

Supplementary Material D

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
<p>Year and author: Chodosh 2005</p> <p>Country: USA</p> <p>Study type: Systematic review</p> <p>Evidence level: I</p>	<p>Aims: To assess the effectiveness and essential components of self management programmes for hypertension, osteoarthritis and diabetes</p> <p>Participants: Patients with diabetes, hypertension or osteoarthritis Classified as older but no definition of what 'older' was.</p> <p>Search period: Up to Sept. 2004</p> <p>Search method: Cochrane Library MEDLINE PsycINFO Nursing and Allied Health Indexed Bibliographies Health Care Quality Improvement Projects</p>	<p>Inclusion: Randomised controlled trials</p> <p>Exclusion: No details</p>	<p>Exposure: Self management interventions</p> <p>Comparison: Usual care or control</p> <p>Outcome measures: A1c Fasting blood glucose Blood pressure Pain Function</p> <p>Follow-up time: For hypertension- 6 weeks to 9 months For diabetes - 3 months to 32 weeks</p>	<p>Results: 53/780 potential studies included. 26 diabetes, 13 hypertension, 14 osteoarthritis.</p> <p>Hypertension 17 comparisons from 13 studies - Self management interventions decreased systolic blood pressure by 5mmHg (ES -0.39; 95%CI -0.51 to -0.28) and decreased diastolic blood pressure by 4.3mmHg (ES -0.51, 95%CI -0.73 to -0.30). P values were not given.</p>	<p>Author's conclusions: Self management programmes for diabetes and hypertension probably produce clinically important benefits</p> <p>Heterogeneity and the potential of publication bias means that the findings should be interpreted with caution.</p> <p>The important components for these programmes could not be isolated</p> <p>Reviewer's conclusions: Indirect population as included osteoarthritis, also included education only and self monitoring only interventions and not subgrouped in analysis. Not detailed the theoretical basis of any of the interventions. 'older' people not defined. There was an observed benefit in A1c and blood pressure. There was significant heterogeneity and potential publication bias.</p> <p>Source of funding: Centers for Medicare & Medicaid Services</p>

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	database Contact with experts				Additional comments:
Internal validity:	+				
Study results – precision:	+				
Applicability (external validity):	X				
Overall score:	?				

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
<p>Year and author: Bosworth 2008 Bosworth 2009a</p> <p>Country: USA</p> <p>Study type: RCT</p> <p>Evidence level: II</p>	<p>Aims: To evaluate a randomised controlled trial involving a tailored behavioural intervention to improve blood pressure control</p>	<p>Study setting: Primary care clinics</p> <p>Participant characteristics: Identified through medical database using diagnostic code. 636/ 7646 potentially eligible 66% female, 47.5% African American, 36.5% 12th grade or less education, mean age 61.5 years</p> <p>Inclusion: Diagnosis of hypertension, using hypertensive medication</p> <p>Exclusion: Not using or prescribed hypertensive medication, not residing in catchment area, kidney disease, planning a pregnancy, pregnant or breastfeeding, myocardial infarction, diagnosis of metastatic cancer in prior 3 months, cognitive disability, impaired hearing or speech, unable to fit cuff.</p>	<p>Exposure: n=319</p> <ol style="list-style-type: none"> 1) Tailored behavioural intervention alone 2) Home blood pressure monitoring and Tailored behavioural intervention <p>Intervention was telephone counseling every 8 weeks including risk of hypertension, knowledge, communication and social support, medication, weight management, exercise, diet, stress, smoking and alcohol use, goal setting</p> <p>Handouts were mailed after each intervention for reinforcement</p> <p>Comparison: n=317 Usual care or Home blood pressure monitoring alone</p> <p>Outcome measures: Morisky Self Reported Medication Taking Scale Blood pressure control Health care utilisation</p> <p>Follow-up time: 24 months</p>	<p>Results:</p> <p>The intervention group had a 9% increase in self reported medication adherence from baseline to 6 month follow-up while the increase in the control group was 1%. No P- values given.</p> <p>The combined intervention had the greatest increase in the proportion of patients with blood pressure control. At 24 months the adjusted improvement compared to usual care was 11% (P=0.012) for the combined group and 4.3% (NS) for the behavioural intervention alone group and 7.6% in the BP home monitoring group (NS).</p> <p>Compared with the usual care group the adjusted 24 months difference in systolic blood pressure was 0.6mmHg (NS) in the behavioural intervention alone group, -0.6mmHg in the home BP monitoring group (NS) and -3.9mmHg in the combined group (P=0.01). This was also reflected in decreases in diastolic blood pressure.</p> <p>There were no differences</p>	<p>Author's conclusions: Intervention is easy to administer and has indicated improvements in medication adherence at 6 months and combined intervention was effective in improving blood pressure control at 24 months</p> <p>Reviewer's conclusions: May not be representative of eligibles 27% were functionally illiterate Low attrition</p> <p>Source of funding: NHLBI, Pfizer Health Literacy Communication Initiative, American Heart Association</p> <p>Additional comments: Health Decision Model, Trans Theoretical Model using motivational interviewing</p> <p>Delivered by nurse Individualised intervention</p>

