

# The effect of community-based interventions for cardiovascular disease secondary prevention on behavioural risk factors

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- 1 The effect of community-based interventions for cardiovascular disease
- 2 secondary prevention on behavioural risk factors.
- 3 Dr Emma R Lawlor,\* UKCRC Centre of Excellence for Public Health (Northern
- 4 Ireland), School of Medicine, Dentistry and Biomedical Sciences, Queen's University
- 5 Belfast, Clinical Sciences Block B, Royal Victoria Hospital, Belfast, Northern Ireland,

6 UK.

- 7 Email: elawlor01@qub.ac.uk
- 8 Dr. Declan T Bradley, UKCRC Centre of Excellence for Public Health (Northern
- 9 Ireland), School of Medicine, Dentistry and Biomedical Sciences, Queen's University
- 10 Belfast, Northern Ireland, UK.
- 11 Public Health Agency Northern Ireland, Belfast, Northern Ireland, UK.
- 12 Email: dbradley09@qub.ac.uk
- 13 **Professor Margaret E Cupples**, UKCRC Centre of Excellence for Public Health
- 14 (Northern Ireland), School of Medicine, Dentistry and Biomedical Sciences, Queen's
- 15 University Belfast, Belfast, Northern Ireland, UK.
- 16 Department of General Practice and Primary Care, Queen's University Belfast,
- 17 Belfast, Northern Ireland, UK.
- 18 Email: m.cupples@qub.ac.uk
- 19 Dr. Mark A Tully, UKCRC Centre of Excellence for Public Health (Northern Ireland),
- 20 School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast,

21 Belfast, Northern Ireland, UK.

22 Email: m.tully@qub.ac.uk

23 **Corresponding author:** Dr Emma Lawlor, elawlor01@qub.ac.uk

24 Word Count: 3254

\* Present address: MRC Epidemiology Unit, University of Cambridge School of
 Clinical Medicine, Box 285 Institute of Metabolic Science, Cambridge Biomedical
 Campus, Cambridge, CB2 0QQ, UK.

#### 28 ABSTRACT

Cardiovascular disease (CVD) is the leading cause of death worldwide, and its 29 prevalence is increasing; with limited healthcare resources, secondary prevention 30 programmes outside traditional hospital settings are needed, but their effectiveness 31 32 is unclear. We aimed to assess the effectiveness of secondary prevention cardiovascular risk reduction programmes delivered in venues situated within the 33 community on modification of behavioural risk factors. We searched five databases 34 35 (MEDLINE, EMBASE, CINAHL, PsycINFO, Cochrane library) to identify trials of health behaviour interventions for adults with CVD in community-based venues. 36 Primary outcomes were changes in physical activity, diet, smoking and/or alcohol 37 consumption. Two reviewers independently assessed articles for eligibility and risk of 38 bias; statistical analysis used Revman v5.3. Of 5905 articles identified, 41 articles 39 (38 studies) (n=7970) were included. Interventions were mainly multifactorial, 40 educational, psychological and physical activity-based. Meta-analyses identified 41 increased steps/week (Mean Difference (MD): 7480; 95% CI 1940, 13020) and 42 minutes of physical activity/week (MD: 59.96; 95% CI 15.67, 104.25) associated with 43 interventions. There was some evidence for beneficial effects on peak VO<sub>2</sub>, blood 44

pressure, total cholesterol and mental health. Variation in outcome measurements 45 reported for other behavioural risk factors limited our ability to perform meta-46 analyses. Effective interventions were based in homes, general practices or 47 outpatient settings, individually tailored and often multicomponent with a theoretical 48 framework. Our review identified evidence that interventions for secondary CVD 49 prevention, delivered in various community-based venues, have positive effects on 50 51 physical activity; such opportunities should be promoted by health professionals. **Highlights** 52 Our meta-analysis provides strong evidence that interventions for secondary 53

- CVD prevention, delivered in community-based venues, are effective in
   promoting PA; evidence for beneficial effects on peak VO2, blood pressure,
   total cholesterol and mental health is less clear.
- Evidence of their effectiveness on other behavioural risk factors is limited due to heterogeneity of reported outcome measurements.
- Effective interventions were individually tailored, based in homes, general
   practices or outpatient settings and tended to be multicomponent with a
   theoretical framework.

## 62 INTRODUCTION

Globally, cardiovascular disease (CVD) is the leading cause of mortality.[1] CVD
morbidity rates are also rapidly rising, with an estimated worldwide prevalence of
200.5 million in 2015.[2] This has had large direct and indirect social and economic
consequences, costing the UK economy in 2015 approximately £24.0 billion.[3]
Although secondary prevention and cardiac rehabilitation (CR) can reduce CVD
morbidity and mortality, their uptake is poor; in the UK, only 47% of patients attend

CR after a cardiac event.[4] Reasons for lack of participation include travel distance, 69 belief in ability to manage their condition alone and lack of time.[5] Many individuals 70 with CVD fail to change their behavioural risk factors and there is a need for 71 improved methods of delivering secondary prevention services.[6] The use of non-72 traditional healthcare settings (such as community centres, churches and leisure 73 centres) and home-based programmes in helping to overcome barriers and improve 74 uptake of secondary CVD prevention has been studied. Clark et al.'s (2010)[7] 75 review of 39 randomised control trials (RCTs) on home-based secondary prevention 76 77 programmes for coronary heart disease (CHD) found small to moderate significant improvements for quality of life, systolic blood pressure, smoking cessation, total 78 cholesterol and depression. Devi et al. (2015)[8] review of RCTs evaluating internet 79 delivered secondary interventions for CHD found some evidence for beneficial 80 effects on quality of life, dietary outcomes and PA. However, both reviews found 81 studies were of low quality and there was much heterogeneity in outcome measures 82 used. Furthermore, previous systematic reviews have focused on particular settings 83 (e.g. participants' homes),[7] specific behavioural risk factors (e.g. smoking)[9] or 84 different modes of delivery (e.g. internet).[8,10,11] There is a lack of evidence for the 85 relative effectiveness of interventions which involve various modes of delivery in 86 different venues situated within the community, on multiple behavioural risk factors. 87 Thus, we aimed to conduct a systematic review, including meta-analysis to examine 88 the effectiveness of interventions, delivered in community-based venues, on 89 modification of behavioural risk factors in the secondary prevention of CVD. We also 90 included biophysical outcomes, mental and physical health measures and total 91 mortality in our analyses in order to gain insight into the potential wider health 92 benefits of the included studies. 93

#### 94 **METHODS**

#### 95 Protocol & registration

96 We designed the review protocol (www.crd.york.ac.uk/PROSPERO; registration no.

97 CRD42015030014) based on the PRISMA statement[12]

#### 98 Eligibility criteria

We considered studies to be eligible if participants were community-dwelling adults 99 aged ≥18 years with a CVD diagnosis. Interventions needed to have a 100 lifestyle/behaviour change focus for secondary CVD prevention and address one or 101 more of: physical activity (PA), diet, smoking and/or alcohol. Comparisons were 102 either no intervention or minimal intervention. Eligible studies were those that had 103 interventions delivered within a venue situated in the community, including general 104 practices, participants' homes and community centres, excluding hospitals. 105 106 Community and population level interventions were not eligible for inclusion. Primary outcomes were the change of a behavioural risk factor for CVD: PA, diet, smoking 107 and/or alcohol consumption. Secondary outcomes included peak VO<sub>2</sub>, blood 108 109 pressure, total cholesterol, body mass index (BMI), waist circumference, mental and physical health, and total mortality. We included studies with a minimum of three 110 months' follow-up from baseline: study designs included randomised controlled trials 111 (RCT), cluster RCTs, guasi-experimental designs using a control population for 112 comparison, interrupted time-series studies, and prospective controlled cohort 113 studies.[13] Limits were set to publications in English language but no regional 114 restrictions were applied. 115

#### 116 Information sources

We conducted searches in MEDLINE, EMBASE, CINAHL, PsycINFO and Cochrane 117 library from January 2005 to 8th June, 2015 related to the concepts: CVD, health-118 related behaviours, preventive interventions[14] and study design[13] (Appendix 1). 119 120 Relevant terms were searched as subject headings, and key words relating to the subject headings were entered as truncated terms (using \*), and/or searched for as 121 adjacent terms (using "adj") (title and abstract). Terms relating to the concept of 122 123 setting were not included in the search to avoid potentially excluding or misclassifying settings, especially in different countries. We searched reference lists 124 125 of relevant systematic reviews for other potentially eligible studies.

