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RESEARCH

Exercise on prescription for women aged 40-74 recruited through primary care: two year randomised controlled trial

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ABSTRACT

Objective To assess the effectiveness of a primary care based programme of exercise on prescription among relatively inactive women over a two year period.

Design Randomised controlled trial.

Setting 17 primary care practices in Wellington, New Zealand

Participants 1089 women aged 40-74 not undertaking 30 minutes of moderate intensity physical activity on at least five days of the week

Intervention Brief physical activity intervention led by nurse with six month follow-up visit and monthly telephone support over nine months.

Main outcome measure Physical activity assessed at baseline and 12 and 24 months. Secondary outcomes were quality of life (SF-36), weight, waist circumference, blood pressure, concentrations of fasting serum lipids, glycated haemoglobin (HbA_{1c}), glucose, insulin, and physical fitness.

Results Mean age was 58.9 (SD 7) years. Trial retention rates were 93% and 89% at 12 and 24 months, respectively. At baseline, 10% of intervention participants and 11% of control participants were achieving 150 minutes of at least moderate intensity physical activity a week. At 12 months rates increased to 43% and 30% and at 24 months to 39.3% and 32.8% (P<0.001), respectively. SF-36 physical functioning (P=0.03) and mental health (P<0.05) scores improved more in intervention compared with control participants, but role physical scores were significantly lower (P<0.01). There were no significant differences in clinical outcomes. More falls (P<0.001) and injuries (P=0.03) were recorded in the intervention group.

Conclusions This programme of exercise on prescription increased physical activity and quality of life over two years, although falls and injuries also increased. This finding supports the use of exercise on prescription programmes as part of population strategies to reduce physical inactivity.

Trial registration Australian New Zealand Clinical Trials Registry (ANZCTR) ANZCTRN012605000490673.

INTRODUCTION

Physical inactivity is a major contributor to chronic disease, including ischaemic heart disease, stroke, breast cancer, colon cancer, and type 1 diabetes.[1-4] The United Kingdom government has set a target for 70% of the population to be active by 2020[1]—that is, 30 minutes of moderate intensity physical activity five times a week, as recommended by the US Surgeon General in 1996.[5] Currently, only 40% of men and 28% of women in the UK are meeting this target,[6] with similar proportions among adults in New Zealand.[7] Although it is widely recognised that population increases in physical activity would have important public health benefit, few long term evaluations of physical activity interventions have shown improvements in clinical risk indices with increases in physical activity. Secondary prevention studies have shown that lifestyle interventions can prevent progression to diabetes,[8-10] but these studies used interventions that were too intensive and expensive to be practical from a population perspective. Studies evaluating strategies to promote physical activity in general populations have often had methodological limitations including lack of randomisation or control groups, short duration, extensive screening and exclusion criteria, and failure to blind assessors to treatment allocation.[11]

"Exercise on prescription" interventions that involve a health professional's written advice to a patient to be more physically active have been used with variable success.[12 13] The "green prescription" programme, which is widely implemented throughout primary care in New Zealand, has been shown to produce significant improvements in levels of physical activity and quality of life among "relatively inactive" (not undertaking the recommended 30 minutes on at least five days of the week) adults aged 40-79 in primary care over a 12 month period.[14] The green prescription intervention is cost effective[15 16] and produced a 10% incremental increase in adherence to physical activity among those receiving the intervention compared with the control group. Although changes in clinical indices were not statistically significant, there were trends towards reduced systolic and diastolic blood pressure and total cholesterol concentrations, which were potentially clinically significant.[17] It was not known, however, how long the increase in physical activity would be sustained past one year. We used a randomised controlled trial design to test the

