To delivery of child (62.6% follow-up)	2nd trimester Mean (SD) Active: 1.3 (0.7) Passive: 1.2 (0.6) Control: 0.8 (0.7)	3rd trimester Mean (SD) Active: 1.1 (0.7) Passive: 1.0 (0.6) Control: 0.8 (0.8) Group x trimester p=0.106	**Adverse effects:** Not reported **Inequality issues:** Not reported
Hardcastle et al, 2008 **REFID** 3773 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=334 **Selection/recruitment criteria** Patients with a BMI >28kg/m^2 at risk for coronary heart disease **Participant characteristics** **Mean age** 51 **Gender** 33% female, 67% male **Ethnicity** Not reported **SES** Not reported	**Setting**: Primary care **Provider**: Physical Activity Specialist and Registered Dietician **Mode of delivery**: Face-to-face (individual)	**Comparison** N=203 intervention vs. N=131 Usual care **Type**: Multi-session **Focus**: Lifestyle counselling based on motivational interviewing for diet and physical activity	**Intensity**: Up to 5 sessions, 20-30 minutes each over 6 months	**Target behaviour outcome(s)** Diet **Prioritised main outcome** Portions of fruit and vegetables per day **Measured**: Self-report using five-a-day community evaluation tool questionnaire	**Duration of follow up** 6 months (65% follow up)	NA	6 months Intervention: +1.05 Control: +0.73 Mean difference: +0.32 (-1.36 to +0.72)	**Adverse effects:** Not reported **Inequality issues:** None reported

Keogh et al, 2011 **REFID** 15882 **Country** Ireland **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=121 **Selection / Recruitment criteria:** Adults with type 2 diabetes for more than a year who had persistently poor glycaemic control **Participant characteristics:** **Mean age** 58.6 **Gender** 63.6% Male, 36.4% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean years diagnosed 9.4	**Setting**: Home **Provider**: Health psychologists **Mode of delivery**: Face-to-face (patient with family member); then remote (telephone)	**Comparison:** N=60 Intervention vs. N=61 Usual care **Type**: Multi-session **Focus**: Improvement of diabetes-related outcomes using health psychology and motivational interviewing, and involving family members	**Intensity**: First 2 sessions 45 minutes each (face-to-face at home) Third session 10 – 15 minutes follow-up telephone call	**Target behaviour outcome(s):** Diet (and physical activity) **Prioritised main outcome:** Fat intake (days/week) **Measured**: Self-report using the Summary of Diabetes Self-care Activities Questionnaire	**Duration of follow-up:** 6 months (88.4% follow-up)	NA	<u>6 months</u> mean (SD) Intervention: 3.51 (2.26) Control: 3.36 (2.16) Significance not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Koelewijn-van Loon et al, 2009 **REFID** 2310 **Country** The Netherlands **Design** Cluster RCT **Internal validity** **+** **External validity** ++	**Number randomised** N= 615 patients, 25 practices **Selection/recruitment criteria** Adult patients eligible for cardiovascular risk management. Patients with existing CVD were excluded. Practices that employed a practice nurse and used electronic patient records were included **Participant characteristics** (based on 589 participants) **Mean age** 57 **Gender** 44.8% male, 55.2% female **Ethnicity** Not reported **SES** 22.8% high SES status, 38.7% intermediate SES status, 34.6% low SES status	**Setting**: Not reported **Provider**: Practice nurse trained in intervention delivery **Mode of delivery**: Face-to-face, telephone	**Comparison** N= 322 Cardiovascular risk management intervention (13 practices) Vs. N= 293 Usual care (12 practices) **Type**: Multi-session **Focus**: Lifestyle adherence and cardiovascular risk	**Intensity**: 2 sessions of 15 to 20 minutes, 2 weeks apart, and 1 telephone call of 10 minutes 2 weeks after the second face-to-face session	**Target behaviour outcome(s)** Diet (and physical activity, smoking, alcohol) **Prioritised main outcome:** Fat consumption **Measured**: Self-report using Dutch Fat list	**Duration of follow up** 12 months (84.6% follow-up; 79.3% final analysis)	NA	<u>12 months</u> mean (SD) Intervention: 14.4 (5.4) Control: 15.4 (5.4) p=0.034	**Adverse effects:** Not reported **Inequality issues:** Not reported
Lindahl et al, 2008 **REFID** 2664 **Country** Sweden **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=200 (directly invited & randomised) **Selection / Recruitment criteria:** Individuals with impaired glucose tolerance and BMI of >27 **Participant characteristics:** **Mean age** 52.9 **Gender** 34.5% Male, 65.5% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean BMI 30.7 *Education level*: Low 69.3% Medium 21.4% High 8.3%	**Setting**: Residential wellness centres **Provider**: Unclear **Mode of delivery**: Face-to-face (in groups); telephone (individually)	**Comparison:** N=100 Intervention vs. N=94 Usual care N.B. 200 ppl were directly invited and randomised; 194 ppl completed baseline measurements; 168 ppl completed 5-year follow-up (included in final analysis). **Type**: Multi-session **Focus**: Residential lifestyle programme for individuals with	**Intensity**: 1 month stay at a wellness centre, entailing 140hrs of activities: - Daily aerobic physical activity of moderate intensity for 2.5hrs - Tailored diet with reduced fat and high fibre content - Prohibition of alcohol consumption - Group treatment for smoking cessation - Behaviour change, stress management, relapse prevention sessions - Follow-up telephone call	**Target behaviour outcome(s):** Lifestyle change (diet and physical activity **Prioritised main outcome:** % Vegetables at least once per day **Measured**: Self-report (questionnaire)	**Duration of follow-up:** Longest follow-up period = 5 years (86.6% or 168/200 = 84.0% of the pts completed the 5-year follow-up)	NA	<u>1 year</u> Intervention: 88.8% Control: 76.1% p<0.05 <u>3 years</u> Intervention: 75.6% Control: 79.3% <u>5 years</u> Intervention: 81.5% Control: 70.0%	**Adverse effects:** Not reported **Inequality issues:** It is stated in their discussion that the differences in the risk factor reduction cannot be explained by differences in educational level between study groups.

			impaired glucose tolerance						
Morey et al, 2009 **REFID** 2710 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=641 **Selection / Recruitment criteria:** Overweight (BMI≥25), long-term (≥5 years) survivors of colorectal, breast and prostate cancer between the age of 65 and 91 **Participant characteristics:** **Mean age** 73.1 **Gender** 45.6% Male, 54.4% Female **Ethnicity** White 88.8% **SES** Not reported **Other:** College attended 61.7% Mean BMI 29.2	**Setting**: Home **Provider**: Research team and health counselors **Mode of delivery**: Remote (post and telephone)	**Comparison:** N=319 Intervention vs. N=322 Waiting list **Type**: Multi-session **Focus**: Improvement of lifestyle behaviours in older, overweight long-term cancer survivors using remote methods based on Social Cognitive Theory and the Transtheoretical Model	**Intensity**: For period of 12 months: - Personally tailored workbook - Telephone counselling (weekly during first 3 weeks; every other week for 1 month; monthly then onwards) of 15 - 30 minutes - Automated telephone prompts - Tailored progress report sent every 12 weeks	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Change in fruits and vegetables (daily servings) **Measured**: Self-report (questionnaire and recall visits)	**Duration of follow-up:** 12 months (87.1% follow-up)	NA	<u>12 months</u> Intervention: +1.24 Control: +0.13 Mean arm difference 1.11 95% CI 0.76 to 1.47 p <0.0001	**Adverse effects:** Changes in health status were monitored; 201 AEs were reported, most were non-serious. 106 of 201 AEs were classified as possibly attributable to the intervention; 32 involved hospitalization and were considered serious. **Inequality issues:** Not reported
Osborn et al, 2010 **REFID** 19691 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=118 **Selection/recruitment criteria** Puerto Rican patients with Type 2 Diabetes **Participant characteristics** Characteristics provided for intervention and control completers only: **Mean ages** 57-58 **Gender** 30-38% female, 62-70% male **Ethnicity** 100% Puerto Rican **SES** Not reported	**Setting**: Clinic **Provider**: Medical assistant **Mode of delivery**: Face-to-face (individual level)	**Comparison** N=48 culturally targeted Information Motivation Behaviour (IMB) intervention vs. N=43 Usual care **Type**: Extended **Focus**: Lifestyle intervention (diet and physical activity) for Type 2 Diabetes self-care	**Intensity**: 1 session lasting 90 minutes	**Target behaviour outcome(s)** Diet **Prioritised main outcome** Frequency of adhering to dietary recommendations (scored 0-7, higher scores reflect more days adhering to diet) **Measured**: Self-report using the diet subscale of the Summary of Diabetes Self-Care Activities questionnaire	**Duration of follow up** 3 months (81% follow up)	<u>3 months:</u> Mean diet score (SD) at follow-up Intervention: 4.42 (1.82) Control: 3.65 (1.93) Mean difference: +0.77 p<0.05 (ANCOVA)	NA	**Adverse effects:** Not reported **Inequality issues:** Culturally targeted intervention for a minority ethnic group.
Patrick et al, 2011 **REFID** 532 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=441 **Selection / Recruitment criteria:** Men aged between 25 to 55 years with BMI ≥ 25 (overweight or obese) **Participant characteristics:** **Mean age** 43.9 **Gender** 100% male **Ethnicity** White 71.0%, Black 5.2%, Hispanic 18.1%, Other 5.7% **SES** Not reported **Other:** Mean BMI 34.3 *BMI categories*: Overweight 15.6% Obese I 41.7% Obese II 33.8% Obese III 8.8%	**Setting**: Internet **Provider**: Computer **Mode of delivery**: Remote (internet-based)	**Comparison:** N=224 Intervention vs. N=217 Waiting list **Type**: Multi-session **Focus**: Internet-based behaviour change programme based on social cognitive theory to improve weight-related behaviours and induce weight loss	**Intensity**: Weekly learning activities	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Servings of fruit and vegetables per 1,000kcal/day **Measured**: Self-report (questionnaire)	**Duration of follow-up:** 6 months (66.0% follow-up) 12 months (70.1% follow-up)	NA	<u>6 months</u> Mean (SE) Intervention: 2.11 (0.09) Control:1.64 (0.09) Group x Time effect p<0.001 <u>12 months</u> Intervention: 2.11 (0.10) Control: 1.73 (0.10)	**Adverse effects:** Not reported **Inequality issues:** Not reported

	Education level: High school 8.4% Some college 28.6% College graduate 29.9% Postgraduate 33.1% Marital status: Married/With partner 70.3% Single/Separated/Divorced 29.7%							Group x Time effect p<0.002	
Sallit et al, 2007 **REFID** 2555 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 216 **Selection/recruitment criteria** Female weight concerned smokers aged 19 years and older **Participant characteristics** **Age range** 21 to 59, means 33 to 36 **Gender** 0.0% male, 100% female **Ethnicity** Intervention: 77% white, 9% Hispanic, 7% African American, 7% other; Control: 67% white, 19% Hispanic, 10% African American, 3% other **SES** Not reported **Other:** Education: 0.9% some high school, 6.9% high school, 2.8% technical, 18.1% associates, 29.2% college graduate or above Annual household income (US$): 3.2% $0 to $19,999, 22.2% $20,000 to $49,000, 33.8% more than $50,000.	**Setting:** Community **Provider:** PhD dietician professor **Mode of delivery:** Face-to-face	**Comparison** N= 125 intervention vs. N= 91 Assessment only **Type:** Multi-session **Focus:** Weight control programme for dietary and smoking behaviours	**Intensity:** 1 hour once a week for 12 weeks	**Target behaviour outcome(s)** Diet, physical activity and smoking **Prioritised main outcome for meta-regression:** Healthy eating index **Measured:** Self-report, three day food records	**Duration of follow up** 9 months (59.2% follow-up)	End of intervention Mean (SD) Intervention: 75.86 (9.62) Control: 64.77 (11.67) No between group significance measures reported 3 months post intervention Mean (SD) Intervention: 75.04 (9.95) Control: 64.29 (14.04) No between group significance measures reported	9 months post intervention Mean (SD) Intervention: 71.80 (12.32) Control: 59.47 (15.45) No between group significance measures reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Stolley et al, 2008 **REFID** 2992 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=213 **Selection / Recruitment criteria:** Non-pregnant African American women aged between 30 and 65 with BMI between 30 and 50 (obese) **Participant characteristics:** **Mean age** 46.0 **Gender** 100% female **Ethnicity** 100% African American **SES** Not reported **Other:** Mean BMI 39.2 Education 14.9 years Median income $42,500 Full-time employed 71.9% Married/co-habiting 34.3%	**Setting**: University campus **Provider**: Unclear **Mode of delivery**: Face-to-face (mainly in groups but individual MI sessions were also offered, which could be in-person or by telephone)	**Comparison:** N=107 Culturally tailored intervention vs. N=106 General health (Control) **Type**: Multi-session **Focus**: Culturally adapted lifestyle intervention for black women based on Social Cognitive Theory that is focused on changes in cognitions behaviours and social support related to weight loss	**Intensity**: Twice weekly group weight loss sessions (one 90mins-long and the other 60mins-long) for 6 months. Additionally, individual monthly MI sessions lasting 20 to 30 minutes were also offered.	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Vegetables (servings/day) **Measured**: Interviewer-administered questionnaire	**Duration of follow-up:** 6 months (93% follow-up)	NA	6 months (end of intervention) (mean/SD) Intervention: 3.94 (3.25) Control: 3.39 (2.47) Difference between adjusted means 0.50 95% CI -0.23 to 1.23 p=0.18	**Adverse effects:** Not reported **Inequality issues:** Not reported

Thoolen et al, 2009 **REFID** 2246 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=227 **Selection/recruitment criteria** Patients recently diagnosed with diabetes (screen detected) **Participant characteristics** **Mean age** 62 **Gender** 36-45% female, 55-64% male **Ethnicity** Not reported **SES** Not reported	**Setting**: Not reported **Provider**: Nurse **Mode of delivery**: Face-to-face (individual and group level)	**Comparison** N=119 Beyond Good Intentions intervention vs. N=102 Usual care **Type**: Multi-session **Focus**: Diabetes self-management (diet, physical activity and medication)	**Intensity**: 6 sessions (2 individual, length not reported; and 4 group, 2 hours each) over 12 weeks	**Target behaviour outcome(s):** Diet **Prioritised main outcome :** Fat consumption **Measured**: Self-report using the Dutch Fat Consumption Questionnaire	**Duration of follow up** 3 months (86% follow up) 12 months (79% follow up)	<u>3 Months</u> Mean (SD) Intervention: 25.9 (0.6) Control: 27.1 (0.6) Mean difference 1.2, significance Not reported	<u>12 months</u> Mean (SD) Intervention: 25.3 (0.6) Control: 26.4 (0.6) Effect size Eta square 0.03 (small) Group x Time interaction P<0.01)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Toobert et al, 2010 **REFID** 1780 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 279 **Selection/recruitment criteria** Postmenopausal women with type 2 diabetes for at least 6 months from the Pacific Northwest who received their care from primary care clinics **Participant characteristics** **Mean age** 61 **Gender** 0.0% male, 100% female **Ethnicity** 94% non-Hispanic white, 2.9% Hispanic , 1.4% Native American Indian **SES** Not reported **Other:** <u>Employment:</u> 38% employed, 43% retired <u>Average income</u>: US$30,000 to $39,000 <u>Education:</u> 42% college education	**Setting**: Non-residential retreat (3 day retreat); setting not reported for rest of intervention **Provider**: Dietician (dietary components), exercise physiologist (physical activity component), professionals with at least Master's level training and peer leader led the support groups **Mode of delivery**: Face-to-face	**Comparison** N= 163 Mediterranean Lifestyle program vs. N= 116 Usual care The intervention group was further randomised to receive faded maintenance or personalised maintenance. No differences were found and results were combined and compared to the control **Type**: Multi-session **Focus**: Long-term multiple behaviour changes	**Intensity**: 3 day retreat + weekly sessions of 1 hour for 6 months. Followed by either faded weekly sessions (faded maintenance) or 4 sessions (personalised maintenance) over 18 months. Total intervention period of 24 months.	**Target behaviour outcome(s)** Physical activity and dietary changes **Prioritised main outcome:** Healthy eating **Measured**: Self-report on Kristal Questionnaire	**Duration of follow up** 5 years (69.7% follow-up)	NA	Adj. mean (SD) <u>6 Month</u> Intervention: 1.79 (.38) Control: 2.04 (0.42) <u>12 Month</u> Intervention: 1.81 (0.35) Control: 2.05 (0.40) <u>24 Month</u> Intervention: 1.83 (0.40) Control: 2.06 (0.41) <u>36 Month</u> Intervention: 1.96 (0.42) Control:2.03 (0.42) <u>48 Month</u> Intervention: 2.03 (0.43) Control:2.06 (0.46) <u>60 Month</u> Intervention: 1.99 (0.41) Control: 2.01 (0.42) <u>72 Month</u>	**Adverse effects:** Not reported **Inequality issues:** Not reported