## 126 Study selection

We imported results from searches into Refworks (v3.1, ProQuest, U.S.A.) and removed duplicates. Study titles and abstracts were screened independently by ERL and DTB. We obtained full text papers that were deemed potentially relevant and also screened independently for eligibility. In cases of disagreement or uncertainty, we reached consensus via a third reviewer (MEC or MAT).

#### 132 Data collection process

Data were extracted from our included studies independently by ERL and DTB and cross-checked for consistency. If studies provided data for multiple follow-up time points, we extracted data for the time furthest from baseline. We made attempts to contact authors to retrieve missing data.

#### 137 Risk of bias

138 ERL and DTB assessed the studies independently, using the Cochrane

139 Collaboration's tool for assessing risk of bias,[15] as being 'high', 'low' or 'unclear' for

each criterion and overall. Due to the nature of the studies, blinding of participants

was not always feasible therefore we assessed 'Blinding of participants, personnel
and outcome assessors' rather than blinding of participants alone.

#### 143 Synthesis of results

We analysed data using Review Manager (RevMan version 5.3; Nordic Cochrane 144 Centre, Copenhagen, Denmark). We used the random effects model to acknowledge 145 heterogeneity; unstandardized mean differences were used in analysis and 95% 146 confidence intervals (CI) were reported. We tested statistical heterogeneity using the 147 I<sup>2</sup> statistic and categorised heterogeneity into: low (0% to 30%), moderate (30% to 148 60%), substantial (60% to 90%) and considerable (90% to 100%). We categorised 149 follow-up from baseline outcome assessment times into subgroups of: 3 to 6 months, 150 151 7 to 12 months and >12 months.

#### 152 Additional analysis

Five studies presented their outcome data as mean change from baseline; all other studies reported the follow-up measurement values. To include data from these five studies in our analyses, we added/subtracted, as appropriate, values for change to/from the baseline means and used the standard deviation (SD) for the baseline mean in initial meta-analyses. Sensitivity analyses were conducted excluding these studies. We also conducted further sensitivity analyses, in which we excluded studies deemed to be at high risk of bias overall.

#### 160 **RESULTS**

Our electronic database searching yielded 5905 papers; three were added from reference lists of systematic reviews (Figure 1). We removed duplicates, leaving 5758 papers for title and abstract screening; full text versions of 157 papers were assessed. In total, 41 articles, reporting 38 studies, met our inclusion criteria. Six articles[16-21] reported the outcomes of three studies; for each study, the earlier
article was used as the study reference. Common reasons for exclusion were
participants' age (<18 years), no reported control group, no outcomes relevant to this</li>
review and lack of behaviour change intervention.

#### 169 Study characteristics

170 Studies included 7970 participants with a mean age of 62.3 years (SD 5.3) and 78%

of participants were male. Participants' diagnoses were reported as coronary heart

disease (CHD),[22-32] acute coronary syndrome (ACS)[19,33-38] and myocardial

infarction (MI).[16,39-46] Only one study was specifically aimed at socio-

economically deprived communities.[18]

175 The majority of interventions were multicomponent, with PA, psychological and

educational content (Table 1). For fourteen studies, the main focus was on

increasing PA,[29,31,32,36,38,39,44,46-52] one focused on smoking cessation[28]

and one on uptake of Mediterranean diet.[42] All others (n=22) focused on a

179 combination of behavioural risk factors. Only fifteen studies reported using a

theoretical framework, including the Social Cognitive (n=7)[16,26,32,36,44,50,51]

and Transtheoretical Models (n=3).[23,44,53] Most studies recruited participants

182 from hospitals, as inpatients or outpatients, and six recruited from general

183 practice.[17,22,26,47,48,54]

184 The majority of interventions (n=25) were home-based: three of these used

exclusively internet delivery, [18,29,54] 14 used exclusively telephone

delivery,[16,23,24,28,31,38,41,43,44,50-52,55,56] two used both online and

telephone delivery, [34,48] two used printed information [32,46] and four used home-

visits[39,42,45,53] with one of these also including telephone contact.[39] Seven

- studies were general practice/primary care-based.[19,22,26,33,37,40,47] Various
- 190 professional disciplines were involved in intervention delivery, most frequently nurses
- 191 (n=15),[22,26,28,30,35-37,41,43,45,47,52-54,56] doctors
- 192 (n=10),[19,26,30,33,34,37,39,41,46,47] dieticians (n=4)[23,35,40,42] and
- 193 physiotherapists (n=3).[29,39,49] Studies varied in length of follow-up: most were
- 194 less than 12 months after baseline.
- 195 Twenty-seven studies used a two-group RCT (four of these were described as
- 196 prospective),([16,37,41,43]) seven a three-group RCT design,[24,32,40,42,52,55,56]
- 197 two a cluster RCT,[26,48] one was a pilot study[28] and one was a follow-up of a
- 198 RCT by review of national datasets.[22] In regards to the 3-group RCT studies, one
- study[24] had two intervention groups that could be combined into a single group
- following Cochrane collaboration guidance.[57] Two studies[25,28] had two eligible
- intervention groups but had outcomes that could not be pooled. The remaining
- studies[18,29,34,42] had one intervention group that was eligible for inclusion.

# Table 1; Characteristics of included studies

Study/ Country	Study population + source	Mean age (years)*	Sample size	Study design	Intervention (Duration, content, intensity, theoretical framework, professional involvement)	Control	Outcomes	Follow-up	Mode of delivery of intervention
Setting: Pa	articipants' ho	mes							
Internet ba	ased delivery								
Devi et al. (2014),[54] England	Patients with stable angina; GP CHD register, postal invitation	I: 66 (SD 8) C: 66 (SD 10)	l: 36 C: 37	Randomized Controlled Trial (RCT)	6 wks: Web-based programme (introductory home visit); tailored goals for PA, diet, managing emotions & smoking review via website, email or chatroom contact with cardiac nurses.	Usual GP care (CHD annual check)	Primary: Step count Secondary: sedentary & moderate PA, EE, weight, SBP, DBP, body fat, diet, anxiety, depression, SE (general; diet; knowledge); SEE disease perception, satisfaction, HRQoL	6 wks & 6 mths	Interactive website, email & chatroom
Lindsay et al. (2008; 2009),[18, 17] England	Patients on GP CHD register	Overall: 63	l: 54 C: 54	RCT	9 mths: Given computer, broadband subscription, access to health portal; wkly drop-in sessions; phone-in support. For 6 mths:,moderator-led discussion forums & one-to-one instant messaging	Computer; broadband subscription, wkly drop-in sessions; phone-in support	Moderate PA, alcohol, smoking, second-hand smoke, diet, healthcare visits, sources of info, social support, mental health, confidence in managing health, health locus of control	6 mths & 9 mths	Website health portal
Reid et al. (2012),[29] Canada	Patients with CHD; not accessing CR; hospital	Overall: 56 (SD 9) I: 57 (9) C: 56 (9)	l: 115 C: 108	RCT	6 mths: Tailored PA plan; website access for PA tracking; 5 online tutorials (wks 2, 4, 8, 14 & 20); emails with exercise specialist.	Usual care, cardiologist: PA guidance & education booklet	Primary: Step count Secondary: ≤moderate leisure time PA, HRQoL, smoking, medication	6 & 12 mths	Interactive website & email
Telephone	based deliver	<u>y</u>		1	F	T.		1	n
Butler et al. (2009),[50] Australia	Patients at CR OP programme	I: 63 (SD 10) C: 65 (11)	l: 44 C: 46	RCT	6 wks: PA self-monitoring (pedometer); behavioural counselling & goal setting via telephone; 2 PA info brochures; based on SCT.	2 PA info brochures	Primary: Total PA & walking sessions Secondary: SEE, outcome expectancies, self-management, psychological distress, METS weight, WC.**	6 wks & 6 mths	Telephone calls
Furber et	Cardiac	l: 67 (SD 11)	l: 95	RCT	See Butler et al. (2009)	See Butler et	Primary: Total PA &	See Butler et	See Butler et