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		Poor understanding of english		between groups in health service utilisation	
Bias	Judgement			Support for judgement	
Random sequence generation	Low risk			Computer randomised	
Allocation concealment	Low risk			Sequential envelopes generated by statistician	
Blinding	High risk			No blinding reported	
Incomplete outcome data	Unclear risk			Attrition low but not sure if ITT conducted	
Selective reporting	Low risk			A priori outcomes reported	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
<p>Year and author: Bosworth 2009 Bosworth 2005</p> <p>Country: USA</p> <p>Study type: RCT – cluster randomised</p> <p>Evidence level: II</p>	<p>Aims: Examine the effectiveness of two interventions to improve blood pressure control</p>	<p>Study setting: Primary care clinic of the Durham VA Medical centre – 32 providers</p> <p>Participant characteristics: 4017 potential participants, letters to 816 and randomised 588. Mean age 63 years, 98% male, 40% African American, 51% had high school education or less. Baseline blood pressure, systolic 140, diastolic 76mmHg</p> <p>Inclusion: Followed by one of the 32 providers, diagnosis of hypertension, filled prescription for hypertensive drugs in the previous year.</p> <p>Exclusion: Chronic kidney disease</p>	<p>Exposure: n=155 provider decision support group Providers received a computer assisted medication decision support system</p> <p>N=144 to tailored behavioural intervention Nurse telephoned patients 1 week after randomisation and then every 2 months for 24 months. Content: memory, health literacy aids, social support, hypertension knowledge, patient/provider communication, medication refill reminders, appointment compliance, health behaviours, medication side effects.</p> <p>N= 150 to combined group Combination of patient and provider interventions above</p> <p>Comparison: n=143 Hypertension reminder group – Just received patients most recent BP and medication regime</p> <p>Outcome measures: Blood pressure control</p> <p>Follow-up time:</p>	<p>Results:</p> <p>There were no significant differences in changes in blood pressure control in the intervention compared with the control groups. Although the tailored behaviour intervention group had the largest change in those with adequate blood pressure control this was not significant.</p> <p>Systolic blood pressure improved over time (P=0.003) but there were no differences between groups.</p> <p>All of the intervention groups showed improvement in blood pressure control over time.</p> <p>There were no differences between groups in health care utilisation</p>	<p>Author's conclusions: Effective in increasing blood pressure control but not statistically different from control</p> <p>Reviewer's conclusions: May not be representative of eligibles. No effect of intervention on blood pressure compared with usual care.</p> <p>Source of funding: Department of Veterans Affairs</p> <p>Additional comments: Behavioural theories included Trans Theoretical Model</p> <p>Individualised</p> <p>Led by nurse</p>

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			24 months or dropout		
Bias	Judgement		Support for judgement		
Random sequence generation	Unclear risk		Randomisation unclear, however allocation okay so randomisation is probably acceptable too		
Allocation concealment	Low risk		Allocation concealment okay done centrally by statistician		
Blinding	Low risk		Outcome assessors blinded		
Incomplete outcome data	Low risk		Flow chart of attrition and reasons ITT analysis conducted		
Selective reporting	High risk		No evidence of health care utilisation being listed a priori in this paper		