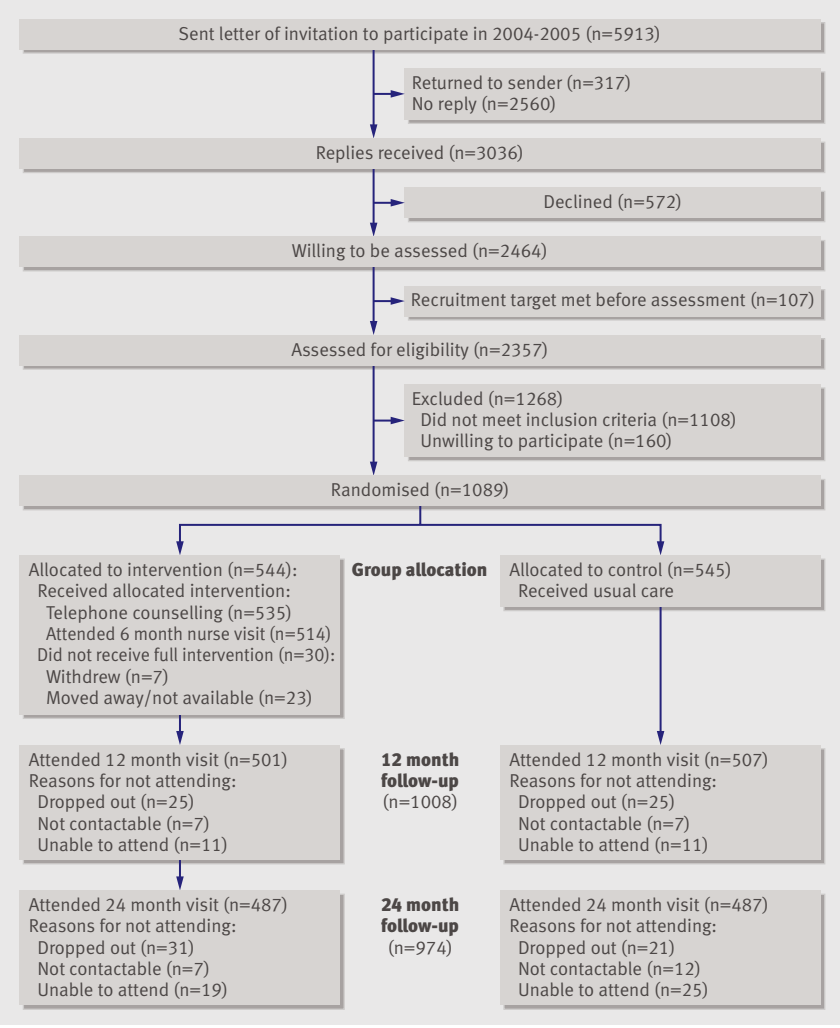

Fig 1 | Recruitment and retention of participants

effectiveness and sustainability of a primary care based programme of exercise on prescription over two years.

METHODS

Participants

Eligibility criteria included women 40-74 who were physically inactive, as determined by a one question screening tool: "As a rule, do you do at least half an hour of moderate or vigorous exercise (such as walking or a sport) on five or more days of the week?"[18 19] The screening question has been validated against the longer physical activity questionnaire (the NZPAQ-LF), which showed that the single item question had good sensitivity (76.7%), high specificity (81.1%), and a high positive predictive value (86.7%) for identifying those not achieving the recommended 150 minutes of moderate level physical activity a week.[19]

Participants were excluded if they had a medical condition that might be adversely affected by increasing their physical activity, as determined by the physical activity readiness questionnaire (PAR-Q)[20] and subsequent assessment by their own general practitioner.