al. (2010),[51] Australia	patients; from referral database	C: 65 (12)	C: 106			al. (2009)	walking sessions Secondary: SEE, outcome expectancies, self-management, psychological distress	al. (2009)	al. (2009)
Hanssen et al. (2007),[41] Norway	Patients with acute MI; hospital	l: 61 (SD 11) C: 60 (13)	l: 97 C: 96	Prospective RCT	6 mths: Nurse-led telephone (wks 1-4, 6, 8, 12 & 24) & open telephone line: info on risk reduction, emotional support, coping, goal setting, GP/cardiologist review; theoretical basis (Lazarus & Folkman).	Usual care (physician OP clinic at 6-8 wks; GP)	Primary: HRQoL Secondary: Smoking, PA sessions	3 & 6 mths	Telephone calls
Hawkes et al. (2013);[16] Turkstra et al. (2013),[21] Australia	Patients with MI or PCI; hospital	l: 61 (SD 11) C: 60 (11)	l: 156 C: 170	Parallel group prospective RCT	6 mths: Up to 10 x 30min telephone health coaching sessions: CHD risk factor profile, feedback on risk profile, SMART goals; follow-up with usual healthcare providers; posted educational resources; based on SCT.	Usual care, 'My Heart My Life' educational resource; & quarterly newsletter	Primary: HRQoL, total PA Other: Diet, BMI, smoking, QALY, healthcare visits, satisfaction, hospital admissions, medication	6 mths	Telephone calls, posted printed info & healthcare providers if required
Lear et al. (2006),[23] Canada	Patients with ischemic heart disease; hospital	l: 65 (SD 9) C: 63 (10)	l: 130 C: 119	RCT	48 mths: 6 telephone calls: counsel, answer questions, reviewed treatment at 6, 12, 24 & 36 mths (case manager); dietician or exercise specialist available; own physician if required; participant & physician given progress report; TTM based counselling.	Usual care of GP	PA sessions, METs, diet, HRQoL, WC, SBP, DBP, smoking, LDL, HDL, glucose, TC, TC/HDL, TG, CVD risk	12, 24, 36 & 48 mths	Telephone calls; venue of counselling unclear
Lian et al. (2014),[24] China	Patients with CAD; hospital	Morning (I): 64 (SD 9) Evening (I): 62 (10) C: 61 (10)	Morning (I): 89 Evening (I): 89 C: 97	3 group RCT	12 wks: Walk ≥30 min/day on ≥5 days/wk at moderate intensity in morning or evening; advice on smoking & diet by nutritionists; telephoned wkly to ensure adherence.	Maintain usual level of PA. Given advice on smoking & diet.	Walking & total PA, TC, LDL, HDL, TG, BMI, weight, fibrinogen, white blood cell count, platelet count***	12 wks	Telephone calls
Mittag et al. (2006),[43] Germany	Patients with MI, CABG or PCI; hospital	I: 59 (SD 10) C: 61 (10)	l: 154 C: 143	Prospective RCT	12 mths: Mthly nurse telephone contact (mean of 10); counselling on PA, diet, smoking, stress, psychosocial & medical problems; based on cognitive-behavioural & health psychology; posted 6 flyers on general health.	6 flyers on general health topics posted every second mth	Anxiety, depression, being active, diet, BMI, TC, HDL, SBP, smoking, diabetes, CVD risk	12 mths	Telephone calls
Pinto et al. (2011),[44] USA	Patients with history of MI, stable angina & CABG that completed	l: 63 (SD 9) C: 64 (10)	l: 44 C: 52	RCT	6 mths: PA counselling based on TTM & SCT, using motivational interviewing via telephone wkly over first 2 mths, biwkly for 2 mths mthly for 2 mths, by Coordinator; self-monitoring (logs & pedometer); posted	Received calls at same intervals to administer symptom	Primary: ≤moderate PA/wk Secondary: Motivational readiness for exercise,	6 & 12 mths	Telephone calls; posted feedback reports

	CR				feedback reports at wks 4, 8, 12, 16 & 20; posted printed materials on CVD health.	questionnaire. Posted printed	TC, LDL, HDL,CRP, medication, peak VO <sub>2</sub> ,		
						CVD info	QoL(physical function)		
Reid et al. (2007),[28] Canada	Smokers with CHD; hospital inpatients	l: 54 (SD 9) C: 53.9 (9.0)	l: 50 C: 49	2 group pilot study	8 wks: Automated telephone calls 3, 14 & 30 days after discharge to assess smoking status; additional counselling available from	Usual care; smoking cessation	Smoking	12 & 52 wks	Telephone calls
					nurse-specialist; pharmacotherapy available.	programme; community resources			
Reid et al. (2011),[38] Canada	Patients with ACS not	Overall: 61 (SD 10)	l: 69 C: 72	RCT	12 mths: 1 face to face & 8 telephone contacts of motivational counselling with physiotherapist: gaining commitment	Usual care (Cardiology Discharge	Distance travelled, ≤moderate PA	6 & 12 mths	Telephone calls; venue of face-to-face
ounada	CR; hospital inpatients	l: 60 (10)	0.72		identifying valued outcomes, setting goals, action planning, self-monitoring, identifying	Book (health info; walking			contact unclear
		C: 61 (10)			opportunities for PA, problem solving, feedback, encouragement, intensity management & links to medical care; ecological perspective	programme)); brief PA advice from cardiologist)			
Senuzun	Patients with	I: 55 (SD 8)	I: 30	RCT	12 wks: Written & audio-visual education;	OP care	METs, exercise	12 wks	Telephone
et al.	CHD; hospital	, , , , , , , , , , , , , , , , , , ,			telephone call every 2 wks for self-efficacy		tolerance, SEE, TC, TG,		calls; delivery
(2006),[31]	inpatients	C: 53 (7)	C: 30		enhancing counselling sessions: reviewed		HDL, LDL, BMI, SBP,		of materials
Turkey					PA diary, walking goals, physiological		DBP		unclear
Wister et	Patients:	Secondary	Secondary	3 group RCT	12 mths: Annual health report card posted:	l Isual care	Primary: Global CVD risk	12 mths	Telephone
al.	recruited by	prevention	prevention	o group ito i	Telehealth counselling 6 mthly from 2		Thindry: Clobal CVD lisk	12 11013	calls, posted
(2007),[55]	GPs; poster,	group	group (I):		clinical lifestyle counsellors on smoking,		Secondary: PA sessions,		report cards &
Canada	newspaper	(I): 57 (SD 5)	153		PA, diet & stress; summaries of counselling		health confidence,		printed info
	and radio		0.110		sessions & educational materials posted.		perceived stress, diet,		
	adverts	C: 57 (5)	C: 143				IC, HDL, HRQOL,		
							BMI, WC.		
Wu et al.	Male patients	Home-based	Home based	3 group RCT	12 wks: tailored PA programme; updated	Normal levels	Primary: HR recovery	12 wks	Telephone
(2000),[52] Taiwan	CARG.		18		wks by rehabilitation purses: advised to	UFA	Secondary: Resting &		'office'
Taiwan	referred by	01 (00 0)	10		exercise ≥3 times a wk.		peak HR, workload, peak		consultation
	surgeons	C: 62 (10)	C: 18				VO <sub>2</sub>		
Yates et	Patients with	Average age	Telephone	3 group RCT	9 wks: CR booster sessions delivered by	Usual care (1	Physical function (QoL);	3 & 6 mths	Telephone
al.	CABG or MI	for each	(I): 23		nurse at 3 & 9 wks via telephone: praised,	telephone call	PA sessions; HR, SBP &		calls
(2005),[56]	who had	group not	C: 19		encouraged, discussed barriers to goals;	at 4-6 WKS to	DRA		
USA	CR	given.	0.10		guided by dandula's self-enicacy theory.	assess satisfaction &			
						risk reduction)			
Internet &	telephone bas	ed delivery				,			•