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
<p>Year and author: Burke 2008</p> <p>Country: Australia</p> <p>Study type: RCT</p> <p>Evidence level: II</p>	<p>Aims: Examine changes following a self management programme for hypertensives</p>	<p>Study setting: Not clear</p> <p>Participant characteristics: 241 Recruited by advertisement. 33.5% female, baseline blood pressure systolic 126.5, diastolic 76.5mmHg</p> <p>Inclusion: Aged 40 to 70 years, treated for at least 3 months with one or two anti-hypertensive medications</p> <p>Exclusion: -</p>	<p>Exposure: n=123 Activity, Diet and Blood Pressure Trial (ADAPT) 16 week – individual and 6 interactive group workshops(1.5 hrs) and five printed modules on lifestyle, physical activity, diet and weight loss, goal setting, injury prevention, stress management, alcohol consumption, smoking cessation. Social support as motivators was encouraged. Also received tri-monthly newsletters.</p> <p>Comparison: n=118 Usual care +educational material from National Heart Foundation of Australia + 4 contact points</p> <p>Outcome measures: Perceived barriers to health Self efficacy Ways of Coping Checklist Social support Food diary Self reported physical activity Alcohol Anthropometric measures Short Fat-Intake Questionnaire</p> <p>Follow-up time: 1 year</p>	<p>Results: Self efficacy for diet and physical activity was significantly higher in the intervention group at the end of the intervention (P=0.007 and P=0.001 respectively) but this was not sustained at one year follow-up.</p>	<p>Author's conclusions: Cognitive changes and modification of behaviours were observed with a lifestyle programme aimed at hypertensive patients</p> <p>Reviewer's conclusions: Self selected Positive changes were not sustained over time</p> <p>Source of funding: Australian National Health and Medical Research Council and Australian Fisheries Research and Development Corporation</p> <p>Additional comments: Health Belief Model, Theory of Planned Behaviour, Social Cognitive Theory, Decisional Balance</p> <p>Individual and group sessions (15-25 participants)</p> <p>Led by facilitators – not described</p>

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Bias	Judgement			Support for judgement	
Random sequence generation	Low risk			Computer generated	
Allocation concealment	Low risk			Done centrally by someone not involved in the trial	
Blinding	High risk			No blinding	
Incomplete outcome data	High risk			No reasons given for attrition although <20% overall and ITT conducted	
Selective reporting	Low risk			A priori outcomes reported	

Note Decisional Balance is closely related to social cognitive theory and measures the relative importance to the individual of the benefits and harms associated with behavioural change.

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
<p>Year and author: Green 2008</p> <p>Country: USA</p> <p>Study type: RCT</p> <p>Evidence level: II</p>	<p>Aims: To determine if a new model of care that uses Web services, home blood pressure monitoring and pharmacist assisted care improves BP control</p>	<p>Study setting: A secure internet site</p> <p>Participant characteristics: Recruited from 10 medical centres in Washington State n = 778 Mean age 59.1 years, 52.2% female, 82.8% White, 41.6% some post high school education, baseline BP 151.9/89.1</p> <p>Inclusion: Uncontrolled blood pressure, taking anti-hypertensive medication Aged 25 to 75 years. No diagnosis of diabetes, cardiovascular or renal disease. Ability to use a computer, access to a computer, an e-mail address.</p> <p>Exclusion:</p>	<p>Exposure: n=259 1) Home BP + web based training – given a home BP monitor and training in how to use it and to take BP at least twice a week with 2 measurements. The goal was to have a BP of 135/85 or less. Also received training on website which included secure e-mail, refilling medications, viewing portions of medical records, use of health library, links to Group Health and community resources for lifestyle and behavioural change.</p> <p>N=261 2) Web services, home blood pressure monitoring and pharmacist assisted care As above plus additional contact from pharmacist to discuss medication and to set some lifestyle goals and to detail an action plan.. The e-mail contact very 2 weeks until BP was controlled</p> <p>Comparison: n=258 Usual care – told their BP was not under control and to work with their physician to improve it</p>	<p>Results: No differences in BP control between usual care and Home BP +Web group, although the home BP and Web group did have a significant decrease in SBP (mean change -2.9mmHg, P=0.02).</p> <p>The addition of pharmacist intervention to home BP + Web intervention resulted in 25% more patients with controlled BP compared to those receiving usual care (31%, P<0.001) and 20% more with controlled BP than home BP =Web intervention (36%, P<0.01)</p> <p>There were greater reduction in SBP in the home BP+ web + pharmacist group (difference between adjusted mean change -8.9mHg, 95%CI -11.4 - -6.31, P<0.001) compared to usual care and similarly in the group without the Pharmacist (-6.0mmHg, 95%CI -8.5 to -3.5, P<0.001). DBP also in the home BP + web + pharmacist group also decreased compared to usual care (net change -</p>	<p>Author's conclusions: Web based pharmacist led care improved BP control, particularly so for those with baseline SBP >160mmHG</p> <p>Reviewer's conclusions: Query around representativeness as 778/2937 were randomised</p> <p>There were differences at baseline in gender and already have a home BP monitoring set. Study limited to those with access to computer and with no major comorbidities.</p> <p>Source of funding: National Heart Lung and Blood Institute</p> <p>Additional comments: Based on Chronic Care Model</p> <p>Additional assistance led by pharmacists with additional training</p>