								Intervention: 1.99 (0.41) Control: 2.03 (0.42) <u>84 Month</u> Intervention: 2.01 (0.39) Control: 2.07 (0.40) Group x Time interaction p<0.001	
van Wier et al, 2009 **REFID** 2781 **Country** Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=1386 **Selection / Recruitment criteria:** Overweight (BMI≥25) adult employees of 7 chosen companies who have access to internet and with no diagnosis or treatment for disorders that would make physical activity difficult **Participant characteristics:** **Mean age** 43 **Gender** 67.0% Male, 33.0% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean BMI 29.6 Highly educated 60.4% Married/cohabiting 84.7%	**Setting**: Workplace / Home **Provider**: Trained counselors (dieticians and movement scientists) **Mode of delivery**: Remote Intervention 1: Telephone Intervention 2: Internet (interactive website + e-mail)	**Comparison:** N=462 Telephone intervention N=464 Internet intervention vs. N=460 Usual care **Type**: Multi-session **Focus**: Lifestyle counselling for overweight employees; comparison between telephone and internet methods	**Intensity**: Telephone every 2 weeks until all modules completed Internet access to interactive website, and communication from counselor by e-mail as each module completed	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** % consuming at least 2 pieces fruit/day (meeting public health guidelines) **Measured**: Self-report (questionnaire)	**Duration of follow-up:** 6 months (58.2% completed the follow-up questionnaire)	NA	<u>6 months</u> Control: 41.8% Phone: 43.3% vs. control OR 1.1 95% CI 0.7 to 1.6 p=0.80 Internet 39.5% vs. control OR 0.90 95% CI 0.6 to 1.4 p=0.80	**Adverse effects:** Not reported **Inequality issues:** Not reported
White et al, 2012 **REFID** 26 **Country** Australia **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=183 **Selection / Recruitment criteria:** Older adults diagnosed with type 2 diabetes (T2d) or cardiovascular disease (CVD) **Participant characteristics:** **Mean age** 61.2 **Gender** 39% Male, 61% Female **Ethnicity** White 99% **SES** Not reported **Other:** Married 76% Retired 39% Homemaker 31% T2d only 49% T2d + CVD 45% CVD only 6%	**Setting**: Community health centres **Provider**: Health professionals **Mode of delivery**: Face-to-face (group level)	**Comparison:** N=130 Intervention vs. N=53 Waiting list **Type**: Multi-session **Focus**: The Theory of Planned Behaviour (TPB)-based interactive group sessions to promote regular physical activity and healthy eating amongst older adults with T2D and/or CVD	**Intensity**: Weekly 2hr group sessions held over for 4 weeks	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Healthy eating (eating foods low in saturated fats; eating low-fat dairy products and fat-trimmed meat; using mono- and poly-unsaturated oils) 7-point scale **Measured**: Self-report	**Duration of follow-up:** 1 week post-intervention (HE 73% & physical activity 73% follow-up) 6 week post-intervention (HE 63% & physical activity 61% follow-up)	<u>1 week</u> Mean (SD) Intervention: 6.20 (SD) Control: 5.50 (1.50) <u>6 weeks</u> Intervention: 6.10 (1.08) Control: 5.55 (1.43) Time x Condition effects NS	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Wood et al, 2008 **REFID** 3456	**Number randomised** N=5,405 **Selection/recruitment criteria** Patients younger than 80 years with	**Setting**: 12 general hospitals in France, Italy, Poland, Spain, Sweden, UK. 12 general-practice centres in Denmark, Italy, Poland, Spain, The Netherlands,	**Comparison** N= 1,589 EUROACTION (coronary heart disease hospital-	**Intensity**: Hospital patients: At least 8 weekly sessions over 16 weeks General practice	**Target behaviour outcome(s)** Physical activity and diet	**Duration of follow up** 12 months (73.3% follow -up).	Not reported	<u>12 months</u> Hospital: Intervention: 79%	**Adverse effects:** Not reported **Inequality issues:** Not reported

Country Denmark, France, Italy, Poland, Spain, Sweden, The Netherlands, UK **Design** Cluster RCT **Internal validity** ++ **External validity** ++	coronary heart disease or patients in general practice who were between 50 and 80 years considered at high risk of developing CVD **Participant characteristics** **Mean age** 62.6 **Gender** 45.2% male, 54.8% female **Ethnicity** Not reported **SES** Not reported	UK. **Provider**: Nurse (coordinator), physiotherapist and dietician **Mode of delivery**: Face-to-face (group level)	based patients) vs. N= 1,189 EUROACTION (high-risk CVD general practice-based patients Vs. N= 2,627 Usual care **Type**: Multi-session **Focus**: Family-based lifestyle change	patients: Weekly sessions open ended	**Prioritised main outcome:** % consuming oily fish at least 3 times per week **Measured**: Self-report			Control: 67% Difference 8.7% 95 % CI -33.3 to +50.6% p=0.62 GP intervention: 83% Control: 66% Difference 16.8% 95 % CI -1.7 to +35.2% p=0.07	
Wright et al, 2011 **REFID** 958 **Country** Australia **Design** RCT **Internal validity** **+** **External validity** +	**Number randomised** N= 178 **Selection/recruitment criteria** Adults aged between 40 and 65 years requiring primary or secondary prevention of CVD (i.e. having one or more of the risk factors: overweight or obesity, hypercholesterolemia, hypertension, smoking, family history or previous cardiac event Recruited by newspaper advertisement, newspaper community announcements and media publicity on broadcast radio and community television **Participant characteristics** **Mean age** 54.0 **Gender** 47.8% male, 52.2% female **Ethnicity** Not reported **SES** Not reported **Other:** <u>Education:</u> 51.7% 12 years or less; 48.3% 12 years or more	**Setting**: Tailored feedback: Remote Small group counselling: University seminar room **Provider**: Tailored feedback: Electronic media Small group counselling: Dietician **Mode of delivery**: Tailored feedback: mailed materials Small group counselling: Face-to-face (group level)	**Comparison** N= 58 Tailored printed dietary feedback N= 58 Small group nutrition counselling vs. N= 62 Waitlist control **Type**: Multi-session **Focus**: Improved dietary behaviours	**Intensity**: Tailored feedback: 3 installments of mailed feedback reports over 3 months Small group counselling: 2 sessions of 90 minutes over 3 months. Groups consisted of 10 to 15 people Waitlist: for 4 months	**Target behaviour outcome(s)** Improved behaviours **Prioritised main outcome:** Daily servings of vegetables **Measured**: Self-report, 7-day estimated dietary record dietary	**Duration of follow up** 3 months (78.1% follow-up)	<u>3 months</u> Mean (SE) Tailored feedback Intervention: 2.9 (0.2) Nutrition education intervention: 2.9 (0.2) Control: 2.5 (0.2) Significance not reported	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

Physical activity

STUDY	POPULATION AND PARTICIPANT CHACTERISTICS	CONTEXT, (SETTING PROVIDER and DELIVERY)	CONTENT (INTERVENTION TYPE) FOCUS	INTENSITY	OUTCOMES and MEASUREMENT	FOLLOW UP	RESULTS Short term (≤6months) With CI or p value	RESULTS Longer term (>6months) With CI or p value	NOTES
Armit et al, 2009 **REFID** 2895 **Country** Australia **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=136 **Selection/recruitment criteria** Inactive patients 50 to 70 years (not meeting recommended 150 minutes of moderate intensity physical activity in previous week) Recruited by a research assistant in the waiting rooms of two general practice sites (that involved 10 GPs) in Brisbane, Queensland. **Participant characteristics** **Mean age** 58 years 57% aged 50 to 59 years 43% aged 60 to 70 years **Gender** 40% male, 60% female **Ethnicity** Not reported **SES** Not reported **Other:** Education: 38% below year 12; 14% Year 12; 48% Tertiary. Language spoken at home: 97% English, 3% other language	**Setting**: 2 general practices **Provider**: Intervention 1 and 2: General practitioners instructed on use of the brief intervention materials for delivery of usual care; 3 Exercise Scientists (ES) for delivery of counselling and follow up phone sessions. Usual care: General practitioner only **Mode of delivery**: Intervention 1 and 2: Face-to-face (individual level), paper media materials, telephone follow up	**Comparison** Intervention 1 N= 45 ES Counselling + GP usual care Intervention 2 N= 45 ES Counselling + pedometer + GP usual care vs. Control N= 46 Usual care (3 to 5 minutes of brief verbal physical activity advice and written information (‘getting started booklet’) **Type**: Multi-session **Focus**: Increased physical activity among mid-age and older adults	**Intensity**: Intervention 1 and 2: 1 session of 30 minutes approximately 1 week after recruitment and 3 follow up phone calls of 10 to 15 minutes each over 12 weeks. Usual care: 1 session of 3 to 5 minutes	**Target behaviour outcome(s)** Increased physical activity **Prioritised main outcome:** % meeting National Physical Activity Guidelines (NPAG): reporting ≥150 minutes of physical activity in at least 5 sessions per week **Measured**: Self-reported physical activity (Active Australia Physical Activity Questionnaire; AAPAQ). Supported by physiologic measures.	**Duration of follow up** 24 weeks post randomization (92.6% follow up)	3 months Intervention 1: 42% OR 2.07 95% CI 0.86 to 5.02 Intervention 2: 27% OR 1.03 95% CI 0.41 to 2.62 Control: 26% meeting NPAG	6 months Intervention 1: 33% OR 1.14 95% CI 0.47 to 2.76 Intervention 2: 51% OR 2.39 95% CI 1.01 to 5.64 Control: 30% meeting NPAG	**Adverse effects:** Not reported **Inequality issues:** Not reported
Burke et al, 2008 **REFID** 3635 **Country** Australia **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 241 **Selection/recruitment criteria** Adults aged 40 to 70 years with BMI >25kg/m2 and treated with one1 or 2 antihypertensive drugs for at least 3 months Recruited by advertisement (volunteer) **Participant characteristics** **Mean age** 56.2 **Gender** 44.4% male, 55.6% female **Ethnicity** Not reported **SES** Not reported **Other:** 2.5% smokers	**Setting**: Clinical trials centre **Provider**: Dietician or program coordinator **Mode of delivery**: Face-to-face (primarily group, with individual outcome measurement); remote (telephone, paper materials)	**Comparison** N= 123 Lifestyle program (Activity, Diet, and Blood Pressure Trial; ADAPT) vs. N= 118 Usual care **Type**: Multi-session **Focus**: Decreased CV risk and lifestyle change	**Intensity**: 4 month intervention period (dose and frequency not reported) + 6 follow up sessions over the first year (12 month intervention)	**Target behaviour outcome(s)** Physical activity and diet **Prioritised main outcome:** physical activity of at least moderate activity hours per week **Measured**: 7-day recall of leisure time and occupational activity	**Duration of follow up** 4 months (84.2% follow-up) – reported elsewhere 12 months (79.7% follow-up) – reported elsewhere 36 months (58.1% follow-up)	Not reported	36 months (24 months post intervention) Intervention: 3.8, 95%CI 3.3 to 4.3) Control: 3.1 (95% CI 2.7 to 3.6) No between group significance measures reported	**Adverse effects:** Not reported **Inequality issues:** Not reported

Clark et al., 2004 **REFID** 6036 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=100 **Selection/recruitment criteria** Overweight individuals with Type 2 Diabetes **Participant characteristics** **Mean age** 59.5 **Sex** 42% female, 58% male **Ethnicity** Not reported **SES** Not reported	**Setting**: Clinic (diabetes centre) **Provider**: Not reported **Mode of delivery**: Face-to-face (individual level) with remote (telephone) follow-up	**Comparison** N=265 intervention vs. N=257 Usual care **Type**: Multi-session **Focus**: Lifestyle intervention to reduce the amount of fat consumed and increase the amount of physical activity	**Intensity**: 2 face-to-face session lasting 30 minutes, followed by 3 follow-up phone calls lasting 10 minutes (6 months intervention)	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Amount of physical activity over previous 7 days **Measured**: Physical Activity Scale for the Elderly questionnaire (PASE)	**Duration of follow up** 6 months (99% follow up) 12 months (94% follow up)	3 months (during intervention) Intervention: 3.40 Control: 2.83	12 months (6 months post intervention) Intervention: 3.24 Control: 2.57 p=0.87 for between group difference	**Adverse effects:** Not reported **Inequality issues:** Not reported
Debussche et al, 2011 **REFID** 7030 **Country** Reunion Island **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 398 **Selection/recruitment criteria** Men and non-pregnant women older than 18 years with type 2 diabetes (defined as either non-insulin requiring or insulin treated but with no insulin treatment within the first year of diagnosis) Recruited from the 2 endocrinology departments of the regional hospital of the island **Participant characteristics** **Mean age** 53.7 from 319 followed up **Gender** 60.8% male, 39.2%, female male from 319 followed up **Ethnicity** Not reported **SES** Authors report low literacy levels and employment rates similar between groups at baseline	**Setting**: Hospital **Provider**: Nurse, dietician **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 206 Lifestyle counselling vs. N= 192 Usual care **Type**: Multi-session **Focus**: Physical activity	**Intensity**: 4 sessions at months 0, 3, 6 and 9 and postal and telephone reminders for adherence at sessions	**Target behaviour outcome(s)** **Prioritised main outcome:** Change in leisure physical activity score **Measured**: Baecke Questionnaire	**Duration of follow up** 12 months (80.2% follow-up).	NA	12 months (3 months post intervention) Mean differences from baseline Intervention: 0.12 Control: -0.01 p=0.38 for difference between groups	**Adverse effects:** Not reported **Inequality issues:** Not reported

Di Loreto et al. 2003 **REFID** 6629 **Country** Italy **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=340 **Selection/recruitment criteria** Diabetes patients (duration of diabetes at least two years) **Participant characteristics** **mean age** 62 **Sex** 47% male **Ethnicity** Not reported **SES** Not reported	**Setting**: Outpatient Diabetes Clinic **Provider**: Physician **Mode of delivery**: Face-to-face (individual level) with remote (telephone) follow-up	**Comparison** N=182 intervention vs. N=158 Usual care **Type**: Multi-session **Focus**: Physical activity	**Intensity**: 30 minute usual care session, 30 minute initial counselling session, plus follow-up phone calls (up to 15 minutes)15 minute follow-up session every three months for 24 months	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Energy expenditure through voluntary physical activity (change in METS x h/week from baseline (SE) **Measured**: Self-report using the Modifiable Activity Questionnaire	**Duration of follow up** 24 months (99% follow up)	NA	<u>24 months</u> Intervention: 27.1 (2.0) Control: 4.1 (0.8) p<0.001 for difference between groups	**Adverse effects:** Not reported **Inequality issues:** Not reported
Eakin et al, 2007 **REFID** 20579 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 200 **Selection/recruitment criteria** Adults aged 30 years and older with greater than 1 or more chronic conditions (hypertension, chronic pain, hypercholesterolemia, depression, type 2 diabetes, osteoarthritis, obesity, chronic lung disease, heart disease, osteoporosis, hepatitis, history of cancer, previous stroke, multiple sclerosis) Recruited from an urban community health centre in the Denver metro area. Letters sent by clinic providers and recruitment calls made by research assistants. **Participant characteristics** **Mean age** 49.5 **Gender** 21.5% male, 78.5% female **Ethnicity** 75% Hispanic/Latino, 15% Anglo, 9% other **SES** Not reported **Other:** <u>Yearly household income</u>: 34% less than US$10,000; 47.5% US$10,000 to $30,000; 13% greater than US$30,000 <u>Education</u>: 68% elementary/some high school, 15% high school graduate, 16.5% some college/college graduate <u>Language:</u> 66.5% Spanish, 33.5% English	**Setting**: An urban community health centre clinic or the patients home (setting based on participant preference) **Provider**: Experienced health educator trained in intervention delivery; printed materials **Mode of delivery**: Face-to-face (individual level), telephone, and printed materials.	**Comparison** N= 101 Lifestyle intervention vs. N= 99 Usual care **Type**: Multi-session **Focus**: Changes in dietary behaviour and physical activity	**Intensity**: 2 sessions face-to-face of 60 to 90 minutes (3 months apart), 3 follow up phone calls (at 2 and 6 weeks after the initial visit and 2 weeks after the second visit) and 3 tailored newsletters. (14 week intervention)	**Target behaviour outcome(s)** Changes in dietary behaviour and physical activity **Prioritised main outcome:** Physical activity: total minutes of walking per week and consistent with USA physical activity recommendations. **Measured**: Behavioural Risk factor Surveillance Survey Physical Activity items	**Duration of follow up** 6 weeks (68.5% follow-up) 6 months (81% follow-up).	<u>6 weeks</u> (during intervention) Change in minutes of walking per week Intervention: 11 Control: 47	<u>6 months</u> (10 weeks post intervention) Change in minutes of walking per week Intervention: 16 Control: -11 No significant difference between groups over time p=0.132	**Adverse effects:** Not reported **Inequality issues:** Effects applicable to low income, low literacy and predominantly Hispanic/Latino population