Participants were recruited from two sources. The first source was an existing cohort of 50-74 year old women recruited by invitation letter from their general practitioner to a previous observational study of postmenopausal women between 1999 and 2002 from 10 primary care practices in Wellington.[21] The remainder of the participants were 50-70 year old women (40-60 years for Maori and Pacific women) recruited from 13 primary care practices in 2004-5, including two Maori health clinics. General practitioners at participating practices were asked to identify women in the age group from their practice register, excluding patients deemed inappropriate for participation in a physical activity trial. The general practitioners sent letters to those identified as suitable, inviting them to participate in a lifestyle study. The invitation letter requested that women contact the research team if they were interested in learning more about the study using the reply slip and prepaid envelope supplied. A research nurse telephoned those who replied to determine eligibility and to invite them to an interview. Interviews were held at one of six community healthcare settings.[22]

Outcome measures

Our primary outcome measure was the proportion of those achieving the recommended 150 minutes of at least moderate intensity physical activity, as assessed by the long form of the physical activity questionnaire. This self reported questionnaire asks participants about physical activity carried out in the past seven days in relation to activity type, context, intensity, and duration. It has been validated against an objective measure of energy expenditure (heart rate monitoring) and self reported physical activity logs and against the validated international physical activity questionnaire (IPAQ-Long)[23] in a study of 186 adults.[24 25]

Secondary outcomes included quality of life assessed with the short form 36 questionnaire (SF-36)[26]; weight, waist circumference, and blood pressure, recorded by trained research nurses at each visit; and concentrations of fasting serum lipids, glycated haemoglobin (HbA_{1c}), glucose, and insulin, measured from blood samples tested at one laboratory accredited by International Accreditation New Zealand (IANZ). Physical fitness was measured with a three minute step test. Twelve month recall of falls and injuries was monitored for adverse events. Outcome measures were assessed at baseline, 12 months, and 24 months. Demographic characteristics and information about medical conditions and current medications were collected at each assessment.

Randomisation and blinding

A researcher not involved in the recruitment process carried out computer generated block randomisation. We maintained allocation concealment until after we obtained written consent and completed baseline measures. After baseline measures the nurse opened sequentially numbered opaque envelopes containing the allocated treatment group (intervention or control).

Nurses assessing participants at 12 and 24 month follow-up visits were blind to group allocation, and participants were asked not to discuss group allocation with the assessing nurse.

Intervention

The intervention we assessed was built on an existing primary care programme, the green prescription, in which the general practitioner or practice nurse briefly counsels (7-13 minutes) patients using motivational interviewing techniques to increase physical activity among those who are physically inactive. The details of the exercise advice are written on a "green script," which is given to the patient and faxed to a community based exercise facilitator who provides telephone support over a three month period, assisting with choice of activity, goal setting, and ways to overcome personal barriers to physical activity.[14 27] In our study a primary care nurse delivered the green prescription and follow-up was extended to include telephone calls over a nine month period (average of five calls, each lasting 15 minutes) with an added 30 minute visit with the primary care nurse at six months. The recommended goal was moderate intensity physical activity such as brisk walking, with a goal of achieving 30 minutes five days a week. The nurse noted clinical details including weight, height, waist circumference, smoking status, and any relevant medical conditions on the faxed script.

During the visit at six months the nurse established whether the participant had increased her physical activity to the target level, provided encouragement and motivation, and measured blood pressure, weight, and waist circumference. Tools to assist with choosing appropriate types of activities and motivational aids, such as fridge magnets and activity record charts, were also offered. Further details about the intervention are available elsewhere.[22] Control participants received usual care from their primary care practice.

Table 1 | Characteristics of participants in intervention and control groups at baseline. Figures are means (SD) unless stated otherwise

Characteristic	Intervention (n=544)	Control (n=545)
Age (years)	59.1 (6.8)	58.7 (6.9)
Body mass index	29.2 (5.8)	29.2 (6.1)
Leisure exercise/week (mins)	58 (84)	60 (91)
Quality of life (SF-36):		
Role physical	90.4 (18.7)	89.8 (14.4)
Bodily pain	72.0 (23.0)	74.2 (23.3)
Vitality	59.0 (14.2)	59.5 (13.5)
Social functioning	89.2 (18.2)	89.2 (18.3)
Role emotional	92.2 (16.5)	93.4 (14.3)
Mental health	71.2 (11.9)	71.7 (10.6)
General health	76.4 (17.9)	78.0 (17.9)
No (%) of participants:		
Current smokers	67 (12)	70 (13)
Lower socioeconomic status[29]	87 (16)	75 (14)
With tertiary education	230 (42)	246 (45)
European	411 (76)	435 (80)
Maori or Pacific Islander	79 (15)	64 (12)