Antypas & Wangberg (2014),[48] Norway	Patients with CVD (majority MI); referred by GP	Intervention (I): 60 Control (C): 59	I: 7 8 clusters C: 12 10 clusters	2 group cluster RCT	Duration unclear. Tailored content on website & forum; messages via website & text: plan training activities/set wkly goals & remind of activities & to text post-activity; online graph feedback.	Generic website; info on CR, discussion forum, activity calendar	Primary: Total PA Secondary: SEE, social support, depression, anxiety, stage of change	1 & 3 mths	Website; online forum with text & email reminders
Blasco et al. (2012),[34] Spain	Patients with ACS; ≥1 CVD risk factor; hospital	I: 61 (SD 12) C: 61 (12)	l: 87 C: 83	RCI	12 mths: Tele-monitoring, 3 visits to cardiologist, written & verbal info on CVD prevention; sent feedback on outcomes via text message.	3 visits to cardiologist, written & verbal CVD prevention info	Smoking, LDL, SBP, DBP, Hb1A, BMI, HRQoL, anxiety	12 mth	Lext message & web-based tele- monitoring; clinic visits
Printed ma	terials based	delivery							
Sniehotta et al. (2005),[32] Germany	Patients with CHD, recruited during inpatient CR treatment	Overall: 58 (SD 10)	Not stated	3 group RCT	6 wks: Both intervention groups given individual planning session, using SCT, before discharge. Planning group: booklet for action & coping plans; Personalized wkly diary: one group also posted 6 wkly diaries; tailored personal plans.	Usual care	Behavioural intentions, SEE, action & coping planning, general PA, strenuous PA	2 & 6 mths after discharge	Printed materials. One group posted diaries
Wolkanin- Bartnik et al. (2011),[46] Poland	Patients with acute MI; OP clinic	Overall: 70	l: 59 C: 56	RCT	3 mth intervention: Exercise guidebooks & diaries; offered phone consultations with doctor.	OP care	PA tolerance, resting & exercise HR, SBP, DBP, peak workload, HR recovery; CVD events, mortality, admissions; leisure time PA	3 & 12 mths	Printed materials; option of telephone calls
Home visit	based deliver	y							
Goodman et al. (2008),[53] England	Patients on waiting list for CABG with at least one poorly controlled risk factor	l: 64 C: 66	l: 94 C: 94	RCT	12 mths (mean): Mthly appt with cardiac homecare nurse, assessed cardiac risk, counselling (motivational interviewing based on TTM); given manual; could telephone between visits. Baseline appt pre-surgery (mean wait 9 mths).	Usual care (hospital helpline telephone numbers & pre-surgery info day)	Primary: Anxiety, depression, TC, HDL, SBP, DBP, BMI, length of inpatient stay Secondary: Smoking, HRQoL, blood glucose	3 & 6 mths after baseline (unless CABG); admission & 3 mths post CABG	Home visits; printed info; option of telephone calls
Logan et al. (2009),[42] Northern Ireland	Patients with recent MI or unstable angina; Hospital Cardiology Directorate	Nutritional counselling (I): 58 (SD 8) Behavioural counselling (I): 58 (9)	Nutritional counselling (I): 14 Behavioural counselling (I): 10	3 group RCT	6 mths: Nutritional counselling (I): Diet advice & sheet (health benefits, recipes & sample meal plan); home visit from dietitian at wk 1 (optional) & at mths 1, 2 & 4; optional telephone contact with researcher. Behavioural counselling (I): as above but based on learning theory & stage of	Usual care (conventional dietary advice & diet sheet)	Diet, stage of change, vitamin C, oleic acid, EPA	6 & 12 mths	Home visits; printed info; option of telephone calls

		C: 56 (11)	C: 12		change model.				
Sinclair et al. (2005),[45] England	Patients hospitalised with suspected MI; recruited on admission	Not stated	l: 163 C: 161	RCT	6-8 wks: Nurse home-visits, 1–2 & 6–8 wks post discharge: guidance on risk factor reduction & activity; extra visits & telephone contacts if required; individualised info booklet: 6-wk PA programme, personal risk factors, useful telephone numbers, advice.	Usual care (general advice, OP follow-up, access to CR)	Primary: HRQoL Secondary: ADL, mortality, hospital readmissions, length of inpatient stay, OP attendances & car driving	Up to 100 days after baseline	Home visits, printed info; option of telephone calls
Home visit	t & telephone l	based delivery	/				<b>.</b>		
Oerkild et al. (2012),[39] Denmark	Patients with recent MI, PCI or CABG; CVD database	I: 77 (SD 6) C: 77 (8)	l: 19 C: 21	RCT	12 mths: 2 home visits in 6 wk interval from physiotherapist to develop PA programme, telephone calls between visits to answer questions; risk factor & medical management by cardiologist at baseline, 3, 6 & 12 mths; telephone calls at 4 & 5 mths	Usual care (risk factor intervention & medical management by	Primary: Exercise capacity Secondary: Lower limb strength, PA (hrs; intensity), TC, LDL,HDL,	3, 6 & 12 mths	Home visits; telephone calls
					by cardiologist to encourage PA; dietary counselling & smoking cessation offered.	cardiologist)	DBP, SBP, smoking, BMI, WHR, HRQoL, anxiety, depression, comorbidity, mortality, admissions		
Method of	delivery uncle	ar							
Astengo et al. (2010),[49] Sweden	Patients with stable angina on waiting list for PCI	I: 62 (SD 7) C: 65 (SD 8)	l: 28 C: 28	RCT	8 mths: Began 2 mths pre-PCI; bicycle ergometer ≥30 mins, ≥5 days/wk, resistance exercises & mthly meetings with physiotherapist to adjust intensity of exercise & motivate.	Usual care	TC, LDL, HDL, TG, HbA1c, CRP, interleukin, serum amyloid, 2h & fasting glucose, ApoA-1, ApoB, HR, workload, days & sessions of PA	1 wk pre PCI, 3 & 6 mths post PCI	Setting of meetings unclear
Setting: Ge	eneral practice	e/primary care	•						
Adams et al. (2007),[40] USA	Participants with ≥1: angina, CABG, CHF, MI, PTCA, stent, cathet- erization	Leap for life: 62 (SD 9) CR 61 (10) Traditional care (C): 64 (10)	Leap for Life (I): 25 CR (I): 78 C: 114	3 group RCT	Leap for life: 8-hr workshop by MDT; given workbook: info on CVD, medications, PA, diet & stress management. CR: Medical evaluation, exercise training, risk factor modification, education, counselling; one meeting with social worker & dietician.	Scheduled visits, advised on guidelines for PA, nutrition & medications	TC, LDL, HDL, TC/HDL, TG, HR, SBP, DBP, weight, BMI, medication use, depression, anxiety, psychological distress, ADL functional ability, social isolation	3, 6, 9 & 12 mths	University Medical Centre; printed info
Delaney et al. (2008).[22]	Patients with CHD; general	Not stated	l: 673 C: 670	Follow-up of a RCT by review of	12 mths: Nurse-led clinic every 2-6 mths: symptom & drug review, BP, lipid & behavioural risk factor assessment: clinical	Usual care	Total & CVD mortality, coronary events, hospital admissions	4 & 10 yrs	General practice; printed info