Eakin et al, 2010 **REFID** 1467 **Country** Australia **Design** Cluster RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N= 434 **Selection/recruitment criteria** Patients older than 30 years with type 2 diabetes or hypertension Recruited from 10 primary care practices in a socioeconomically disadvantaged community bordering Brisbane **Participant characteristics** **Mean age** 58.2 **Gender** 38.9% male, 61.1% female **Ethnicity** 91% Caucasian **SES** Considered a socioeconomically disadvantaged community **Other:** Education: 44.9% more than high school graduate 36.2% retired	**Setting**: Remote (telephone delivery) **Provider**: Counselors with Bachelor or Masters degree in with public health/health promotion or the allied health sciences (nutrition or exercise) trained in intervention delivery; mailed materials **Mode of delivery**: Telephone, printed materials	**Comparison** N= 228 Telephone counselling (5 practices) vs. N= 206 Usual care (5 practices) **Type**: Multi-session **Focus**: Increased physical activity levels and improve diet	**Intensity**: 4 month intervention phase (10 telephone calls of 20 minutes; weekly for the first 3 weeks then fortnightly until 4 months) + 8 month maintenance phase (8 telephone calls of 20 minutes delivered monthly). 12 month intervention period.	**Target behaviour outcome(s)** Maintenance of behavioural change **Prioritised main outcome:** minutes of moderate-to vigorous physical activity per week **Measured**: Active Australia Survey	**Duration of follow up** 12 months (78.6% follow-up) 18 months (72.6% follow-up)	NA	18 months (6 months post intervention) Intervention: 62.19 (14.20) Control: 74.73 (14.91) Mean difference -12.54 (95% CI -52.95 to 27.88), p=0.543	**Adverse effects:** Not reported **Inequality issues:** Not reported
Elley et al, 2003 **REFID** 4020 **Country** New Zealand **Design** Cluster RCT **Internal validity** **++** **External validity** **++**	**Number randomised** N=878 **Selection/recruitment criteria** **Practices:** 42 rural and urban general practices in one region of New Zealand All urban and rural practices in the central and eastern Waikato region of New Zealand were invited to participate **Participants**: Sedentary 40 to 79 year old patients visiting their general practitioner for scheduled appointments during a five day period identified as not meeting recommended levels of physical activity **Participant characteristics** **Mean age** 57.9 **Gender** 33.7% male, 66.3% female **Ethnicity** 77.2% European origin **SES** 47.4% low income status, **Other:** Education: 25.9% with post-high school qualification	**Setting**: General practice **Provider**: General practitioner (85.4%) or practice nurse (14.6 %) who were trained and prompted to deliver the intervention by a prompt card that the patient was given by the researcher; Exercise specialist delivered follow up telephone support. **Mode of delivery**: Face-to-face (individual level); telephone; mailed paper materials	**Comparison** N= 451 Lifestyle intervention ('Green prescription') counselling programme vs. N= 427 Usual care **Type**: Multi-session **Focus**: Change in physical activity	**Intensity**: 1 session of 7 minutes (GP delivered) or 13 minutes (nurse delivered) and a minimum of 3 follow up phone calls of 10 to 20 minutes by an ES over 3 months.	**Target behaviour outcome(s)** Change in physical activity **Prioritised main outcome:** Leisure exercise (minutes/week) **Measured:** Self-report on physical activity Questionnaire	**Duration of follow up** 12 months (85.4% follow up)	NA	12 months Intervention: 54.6 95% CI 41.4 to 68.4 Control: 16.8 95% CI 6.0 to 32.4 p=0.04	**Adverse effects:** Authors report no evidence of adverse effects **Inequality issues:** Authors report findings are widely generalisable due to including socioeconomically diverse sample from a large geographical region
Eriksson et al, 2009 **REFID** 2774 **Country** Sweden **Design** RCT **Internal validity** **++**	**Number randomised** N=151 (145 analysed) **Selection/recruitment criteria** Individuals aged 18 to 65 years with clinically documented diagnosis of hypertension, dyslipidemia, type 2 diabetes, obesity or any combinations of thereof identified from computerised records from the town of Boden in Northern Sweden. Considered as at moderate to high risk of cardiovascular disease. Recruited by the medical supervisor of the health care centre.	**Setting**: Primary health care centre **Provider**: Dieticians, physiotherapists delivered the interventions. A physician was involved in one session at the beginning of the study and one session at the end. Exercise sessions were led by physiotherapists and physiotherapy assistants. Usual care delivered by a physiotherapist, dietician and physician in group session.	**Comparison** N= 71 Intensive lifestyle intervention vs. N= 74 Usual care **Type**: Multi-session **Focus**: Reduced cardiovascular risk factor levels in	**Intensity**: 3 sessions per week for 3 months on a total of 5 occasions. Sessions lasted 40 to 45 minutes for the first month and increased to 60 minutes during second and third months. Follow up included: 6 sessions in the first year after the 3 month active intervention period; 4	**Target behaviour outcome(s)** Reduced cardiovascular risk factor levels **Prioritised main outcome:** % of participants reporting being moderately or very physically active **Measured**: Self-reported physical	**Duration of follow up** 12 months (81.5% follow up) – reported elsewhere 24 months (80.1% follow up) 36 months post randomisation (79.5% follow	Not reported	36 months Intervention: 59% Control: 43% p<0.0001	**Adverse effects:** Authors report no adverse events (i.e. fractures, sprains, serious cardiovascular were reported**.** **Inequality issues:** Not reported

External validity **++**	**Participant characteristics** **Mean age** 54.4 **Gender** 42.8% male, 57.2% female **Ethnicity** Not reported **SES** Not reported	**Mode of delivery**: Face-to-face (Group level for exercise and counselling)	primary care	sessions during second year; 2 sessions during third year.	activity questionnaire called 'physical activity on prescription'	up)			
Giannuzzi et al, 2008 **REFID** 10871 **Country** Italy **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 3,241 **Selection/recruitment criteria** Patients younger than 75 years who had a recent MI (within <3 months) and had completed a cardiac rehabilitation program lasting approximately 1 month **Participant characteristics** **Mean age** 57.9 **Gender** 86.3% male, 13.7% female **Ethnicity** Not reported **SES** Not reported **Other:** 33.1% more than 5 years education 42.9% retired	**Setting**: 78 cardiac rehabilitation centres across Italy **Provider**: Cardiac rehabilitation team (specialist cardiac nurse, physiotherapist, cardiologist). A clinical psychologist and occupational therapist were recruited when needed. **Mode of delivery**: Face-to-face (individual level)	**Comparison** N= 1,620 Multifactorial educational and behavioural intervention vs. N= 1,621 Usual care **Type**: Multi-session **Focus**: CV events (CV mortality, non-fatal MI, non-fatal stroke, hostpialisation for angina pectoris and revascularisation procedures)	**Intensity**: Monthly sessions from 0 to 6 months and then 1 session every 6 months up to 3 years consisting of 30 minutes of exercise, 1hour of counselling and 30 minutes of reinforcement (3 year intervention)	**Target behaviour outcome(s)** Physical activity and diet **Prioritised main outcome:** Leisure time physical activity score **Measured**: 3-item questionnaire	**Duration of follow up** 6 months (96.3% follow-up) 36 months (90.5% follow-up)	6 months (during intervention) Intervention: 7.5 (2.2) Control: 7.1 (2.3) Mean difference 6.1%, p<0.01	36 months (at the end of intervention) Intervention: 7.5 Control: 7.1 Mean difference 5%, p<0.01	**Adverse effects:** Intervention decreased the absolute risk of overall CV events compared to the control, although this was not significant **Inequality issues:** Not reported
Grandes et al, 2009 **REFID** 2776 **Country** Spain **Design** Cluster RCT **Internal validity** ++ **External validity** +	**Number randomised** N=4,317 patients; N=56 Spanish family physicians **Selection/recruitment criteria** **Physicians:** Physicians from 11 primary care centres that had at least 4 physicians per centre Recruited by inviting 15 research groups of the Spanish Preventative Services and Health Promotion Primary Care Research Network to participate. **Participants:** Patients aged 20 to 80 years identified as not meeting the recommended aerobic physical activity levels (moderate intensity physical activity >30 minutes 5 days per week or vigorous intensity activity for >20 minutes 3 days per week). Recruited from a list of patients systematically by research nurses that were scheduled to see their family physician **Participant characteristics** **Mean age** 50.1 **Gender** 34.3% male, 65.7% female **Ethnicity** Not reported **SES** Not reported **Other:**	**Setting**: 11 public primary care centres **Provider**: Family physicians trained in intervention delivery **Mode of delivery**: Face-to-face (individual level) using web based software to guide implementation of intervention; written materials.	**Comparison** N= 2248 Experimental Program for Physical Activity Promotion (PEPAF). N=29 physicians vs. N= 2069 Usual care. N=27 physicians **Type**: Multi-session **Focus**: Change in physical activity	**Intensity**: 1 session, length of time not reported followed by one session of 15 minutes.	**Target behaviour outcome(s)** Change in physical activity **Prioritised main outcome:** Moderate and vigorous activity, minutes/week **Measured**: 7-Day Physical Activity Recall (PAR) semi-structured interview	**Duration of follow up** 6 months (81% follow up)	NA	6 months Adjusted change from baseline Intervention: 82.58 95% CI 59.94 to 105.23 Control: 65.14 95% CI 42.40 to 87.88 Multivariate-adjusted attributable difference: 18.15 95% CI 5.66 to 30.65 adjusted for baseline measurement, age, sex, stage of change, social class, work situation, smoking, body mass index, and doctors' sex, age and	**Adverse effects:** The authors report that adverse events were considered in this study. **Inequality issues:** Not reported (reported that patient characteristics were representative of the common sociodemographic and clinical characteristics seen in primary care)

	Employment: 4.9% unemployed, 15.5% retired; 24% homemaker, 2.2% student. Education level: 6.1% no education, 30% elementary school, 47% middle or high school, 16.8% university studies; Social class: 6.9% manager large enterprise, 10.8% manager small enterprise, 29.7% intermediate employee, 52.5% manual worker.							previous training in healthy lifestyles promotion	
Groenveld et al, 2011 **REFID** 461 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 573 (433 analysed) **Selection/recruitment criteria** Male construction workers aged 18 to 65 years employed at (>400) companies throughout The Netherlands who had attended a voluntary health screening at the occupational health service and were identified as at risk for CVD. **Participant characteristics** **Mean age** 47.4 **Gender** 100% male, 0.0% female **Ethnicity** Not reported **SES** Not reported **Other:** 32.7% smokers 31.1% blue-collar workers 69.9% white-collar workers	**Setting**: Not reported for face-to-face sessions; remote (telephone) **Provider**: Occupational physician or occupational nurse **Mode of delivery**: Face-to-face (individual level), telephone	**Comparison** N= 293 Lifestyle intervention vs. N= 280 Usual care **Type**: Multi-session **Focus**: Changes in physical activity, diet and smoking	**Intensity**: 3 face-to-face sessions of 45 to 60 minutes and 4 telephone calls of 15 to 30 minutes over 6 months	**Target behaviour outcome(s)** Physical activity and diet **Prioritised main outcome:** Minutes per week of leisure time physical activity **Measured**: Physical activity: Short Questionnaire to Assess Health enhancing physical activity (SQUASH)	**Duration of follow up** 6 months (84.6% follow-up) 12 months (81.3% follow-up)	6 months (end of intervention) Intervention: 589.7 (464.2) Control: 552.8 (424.6) Regression coefficient 59.5, 95% CI -11.3 to 130.3)	12 months (6 months post intervention) Intervention: 543.4 (462.5) Control: 529.4 (409.2) Regression coefficient 30.2, 95% CI -45.3 to 105.8)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Guelinckx et al, 2010 **REFID** 2177 **Country** Belgium **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=195 **Selection / Recruitment criteria:** Obese (BMI > 29.0) white pregnant women consecutively attending the prenatal clinic before 15wk gestation **Participant characteristics:** **Mean age** 28.7 **Gender** 100% female **Ethnicity** 100% White **SES** Not reported **Other:** Mean BMI (pre-pregnancy) = 33.7	**Setting**: Prenatal clinic of a university hospital **Provider**: Active intervention was provided by a trained nutritionist **Mode of delivery**: - Brochure for passive intervention group and active intervention group - In addition, face-to-face group counselling sessions for the active intervention group	**Comparison:** N=65 Active intervention N=65 Passive intervention vs. N=65 Usual care **Type**: - Brief for passive intervention group - Multi-session for active intervention group **Focus**: Lifestyle intervention using brochure or active education to improve lifestyle and reduce gestational	**Intensity**: - Brochure only for passive intervention group - In addition to brochure, three 1hr group educational sessions for active intervention group at 15, 20 and 32 week of pregnancy	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Baecke questionnaire score for physical activity **Measured**: Self-report	**Duration of follow-up:** To delivery of child (62.6% follow-up)	1st trimester Mean (SD) Active 7.47 (1.14) Passive 7.21 (1.14) Control 7.42 (1.08)	2nd trimester Active 7.39 (1.29) Passive 7.11 (1.15) Control 7.31 (1.08) 3rd trimester Active 7.14 (1.31) Passive 7.12 (0.79) Control 6.80 (1.17) p-value for trimester p=0.001	**Adverse effects:** Not reported **Inequality issues:** Not reported

			weight gain in obese pregnant women					p-value for group p=0.478 p-value for (tri x grp) p=0.166	
Hardcastle et al, 2008 **REFID** 3773 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=334 **Selection/recruitment criteria** Patients with a BMI >28kg/m^2 at risk for coronary heart disease **Participant characteristics** **Mean age** 51 **Sex** 33% female, 67% male **Ethnicity** Not reported **SES** Not reported	**Setting**: Primary care **Provider**: Physical Activity Specialist and Registered Dietician **Mode of delivery**: Face-to-face (individual level)	**Comparison** N=203 intervention vs. N=131 Usual care **Type**: Multi-session **Focus**: Lifestyle counselling based on motivational interviewing for diet and physical activity	**Intensity**: Up to 5 sessions, 20-30 minutes each over 6 months	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome** Change in total physical activity (MET-min/week) **Measured**: Self-report 7 day activity using International Physical Activity Questionnaire	**Duration of follow up** 6 months (65% follow up)	NA	6 months (end of treatment) Intervention +245 Control -122 Mean difference +367 95 % CI -739 to +470	**Adverse effects:** Not reported **Inequality issues:** Not reported
Harting et al, 2006 **REFID** 5200 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 1,270 **Selection/recruitment criteria** Patients at high risk of a CV event **Participant characteristics** **Mean age** 61.1 **Gender** 68.9% male, 31.1% female **Ethnicity** Not reported **SES** Not reported	**Setting:** Cardiology outpatient clinic **Provider:** Nurse **Mode of delivery:** Face-to-face (with optional family member/company)	**Comparison** N= 600 intervention (of whom, 160 smokers) vs. N= 607 Usual care (of whom, 160 smokers) **Type:** Multi-session **Focus:** Cardiovascular risk behaviours (smoking, physical activity)	**Intensity:** Average of 2.76 sessions (range 1 to 9) lasting an average of 90 minutes (range 15 to 330); average duration 87 days (range 1 to 616).	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome for meta-regression:** Number (%) of participants 'physically active' **Measured:** Short validated questionnaire	**Duration of follow up** 4 months (92% follow-up) 18 months (81.3% follow-up)	4 months (end of intervention) Intervention: 56.4% control: 52.5% p value not reported	18 months (14 months post intervention) Intervention: 51.2% control: 50.8% p value not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported

Hertogh et al, 2010 **REFID** 1950 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=189 **Selection/recruitment criteria** Healthy post-menopausal women aged 50 to 69 years identified as being low active (participating in less than 2 hours per week in of moderate intensity sports and recreational activities) and not adherent to the international physical activity recommendation (moderate activity for 30 minutes at least five and preferable all days of the week). Bicycling for transportation was not considered moderate intensity exercise. Recruited though random selection out of the female inhabitants of 6 middle sized municipalities in the centre of The Netherlands by invitational letter **Participant characteristics** **Mean age** 58.6 **Gender** 100% female **Ethnicity** Not reported **SES** Not reported **Other:** Education: 5.3% primary education, 30.7% technical or professional school, 30.7% secondary school, 33.3% higher education	**Setting**: 6 fitness centres **Provider**: Qualified sports instructor trained in intervention delivery **Mode of delivery**: Face-to-face (group level). One individual session was encouraged weekly.	**Comparison** N= 96 Exercise program vs. N= 93 No intervention **Type**: Multi-session **Focus**: Compliance to the international physical activity recommendation	**Intensity**: Two group sessions per week of 1 hour each and one individual session per week of at least 30 minutes (encouraged) over 12 months. Groups were made up of 15 to 20 women.	**Target behaviour outcome(s)** Compliance to the international physical activity recommendation **Prioritised main outcome:** Modified Baecke Questionnaire score **Measured**: Modified Baecke Questionnaire	**Duration of follow up** 12 months (96.8% follow up) 24 months post randomisation (75% follow up)	NA	12 months Intervention: 15.2 95% CI 2.5 to 40.8 Control: 10.3 95% CI 1.1 to 29.5 Intervention Effect: 4.9 95% CI 2.1 to 8.2 24 months Intervention: 13.1 95% CI 1.5 to 31.5 Control: 12.3 95% CI 1.6 to 44.9 Intervention Effect: 0.7 95% CI -1.4 to 3.5	**Adverse effects:** Not reported **Inequality issues:** Not reported
Horden et al, 2009 **REFID** 2540 **Country** Australia **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=223 **Selection/recruitment criteria** Patients aged 18 to 75 with type 2 diabetes but without occult coronary artery disease Recruited from hospital clinics and the community **Participant characteristics** **Mean age** 55.5 **Gender** 55% male, 45% female **Ethnicity** Not reported **SES** Not reported	**Setting**: University hospital based gymnasium **Provider**: Accredited exercise physiologist (AEP) **Mode of delivery**: Face-to-face (group level). One individual session was encouraged weekly.	**Comparison** N= 111 Exercise/ Lifestyle intervention vs. N= 112 Usual care **Type**: Multi-session **Focus**: Prevention of myocardial dysfunction	**Intensity**: 2 sessions of 2 hour for four weeks (an additional individual session per week was encouraged) followed by: weekly telephone follow up for 3 months; fortnightly telephone follow up for 3 months; monthly telephone follow up for 5 months (12 month program)	**Target behaviour outcome(s)** Meeting physical activity recommendations for people with type 2 diabetes (150 minutes) **Prioritised main outcome:** Change in the amount of vigorous physical activity (minutes/week) **Measured**: Self-report written questionnaire with items from the Active Australia Survey	**Duration of follow up** 12 months (78.9% follow up)	NA	12 months Mean (SD) Intervention: 24.6 (192.9) Control: -6.0 (193.7) P<0.001 (group x time)	**Adverse effects:** Not reported **Inequality issues:** Not reported