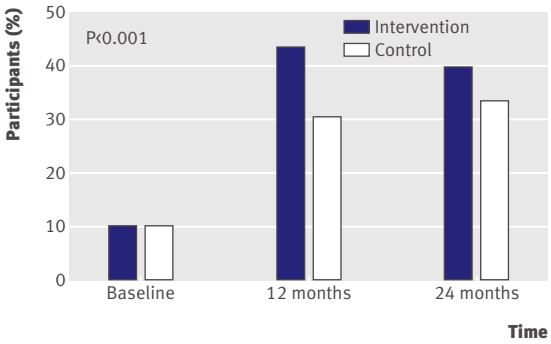

Fig 2 | Proportion of participants achieving at least 150 minutes of moderate intensity physical activity at baseline and 12 and 24 months

Sample size calculation

Based on means, standard deviations, and levels of physical activity achieved in previous trials, we calculated we needed a sample size of 880 to detect a minimum difference between the groups of 7% change in the proportion of women reaching the target level of 150 minutes of at least moderate intensity physical activity each week, allowing for a 10% attrition rate (α=0.05, 80% power).[14 28] This sample size was adequate to detect as significant, a difference between the groups in secondary outcomes of 3 mm Hg diastolic blood pressure, 4 mm Hg systolic blood pressure, 0.25 mmol/l serum cholesterol, 0.1 mmol/l high density lipoprotein cholesterol, and 0.2% HbA_{1c}.

Statistical analyses

We carried out an intention to treat analysis of all participants enrolled in the study according to allocation of randomisation, regardless of adherence to physical activity. For missing data at follow-up assessments, we assumed no change from baseline. Final analyses were undertaken with regression models, adjusted for repeated measures and baseline values, in SAS version 9.2. Non-normally distributed data were log transformed.

RESULTS

We recruited participants from 17 primary healthcare practices in Wellington and in 2004-5 enrolled 1089 less active women. Figure 1 shows the progression of participants through the trial. Characteristics of the study participants were balanced at baseline (tables 1 and 2). Trial retention rates were 93% and 89% at 12 and 24 months, respectively.

Both groups increased their physical activity over the two years. Mean physical activity levels, however, were higher (P=0.01) and a greater proportion reached the target of 150 minutes of at least moderate intensity physical activity in the intervention group compared with the control group at 12 months (233 (43%) *v* 165 (30%), (P<0.001), with levels declining but still

Table 2 | Primary and secondary clinical outcome measures and adverse events in intervention and control groups at baseline and 12 and 24 months. Values are means (SD) unless stated otherwise