Scotland	practices			national datasets	protocols & record cards; leaflets on diet & programme to promote PA.				
Krebs et al. (2013),[37] New Zealand	Patients with ACS & hyper- glycaemia	Overall: 63 (SD 12)	l: 14 C: 15	Prospective 9-mth parallel design RCT	9 mths: nurse posted info: PA (green prescription), smoking cessation & diet; attend GP at 3, 6 & 9 mths to optimise risk factor management; GPs encouraged to promote existing healthcare services;	GP follow-up	Primary: Smoking, SBP, DBP, TC, LDL,HDL, TC/HDL, TG, BMI Secondary: Weight, WC, glucose & HbA1c, medication	9 mths	General practice; posted printed info & existing healthcare resources
Munoz et al. (2007),[33] Spain	Subjects with MI, angina or ischaemia within previous 6 yrs	I: 64 (SD 10) C: 64 (10)	l: 378 C: 340	RCT	3 yrs: Postal reminders to see GP every 3 mths; GPs followed guidelines on CVD prevention, provided advice on diet, PA & smoking cessation.	Usual care	Primary: Total & CVD mortality, CVD events Secondary: SBP, DBP, TC, TG, LDL, HDL, HRQoL, medications, weight, BMI, glucose	3 yrs or until an endpoint occurred	General Practice
Murphy et al. (2009),[26] Ireland	Patients with CHD; general practices	l: 69 (SD 9) C: 67 (10)	l: 360 C: 405	Cluster RCT	18 mths: GP & nurse training in prescribing & behaviour change, administrative support & quarterly newsletter. Tailored care plans: motivational interviewing, goal setting, info booklet, 4-mthly review; based on SCT.	Usual care	SBP, DBP, TC, total & CVD hospital admissions, HRQoL, diet, smoking, ≤moderate PA	18 mths	General practice; printed materials
Ortega et al. (2014),[47] Spain	Low-risk acute coronary patients; primary care & hospital	l: 55 (SD 11) C: 56 (13)	l: 30 C: 44	RCT	6-mths: Cycle ergometer exercise programme supervised by primary care nurses; 3 -5 sessions/wk; appts s at 4, 10 & 16 wks with research physicians to reinforce change in diet & smoking.	Usual care & guidelines on unsupervised walking programme	Primary: Peak VO <sub>2</sub> Secondary: TC, HDL, LDL, TG, SBP, DBP, HR recovery, weight	7 mths	Primary care centres
Redfern et al. (2009; 2010),[19, 20] Australia	ACS survivors not accessing CR; recruited as hospital inpatients	l: 62 (SD 1) C: 67 (1)	l: 67 C: 69	RCT	3 mths: GP consultation, 5 phone calls: risk factor education, assertiveness training & lifestyle goal assessment; cholesterol lowering module: healthy eating & pharma advice; choice of 2 other modules: BP lowering, smoking cessation or PA; info leaflets; pt selected preferred mgmt. option: GP directed, hospital programme, individual programme or self-help.	Usual care (pharmaco- therapy & lifestyle counselling)	PA, smoking, TC, LDL, HDL, TG, SBP, DBP, BMI, medication, depression, knowledge of CVD risk factors, freq. of medical consultations	12 mths	Tertiary referral hospital; telephone calls; printed info; local services
Setting: Of	ther								
Cohen et al. (2014),[35] France	Patients in ICU for ACS; ≥1 education modifiable	I: 58 (SD 11) C: 56 (11)	l: 251 C: 251	2 arm parallel- group RCT	12 mths: Individual consultations (1, 2, 3, 6, 9 & 12 mths, with dietician): diet evaluation, info, leaflets, discussion with partners; nurse consultations for smokers:	Usual care (1 appt with physician & cardiologist)	Smoking, PA, weight, WC, HRQoL, patient knowledge, SBP, DBP, LDL, HbA1c, medication,	12 mths	House of Education

	risk factor						adverse events		
Houle et al. (2011),[36] Canada	Patients hospitalised for ACS; hospital admissions list	I: 58 (SD 8) C: 59 (9)	I: 32 C: 33	RCT	12 mths: Self-monitoring (pedometer); PA info before discharge; family member invited; 1 phone call & 5 face to face OP consultations with nurse: barriers/solutions to increase steps; medical care from own physicians: based on SCT	Usual care (health info, access to CR, follow-up by physicians)	Step count, smoking, LDL, HDL, TC/HDL, TG, fasting glucose, HR, SBP, DBP, WC, SEE, resting HR, ApoB	PA at 3, 6, 9 & 12 mths. Other outcomes at 6 & 12 mths	OP setting; irtelephone call
Michalsen et al. (2006),[25] Germany	Patients with CAD; hospital inpatient stay	I: 59 (SD 9) C: 60 (9)	l: 48 C: 53	RCT	12 mths: 3-day retreat, then wkly 3-hr meetings for 10 wks; then 2-hr meetings every other wk for 9 mths; programme addressed: Mediterranean diet (individual advice, group discussions & cooking classes), stress management (practice techniques ≤30 mins daily) & PA.	Usual care with printed advice	Coronary calcification, HF-HRV, baroreflex, TC, LDL, HDL, TG, HR, BMI, diet, SBP, DBP, angina, HRQoL, medication, EE, relaxation sessions, smoking	12 mths	Non- residential retreat. Setting of follow-up meetings unclear
Pischke et al. (2008),[27] USA	Patients with CAD	I: 57 (SD 8) C: 59 (10)	l: 19 C: 16	RCT	12 mths: 1 wk retreat: Daily lectures by clinical psychologist on diet, cooking classes, grocery store tours, stress management, aerobic exercise & group support meetings; patients' partners invited; twice wkly group sessions for 1 yr; option to continue self-directed community.	Usual care	Anxiety, depression, social dysfunction, insomnia, social support, sense of coherence, proneness to anger, type A behaviour, PA, diet, stress management	1 & 5 yrs	Retreat at local hotel. Setting of follow-up lectures unclear.
Seki et al. (2008),[30] Japan	Males with CAD; hospital OP clinic	I: 69 (SD 3) C: 70 (4)	l: 18 C: 16	RCT	6 mths: Wkly OP CR programme: individualised exercise sessions, exercise prescription (≥30 min aerobic exercise twice wkly at home); diet instruction; education programme; individual counselling by physicians & nurses.	Usual care	Step count, EE, peak VO <sub>2</sub> , AT VO2, muscle strength, flexibility, TC, TG, HDL, LDL, BMI, WC, glucose, body fat, lean body weight, ApoA-I, ApoB, HbA1c	6 mths	Clinic-led