Hyman et al, 2007 **REFID** 4495 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=289 **Selection/recruitment criteria** Currently smoking African Americans with hypertension **Participant characteristics** **Mean age** 53 (range 45 to 64) **Gender** 32.7% male, 67.3% female **Ethnicity** 100% African American **SES** Not reported	**Setting:** Clinic **Provider:** Health educator **Mode of delivery:** Face-to-face, with telephone follow-up and supplementary take-home printed materials	**Comparison** N= 92 simultaneous intervention N=96 sequential intervention vs. N= 93 Usual care **Type:** Multi-session **Focus:** Modifiable lifestyle hypertension risk factors (smoking, diet, physical activity)	**Intensity:** 1 brief in-clinic session on all three behaviours every 6 months and telephone follow-up of 15 minutes up to 18 months	**Target behaviour outcome(s)** Diet and physical activity **Prioritised main outcome for meta-regression:** Pedometer steps per day **Measured:** Steps per day	**Duration of follow up** 6 months (88.2% follow up) 12 months (80.6% follow up) 18 months (79.6% follow up)	NA	6 months (during intervention) Simultaneous intervention: 4149.4 (3446.8) Sequential intervention: 37115.0 (4025.6) Control: 3852.0 (3675.6) p=0.78 18 months (at the end of intervention) Mean (SE) Simultaneous intervention: 3751.4 (2697.0) Sequential intervention: 3744.9 (5515.7) Control: 3648.5 (4285.0) p=0.99	**Adverse effects:** Not reported **Inequality issues:** Trial included African American hypertensive participants only
Keogh et al, 2011 **REFID** 15882 **Country** Ireland **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=121 **Selection / Recruitment criteria:** Adults with type 2 diabetes for more than a year who had persistently poor glycaemic control **Participant characteristics:** **Mean age** 58.6 **Gender** 63.6% Male, 36.4% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean no. of years diagnosed = 9.4	**Setting**: Home **Provider**: Health psychologists **Mode of delivery**: Face-to-face (patient with family member); then remote (telephone)	**Comparison:** N=60 Intervention vs. N=61 Usual care **Type**: Multi-session **Focus**: Improvement of diabetes-related outcomes using health psychology and motivational interviewing, and involving family members	**Intensity**: 3 weekly sessions. 2 sessions of 45 minutes each (face-to-face at home) and a 3rd session follow-up telephone call of 10 to 15 minutes (3 week intervention)	**Target behaviour outcome(s):** **Prioritised main outcome:** Exercise (summary of Diabetes Self-care Activities Questionnaire **Measured**: Summary of Diabetes Self-care Activities Questionnaire	**Duration of follow-up:** 6 months (88.4% follow-up)	NA	6 months (approximately 5 months post intervention) Mean (SD) Intervention: 5.39 (4.02) Control: 3.11 (3.29) Difference +2.27 p=0.006	**Adverse effects:** Not reported **Inequality issues:** Not reported

Kirk et al, 2009 **REFID** 2820 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=134 inactive individuals with type 2 diabetes **Selection/recruitment criteria** Individuals with type 2 diabetes identified as inactive and in the contemplation or precontemplation stage of behaviour change Recruited from media adverts diabetes clinics, general practitioner, university newsletters and diabetes exercise/education programmes **Participant characteristics** **Mean age** 61.3 **Gender** 48.5% male, 51.5% female **Ethnicity** Not reported **SES** Not reported **Other:** 48% retired	**Setting**: University (no other information about setting reported) **Provider**: Intervention 1 delivered by trained researcher Intervention 2 delivered by written materials **Mode of delivery**: Intervention 1: Face-to-face (individual level) Intervention 2: paper materials	**Comparison** Intervention 1 N= 47 Person delivered physical activity intervention Intervention 2 N= 52 Written delivered physical activity intervention vs. Control N= 35 Usual care **Type**: Multi-session **Focus**: Change in physical activity	**Intensity**: Intervention 1: 1 session of 30 minutes and follow up telephone calls at 1, 3, 7 and 9 months followed by 1 session of 5 to 10 minutes at 6 months Intervention 2: written materials provided to individuals at baseline who received follow up phone calls at 1, 3, 7, and 9 months. Different written materials were given at 6 months.	**Target behaviour outcome(s)** Changes in physical activity **Prioritised main outcome:** Seven-day recall of minutes of moderate and above activity per week (minutes/week) **Measured**: ActiGraph GT1M accelerometer (objective measure) 7 day physical activity recall using structured interview (subjective)	**Duration of follow up** 6 months (91% follow up) 12 months (86.6% follow up)	NA	<u>6 months</u> (during intervention) Mean (SD) Intervention 1: 306 (260) Intervention 2: 262 (243) Control: 256 (269) Not significant (p value not reported for this time point only) <u>12 months</u> (3 months post intervention) Mean (SD) Intervention 1: 256(365) Intervention 2: 267 (245) Control: 169 (200) Not significant (p value not reported for this time only). Interaction effect p=0.212	**Adverse effects:** Not reported **Inequality issues:** Not reported
Koelewijn-van Loon et al, 2009 **REFID** 2310 **Country** The Netherlands **Design** Cluster RCT **Internal validity** + **External validity** ++	**Number randomised** N= 615 patients, 25 practices **Selection/recruitment criteria** Adult patients eligible for cardiovascular risk management. Patients with existing CVD were excluded. Practices that employed a practice nurse and used electronic patient records were included **Participant characteristics** (based on 589 participants) **Mean age** 57 **Gender** 44.8% male, 55.2% female **Ethnicity** Not reported **SES** 22.8% high SES status, 38.7% intermediate SES status, 34.6% low SES status	**Setting**: Not reported **Provider**: Practice nurse trained in intervention delivery **Mode of delivery**: Face-to-face, telephone	**Comparison** N= 322 Cardiovascular risk management intervention (13 practices) vs. N= 293 Usual care (12 practices) **Type**: Multi-session **Focus**: Lifestyle adherence and cardiovascular risk	**Intensity**: 2 sessions of 15 to 20 minutes, 2 weeks apart, and 1 telephone call of 10 minutes 2 weeks after the second face-to-face session (5 week intervention)	**Target behaviour outcome(s)** Changes in diet and physical activity **Prioritised main outcome:** Moderate to vigorous physical activity minutes per week **Measured**: Modified Dutch version of the Community Healthy Activities Model Program for Seniors questionnaire (CHAMPS)	**Duration of follow up** 12 months (84.6% follow-up; 79.3% final analysis)		<u>12 months</u> (approximately 10 months post intervention) Mean (SD) Intervention: 460 (362) Control: 449 (365) p=0.74	**Adverse effects:** Not reported **Inequality issues:** Not reported

Kolt et al, 2007 **REFID** 4453 **Country** New Zealand **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=186 **Selection/recruitment criteria** Patients older than 65 years identified as participating in less than 30 minutes of activity on 5 or more days per week for 6 months or longer and who had no major health problems and activity was not contraindicated Recruited from patient databases of 3 primary care practices from different socioeconomic regions of Auckland, New Zealand by 2 primary care physician (identified on database by 2 research assistants) **Participant characteristics** **Mean age** 74.2 **Gender** 33.9% male, 66.1% female **Ethnicity** New Zealand European 97.3% **SES** Not reported **Other:** Education level: 38.2% no qualification, 17.7% high school qualification, 12.4% other post-high school qualification, 84.4% retired	**Setting**: 2 primary care practices from different socioeconomic regions of Auckland, New Zealand **Provider**: Exercise counselor **Mode of delivery**: Telephone; mailed paper materials	**Comparison** N= 93 Telephone counselling ('Telewalk') vs. N= 93 Usual care **Type**: Multi-session **Focus**: Change in physical activity	**Intensity**: 8 sessions of between 10.2 to 16.5 minutes over 3 months (weekly calls for the first 4 weeks then fortnightly for the remaining 8 weeks)	**Target behaviour outcome(s)** Change in physical activity **Prioritised main outcome:** Total leisure activity (minutes per week) **Measured**: Auckland Heart Study Physical Activity Questionnaire (AHSPAQ) by telephone	**Duration of follow up** 3 months (94.1% follow up) 6 months (90.9% follow up) 12 months (88.7% follow up)	NA	6 months (3 months post intervention) Mean (SD) Intervention: 199.1 (221.2) Control: 119.2 (147.7) 12 months (9 months post intervention) Intervention: 117.3 (138.8) Control: 244.0 (365.7) Time x group P=0.05 (repeated measures mixed model adjusted for age, sex, clinic and baseline value)	**Adverse effects:** Authors report no evidence of more falls in intervention group compared to control group **Inequality issues:** Not reported
Kuller et al, 2012 **REFID** 248 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=508 **Selection / Recruitment criteria:** Women between the age of 52 and 62 years, with a BMI of 25 to 39.9, waist circumference of >80cm, BP<140/90mmHg with or without antihypertensive therapy, not on lipid-lowering drug, LDL cholesterol between 100 and 160mg and no history of CVD **Participant characteristics:** **Mean age** 57 **Gender** 100% female **Ethnicity** 11.2% Black **SES** Not reported **Other:** Mean BMI = 30.8	**Setting**: Unclear **Provider**: Multidisciplinary team (nutritionists, exercise physiologists and psychologists) **Mode of delivery**: Face-to-face (mainly in groups)	**Comparison:** N=(not reported) Lifestyle change group (LC) vs. N=(not reported) Health education group (HE) control **Type**: Multi-session **Focus**: Non-pharmacological intervention to induce weight loss and increase physical activity levels in order to reduce blood triglyceride levels and number of low-density lipoprotein particles in women	**Intensity**: Intervention group = 40 visits during Year 1; 12 monthly visits during Year 2, 3 and 4 Assessment group = 6 seminars in Year 1; several seminars per year during Year 2, 3 and 4 (Intervention length approximately 36 months)	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Leisure time physical activity (MET hours per week) **Measured**: Self-report (interviewer-administered Modifiable Activity Questionnaire)	**Duration of follow-up:** 48 months (approx. 90% of the pts completed at least part of the 48-month visit) *Specifically for the main outcome*: 6 months (84.3% of the pts provided physical activity data) 18 months (80.1% of the pts provided physical activity data) 30 months (80.9% of the pts provided physical activity data)	NA	6 months (during intervention) Mean change (SD) Intervention -1.0 (11.1) Control -4.1 (14.0) p<0.05 18 months (during intervention) Intervention 5.9 (10.9) Control 0.56 (13.0) p<0.05 30 months (during intervention)	**Adverse effects:** Not reported **Inequality issues:** Not reported

						48 months (85.2% the pts provided physical activity data)		Intervention 4.1 (13.3) Control 0.02 (15.7) p<0.05 48 months (approximately 12 months post intervention) Intervention 1.9 (12.5) Control -0.02 (16.1) Not reported as significant, p value not reported	
Lawton et al, 2008 **REFID** 3082 **Country** New Zealand **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=1,089 **Selection/recruitment criteria** Females aged 40 to 74 years identified as not partaking in 30 minutes of physical activity on at least 5 days per week Recruited from: an existing cohort of 50 to 74 year old women sent letters by their GP for a previous study of postmenopausal women from 10 primary care practices in Wellington, New Zealand; 50 to 70 year olds (40 to 60 year old Maori and Pacific women) from 13 primary care practices including 2 Maori health clinics. Eligible women were sent letters by their GP. **Participant characteristics** **Mean age** 58.9 **Gender** 100% female **Ethnicity** 77.7% European, 13.1% Maori or Pacific Islander **SES** 14.9% lower socioeconomic status **Other:** 43.7% with tertiary education 12.6% current smokers	**Setting**: 17 primary healthcare practices **Provider**: Primary care nurse delivers intervention; Exercise Specialist provides telephone support Physician (usual care) **Mode of delivery**: Face-to-face (individual level); telephone	**Comparison** N= 544 Lifestyle intervention ('Green prescription') counselling programme vs. N= 545 Usual care **Type**: Multi-session **Focus**: Achieving the recommended 150 minutes of at least moderate intensity physical activity	**Intensity**: 1 session of 7 to 13 minutes followed by monthly telephone follow up (average of 5 phone calls of 15 minutes) over a 9 month period with one additional session of 30 minutes at 6 months (9 month intervention)	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Number (%) completing at least 150 minutes physical activity/week **Measured**: International physical activity questionnaire; IPAQ-Long (subjective); energy expenditure measured by heart rate monitor (objective)	**Duration of follow up** 12 months (93% follow up) 24 months (89% follow up)	NA	12 months (3 months post intervention) Number (%) Intervention: 233 (43) Control: 165 (30) p<0.001 24 months (roughly 15 to 17 months follow up) Intervention: 214 (39) Control: 179 (33) p<0.001	**Adverse effects:** More falls (p<0.001) and injuries (p=0.03) were recorded in the intervention group compared to the control group) over the 2 year period. **Inequality issues:** Authors report the inclusion of a representative sample of ethnic minorities
Lindahl et al, 2008 **REFID** 2664 **Country** Sweden **Design** RCT	**Number randomised:** N=200 (directly invited & randomised) **Selection / Recruitment criteria:** Individuals with impaired glucose tolerance and BMI of >27 **Participant characteristics:** **Mean age** 52.9 **Gender** 34.5% Male, 65.5% Female **Ethnicity** Not reported	**Setting**: Residential wellness centres **Provider**: Unclear **Mode of delivery**: Face-to-face (in groups); telephone (individually)	**Comparison:** N=100 Intervention vs. N=94 Usual care N.B. 200 people were directly invited and randomised; 194 people completed	**Intensity**: 1 month stay at a wellness centre, entailing 140hrs of activities: - Daily aerobic physical activity of moderate intensity for 2.5hrs - Tailored diet with reduced fat and high	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** % participant exercising at least once per week **Measured**: Self-report	**Duration of follow-up:** Longest follow-up period 5 years (168/194 = 86.6% or 168/200 = 84.0% of the pts completed the 5-year	NA	1 year (during intervention) Intervention 66.3% Control 17.8% p<0.001 3 years (approximately	**Adverse effects:** Not reported **Inequality issues:** It is stated in their discussion that the differences in the risk factor reduction cannot be explained by differences in educational level

Internal validity + **External validity** +	**SES** Not reported **Other:** Mean BMI = 30.7 *Education level*: Low = 69.3% Medium = 21.4% High = 8.3%		baseline measurements; 168 people completed 5-year follow-up (included in final analysis). **Type**: Multi-session **Focus**: Residential lifestyle programme for individuals with impaired glucose tolerance	fibre content - Prohibition of alcohol consumption - Group treatment for smoking cessation - Behaviour change, stress management, relapse prevention sessions - 4 day follow-up session at 12 months and follow-up telephone call at 6 and 24 months	(questionnaire)	follow-up)		12 months post intervention) Intervention 46.6% Control 23.7% p<0.01 <u>5 years (approximately 36 months post intervention)</u> Intervention 42.9% Control 23.4% p<0.05	between study groups.
Lorig et al, 2006 **REFID** 18282 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N= 958 **Selection/recruitment criteria** Individuals aged at least 18 years with a physician's diagnosis of heart disease, chronic lung disease or type 2 diabetes. In addition to one of these diagnoses, individuals could have other chronic conditions but could not have been in active treatment of cancer for 1 year Recruited by placing links to the study website on established websites and discussion groups (Yahoo!Health, WebMD and SeniorNet.org.) as well as calendar announcements and articles in newspapers directing subjects to study website. After reaching the study website, potential participants left their email address so they could be contacted. **Participant characteristics** **Mean age** 57.5 **(**range 22 to 89) of 780 analysed **Gender** 28.6% male, 71.4% female of 780 analysed **Ethnicity** 88.1% non-Hispanic white of 780 analysed **SES** Not reported **Other:** <u>Education:</u> 15.6 years of education (range 8 to 23) of 780 analysed	**Setting**: Remote (participants accessed computers remotely) **Provider**: Interactive web based program. Trained peer moderators led each workshop but did not deliver content as this was scripted on the web. **Mode of delivery**: Remote (computer, mailed paper materials	**Comparison** N= 457 Internet-based Chronic disease self-management program (CDSMP) + usual care vs. N= 501 Usual care **Type**: Multi-session **Focus**: Improvement in health outcomes	**Intensity**: 6 'workshop' sessions where participants are prompted 3 times per week to log on for a total of 1 to 2 hours per week for 6 weeks.	**Target behaviour outcome(s)** Improvement in health outcomes **Prioritised main outcome:** Change in aerobic exercise (minutes per week) **Measured**: Not reported	**Duration of follow up** 6 months (81.7% follow up) 12 months (81.4% follow up)	NA	<u>12 months</u> Mean (SD) Intervention: 12.1 (80.9) Control: 7.99 (63.4) P=0.340 (Logistic)	**Adverse effects:** Not reported **Inequality issues:** Not reported