Outcome measures	Intervention (n=544)	Control (n=545)	P value*
Primary			
No (%) completing at least 150 minutes physical activity/week:			
Baseline	56 (10)	62 (11)	<0.001
12 months	233 (43)	165 (30)	
24 months	214 (39)	179 (33)	
Median (interquartile range) minutes physical activity/week:			
Baseline	30 (0-90)	30 (0-90)	0.01†
12 months	120 (0-210)	75 (0-170)	
24 months	105 (0-205)	90 (0-190)	
Secondary			
Systolic blood pressure (mm Hg):			
Baseline	122.8 (0.7)	123.4 (0.8)	0.50
12 months	120.6 (0.7)	121.9 (0.7)	
24 months	119.1 (0.7)	119.5 (0.7)	
Diastolic blood pressure (mm Hg):			
Baseline	73.8 (0.4)	74.7 (0.4)	0.96
12 months	71.5 (0.4)	72.4 (0.4)	
24 months	71.6 (0.4)	71.7 (0.4)	
Weight (kg):			
Baseline	73.2 (0.6)	72.7 (0.6)	0.60
12 months	72.6 (0.6)	72.7 (0.6)	
24 months	72.6 (0.6)	72.5 (0.6)	
Waist circumference (cm):			
Baseline	86.7 (0.6)	86.2 (0.6)	0.70
12 months	87.3 (0.5)	87.3 (0.5)	
24 months	88.7 (0.6)	88.7 (0.6)	
Cholesterol (mmol/l):			
Baseline	6.10 (0.05)	6.03 (0.05)	0.90
12 months	5.86 (0.04)	5.83 (0.04)	
24 months	5.65 (0.04)	5.59 (0.04)	
High density lipoprotein cholesterol (mmol/l):			
Baseline	1.65 (0.02)	1.63 (0.02)	0.40
12 months	1.73 (0.02)	1.71 (0.02)	
24 months	1.66 (0.02)	1.66 (0.02)	
HbA_{1c} (%):			
Baseline	5.55 (0.02)	5.46 (0.03)	0.60
12 months	5.70 (0.02)	5.61 (0.02)	
24 months	5.74 (0.02)	5.69 (0.02)	
Insulin (pmol/l):			
Baseline	41.3 (1.2)	41.0 (1.2)	0.70
12 months	45.8 (1.2)	46.7 (1.3)	
24 months	48.6 (1.3)	48.4 (1.3)	
Glucose (mmol/l):			
Baseline	5.02 (0.03)	4.96 (0.02)	0.99
12 months	4.97 (0.03)	4.96 (0.03)	
24 months	4.92 (0.03)	4.87 (0.02)	
Adverse events			
No (%) of falls:			
Baseline	138 (25)	155 (29)	<0.001
12 months	158 (32)	127 (25)	
24 months	179 (37)	143 (29)	
No (%) of injuries:			
Baseline	77 (14)	103 (19)	0.03
12 months	91 (18)	86 (17)	
24 months	92 (19)	66 (14)	

*Analyses took into account repeated measures and adjusted for baseline values. Data that were not normally distributed were log transformed.
†Significance calculated after log transformation of data because of skewed nature of data.

significantly different at two years (214 (39%) *v* 179 (33%), fig 2 and table 2). SF-36 physical functioning (P=0.03) and mental health (P<0.05) subscores were also significantly better in the intervention group at 12 and 24 months, although role physical scores were lower in the intervention group (P<0.01) (table 3). There were no significant differences between groups in any of the secondary clinical outcomes (table 2). There was also no significant difference in the proportions on antihypertensive (P=0.90) or lipid lowering (P=0.80) drugs between the groups over the two years. Adjustment for medication did not significantly change the results on blood pressure and lipid outcome in sensitivity analyses. More falls (P<0.001) and injuries (P=0.03) were recorded in the intervention group compared with the control group over the two years (table 2). We deviated from planned analyses in the omission of data relating to physical fitness (a secondary outcome) as the potential for inaccuracies in the recording of pulse rate meant the quality of the data was questionable and not analysed here.

Although a large proportion of control participants increased their physical activity during the trial, only 2.4% (11/480 women contacted) recalled having received a green prescription from their doctor or nurse during the data collection period.

DISCUSSION

Exercise on prescription can increase physical activity and improve some variables of quality of life over two years among physically inactive women recruited through primary care compared with usual care. In our study, however, the increased levels of physical activity did not produce significant improvements in clinical or biochemical variables, and there were increases in falls and injuries and a reduction in the SF-36 role physical score.

The increases in physical activity were most marked at 12 months. We expected deterioration over time in physical activity after 12 months and, although levels had declined by 24 months, they were still substantially higher than at baseline and significantly higher in the intervention group than in the control group.