Mth= month, Wk= week, yr= year, mins= minutes, info= information, CVD= cardiovascular disease, CABG= coronary artery bypass grafting, CAD= coronary artery disease, TC = total cholesterol, TC/HDL= total cholesterol/ HDL ratio, LDL= low-density lipoprotein, HDL= high-density lipoprotein, HR= heart rate, SBP= systolic blood pressure, DBP= diastolic blood pressure, TG=triglycerides, BMI=body mass index, PA=physical activity, HRQoL= Health-related quality of life, HbA1c=glycated haemoglobin, Apo=apolipoprotein, SE= self-efficacy, SEE=Self-efficacy expectation, AT= anaerobic threshold, PCI= percutaneous coronary intervention, CR= cardiac rehabilitation, EPA= eicosapentaenoic acid, ADL= activities of daily living, EE= energy expenditure, WC.= waist circumference, freq.=frequency, appt = appointment, pt = patient, WHR= waist hip ratio, CRP= c reactive protein, TTM= trans-theoretical model, QALY= quality adjusted life years, OP= out-patient

\* Age shown to nearest whole number of years. \*\* Results for waist circumference divided into male & female sub-groups. The Cochrane collaboration's instructions<sup>57</sup> for combining two subgroups were followed. \*\*\* Results for the two intervention groups were combined using the Cochrane collaboration's instructions<sup>57</sup> for all outcomes reported.

# 1 Risk of bias

Overall, we judged six studies to be at high risk of bias (Table 2).[22,23,40,46,54,55]
Reasons for a judgement of high risk of bias included: lack of random sequence
generation, no blinding of personnel and/or outcome assessor, selective outcome
reporting and inappropriate use of assessments. We judged 21 studies to have a low
risk of bias and 11 as unclear risk of bias.

# 22 Table 2; Risk of bias of included studies

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants, personnel & outcome assessors (performance & detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Overall risk of bias
Setting: Partie	cipants homes						
Internet base	d delivery		Lliab	Low	Lliab		Lliab
(2014)[54]	LOW	LOW	High	LOW	High	LOW	High
Lindsay et al. (2008, 2009)[18,17]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Reid et al.	Low	Low	Low	Low	Unclear	Low	Low
Telephone ba	sed deliverv						
Butler et al. (2009)[50]	Low	Low	Unclear	Low	Unclear	Low	Low
Furber et al. (2010)[51]	Low	Low	High	Low	Unclear	Low	Low
Hanssen et al. (2007)[41]	Low	Low	Unclear	High	Unclear	Low	Low
Hawkes et al. (2013);[16] Turkstra et al. (2013)[21]	Unclear	Unclear	Low	Low	High	Low	Low
Lear et al. (2006)[23]	Low	Unclear	Unclear	High	Unclear	High	High
Lian et al. (2014)[24]	Unclear	Unclear	Unclear	Low	High	Low	Unclear
Mittag et al. (2006)[43]	Low	Low	Unclear	Low	Unclear	High	Low
Pinto et al. (2011)[44]	Unclear	Unclear	Low	Low	High	Low	Low
Reid et al. (2007)[28]	Low	Low	Unclear	Low	Unclear	Low	Low
Reid et al. (2011)[38]	Low	Low	Low	High	Unclear	Low	Low
Senuzun et al. (2006)[31]	Unclear	Unclear	Unclear	Unclear	Unclear	Low	Unclear
Wister et al. (2007)[55]	Low	Low	Low	Low	Unclear	High	High
Wu et al. (2006)[52]	Low	Unclear	Low	Low	Unclear	Low	Low
Yates et al. (2005)[56]	Unclear	Unclear	Unclear	Unclear	Unclear	Low	Unclear
Internet & tele	ephone based	delivery					
Antypas and Wangberg (2014)[48]	Low	Low	Low	High	Unclear	Low	Low
Blasco et al. (2012)[34]	Unclear	Unclear	Low	Low	Unclear	Low	Low

Printed materials based delivery							
Sniehotta et	Unclear	Unclear	Unclear	High	Unclear	Low	Unclear
al. (2005)[32]							
Wolkanin-	Unclear	Unclear	Unclear	Unclear	High	Low	High
Bartnik et al.							
(2011)[46]							
Home visit ba	sed delivery	1		1	1	1	
Goodman et al. (2008)[53]	Low	Unclear	Unclear	Low	Unclear	Low	Low
Logan et al. (2009)[42]	Low	Unclear	Unclear	Low	Unclear	Low	Unclear
Sinclair et al.	Low	Low	Unclear	Low	Unclear	Low	Low
Home visit &	telephone base	d delivery					
Oerkild et al			Unclear	Low	Unclear	Low	Low
(2012)[39]	2011	2011	Choloan	2011	Unitional	2011	2011
Method of del	iverv unclear						
Astengo et	Unclear	Unclear	Unclear	Low	Unclear	Low	Unclear
al. (2010)[49]				-		-	
Setting: Gene	ral practice/pri	mary care					
Adams et al. (2007)[40]	High	High	Unclear	High	Unclear	Unclear	High
Delaney et al. (2008)[22]	Unclear	Unclear	Unclear	Low	Unclear	High	High
Krebs et al. (2013)[37]	Unclear	Unclear	Unclear	Low	Unclear	Low	Unclear
Munoz et al. (2007)[33]	Low	Unclear	Unclear	Low	High	Low	Low
Murphy et al. (2009)[26]	Low	Low	Unclear	Low	Unclear	Low	Low
Ortega et al.	Unclear	Low	Unclear	Low	Unclear	Low	Unclear
Redfern et al. (2009, 2010)[10,20]	Low	Low	Unclear	Low	Unclear	Low	Low
Setting: Other	r	<u> </u>	<u> </u>	<u> </u>	<u> </u>		
Cohen et al. (2014)[35]	Low	Low	Unclear	Low	Unclear	Low	Low
Houle et al. (2011)[36]	Low	Unclear	Unclear	Low	Unclear	Unclear	Low
Michalsen et al. (2006)[25]	Low	Low	Unclear	Low	Unclear	Low	Low
Pischke et al. (2008)[27]	Unclear	Unclear	Unclear	High	Unclear	Low	Unclear
Seki et al. (2008)[30]	Unclear	Unclear	Unclear	Low	Unclear	Low	Unclear

23

# 24 Effectiveness of interventions

Our primary outcome for meta-analysis was PA. We had planned that the primary 25 outcomes would include diet, smoking and alcohol behaviours, but we found 26 insufficient data to include these in meta-analyses. We noted that several studies 27 also reported biophysical outcomes, mental and physical health measures and total 28 mortality; we decided to include them in our analyses in order to gain insight into the 29 potential wider health benefits of the included studies. We included 31 studies (33 30 31 articles) in the meta-analysis: seven studies[18,24,28,32,38,42,48] were excluded due to insufficient data being available or outcomes that could not be pooled. For 32 33 example, 21 different outcome measures were reported in the included studies (Appendix 2). Follow-up from baseline outcome assessment times were categorised 34 into sub-groups of: three to six months, seven to 12 months and over 12 months. 35

36 Physical Activity

In total, eight studies reported a measure of PA that could be included in our metaanalyses. Our meta-analysis of three studies[29,30,36] (322 participants) (Appendix
3) showed a statistically significant increase in numbers of steps per week for
intervention, compared to control groups (mean difference (MD) 7480 steps (95% CI
1940, 13020)) (Table 3a). A further five studies found an increase in minutes of PA
per week attributable to the intervention[16,27,44,50,51] (748 participants; MD 59.96
minutes (95% CI 15.67, 104.25)) with moderate heterogeneity.