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			<p>All groups received a pamphlet 'High Blood Pressure and You' and 'The No Waiting Room'</p> <p>Outcome measures: Percentage of patients with controlled blood pressure Changes in systolic and diastolic blood pressure Changes in medication BMI Physical activity Quality of life Satisfaction Health Care utilisation</p> <p>Follow-up time: 12 months</p>	<p>3.5mmHg, (95%CI -4.9 to -2.1, P<0.001).</p> <p>For those patients with SBP>160mmHg at baseline the home BP + web + pharmacist intervention had 3,3 times more patients with controlled BP compared with usual care RR 3.32 (P<0.001), lower SBP - 13.2mmHg (P<0.001) and DBP -4.6 (P<0.001).</p> <p>BMI, physical activity, health related quality of life did not differ between the three groups.</p> <p>The intervention group were more likely to have their prescriptions refilled than the usual care group (P<0.001) or the home BP=web intervention only (P<0.01)</p>	
Bias	Judgement			Support for judgement	
Random sequence generation	Low risk			Block randomisation	
Allocation concealment	Low risk			Sequential sealed opaque envelopes	
Blinding	Low risk			Outcome assessors blinded	
Incomplete outcome data	Low risk			Flow diagram with reasons ITT conducted, attrition acceptable at 12 months	