Comparison with other studies

The two year follow-up makes this study one of the first primary prevention physical activity trials to show a significant effect of physical activity counselling over two years. The activity counselling trial compared two behavioural counselling approaches of different intensities (intervention arms) with brief advice from a physician and written materials (control arm). The intensive interventions produced more improvement in cardiorespiratory fitness in women but not men over two years, but there was no change in self reported physical activity in men or women.[30] However, there was no true control group. The activity counselling trial also assessed adverse events and found that each year about 30% sustained a musculoskeletal event after the intervention in all three groups, which was higher than

the rate of injury in either group in our trial, although the rate of falls in our trial was about 30%.

The recently reported "ProActive" randomised controlled trial in primary care involved adults with a family history of diabetes who were randomised to a one year behaviour change programme (delivered by telephone or face to face) or to a control group (given an advice leaflet on physical activity).[31] At one year, daytime physical activity had improved in both groups, but there were no significant differences between them. Similar to the present study, the ProActive trial showed improvements on some measures of quality of life but no improvements in clinical variables.[31] The positive impact of physical activity on quality of life, in addition to cardiovascular benefits, has been well documented and is associated with positive health outcomes.[32 33]

The incremental increase in physical activity in our study was more than was found with the briefer green prescription intervention over one year (12.5% *v* 10% at 12 months) and similar improvements were observed in quality of life variables.[14] In the earlier green prescription trial, participants indicated that more follow-up with health professionals might help with adherence to physical activity.[14] The current intervention provided this extended follow-up.

Strengths and limitations

The strengths of this study include the large sample size, the inclusion of a representative sample of ethnic minorities (Maori and Pacific people), high retention rates at two years (89%), and blinding of outcome assessment. Adverse events were monitored and cost variables were collected for subsequent analysis of cost effectiveness. The intervention could be used beyond the research setting as the simple version of the green prescription is already disseminated widely throughout primary care in New Zealand; in 2007, 87% of general practitioners issued a green script and over 20 000 patients were supported nationally.[34] Furthermore, the use of a simple and validated question to identify inactive patients[19] can also be used in everyday primary care to identify those who would benefit from a physical activity intervention.

Limitations of this study include the inability to blind participants to the intervention. Participants in both groups showed a high uptake of physical activity. This positive effect in the control group might have reflected a trend in the population, participation in a study about physical activity, or the fact that those who agreed to take part in a trial were more motivated to change anyway than those who declined. Furthermore, the time spent with the research nurse at each assessment might have acted as an intervention in itself. Contamination is unlikely as few participants in the control group reported having received a green prescription (the basic version of the intervention used) during the study.

Although participants were recruited through primary care, their participation was by special invitation and the delivery of the intervention was not part of routine care. Even so, the basic green prescription is already part of routine care in New Zealand. The focus on older women, the self selected nature of participants, and the overall participation rate of 19.5% (1089/5913 invited minus 317 returned to sender) might further limit the generalisability of results to younger women and to men. Of those assessed for eligibility, however, we excluded 47% as they were already physically active, which is in line with national data on physical activity levels.[7]

The absence of a significant difference in secondary clinical end points is not surprising and might be partly due to the increase in overall physical activity in the control group. Therefore, while this sample size was large enough to detect quite small differences in physical activity between the groups, it was not large enough to detect as significant any differences in clinical outcomes. There is, however, a well established relation between increasing physical activity and health benefit, so showing a small increase across a population has health benefits and can be cost effective considering the low cost of the intervention.[16]

The use of a self reported measure as the main outcome is a potential weakness but, when validated against an objective measure, the physical activity questionnaire performed well.[24 25] Objective measures of physical activity, such as activity monitors, would have added to the validity of these findings. Adverse events of falls and injuries were also self reported so were open to recall bias.