44 Biophysical outcomes

We found a statistically significant increase in peak VO<sub>2</sub> for intervention groups
compared to controls (4 studies;[30,44,47,52] 240 participants; MD 2.06 mL/kg/min
(95% CI 0.08, 4.04)) but with substantial heterogeneity.

48 For diastolic blood pressure (DBP), we found a statistically significant decrease for

- 49 intervention groups compared to control groups (14
- 50 studies;[19,23,25,26,31,33,34,36,37,39,40,46,47,53] 2849 participants; MD -1.37
- 51 (95% CI -2.52, -0.22)), with moderate heterogeneity. However, for systolic blood
- 52 pressure (SBP), outcomes for intervention and control group participants were not
- 53 significantly different.
- 54 We found no statistically significant difference between intervention and control
- 55 groups (12 studies; [23, 25, 30, 31, 33, 34, 37, 39, 40, 50, 53, 55] 2103 participants) for BMI.
- 56 We found a small but statistically significant decrease in total cholesterol levels
- 57 between the intervention and control groups (15
- 58 studies;[19,23,25,26,30,31,33,37,39,40,43,47,49,53,55] 3150 participants; MD -0.13
- 59 (95% CI -0.25, -0.01)) with moderate heterogeneity.
- 60 Our analysis of six studies[23,30,36,37,50,55] (752 participants) showed no
- 61 significant difference in waist circumference for intervention groups compared to

62 controls.

- 63 Mental and physical health measures
- 64 We found no statistically significant effects for mental health, based on either SF-12
- 65 (4 studies; [26, 33, 35, 39] 1909 participants) or SF-36 (4 studies; [16, 34, 41, 53] 877
- 66 participants) subscales, nor for physical health (SF-12: 4 studies;[26,33,35,39] 1909
- 67 participants; SF-36: 6 studies; [16,34,41,44,53,56] 1014 participants).

68 Total mortality

- Five studies[22,29,33,39,45] (2913 participants) reported 638 deaths in total
- 70 (intervention groups: 303; controls: 335). The odds ratio (OR) for total mortality in
- intervention groups compared to controls was not significantly reduced.

# Table 3 (a); Results of initial meta-analyses

		Meta-analyses								
Outcomes	Number of trials	Number of participants	Effect size (MD; 95%	Heterogeneity (I <sup>2</sup> , %)						
		in studies	CI)							
Physical activity										
Steps per week	3	322	7480 (1940, 13020)*	9						
Minutes per week	5	748	59.96 (15.67, 104.25)*	47						
Peak VO <sub>2</sub>	4	240	2.06 (0.08, 4.04)*	72						
Blood pressure										
Diastolic	14	2849	-1.37 (-2.52, -0.22)*	50						
Systolic	16	3442	-1.79 (-4.09, 0.51)	70						
Body Mass Index	12	2103	-0.16 (-0.62, 0.31)	27						
Total cholesterol	15	3150	-0.13 (-0.25, -0.01)*	60						
Total mortality	5	2913	0.84 (0.70, 1.02)**	0						
Mental wellbeing										
SF 12	4	1909	-0.11 (-0.96, 0.74)	0						
SF 36	4	877	1.45 (-0.00, 2.90)	0						
Physical wellbeing										
SF 12	4	1909	0.50 (-0.19, 1.18)	0						
SF 36	6	1014	1.36 (-0.48, 3.21)	43						
Waist circumference	6	752	-1.32 (-4.02, 1.38)	43						

\* Significant values

\*\* Odds ratio

1 Sensitivity analyses

2 Our first set of sensitivity analyses (Table 3b) that excluded studies[33,39,47,53] which had only reported change in mean values for peak VO<sub>2</sub>, DBP, SBP, BMI, total 3 4 cholesterol, and mental and physical health, and for which we had calculated followup values, showed statistically significant improvements for intervention groups, 5 compared to controls, for DBP[33,39,47,53] (MD -2.04 mmHg (95% CI -3.37, -0.71)), 6 SBP[33,39,47] (MD -3.14 mmHg (95% CI -5.59, -0.69)) and SF-36 mental health[53] 7 (MD 1.74 (95% CI 0.10, 3.38)) (Table 3b). However, we found no significant changes 8 for peak VO<sub>2</sub>[47] BMI,[33,39] total cholesterol,[33,39,47] SF-12 mental health[33,39] 9 10 and physical health based on SF-12[33,39] and SF-36[53] outcomes. We also conducted a second set of sensitivity meta-analyses, in which we excluded 11 studies that we had determined were at high risk of bias overall.[22,23,40,46,54,55] 12 Excluded studies had reported data for DBP,[23,40,46] SBP,[23,40,46,55] 13 BMI, [23, 40, 55] total cholesterol, [23, 40, 55] waist circumference [23, 55] and total 14 15 mortality.[22] These sensitivity analyses identified no statistically significant 16 outcomes.

Sensitivity analyses for PA was not required: all studies included in the metaanalyses reported outcomes as absolute values and none were at high risk of bias
overall.

# Table 3 (b); Results of sensitivity analyses

		S	ensitivity analyses		Sensitivity analyses				
	(e)	xcluding studie	s using substituted out	come data)		(excluding hig	h risk of bias overall	studies)	
Outcomes	No.	No. of	Effect size	Heterogeneity	No.	No. of	Effect size	Heterogeneity	
	of trials	Participants	(MD; 95% CI)	(l², %)	of trials	Participants	(MD; 95% CI)	(l², %)	
Physical activity									
Steps per week	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Minutes per week	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Peak VO <sub>2</sub>	3	166	1.70 (-0.46, 3.85)	76	N/A	N/A	N/A	N/A	
Blood pressure									
Diastolic	10	1829	-2.04 (-3.37, -0.71)*	47	11	2346	-1.35 (-2.73, 0.02)	50	
Systolic	11	2126	-3.14 (-5.59, -0.69)*	59	12	2643	-1.62 (-4.59, 1.35)	73	
Body Mass Index	8	861	-0.08 (-0.73, 0.57)	25	9	1419	-0.31 (-0.71, 0.10)	0	
Total cholesterol	10	1834	-0.15 (-0.32, 0.02)	69	12	2466	-0.11 (-0.26, 0.03)	64	
Total mortality	N/A	N/A	N/A	N/A	4	1570	0.79 (0.53, 1.18)**	0	
Mental wellbeing									
SF 12	2	1151	0.35 (-0.95, 1.65)	0	N/A	N/A	N/A	N/A	
SF 36	3	689	1.74 (0.10, 3.38)*	1	N/A	N/A	N/A	N/A	
Physical wellbeing									
SF 12	2	1151	0.93 (-0.54, 2.40)	35	N/A	N/A	N/A	N/A	
SF 36	5	826	1.28 (-1.04, 3.60)	51	N/A	N/A	N/A	N/A	
Waist circumference	5	456	-1.32 (-4.82, 2.18)	50	4	207	-3.09 (-6.23, 0.04)	0	