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Selective reporting	Low risk			A priori outcomes reported	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
<p>Year and author: Lee 2007</p> <p>Country: Taiwan</p> <p>Study type: RCT</p> <p>Evidence level: II</p>	<p>Aims: Study the effect of a walking programme on blood pressure in older people</p>	<p>Study setting: Rural area of Taiwan, identified from health check database</p> <p>Participant characteristics: 202 randomised of 2312 identified from database</p> <p>Mean age 71.3 years, <4 years education 43.6%, baseline SBP 152.2, DBP 82.1</p> <p>Inclusion: Resident in local township, aged 60 years or more, resting systolic blood pressure (SBP) 140 to 179 mmHg</p> <p>Exclusion: -</p>	<p>Exposure: n=102 Usual care plus six month community based walking intervention delivered by a public health nurse. Individual contacts through face to face or telephone contact. Aim to motivate participants to walk more regularly and increase frequency and duration of walking. Given a pedometer and walking log and advice on physical activity guidelines. Discussed benefits of increased walking, how to overcome barriers, sharing information from others.</p> <p>Comparison: n=100 Usual primary health care</p> <p>Outcome measures: Blood pressure systolic and diastolic (SBP, DBP) Self Efficacy for Exercise Scale Self reported walking</p> <p>Follow-up time: 6 months</p>	<p>Results: A greater reduction in SBP was observed in the intervention group than the control group at six month follow-up (mean differences -7mmHg, P = 0.002), this effect remained after adjusting for other variables.</p> <p>There was a greater improvement in self efficacy in the intervention group compared with controls. Self efficacy for exercise was improved by a mean of 2.1 points compared with 0.8 points in the control group (P=0.001). More participants in the intervention group reported increases in their regular walking compared to controls (P<0.0005).</p> <p>No difference in diastolic blood pressure</p>	<p>Author's conclusions: A six month community based walking programme based on self efficacy theory and led by a public health nurse was effective in decreasing SBP</p> <p>Reviewer's conclusions: Participants may not represent eligibles and had a significantly lower mean age. Low attrition Positive effects of the intervention on SBP and self efficacy. Lack of differences in DBP is unsurprising considering that it was near normal at baseline</p> <p>Source of funding: None reported</p> <p>Additional comments: Theory was Stages of Change and Self efficacy Delivered by public health nurse Individual</p>
Bias	Judgement			Support for judgement	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Random sequence generation	Low risk			Randomised in blocks	
Allocation concealment	Low risk			Randomisation and block size blinded from investigator. Authors used serially numbered sealed opaque envelopes	
Blinding	Low risk			Investigators blinded	
Incomplete outcome data	Low risk			< 20% attrition, ITT analysis, reasons for losses given	
Selective reporting	Low risk			A priori outcomes reported	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
<p>Year and author: Svetky 2009</p> <p>Country: USA</p> <p>Study type: RCT – cluster randomised</p> <p>Evidence level: II</p>	<p>Aims: Evaluate the Hypertension Improvement Project</p>	<p>Study setting: Community based primary care clinics in North Carolina</p> <p>Participant characteristics: Mean age 60.5 years, 61% female, 37% Black, most had completed high school.</p> <p>Baseline blood pressure systolic 133.1; diastolic 74.1</p> <p>Inclusion: 25 years or older, hypertensive based on billing codes.</p> <p>Exclusion: Self reported chronic kidney disease, had a cardiovascular event in previous 6 months, pregnant, breastfeeding or planning a pregnancy.</p>	<p>Exposure: n=293 Physician training plus (n=145) or minus patient intervention (n=148)</p> <p>Physician intervention: 2 on-line training modules of 45 minutes duration. Received laminated decision tree card for treatment and lifestyle modification. Quality Improvement indicator and recorded patient clinical data.</p> <p>Patient intervention: 20 weekly group sessions followed by 12 monthly telephone lifestyle counseling contacts focusing on weight loss, Dietary Approaches to Stop Hypertension dietary patterns, exercise and reduced sodium intake. Self monitoring, goal setting, social support.</p> <p>Comparison: n=281 – Usual care No physician training plus (n=140) or minus patient intervention (n=141)</p> <p>The control groups received educational material only</p> <p>Outcome measures: Change in systolic blood pressure (SBP) at 6 months BMI Physical activity accelerometer</p>	<p>Results:</p> <p>At 6 months the main effect for patient intervention was - 2.6mmHg (95%CI -4.4 - -0.7; P = 0.01). The largest effect was seen in the arms for physician and patient intervention (-9.7 ± 12.7mmHg) P=0.0072 compared with usual care + physician intervention usual care with no physician training and training + no intervention .</p> <p>Those patients with higher baseline BP had a 4.0mmHg greater reduction in SBP than patients who were already at goal blood pressure (P<0.0001) indicating most effective in specific groups</p> <p>Differences did not persist at 18 months</p> <p>In the main effects analysis there was no significant effect of either intervention on moderate to vigorous physical activity.</p> <p>The patient intervention groups showed increased in intake of fruit and vegetables and dairy products and decreased in take</p>	<p>Author's conclusions: Physician and patient training combined was effective in reducing SBP at 6 months. The physician intervention may have enhanced the patient intervention.</p> <p>Reviewer's conclusions: Intervention effective in short term but was not sustained Attrition <20% at 18mth follow-up Not clear if those randomised represented the eligible population contacted.</p> <p>Intervention may be best in targeting higher risk groups as the majority of participants had well controlled BP.</p> <p>Source of funding: National Institutes of Health</p> <p>Additional comments: Motivational interviewing</p> <p>Group intervention (10-15 participants).</p> <p>Led by trained behavioural interventionists supported by community health advisors.</p>