Table 3 | Mean change (95% confidence interval) in quality of life outcomes in intervention and control groups from baseline to 12 and 24 months

	Intervention		Control		
SF-36 subscale	12 months	24 months	12 months	24 months	P value*
Physical function	2.17 (1.12 to 3.21)	−0.09 (−1.13 to 0.94)	0.07 (−0.97 to 1.11)	−0.91 (−1.94 to 0.12)	0.03
Role physical	−1.09 (−2.80 to 0.62)	−2.03 (−3.84 to −0.21)	1.64 (−0.07 to 3.35)	1.35 (−0.47 to 3.16)	<0.01
Bodily pain	−0.53 (−2.56 to 1.49)	−1.56 (−3.67 to 0.56)	0.28 (−1.74 to 2.30)	−0.40 (−2.51 to 1.71)	0.5
Vitality	2.24 (1.33 to 3.15)	1.63 (0.72 to 2.54)	0.98 (0.09 to 1.87)	1.88 (0.97 to 2.78)	0.3
Social functioning	1.21 (−0.55 to 2.97)	−1.14 (−2.95 to 0.66)	0.47 (−1.27 to 2.22)	0.16 (−1.64 to 1.96)	0.8
Role emotional	1.28 (−0.17 to 2.72)	2.02 (0.59 to 3.45)	0.05 (−1.40 to 1.49)	0.73 (−0.69 to 2.16)	0.2
Mental health	1.73 (0.82 to 2.63)	1.49 (0.54 to 2.44)	0.51 (−0.39 to 1.42)	0.39 (−0.56 to 1.34)	<0.05
General health	2.69 (1.54 to 3.84)	1.26 (0.02 to 2.51)	1.17 (0.03 to 2.32)	0.20 (−1.05 to 1.44)	0.09

*Analyses took into account repeated measures and adjusted for baseline values.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Achieving 30 minutes of moderate intensity physical activity on five or more days a week is associated with a substantial reduction in the risk of many chronic diseases and improves quality of life

Secondary prevention studies have shown the effectiveness of programmes for reducing inactivity and chronic disease

Few primary prevention programmes have produced sustainable increases in physical activity

WHAT THIS STUDY ADDS

This programme of exercise on prescription increased physical activity and improved some variables of quality of life over two years

This finding supports the role of exercise on prescription programmes in reducing population levels of physical inactivity

There was a small increase in falls and injuries associated with the programme

Conclusions

Programmes of exercise on prescription can produce sustained increases in physical activity among less active middle aged and older women over two years. Furthermore, a second face to face session with prolonged monthly telephone support might improve the effectiveness of the current brief interventions delivered in primary health care.[14] There is now widespread acceptance that an increase in physical activity to recommended levels has considerable health benefits, including an estimated 20-30% reduction in all cause mortality.[1 35 36] Therefore, reducing physical inactivity by 10% across a primary care population of less active adults could have considerable health impact.

Improving the modifiable risk factors of physical inactivity and obesity at a population level will require multiple measures including legislation, public health media messages, and environmental changes as well as dietary and physical activity programmes.

We thank the women who participated in this trial and the primary care practices from which participants were recruited.

Contributors: BAL was the principal investigator, conceived the study, and contributed to the study design and writing the paper. SBR, CRE, ACD, and AF were coinvestigators and all contributed to the study design. SBR was the project and data manager and performed preliminary data collation and formatting and contributed to writing the paper. CRE and SAM performed the data analyses and contributed to writing the paper. ACD and AF contributed to the interpretation of results and the final draft of the paper. All authors read and approved the final version of the manuscript. Data collection and entry were performed by Selina Brown, Rita Neve, Alice Paul, Jane Bowers, Esther Sweet, and Lucetta Reid. The Kapiti branch of Sport Wellington Region (Helene Kay) provided the telephone counselling to study participants. BAL is guarantor.

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Ethical approval: This work was approved by the Central Region Ethics Committee (formerly the Wellington Ethics Committee) in September 2004 (WGT/04/08/061). Participants gave written informed consent to participate in this study.

Competing interests: None declared.

Provenance and peer review: Not commissioned; externally peer reviewed.

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