Lorig et al, 2010 **REFID** 8954 **Country** USA **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N= 761 **Selection/recruitment criteria** Individuals aged 18 years or older who had physician diagnosed type 2 diabetes who were not pregnant or in treatment for cancer. Recruited through the internet as well as through print and broadcast media. Special effort was made to recruit American Indian/Alaska natives (AI/AN) participants using websites and media associated with tribal and AI/AN organisations. **Participant characteristics** **Mean age** 54.3 **Gender** 27% male, 73% female **Ethnicity** 76% non-Hispanic white, 14.5% American Indians/Alaska natives **SES** Not reported **Other:** Education: 'well educated': mean of 15.7 years of education	**Setting**: Remote (participants accessed computers remotely) **Provider**: Interactive web-based program. 2 trained peers facilitated each program **Mode of delivery**: Remote (primarily web-based, with mailed paper materials, telephone support)	**Comparison** N= 259 Internet based diabetes self-management program (IDSMP) only N= 232 Internet based diabetes self-management program (IDSMP) + email reinforcement vs. N= 270 Usual care **Type**: Multi-session **Focus**: Reduced A1C and fewer symptoms and increased exercise	**Intensity**: 6 weekly online sessions	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Change in aerobic exercise (minutes/week) **Measured**: Physical activities scale	**Duration of follow up** 6 months (83.2% follow up of 761) 18 months (81.1% follow up of 651 [not AI/AN eligible]).		6 months (approximately 4.5 months post intervention) Mean (SD) Intervention 1: 12.09 (145) Intervention 2 : 1.41 (167) Control: -1.97 (130) P=0.496 (intervention 1 vs. control) P=0.238 (ITT) p=0.779 (intervention 2 vs. control) P=0.306 (ITT) 18 months (approximately 16.5 months post intervention) Intervention 1: 6.049 (141) Intervention 2: -0.676 (152) Control: -0.575 (196) p=0.827 (control vs. both interventions combined) p=0.873 (ITT)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Luoto et al, 2011 **REFID** 7772 **Country** Finland **Design** cRCT **Internal validity** +	**Number randomised:** N=442 **Selection / Recruitment criteria:** Euglycaemic pregnant women (8 – 12wk gestation) with min. of 1 GDM risk factor **Participant characteristics:** **Mean age** 29.8 **Gender** 100% female **Ethnicity** Not reported **SES** Not reported **Other:** Mean BMI (pre-pregnancy) = 26.4	**Setting**: Maternity clinics **Provider**: Nurses **Mode of delivery**: Face-to-face (individual level)	**Comparison:** N=246 Intervention vs. N=196 Usual care **Type**: Multi-session **Focus**: Prevention of GDM and high birth weight of the newborns through lifestyle	**Intensity**: 5 counselling sessions which took place at antenatal visits (the first visit was limited to max. of 2hrs)	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Total MET minutes/week **Measured**: Self-report (questionnaire)	**Duration of follow-up:** Between pre-pregnancy and 36 to 37 weeks gestation - 29 non-respondents to final survey (6.6%) - 14 miscarriages (3.2%)	NA	36-37week GA (end of intervention) Intervention 963 Control 1149 Group difference in change: Adjusted co-efficient = -56 (95% CI -280 to 168)	**Adverse effects:** There was no statistically significant differences between incidences of adverse effects between the groups. **Inequality issues:** Not reported

External validity +	Overweight (BMI>25) = 59.6% *Education level*: University degree = 23.6% Polytechnic education = 41.4% Basic/Secondary education = 33.1%		counselling			→ Total of 90.3% included in the final analysis		Adjusted p-value = 0.63	
Marcus et al, 2007 **REFID** 4458 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 239 **Selection/recruitment criteria** Healthy adults aged 18 to 65 years identified as underactive (participated in moderate to vigorous physical activity for 90 minutes or less per week) Recruited through newspaper advertisements and advertisements on employees pay stubs, email and Intranet postings on a hospital worksite **Participant characteristics** **Mean age** 44.5 **Gender** 18.0% male, 82.0% female **Ethnicity** 90.3% Caucasian **SES** Not reported **Other:** 70.6% college educated or above; 60.8% had total household income above US$50,000; 90.4% employed	**Setting**: Not reported **Provider**: Health educator; paper materials **Mode of delivery**: Telephone-based individualised feedback: Telephone Print-based individualised feedback: printed materials	**Comparison** N= 80 Telephone-based individualised feedback N= 81 Print-based individualised feedback vs. N= 78 Attention control (Assessment only) **Type**: Multi-session **Focus**: Increased physical activity	**Intensity**: 14 sessions over 12 months. The dose of contacts was more frequent at the beginning of the study (i.e. weekly for the first month)	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Minutes per week of physical activity (moderate, hard and very hard) **Measured**: 7-day Physical Activity Recall (PAR) Interview	**Duration of follow up** 6 months (91.2% follow-up) 12 months (85.4% follow-up)	NA	<u>6 months</u> (during intervention) Mean (SD) Intervention 1: 123.32 (97.64) Intervention 2: 129.49 (156.46) Control: 77.67 (101.79) p<0.01 favouring intervention 1 compared to control p<0.01 favouring intervention 2 compared to control non-significance between intervention 1 and 2 <u>12 months</u> (end of intervention) Intervention 1:100.59 (119.68) Intervention 2: 162.37 (165.17) Control: 81.92 (127.07) Non-significance between intervention 1 and control p<0.001 favouring intervention 2 compared to control p<0.05	**Adverse effects:** Not reported **Inequality issues:** Not reported

								favrouring intervention 2 compared to intervention 1	
McMurdo et al, 2010 **REFID** 1498 **Country** UK **Design** RCT **Internal validity +** **External validity +**	**Number randomised** N= 204 **Selection/recruitment criteria** Community dwelling females aged 70 years and older identified as inactive (no participation in moderate intensity physical activity of at least 30 minutes 5 days per week or at least 20 minutes of continuous vigorous intensity physical activity 3 or more times per week). Recruited from 4 local general practices in Dundee, Scotland through the Scottish Primary Care Research Network. The principle GP provided a list of all eligible females excluding those with terminal illness, recent bereavement, severe heart disease chronic obstructive disease of dementia or those living in a nursing home. The GP invited eligible females to participate by letter. **Participant characteristics** **Mean age** 77.3 **Gender** 100% female **Ethnicity** Not reported **SES** 39.5% most deprived, 59.5% most affluent on deciles of Scottish Index of Multiple deprivation	**Setting**: Primary care, City of Dundee, Scotland; participants home for part of intervention delivery **Provider**: Study coordinators trained in intervention delivery **Mode of delivery**: Face-to-face (individual level), telephone, written paper materials	**Comparison** N= 68 Behaviour change intervention N= 68 Behaviour change intervention + pedometer vs. N= 68 Usual care **Type**: Multi-session **Focus**: Change in daily activity levels	**Intensity**: 1 'brief' session and telephone follow up weekly for the first month, then fortnightly for 2 months then monthly for 3 months (6 month intervention)	**Target behaviour outcome(s)** Change in daily activity levels **Prioritised main outcome:** Accelerometer vector maximum **Measured**: Accelerometry	**Duration of follow up** 6 months (88% follow up)	<u>3 months</u> Mean (SE) Intervention 1: 13,305 (5,142) Intervention 2: 5,504 (4,465) Control: -2290 (3,715) p=0.049	<u>6 months</u> (end of intervention) Mean (SD) Intervention 1: Not reported Intervention 2: Not reported Control: Not reported Accelerometry counts in both intervention groups declined to near baseline levels	**Adverse effects:** More adverse events were recorded in both intervention groups than the control Intervention 1: N=16 Intervention 2: N=9 Control: N=6 The authors report that 'no excess of events was identified in the intervention groups that could plausibly be related to the interventions) **Inequality issues:** Not reported

Moore et al, 2006 **REFID** 5276 **Country** USA **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=250 **Selection / Recruitment criteria:** Individuals who recently had a cardiac event **Participant characteristics:** **Mean age** 62.4 **Gender** 62% Male, 38% Female **Ethnicity** 81.2% Caucasian, 16.8% Black, 2% Other **SES** Not reported **Other:** Income: <$30,000 = 25.2% $30,000-60,000 = 36.8% >$60,000 = 31.2% Mean length of education = 14.1 years Married = 72.4%	**Setting**: Cardiac rehabilitation program (allocated room near outpatient) **Provider**: Cardiac nurse **Mode of delivery**: Face-to-face (in groups)	**Comparison:** N=119 Intervention vs. N=131 Usual care **Type**: Multi-session **Focus**: Lifestyle modification program designed to increase exercise maintenance in the year following a cardiac rehabilitation program	**Intensity**: Three 1.5hr sessions once a week during the last 3 weeks of CRP and 2 sessions held at 1 and 2 months after CRP (1 year intervention) Mean (SD) session length per participant 52 minutes (29)	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Amount of exercise (hours per month) **Measured**: Primarily measured using portable wristwatch heart rate monitors, supported by data from exercise diaries	**Duration of follow-up:** 2 months from baseline / completion of intervention (85.2% follow-up) 12 months from baseline (81.2% follow-up)	1 Month (during intervention) Mean (SD) Intervention 11.5 (7.8) Control 10.6 (9.2) Difference +0.9 Non-significant between group effect, p value not reported	12 Month (end of intervention) Mean (SD) Intervention 7.6 (7.0) Control 7.1 (SD 8.2) Difference +0.5 Non-significant between group effect, p value not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Morey et al, 2009 **REFID** 2710 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=641 **Selection / Recruitment criteria:** Overweight (BMI≥25), long-term (≥5 years) survivors of colorectal, breast and prostate cancer between the age of 65 and 91 **Participant characteristics:** **Mean age** 73.1 **Gender** 45.6% Male, 54.4% Female **Ethnicity** 88.8% White **SES** Not reported **Other:** College attended = 61.7% Mean BMI = 29.2	**Setting**: Home **Provider**: Research team and health counsellors **Mode of delivery**: Remote (post and telephone)	**Comparison:** N=319 Intervention vs. N=322 Waiting list **Type**: Multi-session **Focus**: Improvement of lifestyle behaviours in older, overweight long-term cancer survivors using remote methods based on Social Cognitive Theory and the Transtheoretical Model	**Intensity**: For period of 12 months: - Personally tailored workbook - Telephone counselling (weekly during first 3 weeks; every other week for 1 month; monthly then onwards) of 15 - 30 minutes - Automated telephone prompts - Tailored progress report sent every 12 weeks	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Change in number of minutes of endurance exercise per week **Measured**: Self-report	**Duration of follow-up:** 12 months (87.1% follow-up)	NA	12 months (end of intervention) Intervention 36.3 Control 23.4 Mean arm difference 12.9 95% CI 1.89 to 27.6 p=0.004 arm effect	**Adverse effects:** Changes in health status were monitored; 201 AEs were reported, most were non-serious. 106 of 201 AEs were classified as possibly attributable to the intervention; 32 involved hospitalization and were considered serious. **Inequality issues:** Not reported
Muniz et al, 2010 REFID 8775 **Country** Spain **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N=1,757 **Selection/recruitment criteria** Patients recently discharged following acute coronary syndrome hospitalisation **Participant characteristics** **Age range** 63 **Gender** 76.0% male, 24.0% female **Ethnicity** Not reported **SES** Not reported	**Setting:** Hospital **Provider:** Physician **Mode of delivery:** Face-to-face (individual level)	**Comparison** N= 867 intervention vs. N= 890 Usual care **Type:** Multi-session **Focus:** Lifestyle risk factors for CVD secondary prevention	**Intensity:** 2 face-to-face sessions lasting 30 to 40 minutes each, over two months	**Target behaviour outcome(s)** Increased physical activity **Prioritised main outcome for meta-regression:** Exercise 5 times per week (% participants) **Measured:** Self-report (% of participants)	**Duration of follow up** 6 months (85.9% follow-up)	NA	6 months (4 months post intervention) Intervention: 29.4% Control: 23.4% Adjusted OR 1.29 (95% CI 1.02 to 1.64), p=0.033	**Adverse effects:** Not reported **Inequality issues:** Not reported

Nies et al, 2003 **REFID** 6414 **Country** USA **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N= 197 **Selection/recruitment criteria** Women aged 30 to 60 years considered physically sedentary or mostly inactive (engaged in physical exercise very infrequently or not at all as self-reported) from the metropolitan communities of states in the north and south of the USA. Recruited via flyers placed around the community (e.g. churches, salons and colleges), newspapers, radio and television advertisements **Participant characteristics** **Mean age 44.4** **Gender** 100% female **Ethnicity** 47.9% African American, 52.1% European American **SES** 17.8% higher income African American, 29.4% higher income European American, 29.9% lower income African American, 29.4% lower income European American. **Other:** 52.5% overall lower income per year (>$50,000), 47.5% higher income per year (<$50,000). Education: 26.0% high school, 54.3% college, 15.0% graduate school	**Setting**: Participants homes where they received phone calls **Provider**: Research assistant trained to follow the intervention script. **Mode of delivery**: Telephone	**Comparison** N= 67 Telephone counselling intervention N= 60 Attention control vs. N= 70 No intervention **Type**: Multi-session **Focus**: Increased physical activity among sedentary women	**Intensity**: Intervention: 16 telephone calls of no less than 10 minutes over 24 weeks (weekly for the first 8 weeks, then fortnightly for the remaining 16 weeks) (6 month intervention) Attention control: 16 telephone of approximately 2 minutes over 24 weeks	**Target behaviour outcome(s)** Increased physical activity among sedentary women **Prioritised main outcome:** Change in minutes walked per day **Measured**: Self-report estimation	**Duration of follow up** 6 months (81% follow up)	NA	6 months (end of treatment) Mean (SD) Intervention: 2.34 (79.4) Controls: -2.23 (90.4) p<0.05	**Adverse effects:** Not reported **Inequality issues:** Findings applicable to African American and European American women as well as high and low income women
Nijamkin et al, 2012 **REFID** 34 **Country** USA **Design** RCT **Internal validity** **++** **External validity** **+**	**Number randomised** N= 144 **Selection/recruitment criteria** Hispanic Americans aged 18 years and above with obesity who had recently (6 months ± 6 weeks recruitment) undergone laparoscopic Roux-en-Y gastric bypass surgery (RYGB) for reversing morbid obesity at the Palmetto General Hospital in Hialeah, Florida. Only those who attended at least 5 nutrition counselling sessions were included. Recruited from the Laparoscopic Institute of South Florida by telephone calls and flyers in waiting rooms. **Participant characteristics** **Mean age** 44.5 **Gender** 16.7% male, 83.3% female **Ethnicity:** 100% Hispanic American **SES** Not reported **Other:** Employment: 23.6% unemployed, 14.6% disabled, 56.9% employed, 4.9% retired. Education: 13.7 average years. Occupation: 27.8% office administrator, 18.1% professional, 22.9% housewife,	**Setting**: Laparoscopic Institute of South Florida **Provider**: Registered dietician (option to have additional counselling with a dietician, psychologist or other health professional). **Mode of delivery**: Face-to-face (group level), email and telephone reminders, printed materials for one missed session only	**Comparison** N= 72 Comprehensive nutrition and lifestyle educational intervention vs. N= 72 Usual care **Type**: Multi-session **Focus**: Physical activity changes over time	**Intensity**: 6 group sessions of 90 minutes delivered fortnightly for 6 weeks starting at 7 months following surgery. Groups consisted of up to 12 people.	**Target behaviour outcome(s)** Physical activity changes over time **Prioritised main outcome:** Minutes of physical activity per week **Measured**: Short Questionnaire to Assess Health Enhancing Physical Activity	**Duration of follow up** 6 months (92.4% follow up)	NA	6 months (approximately 4.5 months post intervention) Mean (SD) Intervention: 59.63 (48.1) Control: 39.32 (33.7) p=0.023	**Adverse effects:** Not reported **Inequality issues:** Findings applicable to Hispanic Americans