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			Biochemical measures Lipid profile Follow-up time: 6 months 18 months	of total and saturated fat. The effects of dairy did not persist at 18 months although the other factors did persist. The patient intervention but not the physician intervention led to a significant reduction in weight ($P < 0.0001$). The effect did not persist at 18 months follow-up	
Bias	Judgement		Support for judgement		
Random sequence generation	Low risk		Computer randomisation		
Allocation concealment	Low risk		Central allocation by a statistician		
Blinding	Low risk		Blinding of outcome assessors		
Incomplete outcome data	Low risk		Pt flow diagram, attrition <20%, ITT		
Selective reporting	Low risk		A priori outcomes reported		

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
<p>Year and author: Xue 2008</p> <p>Country: China</p> <p>Study type: RCT</p> <p>Evidence level: II</p>	<p>Aims: To evaluate the benefits of a cognitive behavioural self management programme for hypertension</p>	<p>Study setting: Community and anti-hypertensive club in Shanghai</p> <p>Participant characteristics: Identified through clinic records. 140 from 569 eligible (287 were not interested). Mean age 57.45 years, 58.5% female, duration of disease 8.0 years, junior middle school and below as highest educational attainment 37.9%. Baseline blood pressure systolic 141.65, diastolic 89.57mmHg.</p> <p>Inclusion: Adults aged 18 to 69 years with physician diagnosis of mild to moderate hypertension (systolic blood pressure 140 to 180mmHg and/ or diastolic blood pressure 90 to 100 mmHg) with no evidence of serious co-morbidity such as diabetes and angina.</p>	<p>Exposure: n= 70 Cognitive behavioural intervention. Four group sessions over 5 weeks (10-12 participants) and 2.5hr sessions. Content: Basic facts on hypertension, self monitoring, physical activity, diet, alcohol, smoking, medication, goal setting and action planning.</p> <p>Also received a copy of the Hypertension Manual</p> <p>Comparison: n= 70 Wait list + information booklet</p> <p>Outcome measures: Blood pressure Weight, height and waist circumference, biochemical tests, physical activity, diet smoking, drinking Health Related Quality of Life (SF12)</p> <p>Follow-up time: Approx 4 months after end of treatment</p>	<p>Results: The intervention but not the control group experienced a significant decrease in both systolic (P<0.001) and diastolic blood pressure (P<0.001) at 1 month and 4 months after the end of the intervention. Significant difference in BMI at 4 months follow-up (mean difference 0.31 (95%CI 0.00 – 0.62; P = 0.048). The intervention group demonstrated a greater increase in physical activity per week than the control group (P<0.001). No differences in dietary behaviours between groups The intervention group had a significant improvement in HRQoL compared to the control group at 4 months follow up for physical (P=0.01) and mental (P=0.038) components.</p>	<p>Author's conclusions: A simple cognitive behavioural self management intervention led to clinically significant decreases in systolic and diastolic blood pressure and decreased BMI and increased physical activity levels.</p> <p>Reviewer's conclusions: May not be representative of eligible population. Attrition low Short duration follow-up Positive effects on blood pressure and participation in physical activity.</p> <p>Source of funding: Great Britain China Educational Trust, Henry Lester Trust Ltd.</p> <p>Additional comments: Cognitive behavioural Group intervention led by community doctor</p>

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		Exclusion: Diagnosis of diabetes, secondary forms of hypertension, target organ damage, congestive heart failure, angina, other life threatening co-morbidity such as cancer or terminal liver or kidney failure, disability preventing a walking exercise regime, inability to read or write in Chinese or cognitive disability.			
Bias	Judgement		Support for judgement		
Random sequence generation	Low risk		Randomisation codes generated by computer programme		
Allocation concealment	Low risk		Randomised by doctor who was not involved in the research in any other way		
Blinding	Low risk		Researchers were blinded		
Incomplete outcome data	Unclear risk		Attrition low, ITT analysis, however no reasons given for drop outs		
Selective reporting	Low risk		A priori outcomes reported		