\* Significant values

\*\* Odds ratio

# 1 Intervention settings and components

2	We were unable to conduct subgroup meta-analyses of the effect of different settings
3	and components due to the variety of these within the studies included in this review.
4	However, 14 of the studies included in our meta-analysis reported statistically
5	significant improvements on intervention outcomes: eight of these studies were
6	implemented in participants' homes,[16,23,31,44,46,51,52,55] four in general
7	practice/primary care,[19,26,33,47] one at an outpatient setting[36] and one was
8	clinic-led.[30] Nine of these studies used telephone delivery of the
9	intervention.[16,19,23,31,36,44,51,52,55] Their interventions were based on the
10	Social Cognitive Theory, [16, 26, 36, 51] the Transtheoretical Model, [23] and a
11	combination of the Transtheoretical Model and Social Cognitive Theory.[44] All these
12	interventions were individually tailored to participants; nine studies described a
13	psychological component, including counselling,[23,30,44,51,55] self-
14	monitoring,[36,51] goal setting,[26,31,36,51] motivational interviewing,[26,44] health
15	coaching,[16] self-efficacy enhancing counselling sessions[31] and social persuasion
16	strategies.[31] Only one study did not report using an education component[52] and
17	six provided printed educational materials.[16,19,26,31,46,55] Eight studies focused
18	on PA[30,31,36,44,46,47,51,52] and three used pedometers and diaries.[36,46,51]
19	In terms of overall risk of bias, we judged three of these studies to be of high risk of
20	bias,[23,46,55] three studies to be of unclear risk,[30,31,47] and the eight other
21	studies were deemed to be low risk. We found only three studies[16,44,52] to be low
22	risk of bias for both outcome measurement and overall, reporting significant
23	improvement for minutes of PA per week, [44] peak VO <sub>2</sub> [52] and SF-36 mental [16]
24	and physical health[44] subscales

#### 25 **DISCUSSION**

26 Our study has shown that interventions for secondary CVD prevention, delivered in various venues within the community, can increase PA. This is important, as 27 insufficient PA is a modifiable risk factor for CVD and premature mortality[58] and 28 there is a need for effective approaches to prevention outside of traditional medical 29 settings. Evidence for positive effects on peak VO<sub>2</sub>, blood pressure, total cholesterol 30 31 and mental health was less clear. Interventions that reported effectiveness were delivered at home, general practice/primary care or outpatient settings, 32 individualised, multicomponent and based on a theoretical framework. The relative 33 34 effectiveness of interventions with different settings, or component designs or delivery modes could not be determined due to their heterogeneity. 35 Our initial meta-analyses showed a statistically significant improvement in peak VO<sub>2</sub> 36 among the intervention groups. However, there was substantial heterogeneity in the 37 data and the sensitivity analyses excluding studies that reported outcome data as 38 mean change from baseline, did not confirm this improvement. A previous systematic 39 review[59] also found a significant improvement in peak VO<sub>2</sub> for intervention 40 participants but, this finding was based on a small number of studies. 41 We found total cholesterol to have a statistically significant decrease in the initial 42 meta-analyses but this was not confirmed in the sensitivity analyses. This initial 43 finding may be attributed to our use of data from studies that were excluded from the 44 subsequent sensitivity analyses, which had a high risk of bias overall or for which we 45

46 derived data inappropriately.

For DBP, our initial meta-analysis and the sensitivity analysis with exclusion of
studies reporting outcome data as mean change from baseline, both found

49 statistically significant decreases. However, this was not confirmed when studies with
50 high risk of bias were removed, two of which had reported a statistically significant
51 effect.

For DBP, SBP and SF-36 mental health subscale, initial meta-analyses showed no 52 statistically significant effects but the sensitivity analyses excluding studies reporting 53 outcome data as change in mean from baseline showed significant improvement. 54 The substituted data used initially may have hidden a true positive effect of the 55 interventions but the sensitivity analyses included fewer participants, so results must 56 be interpreted with caution. Given the contradictory findings between SF-12 and SF-57 58 36 for mental health outcomes and that previous literature has shown that SF-12 and SF-36 are comparable measures, [60] there is a need for further study data to allow 59 conclusive evaluation of these effects of community-based interventions. 60

Relevant other outcomes, such as behaviour change relating to diet, smoking and
alcohol use, or health service usage, hospital admissions and CVD events could not
be included in the meta-analysis. For many studies included in our review these
outcomes were not reported; for others, the multiplicity of different outcome
measures used prevented pooling of data for analyses.

Nineteen studies which were identified as being eligible for inclusion in our review used internet and/or telephone as an intervention component. Fourteen of these studies were included in our meta-analyses and were found to contribute to significant changes in PA behaviour. This interest in technology for CVD prevention is justified: 86% of households (22.5 million) in Great Britain have internet access[61] and previous systematic reviews, focused on telephone/internet CVD prevention interventions, reported favourable outcomes.[9,11] This review adds to that evidence base: one previous review[9] included only interventions delivered primarily by
internet and the other[11] included both internet and telephone delivery but focused
on primary CVD prevention.

In concordance with NICE recommendations[62], the majority of studies included in 76 our review were multicomponent. Further, previous systematic reviews, one focused 77 on home-based programmes for secondary CVD prevention and the other focused 78 on PA[7,63] also found that effective healthy behaviour change interventions were 79 those combining multiple components such as education, engagement in PA and 80 psychological support. This systematic review differs from those reviews by 81 82 examining the effectiveness of interventions, involving different modes of delivery and different community venues, for behaviour change in secondary CVD 83 prevention. 84

#### 85 Limitations

Since the majority of included studies evaluated complex multifactorial interventions, 86 we could not determine the independent contributions of different intervention 87 components or optimal combinations. Differing content of control conditions across 88 89 trials resulted in difficulty deciding if some were 'minimal intervention'. We did not limit our inclusion criteria to include only randomised studies but also included 90 91 studies which reported other designs with control groups and interrupted time series. 92 Though randomised study designs are considered most robust and can be used to 93 infer causation, we recognise that that these are not always appropriate to address questions related to community-based interventions, especially health system 94 95 interventions or implementation strategies.[64] Our exclusion of simple pre- and post-intervention studies may have resulted in the exclusion of relevant uncontrolled 96

before and after studies that may have increased the applicability of the results and 97 extended the number of settings included [65]. In planning future updates to this 98 review and those with similar scope, full consideration needs to be given to including 99 100 a wider range of study designs. Also, different countries use a variety of terms for healthcare venues, so some settings may have been categorised inappropriately. 101 The majority of follow-up times were less than 12 months and there was limited 102 103 availability of longer-term data, so long-term behaviour change could not be determined. 104

The heterogeneity of measurements reported by studies limited the number of 105 106 outcomes for inclusion in our meta-analyses: future research should plan to include standardised and objective outcome measures that have been reported previously in 107 order to allow further meta-analyses and provide conclusive evidence to inform 108 109 planning of services. We found scant detail on the content, setting, bias potential, theoretical foundation of interventions and on outcomes relating to health service 110 utilisation and cost. Despite socio-economic position being negatively associated 111 with healthy lifestyle behaviours,[66] only one study focused on socio-economically 112 deprived communities, thus there is a need for further study of this sub-group. 113 114 Similar to previous work, [7] we found few female participants in studies: greater efforts to include women would allow findings to be more generalisable. 115

#### 116 CONCLUSION

This novel review provides evidence for the effectiveness of a variety of secondary
CVD prevention programmes, delivered in venues within the community on
modification of behavioural risk factors and highlights their positive effects on PA,
peak VO2, blood pressure, total cholesterol and mental health. Healthcare

- 121 professionals may recommend participation in interventions that are based on
- 122 theoretical frameworks, tailored to individuals and delivered in community-based
- settings to promote reduction of CVD risk.

### 124 Contributions

- 125 All authors were responsible for study conception, design and initial search strategy.
- 126 ERL and DTB carried out the independent screening of articles, data extraction and
- 127 quality assessments. ERL was responsible for data analysis and for drafting the
- 128 manuscript. MEC and MAT provided consensus for inclusion of articles and
- 129 differences in extracted data. All authors contributed to manuscript revisions. All
- authors read and approved the final manuscript.

#### 131 **Conflict of interest**

132 The authors declare that there are no conflicts of or competing interests.

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