	9.7% student, 7.6% educator, 13.9% other.								
Patrick et al, 2011 **REFID** 532 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=441 **Selection / Recruitment criteria:** Men aged between 25 to 55 years with BMI ≥ 25 (overweight or obese) **Participant characteristics:** **Mean age** 43.9 **Gender** 100% male **Ethnicity** 71.0% White, 5.2% Black, 18.1% Hispanic, 5.7% Other **SES** Not reported **Other:** Mean BMI = 34.3 BMI categories: Overweight = 15.6% Obese I = 41.7% Obese II = 33.8% Obese III = 8.8% Education level: High school = 8.4% Some college = 28.6% College graduate = 29.9% Postgraduate = 33.1% Marital status: Married/With partner = 70.3% Single/Separated/Divorced = 29.7%	**Setting**: Internet **Provider**: Computer **Mode of delivery**: Remote (internet-based)	**Comparison:** N=224 Intervention vs. N=217 Waiting list **Type**: Multi-session **Focus**: Internet-based behaviour change programme based on social cognitive theory to improve weight-related behaviours and induce weight loss	**Intensity**: Weekly learning activities for 6 months	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** IPAQ total walking **Measured**: Self-report (questionnaire)	**Duration of follow-up:** 6 months (66.0% follow-up) 12 months (70.1% follow-up)	NA	6 months (end of intervention) Mean (SE) Intervention 84.75 (5.16) Control = 65.31 (5.36) group x time interaction effect p=0.014 12 months Mean (SE) Intervention 85.62 (5.38) Control 69.93 (5.39) group x time interaction effect p=0.049	**Adverse effects:** Not reported **Inequality issues:** Not reported
Penn et al., 2009 **REFID** 9438 **Country** UK **Design** RCT **Internal validity** + **External validity** ++	**Number randomised:** N=102 **Selection/recruitment criteria:** Overweight individuals with Impaired Glucose Tolerance **Participant characteristics:** **Mean age** 57 **Sex** 59% female, 41% male **Ethnicity** Not reported **SES** Not reported **Other:** (by type of work) manual 45-50%; non-manual 37%; info not available 12-18%	**Setting**: Clinic **Provider**: Dietician and physiotherapist **Mode of delivery**: Face-to-face (individual and group level) plus remote follow-up (newsletter)v	**Comparison** N=51 intervention vs. N=51 Usual care **Type**: Multi-session **Focus**: Lifestyle intervention to prevent the development of type 2 diabetes	**Intensity**: 30 minutes per session, at randomisation, two weeks post randomisation, monthly for the first 3 months, then every three months thereafter for up to 5 years **Measured**: Self-report using a three day (24hr) activity diary	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome** % sustained beneficial change (>0.01 METS units) for at least two years	**Duration of follow up** 12 months (80% follow up) 24 months (71% follow up) 36 months (59% follow up) 48 months (55% follow up) 60 months (41% follow up)	NA	3.1 years (mean duration of follow up) Intervention: 35% Control: 37% Mean difference: -2% Reported as non-significant (95% CI/p-values not reported)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Pinto et al, 2011 **REFID** 755	**Number randomised** N= 130 **Selection/recruitment criteria** Patients aged over 40 years who had completed a phase 2 cardiac	**Setting**: Participants homes **Provider**: Intervention coordinator	**Comparison** N= 64 Maintenance exercise counselling Vs.	**Intensity**: Weekly telephone calls of 15.8 minutes (on average) for 2 months then biweekly calls for 2 months and	**Target behaviour outcome(s)** Maintenance of exercise participation **Prioritised main**	**Duration of follow up** 6 months (82.3% follow up)		6 months (during intervention) Intervention: 35%	**Adverse effects:** Not reported **Inequality issues:** Not reported

Country USA **Design** RCT **Internal validity** ++ **External validity** ++	rehabilitation program (12 week program including exercise training three times per week for about 90 minutes per session). Recruited from cardiac rehabilitation patients scheduled to complete phase 2 programs received an invitation to participate from case managers. A research assistant telephone screened for eligible participants **Participant characteristics** **Mean age** 63.6 **Gender** 79.2% male, 20.8% female **Ethnicity** 93.8% Non-Hispanic white, 3.1% non-Hispanic black, 3.1% other **SES** Not reported **Other:** Household income: 27.7% <$39,999; 28.5% $40,000 to $70,000; 35.4% >$80,000. Education: 20.8% high school diploma or less, 6.9% vocational/trade school, 26.9%some college, 21.5% Bachelor degree, 23.8% graduate school Employment status: 40.8% employed full time, 9.2% employed part time, 1.5% unemployed, 9.2% homemaker/medical leave, 39.2% retired	**Mode of delivery**: Telephone	N= 66 Attention control **Type**: Multi-session **Focus**: Maintenance of exercise participation among patients who had completed cardiac rehabilitation	monthly calls for the last 2 months (6 month intervention)	**outcome:** % participants meeting physical activity guidelines **Measured**: 7-Day Physical Activity recall (7-Day PAR)	12 months (73.8% follow up)		Control: 26% aOR 1.50, 95% CI 0.69 to 3.26, p=0.31 12 months (end of intervention) Intervention: 47% Control: 29% aOR 2.23, 95% CI 0.89 to 5.60, p=0.09	
Prestwich et al, 2009 **REFID** 2244 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 155 (154 analysed) **Selection/recruitment criteria** University students aged between 18 and 40 years who had signed up to a psychology experiments mailing list and were identified as exercising less than 3 times per week **Participant characteristics** **Mean age** 23.76 **Gender** 41.9% male, 58.1% female **Ethnicity** Not reported **SES** Not reported	**Setting**: Remote **Provider**: Electronic media for SMS delivery (not clear for delivery of implementation intentions) **Mode of delivery**: Intervention 1: remote Intervention 2: remote plus text message Intervention 3: text message	**Comparison** Intervention 1 N= 29 Implementation intention only Intervention 2 N= 29 Implementation intentions + SMS Intervention 3 N= 31 SMS only vs. Control N= 31 Assessment only **Type**: Intervention 1: brief All others multi-session **Focus**: Increased physical activity	**Intensity**: Intervention 1: Delivered once Intervention 2: Delivered once + at least 1 text message (participants able to choose message dose [average 3.7 messages]) Intervention 3: At least 1 text message (participants able to choose message dose [average 3.7 messages]) Intervention 4: Motivational message delivered once (1 month intervention)	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Exercise behaviour **Measured**: Self-report	**Duration of follow up** 1 month (87.7%follow-up)	1 month (end of treatment) Intervention 1: 1.03 (1.06) Intervention 2: 1.50 (1.29) Intervention 3: 1.12 (1.00) Control: 0.96 (1.00) P=0.08 favouring intervention 2 Non-significant for other comparisons	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

Reid et al, 2012 **REFID** 88 **Country** Canada **Design** RCT **Internal validity** **++** **External validity** **++**	**Number randomised** N= 141 **Selection/recruitment criteria** Patients hospitalised with acute coronary artery syndromes who underwent successful percutaneous coronary revascularisation and were not planning to attend cardiac rehabilitation Recruited during an index hospitalisation at a single cardiac centre on Ottawa Canada (University of Ottawa Heart Institute) by a research coordinator **Participant characteristics** **Mean age** 60.5 **Gender** 73.0% male, 27.0% female **Ethnicity** Not reported **SES** Not reported **Other:** Education: 12 year average Employment: 46.1% employed, 53.9% not employed	**Setting**: University hospital and remote (where participants received phone calls) **Provider**: 3 physiotherapists trained in intervention delivery (face-to-face session , individual level and telephone follow up). Intervention and control groups both received printed materials (booklet) and a 5 to 10 minute session with a cardiologist whilst in hospital. **Mode of delivery**: Face-to-face (individual level, 1st contact), telephone (remaining 8 contacts), printed materials.	**Comparison** N= 69 Motivational counselling vs. N= 72 Usual care **Type**: Multi-session **Focus**: Change in physical activity levels among cardiac patients	**Intensity**: 1 face-to-face session of 25 to 35 minutes at week 0 followed by 8 telephone sessions of 10 to 15 minutes at weeks 2, 4, 8, 14, 20, 24, 40 and 52. (12 month intervention). Both intervention and control received a 5 to 10 minute discussion in-hospital with a cardiologist as part of usual care.	**Target behaviour outcome(s)** Change in physical activity levels **Prioritised main outcome:** Kilometres travelled over 7 days (pedometer) **Measured**: 7-Day Physical Activity recall (7-Day PAR), pedometer	**Duration of follow up** 6 months (78% follow up) 12 months (68.1% follow up)	NA	6 months Mean (SD) Intervention: 30.6 (16.7) Control: 29.8 (19.0) P value not reported 12 months Intervention: 38.3 (25.9) Control: 34.5 (24.5) p value not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Smeulders et al 2009 **REFID** 10068 **Country** The Netherlands **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised** N=317 **Selection/recruitment criteria** Patients with diagnosed congestive heart failure (CHF) for 6 months who received information about the study and were eligible after being admitted at least once to hospital based on cardiac decompensation Recruited from 6 hospitals in The Netherlands **Participant characteristics** **Mean age** 66.7 **Gender** 72.6% male, 27.4% female **Ethnicity** Not reported **SES** Not reported **Other:** 89% not employed, 66% middle education level, 67.2% not living alone	**Setting:** Hospital **Provider:** Intervention was delivered by a cardiac nurse specialist (professional leader) and a CHF patient (peer leader) both trained in intervention delivery**.** Usual care was delivered by a Cardiologist and/or nurse specialist. **Mode of delivery:** Face-to-face (group level), telephone (with co-participants)	**Comparison** N= 186 Chronic disease self - management programme (CDSMP) + usual care vs. N= 131 Usual care **Type:** Multi-session **Focus:** Health behaviour	**Intensity:** 6 weekly group sessions of 2.5 hours each	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome for meta-regression:** Minutes per month of walking for exercise **Measured:** Modified version of the Physical Activities Scale	**Duration of follow up** 6 months (86.4% follow-up) 12 months (83.6% follow-up)	NA	6 months (approximately 4.5 months post intervention) Intervention: 753.3 (1050.1) Control: 531.0 (780.4) p=0.068 12 months (approximately 10.5 months post intervention) Intervention: 628.2 (762.7) Control: 552.8 (706.5) p=0.269	**Adverse effects:** Not reported **Inequality issues:** Not reported

ter Bogt et al, 2010 **REFID** 1047 **Country** Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=457 **Selection / Recruitment criteria:** Individuals with BMI between 25 and 40 and with either hypertension or dyslipidaemia, or both **Participant characteristics:** **Mean age** 56.2 **Gender** 46.9% Male, 53.1% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean BMI = 29.5 Obese (BMI≥30) = 35.5%	**Setting**: General practice **Provider**: Nurse practitioners **Mode of delivery**: Face-to-face (individually)	**Comparison:** N=225 Intervention vs. N=232 Usual care **Type**: Multi-session **Focus**: Lifestyle counselling given by nurses, guided by a standardised computerised computer programme to prevent weight gain in overweight individuals	**Intensity**: 4 visits (1, 2, 3 and 8 months after baseline) followed by 1 telephone feedback session (8 month intervention)	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Minutes per week of physical activity **Measured**: Self-report (questionnaire)	**Duration of follow-up:** 1 year (74.6% follow-up)	NA	12 months (4 months post intervention) Intervention : -126, 95% CI -304 to 53 Control: -68 95% CI -225 to 89 p value for comparison of mean change scores p=0.52	**Adverse effects:** Not reported **Inequality issues:** Not reported
Thoolen et al., 2009 **REFID** 2246 **Country** The Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=227 **Selection/recruitment criteria** Patients recently diagnosed with diabetes (screen detected) **Participant characteristics** **Mean age** 62 **Gender** 36-45% female, 55-64% male **Ethnicity** Not reported **SES** Not reported	**Setting**: Not reported **Provider**: Nurse **Mode of delivery**: Face-to-face (individual and group level)	**Comparison** N=119 Beyond Good Intentions intervention vs. N=102 Usual care **Type**: Multi-session **Focus**: Diabetes self-management (diet, physical activity and medication)	**Intensity**: 6 sessions (2 individual, length not reported; and 4 group, 2 hours each) over 12 weeks	**Target behaviour outcome(s)** Exercise **Prioritised main outcome:** Weekly physical activity **Measured**: Self-report using Physical Activity Scale for the Elderly (PASE), higher score better	**Duration of follow up** 3 months (86% follow up) 12 months (79% follow up)	3 months (during intervention) Mean (SD) Intervention 162 (75) Control 135 (69) Difference 27 (Significance not reported)	12 months (9 months post intervention) Mean (SD) Intervention 152 (76) Control 127 (66) Effect size Eta square 0.06 (small) Group x Time interaction significant at p<0.0001)	**Adverse effects:** Not reported **Inequality issues:** Not reported
Tingstrom et al, 2006 **REFID** 5189 **Country** Sweden **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 207 **Selection/recruitment criteria** Participants younger than 70 years with a recent event (1.5 to 2 months after the event) of coronary artery disease (CAD) event (myocardial infarction and/or treated with percutaneous coronary intervention and/or treated with coronary bypass grafting). Participants with planned bypass surgery were excluded. **Participant characteristics** **Mean age** 59.2 **Gender** 69.6% male, 25.6% female **Ethnicity** Not reported **SES** Not reported **Other:** Education level: 44.4% 6 to 9 year compulsory school, 40.6% 2 to 4 year	**Setting**: Library setting **Provider**: Tutor (nurse, physiotherapist or dietician from the rehabilitation teams) acting as a facilitator and supporter rather than an educator. **Mode of delivery**: Face-to-face (group level)	**Comparison** N=104 Problem based learning (PBL) rehabilitation program + usual care vs. N= 103 Usual care **Type**: Multi-session **Focus**: Change in physical activity among cardiac patients	**Intensity**: 13 small group sessions of 1.5 hours each over 12 months with more frequent meetings during the first 2 months. Groups consisted of 6 to 9 people. Authors report that the number of group sessions during the second 6 month interval was only 2 or 3.	**Target behaviour outcome(s)** Change in physical activity **Prioritised main outcome:** Counts per minute (as measured by CSA/MTI activity monitor) **Measured**: Self-reported physical activity via interview (subjective), accelerometry (objective)	**Duration of follow up** 12 months (96.6% follow up)	NA	12 months (end of intervention) Mean (SD) Intervention: 330 (136) Control: 330 (134) p=0.979	**Adverse effects:** Not reported **Inequality issues:** Not reported

	upper secondary school, 11,6% university degree								
Toobert et al, 2010 **REFID** 1780 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 279 **Selection/recruitment criteria** Postmenopausal women with type 2 diabetes for at least 6 months from the Pacific Northwest who received their care from primary care clinics **Participant characteristics** **Mean age** 61 **Gender** 0.0% male, 100% female **Ethnicity** 94% non-Hispanic white, 2.9% Hispanic , 1.4% Native American Indian **SES** Not reported **Other:** Employment: 38% employed, 43% retired Average income: US$30,000 to $39,000 Education: 42% college education	**Setting**: Non-residential retreat (3 day retreat); setting not reported for rest of intervention **Provider**: Dietician (dietary components), exercise physiologist (physical activity component), professionals with at least Master's level training and peer leader led the support groups **Mode of delivery**: Face-to-face	**Comparison** N= 163 Mediterranean Lifestyle program vs. N= 116 Usual care The intervention group was further randomised to receive faded maintenance or personalised maintenance. No differences were found and results were combined and compared to the control **Type**: Multi-session **Focus**: Long-term multiple behaviour changes	**Intensity**: 3 day retreat + weekly sessions of 1 hour for 6 months. Followed by either faded weekly sessions (faded maintenance) or 4 sessions (personalised maintenance) over 18 months. Total intervention period of 24 months.	**Target behaviour outcome(s)** Physical activity and dietary changes **Prioritised main outcome:** Weighted frequency of all activity per week **Measured**: Self-report using CHAMPS activities questionnaire for Older Adults	**Duration of follow up** 5 years (69.7% follow-up)	NA	Adj. mean (SD) 6 Month (during intervention) INT 26.2 (13.6) CON 18.2 (12.6) 12 Month (during intervention) INT 22.3 (12.3) CON 16.5 (10.5) 24 Month (end of intervention) INT 23.4 (15.3) CON 18.1 (10.8) 36 Month (12 months post intervention) INT 20.4 (14.7) CON 15.5 (10.6) 48 Month (24 months post intervention) INT 17.1 (12.5) CON 15.8 (11.7) 60 Month (36 months post intervention) INT 17.0 (10.5) CON 15.7 (10.7) 72 Month (48 months post intervention) INT 15.8 (10.4) CON 14.4 (10.5) 84 Month (60 months post intervention) INT 14.7 (11.1)	**Adverse effects:** Not reported **Inequality issues:** Not reported

								CON 14.6 (11.3) Group x Time interaction p<0.001	
Toobert et al, 2011 **REFID** 1025 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=280 **Selection / Recruitment criteria:** Women of Latin ethnicity aged between 30 and 75 years with diagnosis of type 2 diabetes **Participant characteristics:** **Mean age** 57.2 **Gender** 100% female **Ethnicity** 100% Latina **SES** Not reported **Other:** Mean BMI = 34.3 Income: <$29,999 = 43.4% $30,000 - $49,999 = 24.4% $50,000 - $69,999 = 14.9% $70,000 - $89,999 = 9.2% >$90,000 = 8.2% Education level: 0 - 11th grade = 23.6% High school = 30.0% Some college = 29.4% University graduate = 17.1%	**Setting**: Allocated intervention site **Provider**: Unclear (assumed to be programme facilitators) **Mode of delivery**: Face-to-face (group level)	**Comparison:** N=142 ¡Viva Bien! vs. N=138 Usual care **Type**: Multi-session **Focus**: Improvements in lifestyle behaviours through improvements of psychosocial variables for Latinas	**Intensity**: - 2.5 day retreat - Weekly group meetings of 4 hours each for first 6 months - Twice monthly group meetings of 4 hours each for further 6 months	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Physical activity (days per week) **Measured**: Self-report (questionnaire)	**Duration of follow-up:** 6 months and 12 months - The number of complete cases varied depending on the outcome measured - For the outcome of interest (PA), there were 179 complete cases (63.9% follow-up)	NA	6 months (during intervention) Mean (SD) Intervention 5.8 (2.2) Control 5.1 (SD 2.4) Effect size 0.20 12 months (end of intervention) Intervention 6.9 (4.4) Control 6.4 (4.3) Effect size 0.09 Condition F-value 2.94 Condition by time F-value 0.16	**Adverse effects:** Not reported **Inequality issues:** Not reported
Vale et al, 2003 **REFID** 19175 **Country** Australia **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=792 **Selection/recruitment criteria** Patients hospitalised for CABG, PCI, acute MI or unstable angina, coronary angiography with planned revascularisation. **Participant characteristics** **Mean age** 58 **Gender** 77.0% male, 23.0% female **Ethnicity** Not reported **SES** Not reported	**Setting:** Recruited from hospital, delivered via telephone and mail **Provider:** Dietician or nurse **Mode of delivery:** Remote (telephone)	**Comparison** N= 398 COACH programme vs. N= 394 Usual care **Type:** Multi-session **Focus:** Coronary risk factors	**Intensity:** 5 telephone coaching session, median call length 20 to 30 minutes (18 week intervention)	**Target behaviour outcome(s)** Diet and physical activity **Prioritised main outcome for meta-regression:** % taking up walking since discharge **Measured:** % of participants	**Duration of follow up** 6 months (85.7% follow up)	NA	6 months (approximately 1 month post intervention) Intervention: 69% Control: 44% p<0.0001	**Adverse effects:** Not reported **Inequality issues:** Not reported

van Sluijs et al, 2005 **REFID** 5475 **Country** The Netherlands **Design** Cluster RCT **Internal validity** ++ **External validity** ++	**Number randomised** N= 396 (358 analysed) **Selection/recruitment criteria** **Practice:** No eligibility criteria for practices **Participants:** Patients aged 18 to 70 years diagnosed with hypertension, hypercholesterolemia, non-insulin dependent diabetes (type 2 diabetes) or any combination of these conditions and identified as not regularly physically active in the past 6 months (i.e. not in the maintenance stage for regular physical activity). Recruited through random selection by the research team (90 patients per practice). Participants received a personal invitation letter from their GP. **Participant characteristics** **Mean age** 55.5 **Gender** 50.8% male, 49.2% **Ethnicity** Not reported **SES** Not reported **Other:** Employment status: 29.7% full time, 24.2% part time, 46.1% unemployed Education level: 36.5% low, 43.1% medium, 20.4% high	**Setting**: 29 general practice settings (rural and city practices included) **Provider**: General practitioner or nurse practitioner (2 face-to-face sessions); physical activity counselor (2 booster telephone sessions). All trained in intervention delivery. **Mode of delivery**: Face-to-face (individual level, first 2 sessions); telephone (2 follow up phone calls)	**Comparison** N= 191 Physician based assessment and counselling for exercise (PACE) vs. N= 205 Usual care **Type**: Multi-session **Focus**: Change in physical activity	**Intensity**: 2 face-to-face sessions 4 weeks apart and 2 follow up phone calls (1 phone call 2 weeks after the initial visit and the second call 8 weeks after the second visit) (3 month intervention)	**Target behaviour outcome(s)** Change in physical activity **Prioritised main outcome:** % participants meeting ACSM/CDC guidelines for physical activity **Measured**: Self-report questionnaire	**Duration of follow up** 6 months (89.4% follow up) 12 months (86.3% follow up)	NA	12 months (approximately 9 months post intervention) % not reported for intervention and control groups AOR 0.99 95% CI 0.62 to 1.57 , p=0.95	**Adverse effects:** Not reported **Inequality issues:** Not reported
van Wier et al, 2009 **REFID** 2781 **Country** Netherlands **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=1386 **Selection / Recruitment criteria:** Overweight (BMI≥25) adult employees of 7 chosen companies who have access to internet and with no diagnosis or treatment for disorders that would make difficult **Participant characteristics:** **Mean age** 43 **Gender** 67.0% Male, 33.0% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean BMI = 29.6 Highly educated = 60.4% Married/cohabiting = 84.7%	**Setting**: Workplace / Home **Provider**: Trained counselors (dieticians and movement scientists) **Mode of delivery**: Remote Intervention 1 = Telephone Intervention 2 = Internet (interactive website + e-mail)	**Comparison:** N=462 Telephone intervention N=464 Internet intervention vs. N=460 Usual care **Type**: Multi-session **Focus**: Lifestyle counselling for overweight employees; comparison between telephone and internet methods	**Intensity**: Telephone = every 2 weeks until all modules completed Internet = access to interactive website, and communication from counselor by e-mail as each module completed	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Meeting exercise guidelines (at least 30 minutes physical activity 5 days a week) **Measured**: Self-report (questionnaire)	**Duration of follow-up:** 6 months (58.2% completed the follow-up questionnaire)	NA	6 months (end of intervention) Control 38.5% Phone 49.8% vs. Control OR 1.8 95% CI 1.3 to 2.6 p<0.001 Internet 44.1% vs. Control OR 1.4 95% CI 0.97 to 2.1 p=0.07	**Adverse effects:** Not reported **Inequality issues:** Not reported

Vermunt et al, 2011 **REFID** 343 **Country** The Netherlands **Design** RCT **Internal validity** **+** **External validity** **++**	**Number randomised** N= 925 **Selection/recruitment criteria** Individuals older than 40 and younger than 70 considered at risk of diabetes (with a diabetes risk score of more than 13 points). Recruited by 48 general practitioners from a cooperation of 14 primary care practices in Eindhoven and 5 surrounding villages. **Participant characteristics** **Mean age** 57.9 to 59.5 **Gender** 38.8% to 44.1% male **Ethnicity** Not reported **SES** Not reported **Other:** 48.5% to 53.8% low education, 25.4% to 27% average education (overall education percentages not provided)	**Setting**: Primary care practices **Provider**: Individual sessions were delivered on an alternate basis by the general practitioner and nurse trained in intervention delivery. Group sessions delivered by trained dietician. Printed materials (both groups). **Mode of delivery**: Face-to-face (individual and group level); printed materials.	**Comparison** N= 479 Lifestyle intervention vs. N= 446 Usual care **Type**: Multi-session **Focus**: Type 2 diabetes risk reduction	**Intensity**: 1 individual 'admission' session with the general practitioner (10 minutes for usual care and 20 minutes for intervention) followed by 11 individual sessions of 20 minutes over 2.5 years and 5 group sessions of 1 hour	**Target behaviour outcome(s)** Type 2 diabetes risk reduction **Prioritised main outcome:** Total minutes of activity per week **Measured**: Physical activity: Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH)	**Duration of follow up** 6 months (8.9% follow-up) 18 months (8.9% follow-up)	NA	6 months (during intervention): Mean change from baseline (SD) Intervention: 248 (949) Control: 31 (1014) p=0.02 for between group difference 18 months (end of intervention): Intervention: -0.84 (1023) Control: -290 (994) p=0.02 for between group difference	**Adverse effects:** Not reported **Inequality issues:** Not reported
Vestfold Heartcare Study Group, 2003 **REFID** 6338 **Country** Norway **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=197 **Selection/recruitment criteria** Patients hospitalised for CABG, acute MI or unstable angina, or treated in an out-patient clinic with PCI **Participant characteristics** **Mean age** 55 **Gender** 82.2% male, 17.8% female **Ethnicity** Not reported **SES** Not reported	**Setting:** Cardiac rehabilitation clinic **Provider:** Physician, nutritionist, physiotherapist and nurse **Mode of delivery:** Face-to-face (individual and group level)	**Comparison** N= 98 intervention (of whom, 49 smokers) vs. N= 99 Usual care (of whom, 42 smokers) **Type:** Multi-session **Focus:** Multidisciplinary lifestyle cardiac rehabilitation, plus physical exercise	**Intensity:** 2 hour education sessions for six weeks; followed by twice weekly group meetings for 9 weeks; Followed by group meetings every third month for two years	**Target behaviour outcome(s)** Diet and physical activity **Prioritised main outcome for meta-regression:** Regular exercise for more than 1 hour per week **Measured:** % participants	**Duration of follow up** 12 months (84% follow up)	NA	6 months (during intervention): Intervention: 93% Control: 72% p<0.001 24 months (end of intervention) Intervention: 67%% Control: 46% p<0.001	**Adverse effects:** Not reported **Inequality issues:** Not reported

White et al, 2012 **REFID** 26 **Country** Australia **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=183 **Selection / Recruitment criteria:** Older adults diagnosed with type 2 diabetes (T2d) or cardiovascular disease (CVD) **Participant characteristics:** **Mean age** 61.2 **Gender** 39% Male, 61% Female **Ethnicity** 99% White **SES** Not reported **Other:** Married = 76% Retired = 39% Homemaker = 31% T2d only = 49% T2d + CVD = 45% CVD only = 6%	**Setting**: Community health centres **Provider**: Health professionals **Mode of delivery**: Face-to-face (in groups)	**Comparison:** N=130 Intervention vs. N=53 Waiting list **Type**: Multi-session **Focus**: The Theory of Planned Behaviour (TPB)-based interactive group sessions to promote regular physical activity a healthy eating amongst older adults with T2D and/or CVD	**Intensity**: Weekly 2hr group sessions held over for 4 weeks	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Extent to which physical activity was performed (7-point scale) **Measured**: Self-report	**Duration of follow-up:** 1 week post-intervention (HE=73% & PA=73% follow-up) 6 week post-intervention (HE=63% & PA=61% follow-up)	1 week (during intervention) Mean (SD) Intervention 4.95 (1.63) Control 3.95 (1.69) 6 weeks (end of intervention) Intervention 4.60 (1.84) Control 4.19 (1.81) Time x Condition effect p=0.67	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported
Wood et al, 2008 **REFID** 3456 **Country** Denmark, France, Italy, Poland, Spain, Sweden, The Netherlands, UK **Design** Cluster RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=5,405 **Selection/recruitment criteria** Patients younger than 80 years with coronary heart disease or patients in general practice who were between 50 and 80 years considered at high risk of developing CVD **Participant characteristics** **Mean age** 62.6 **Gender** 45.2% male, 54.8% female **Ethnicity** Not reported **SES** Not reported	**Setting**: 12 general hospitals in France, Italy, Poland, Spain, Sweden, UK. 12 general-practice centres in Denmark, Italy, Poland, Spain, The Netherlands, UK. **Provider**: Nurse (coordinator), physiotherapist and dietician **Mode of delivery**: Face-to-face (individual and group level)	**Comparison** N= 1,589 EUROACTION (coronary heart disease hospital-based patients) N= 1,189 EUROACTION (high-risk CVD general practice-based patients vs. N= 2,627 Usual care **Type**: Multi-session **Focus**: Family-based lifestyle change	**Intensity**: Hospital patients: At least 8 weekly sessions over 16 weeks(4 month intervention) General practice patients: Weekly sessions open ended	**Target behaviour outcome(s)** Physical activity and diet **Prioritised main outcome:** % at least 30 minutes at least 4 times per week of physical activity **Measured**: Self-report	**Duration of follow up** 12 months (73.3% follow -up).	NA	12 months (approximately 8 months post intervention) Hospital intervention: 54% Control: 20% difference 35.6% 95 % CI 20.0 to 51.3% p=0.002 GP intervention: 50% Control: 22% difference 29.4% 95 % CI 10.7 to 48.0% p=0.01	**Adverse effects:** Not reported **Inequality issues:** Not reported
Missing data or not usable data for meta-regression									

Broadbent et al, 2009 **REFID**16808 **Country** New Zealand **Design** RCT **Internal validity** ++ **External validity** ++	**Number randomised** N=103 **Selection/Recruitment criteria:** Patients aged younger than 70 years admitted with acute MI Recruited as an inpatient **Participant characteristics:** **Mean age** 54.7 **Gender** 88.3% male, 11.7% female **Ethnicity** 68.0% Caucasian, 13.6% Maori/Pacific Islander, 16.5% Asian, 1.9% other **SES** Employment status: 11.6% unemployed, 14.6% retired, 11.7% part-time, 54.4% full-time **Other** Smoker: 44.7%	**Setting:** Inpatient (hospital) **Provider:** Health psychologist, paper materials **Mode of delivery:** Face-to-face (individual level, one session was delivered with patient spouse), paper materials	**Comparison:** N= 52 Illness perception intervention vs. N= 51 Usual care **Type:** Multi-session **Focus:** Rate of return to work	**Intensity:** 3 individual sessions of 30 minutes and 1 session with patient and spouse for 30 minutes. Length of intervention not provided.	**Target behavior outcomes(s):** Physical activity **Prioritised main outcome(s):** Exercise behaviour **Measured:** Health behavior scale	**Duration of follow up:** 6 months (76.7% follow up)	At hospital discharge: Intervention: Control: 3 months following MI: Intervention: 4.32 Control: 4.02 Units used and p values not reported	6 months following MI: Intervention: 4.42 Control: 4.14 Units used and p values not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
Coull et al, 2004 **REFID** 20636 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 319 **Selection/recruitment criteria** Inpatients and outpatients aged 60 years or older attending secondary care with a diagnosis of angina or acute myocardial infarction (ischaemic heart disease). Entry into the study occurred after completion of any extended cardiac rehabilitation program. Recruited from admission to hospital or attendance at the outpatient department **Participant characteristics** **Mean age** 67.6 **Gender** 60.5% male, 39.5% female **Ethnicity** Not reported **SES** Not reported	**Setting**: Community facilities **Provider**: Volunteer lay health mentors aged 54 to 74 recruited from the local community trained in intervention delivery and considered 'lay health mentors'. 2 mentors delivered each group session. Input from pharmacist, cardiac rehabilitation specialist nurse, dietician, welfare benefits advisor and recreation services. **Mode of delivery**: Face-to-face (group level)	**Comparison** N= 165 Mentoring program vs. N= 154 Usual care **Type**: Multi-session **Focus**: Changes in lifestyle risk factors	**Intensity**: Monthly group sessions of 2 hours for 1 year. Groups consisted of an average of 10 people.	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Amount of exercise activity during the previous week and time spent on actual activities in the previous week **Measured**: Face-to-face interview	**Duration of follow up** 12 months (90.6% follow-up).	NA	12 months (at end of intervention) Intervention: 843 Control: 767 Difference in change score: +147 , 95% CI -8 to +266) SDs for means not reported	**Adverse effects:** Not reported **Inequality issues:** Not reported
King et al, 2006 **REFID** 5225 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 335 **Selection/recruitment criteria** Adults aged 25 years or older diagnosed with type 2 diabetes for 6 months or more residing in Denver, Colorado metropolitan area Recruited from lists provided by 42 physicians (8 practiced in mixed-payer settings and 34 employed by Kaiser Permanente HMO. **Participant characteristics** **Mean age** 61.5 **Gender** 49.8% male, 50.2% female **Ethnicity** 17.8% Hispanic, 76.5% white **SES** Annual income (US$): 27.6% <$30,000; 59% <$50,000; 41% >$50,000 **Other:** Education: 35.8% technical degree,	**Setting**: Community (external to participants primary care setting) **Provider**: intervention staff members trained in intervention delivery who had diverse educations (e.g. specialties in public health occupational therapy, genetic counselling and nutrition) and experience (e.g. four had prior health counselling experience but none had specific experience coaching patients with diabetes) **Mode of delivery**: Face-to-face and computer-assisted	**Comparison** N= 174 Computer-assisted tailored self-management Vs. N= 161 Health risk appraisal with feedback (Control) **Type**: Multi-session **Focus**: Dietary patterns and physical activity levels	**Intensity**: 1 session at baseline and 1 session at 2 months incorporating: counselling (60 minutes), interactive CD-ROM technology (30 to 40 minutes [average 35.3 minutes]) and review of exercises (30 minutes) with 2 follow-up telephone calls of 15 minutes at 1 week and 1 month after baseline (2 month intervention)	**Target behaviour outcome(s)** Physical activity **Prioritised main outcome:** Moderate levels of physical activity (hours per week that moderate activity performed weighted by the METs value of the activity); kcals per kilogram per hour. **Measured**: CHAMP Questionnaire	**Duration of follow up** 2 months (89.9% follow-up).	2 months (end of intervention) Intervention: 22.9 (26.4) Control: 14.9 (17.8) p=0.001	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

	20.0% completed college, 15.2% graduate degree								
Lear et al, 2006 **REFID** 5039 **Country** Canada **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 302 (249 analysed) **Selection/recruitment criteria:** Patients over the age of 18 years with IHD who had completed 4 months of CRP Recruited from 2 hospital-based CRPs **Participant characteristics:** **Mean age** 64.1 **Gender** 54.6% male, 45.4% female **Ethnicity** Not reported **SES** Not reported	**Setting:** Hospital **Provider:** Nurse, case manager, exercise leader (CRP delivered by dieticians, exercise specialists, nurses 'etc') **Mode of delivery:** Face-to-face (individual and group level), telephone delivery, paper materials	**Comparison** N= 151 (130 analysed) Cardiac rehabilitation program (CRP) vs. N= 151 (119 analysed) Usual care **Type:** Multiple intervention over extended period of time **Focus:** Reduced overall cardiovascular risk	**Intensity:** 6 cardiac rehab sessions, 6 telephone calls and three counselling sessions over 1 year and 4 telephone calls and 2 counselling sessions over 3 years (4 year intervention) CRP consisted of 16 weeks of twice weekly sessions 25.5 hours of face-to-face contact	**Target behavior outcomes(s)** Physical activity **Prioritised main outcome:** Exercise capacity (METs) **Measured:** Symptom limited treadmill exercise stress test reported as the estimated maximal METs	**Duration of follow up** 4 year (82.5% follow up)	NA	Mean (SD) <u>12 months</u> (during intervention): Not reported <u>24 months</u> (during intervention): Not reported <u>36 months</u> (during intervention): Not reported <u>48 months</u> (end of intervention): Intervention: 9.8 (2.7) Control: 9.8 (2.6) p=0.765	**Adverse effects:** Not reported **Inequality issues:** Not reported
Little et al, 2004 **REFID** 6223 **Country** UK **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N= 151 **Selection/recruitment criteria** Patients older than 18 years with one or more risk factors for coronary heart disease, diagnosis of hypertension or hyperlipidaemia, BMI >25 or diabetes. Patients were excluded if they had coronary heart disease. Patients were sent letters and those identifying 'less than 30 minutes of exercise, defined as "brisk walking or equivalent"' were included. Recruited randomly from practice databases. **Participant characteristics** **Mean age** 57.44 to 60.44 **Gender** 41.4% male to 47.4% male **Ethnicity** Not reported **SES** Not reported **Other:** <u>Education:</u> 6.53 to 7.19 years of education since age of 10 years	**Setting**: 4 general practices **Provider**: Intervention 1: paper materials Intervention 2: GP Intervention 3: Nurse Intervention 4: GP + paper materials Intervention 5: Nurse + paper materials Intervention 6: GP + nurse Intervention 7: GP + nurse + paper materials **Mode of delivery**: Face-to-face (individual level), paper materials	**Comparison** Missing data Intervention 1 N=(not reported) GP exercise prescription, Nurse counselling and booklet vs. Intervention 2 N=(not reported) GP prescription and nurse counselling, no booklet vs. Intervention 3 N=(not reported) Nurse counselling and booklet, no GP exercise prescription vs. Intervention 4 N=(not reported) Nurse counselling only	**Intensity**: GP exercise prescription was 1 session of 5 to 10 minutes; nurse counselling was 1 session of 15 to 20 minutes	**Target behaviour outcome(s)** Increased physical activity **Prioritised main outcome:** Distance walked in metres in 6 minutes **Measured**: 6-minute walk test	**Duration of follow up** 1 month (77% to 88% follow up)	<u>1 month</u> Intervention 1: 35, 95% CI 1.6 to 68.0 Intervention 2: 22.7, 95% CI 5.6 to 40.0 Intervention 3: 22.7, 95% CI -0.1 to 45.5 Intervention 4: 6.4, 95% CI -15.2 to 28.0 Intervention 5: -7.2, 95% CI -37.3 to 23.0 Intervention 6: 28, 95% CI 12.0 to 44.0 Intervention 7: 4.8, 95% CI -14.3 to 24.0 Control: 9.3, 95% CI -2.4 to 21.0	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

			vs. Intervention 5 N=(not reported) GP exercise prescription and booklet, no nurse counselling vs. Intervention 6 N=(not reported) GP exercise prescription only vs. Intervention 7 N=(not reported) Booklet only vs. Control group N=(not reported) **Type**: Brief **Focus**: Increased physical activity				p values not reported		
Lindstrom et al, 2003 **REFID** 6367 **Country** Finland **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=522 **Selection / Recruitment criteria:** Middle-aged (40 - 64 years old) overweight (BMI>25) glucose-intolerant individuals **Participant characteristics:** **Mean age** 55 **Gender** 33.0% Male, 67.0% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean BMI = 31.3 <u>Years of schooling:</u> 0 - 9 = 40% 10 - 12 = 27% ≥13 = 33% <u>Type of work:</u> Agricultural / Industrial = 9.5% Office work / Student = 43% Homemaker / Retired / Unemployed = 49%	**Setting**: Research centres **Provider**: Physicians, Study Nurses, Nutritionists, Exercise Instructors, Physiotherapists **Mode of delivery**: Face-to-face (individual and group sessions), supplemented by telephone calls and letters	**Comparison:** N=265 Dietary & Exercise interventions vs. N=257 General health info group **Type**: Multi-session **Focus**: One-year comprehensive dietary and exercise interventions followed by two-year maintenance period for middle-aged overweight glucose-intolerant individuals	**Intensity**: Dietary intervention: - Seven 30mins to 1hr individual consultation sessions in the 1st year, then every 3 months thereafter - Voluntary group sessions, expert lectures, low-fat cooking sessions and visits to local supermarkets - Between-visit phone calls and letters Exercise intervention: - Counselling given during the nutritional consultation sessions (as described above) - Annual visits to physicians - Individually tailored progressive endurance exercise sessions - Voluntary group walking and hiking sessions	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Moderate-to-vigorous Leisure-Time Physical Activity (LTPA) **Measured**: Self-report (LTPA questionnaire)	**Duration of follow-up:** 1 year (97.3% follow-up) 3 years (96.6% follow-up	NA	<u>12 months</u> Median (IQR), Change score Intervention: +49 (-41 to 140) Control: +14 IQR -47 to 90 p=0.0073 <u>Change at 36 months</u> Median (IQR) Intervention: +61 (-33 to 168) Control: +6 (-91 to 104) p=0.0057	**Adverse effects:** Not reported **Inequality issues:** Not reported

				- Twice yearly exercise competitions between study centres					
Mata et al, 2009 **REFID** 14293 **Country** Portugal **Design** RCT **Internal validity** + **External validity** ++	**Number randomised** N= 239 **Selection/recruitment criteria** Women aged between 23 and 50 years old (premenopausal) identified as overweight or moderately obese Recruited through the community by media advertisements **Participant characteristics** **Mean age** 38 **Gender** 0.0% male, 100% female **Ethnicity** Not reported **SES** Not reported **Other:** Education: 67% had at least some college education, 23% had between 10 and 12 years of school, 10% had 9 years or less of school education	**Setting**: Not reported **Provider**: PhD or M.S level exercise physiologists, nutritionists/dieticians and psychologists (multidisciplinary team); paper materials **Mode of delivery**: Face-to-face, written materials	**Comparison** N= Exercise-specific motivation intervention vs. N= General health information (control) **Type**: Multi-session **Focus**: Increasing exercise self-motivation and exercise adherence aiming at long-term weight control	**Intensity**: 30 sessions of 120 minutes for 1 year (weekly or bimonthly)	**Target behaviour outcome(s)** Physical activity behavior **Prioritised main outcome:** Minutes per week of leisure time moderate and vigorous physical activity **Measured**: 7-day Physical Activity Recall interview	**Duration of follow up** 12 months (87.0% follow-up).	NA	12 months (end of intervention period) Intervention: 300 Control: 162 p<0.001 SD not provided	**Adverse effects:** Not reported **Inequality issues:** Not reported
Migneault et al, 2012 **REFID** 102 **Country** USA **Design** RCT **Internal validity** ++ **External validity** +	**Number randomised:** N=337 **Selection / Recruitment criteria:** Hypertensive African American adults aged 35 years or over who are on at least one anti-hypertensive medication **Participant characteristics:** **Mean age** 56.6 **Gender** 29.6% Male, 70.4% Female **Ethnicity** 100% Black **SES** Not reported **Other:** Mean BMI 34.4 Median household income $10-20K/year Employed 39.7% Married/Cohabiting 35.2%	**Setting**: Home **Provider**: Automated telephone messages (using African-American voice professionals) **Mode of delivery**: Remote (telephone)	**Comparison:** N=169 Intervention vs. N=168 Usual care **Type**: Multi-session **Focus**: Culturally adapted computer-based interactive telephone counselling system to reduce hypertension in African-Americans	**Intensity**: One call per week for 32 weeks (8 months)	**Target behaviour outcome(s):** Adherence to medication regimen and lifestyle change **Prioritised main outcome:** Moderate or greater physical activity (min/week) **Measured**: Accelerometer validated (48 pts were randomly selected for the validation test) interviewer-administered 7-day physical activity recall	**Duration of follow-up:** 4 months (83.4% follow-up) 8 months (78.6% follow-up) 12 months (77.4% follow-up)	4 months (during intervention) Reported as non-significant, figures and p value not reported Time point Change from baseline No SDs provided	8 months (end of intervention): Intervention: -3.44 Control: 2.77 Difference between score change: -6.21, significance not reported 12 months (4 months post intervention): Reported as non-significant, figures and p value not reported No SDs provided	**Adverse effects:** Not reported **Inequality issues:** Not reported

Osborn et al., 2010 **REFID** 19691 **Country** USA **Design** RCT **Internal validity** + **External validity** +	**Number randomised** N=118 **Selection/recruitment criteria** Puerto Rican patients with Type 2 Diabetes **Participant characteristics** Characteristics provided for intervention and control completers only: **Mean ages** 57-58 **Gender** 30-38% female, 62-70% male **Ethnicity** 100% Puerto Rican **SES** not reported	**Setting**: Clinic **Provider**: Medical assistant **Mode of delivery**: Face-to-face (individual level)	**Comparison** N=48 culturally targeted Information Motivation Behaviour (IMB) intervention vs. N=43 Usual care **Type**: Extended **Focus**: Lifestyle intervention (diet and physical activity) for Type 2 Diabetes self-care	**Intensity**: 1 session lasting 90 minutes	**Target behaviour outcome(s)** Physical Activity **Prioritised main outcome** Frequency of being physically active during the previous 7 days (scored 0-7, higher scores reflect more active days) **Measured**: Self-report using the diet subscale of the Summary of Diabetes Self-Care Activities questionnaire	**Duration of follow up** 3 months (81% follow up)	3 months Mean (SD) Intervention: Data missing Control: Data missing Mean difference: Data missing; p=0.23 (ANCOVA)	NA	**Adverse effects:** Not reported **Inequality issues:** Culturally targeted intervention for a minority ethnic group; although the applicability of the group to a UK setting may be minimal
Orazio et al, 2011 **REFID** 577 **Country** Australia **Design** RCT **Internal validity** + **External validity** +	**Number randomised:** N=102 **Selection / Recruitment criteria:** Adult renal transplant recipients (>6 months post-transplant) with abnormal glucose tolerance **Participant characteristics:** **Mean age** 54.8 **Gender** 60.8% Male, 39.2% Female **Ethnicity** Not reported **SES** Not reported **Other:** Mean BMI = 29	**Setting**: Hospital outpatient **Provider**: Dietician involvement is mentioned but no other mention of what other providers may have been involved in the 'multidisciplinary' intervention **Mode of delivery**: Unclear	**Comparison:** N=56 Intervention vs. N=46 Usual care **Type**: Unclear **Focus**: Using the Transtheoretical Model of Health Behaviour Change or State of Change Model to bring about lifestyle change for reduction of risk factors for obesity and CVD in post-renal transplant patients	**Intensity**: Unclear	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Change in physical activity over time **Measured**: Self-report (Physical Activity Statewide Questionnaire)	**Duration of follow-up:** Not reported	No relevant data to be found in tables. Only one directly relevant section was found on p467: "*There was no change in PA over time for the intervention group (Wilks Lambda = 0.970, F(2,99) = 1.529, P = 0.222, partial eta squared = 0.03), nor was there a significant difference between the control and intervention groups ability to meet PA guideline targets.*"		**Adverse effects:** Not reported **Inequality issues:** Not reported
Parrott et al, 2007 **REFID**14863 **Country** USA **Design** RCT **Internal validity** +	**Number randomised** N=170 **Selection/Recruitment criteria:** University students that check email at least once per day identified as not meeting national physical activity guidelines Recruited from 6 general education courses **Participant characteristics:** **Mean age** 20.2 **Gender** 61.8% male, 38.2% female **Ethnicity** 94% Caucasian **SES** Not reported	**Setting:** Participants home or where they access email **Provider:** Remote delivery **Mode of delivery:** Email (remote delivery)	**Comparison:** Intervention 1 N= 57 Positive messages vs. Intervention 2 N= 57 Negative messages vs. N= 56 Control **Type:** Brief	**Intensity:** Email messages sent every second day for 2 weeks	**Target behavior outcomes(s):** Physical activity **Prioritised main outcome:** Exercise behavior (frequency of 30 minutes of moderate to vigorous exercise sessions **Measured:** Self-report on Godin Leisure Time Exercise Questionnaire	**Duration of follow up:** 3 weeks (100% follow up)	Missing data 2 weeks (end of intervention): Intervention 1: not reported Intervention 2: 3.91 Control: 2.97 p=0.004 between intervention 1 and control, dependent on	NA	**Adverse effects:** Not reported **Inequality issues:** Not reported

External validity +			**Focus:** Exercise behaviour				baseline scores. Intervention 1 has significantly higher baseline score than control p=0.277 for the comparison between intervention 2 and control <u>3 weeks</u> (1 week post intervention): Intervention 1: Not reported Intervention 2: Not reported Control: Not reported p=0.002 between intervention 1 and control dependent on baseline scores. Intervention 1 has significantly higher baseline score than control p=0.791 between intervention 2 and control		
Stolley et al, 2008 **REFID** 2992 **Country** USA **Design** RCT **Internal validity** **+** **External validity** **+**	**Number randomised:** N=213 **Selection / Recruitment criteria:** Non-pregnant African American women aged between 30 and 65 with BMI between 30 and 50 (obese) **Participant characteristics:** **Mean age** 46.0 **Gender** 100% female **Ethnicity** 100% African American **SES** Not reported **Other:** Mean BMI 39.2 Education 14.9 years Median income $42,500 Full-time employed 71.9% Married/co-habiting 34.3%	**Setting**: University campus **Provider**: Unclear **Mode of delivery**: Face-to-face (mainly in groups but individual MI sessions were also offered, which could be in-person or by telephone)	**Comparison:** N=107 Culturally tailored intervention vs. N=106 General health (Control) **Type**: Multi-session **Focus**: Culturally adapted lifestyle intervention for black women based on Social Cognitive Theory that is focused on changes in cognitions behaviours and social support related to weight loss	**Intensity**: Twice weekly group weight loss sessions (one 90mins-long and the other 60mins-long) for 6 months. Additionally, individual monthly MI sessions lasting 20 to 30 minutes were also offered.	**Target behaviour outcome(s):** Lifestyle change **Prioritised main outcome:** Moderate or vigorous physical activity including walking minutes per day **Measured**: International Physical Activity Questionnaire-Long Format (IPAQ) measuring self-reported physical activity in previous 7 days	**Duration of follow-up:** 6 months (93% follow-up)	NA	Missing data <u>6 months</u> (end of intervention) Geometic means Intervention: 112.9 Control: 85.0 p=0.01 No SD's provided	**Adverse effects:** Not reported **Inequality issues:** Not reported

Acronyms table

ACASI	audio computer-assisted self-interview
ACSM	American College of Sports Medicine
AEC	Alcohol Expectance Challenge
AOR	adjusted odds ratio
APSD	anti-social personality disorder
AUDIT(score)	Alcohol Use Disorder Identification Test
BAI	brief alcohol intervention
BALANCE	Birth Control and Alcohol Awareness: Negotiating Choices Effectively
BASICS	Brief Alcohol Screening and Intervention for College Students
BI	brief intervention
BMI	body mass index
CABG	coronary-artery bypass graft
CAE	College of Advanced Education
CAPI	computer-assisted personal interviewing
CARET	Co-morbidity Alcohol Risk Evaluation Tool
CASI	computer-assisted self-interviewing
CBT	cognitive behaviour therapy
CD-5As	computer-delivered 5As based brief intervention
CDC	Centres for Disease Control and Prevention
CDSMP	chronic disease self-management programme
CHAMPS	Community Healthy Activities Model Program for Seniors (questionnaire)
CHD	coronary heart disease
CHF	congestive heart failure
CI	confidence interval
CM	contingency management
CM-Lite	computer-assisted simplified and low-intensity contingency management
CO	carbon monoxide
COACH	Coaching patients on Achieving Cardiovascular Health
CPA	common practice approach
CRP	cardiac rehabilitation program
CV	cardiovascular
CVD	cardiovascular disease
DDQ	Daily Drinking Questionnaire
DHAP	Division of HIV/AIDs Prevention
DIS	Diagnostic Interview Schedule
DWI	driving while intoxicated
ED	emergency department
ETC	emergency department (ED)-initiated tobacco control
EEA	evidence based application approach
EUROACTION	European Action on Secondary and Primary prevention through Intervention to Reduce Events
FFB	Fat and Fibre Behaviour Questionnaire
GSF	gender-specific feedback
GNSF	gender-non-specific feedback
GP	general practitioner
HE	health education

HIV	human immunodeficiency virus
IDS	impaired driving scale
IMB	information motivation behaviour
IPAQ	International Physical Activity Questionnaire
IQR	interquartile range
LTPA (questionnaire)	leisure time physical activity (questionnaire)
ME	motivational enhancement
MET	metabolic equivalent
MI	myocardial infarct
MSM	men who have sex with men
MSW	men who have sex with women
N	number
NA	not applicable
NB	notebook
NCHS	National Centre for Health Statistics
NRT	nicotine replacement therapy
OP	outpatient
OR	odds ratio
p	p value
PACE	Physical Activity Scale for the Elderly
(7-day) PAR	7-day Physical Activity Recall (interview)
PCI	percutaneous coronary intervention
PCP	primary care provider
PHFE	Public Health Foundation Enterprises
PNF	personalised normative feedback
RCT	randomised controlled trial
RSSD	risky single occasion drinking
RR	relative risk
SD	standard deviation
SE	standard error
SEC	standard ethyl-alcohol consumption
SES	socioeconomic status
SQUASH	Short Questionnaire to Assess Health enhancing Physical Activity
STD	sexually transmitted disease
(Alcohol) TLFB	Alcohol Timeline Follow-back
TPP	Theory of Planned Behaviour
T2DM	type 2 diabetes mellitus
UK	United Kingdom
USA	United States of America
WHO	World Health Organization
WSW	women who have sex with women