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*Title:* The effects of a multi-modal intervention trial to promote lifestyle factors associated with the prevention of cardio-vascular disease in menopausal and post menopausal Australian women.

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## ABSTRACT

The purpose of this study was to test the efficacy of a multi-modal intervention (Women's Wellness Program) to improve women's cardio-vascular risk factors. This twelve week randomized experiment with a control group targeted women 50-65 years living in the general population. Women in the intervention group were provided with a consultation with a Registered Nurse at which biophysical cardio-vascular risk measures were taken and health education was provided in both verbal and written form. Women were encouraged to review their smoking, nutrition and water intakes and to commence an exercise program which included aerobic fitness exercises. Women in the control group continued their normal activities. The sample consisted of 90 women aged 50-65 years. Pre- and post-intervention assessment utilized seven measures of cardio-vascular risk factors: waist to hip ratio, body mass index, blood pressure, heart rate, weight, exercise levels and smoking.

Analysis of covariance indicated that the intervention was effective in improving women's aerobic exercise activity and decreasing smoking. The data from all five biophysical outcome measures supported the efficacy of the intervention, with significant decreases seen in the women's waist-hip ratios, body mass index, blood pressure and measured weight. Study implications suggest that this type of intervention may provide an effective, clinically manageable therapy for women who prefer a self-directed approach to preventing and decreasing cardio-vascular risk factors.

# INTRODUCTION

The leading cause of death in Australia in 2000 was cardiovascular disease (CVD) accounting for 39% of all deaths (Australian Bureau of Statistics, 2002). The majority of these deaths from CVD occurred in people aged 50 years and over (ABS, 2002), with the risk of developing CVD increasing with age. The disease burden for

cardiovascular disease in 1996 accounted for 22% of all disease burden, with the health and economic costs being greater than any other disease, accounting for \$3.7 billion and 12% of the total health costs of Australia (ABS, 2002). In American women, CVD is the number one cause of death and is the primary source of disability (American Heart Association, 2004), occurring in 1 in 10 women aged 45-64 and 1 in 5 women aged 65 years and older (Whitlock and Williams, 2003). At the global level, 1 in 3 women die from heart disease (Australian Heart Foundation, 2004).

Cardiovascular disease, therefore, is an important major public health issue for older women, with women developing symptoms at around ten to fifteen years older than their male counterparts (American Heart Association, 1997). Although initially women have a decreased risk of developing CVD than men prior to menopause, their risk equals and eventually outstrips men in the post-menopausal phase (Wagner, 1998). Also importantly, women who have CVD have higher rates of mortality than men with the same disease (Rogers, Jacobsen & Pellikka et al, 1998).

Previous research suggested a protective effect for preventing CVD in post menopausal women from the use of combined oestrogen and progestin therapy (HRT). Recent findings, however, suggests an adverse effect of HRT on coronary disease and a two-fold increase in venous thrombosis and pulmonary embolus in the first year of use. Research also found a lack of CVD prevention in HRT users as compared to placebo. (HERS research group, 2002; Writing group for the Women's Health Initiative Investigators, 2002). Based on these findings, HRT is, therefore, not recommended for preventing CVD in women, so it is timely and very important that other clinical management strategies are explored.

Changes in behaviour and lifestyle including, diet, tobacco intake, and levels of physical activity are associated with the changing rates of death and illness due to CVD over this century (ABS, 2002). Cardiovascular disease is largely preventable, with women being able to modify, treat or control most risk factors, including sedentary lifestyle, smoking, high blood pressure, high cholesterol and obesity (AWHONN, 2004). The three health behaviours of tobacco use, dietary habits and physical inactivity account for approximately one-quarter (23%) of all preventable deaths, (Whitlock & Williams, 2003), and are relatively common among women.

The leading preventable cause of CVD in women is cigarette smoking, which is attributed to more than 50% of myocardial infarctions occurring in middle aged women (Australian Heart Foundation, 2004). The consumption of large amounts of fats within developed countries is associated with obesity and high cholesterol and in turn increases the CVD risk. People who are physically inactive and obese are at a greater risk than others of developing CVD (ABS, 2002), with the ABS claiming that lack of physical activity is one of the factors for the increasing rates of CVD. Recent trends show that more females are smoking (especially in younger age groups) than males (ABS, 2002), the proportion of obese women is higher than that of men and fewer women than men report engaging in physical activity (Whitlock & Williams, 2003).

Research has shown that many women do not necessarily, however, have control over SES influences and their associations with these preventable causes. It has been found that lone mothers, for example, were significantly more likely to be smokers than partnered mothers, with no significant differences seen between the two groups for obesity or physical activity (Siahpush, Borland & Scollo, 2002; Young, James & Cunningham, 2003). Smoking was identified for lone mothers as being linked to considerable life stresses, depression and distress, suggesting links

between the health behaviours, psychosocial factors and CVD health (Young, James & Cunningham, 2003).

The challenge for health professionals is to promote women to accommodate these health behaviour and lifestyle changes in an effective and manageable way. For example In exploring women who participate in physical activity, it has been found that physiological, behavioural and psychological variables are all related, (Sallis, Howell and Mofstetter, 1992; Sallis & Havill, 1990). Smokers have been found to be more likely to drop out of exercise programs (Dishman & Sallis, 1994) and although percentage of body fat is not a powerful predictor of physical activity habits, it has been found that obese people are more likely to be inactive (Pate et al., 1995). Facilitative strategies such as education, coaching, feedback and supportive phone calls have on the other hand been found to increase participation to exercise programs (Waltman, Twiss, Gross et al, 2003).

According to Association of Women's Health, Obstetric and Neonatal Nurses (2004), health care professionals have failed to discuss and screen for CVD in women and have not been in the forefront of encouraging behaviour modification and positive lifestyle activities. It is important therefore to provide for health professionals an effective, clinically manageable therapy for use with women to prevent and decrease cardio-vascular risk factors. The aim of this study is to evaluate the effectiveness of a multi-modal intervention (WWP) for women to promote lifestyle factors associated with the prevention of cardiovascular disease, specifically, assessing dietary habits, increased physical activity and tobacco cessation.

# **METHODS**

## **Subjects**

The sample was recruited from a subset of women who participated in a study titled; *'The Queensland Midlife Women's Health Study' (QMWHS)* conducted in 2001, where 1500 women, randomly selected from the electoral role from six selected postcodes in South-East Queensland, were invited to take part in a survey questionnaire. Six-selected postcodes from the regions were used to enable low and high socio-economic, and rural and metropolitan areas to be cross-tabulated in the study. Women were considered eligible for inclusion in the study if they are able to speak, and understand English, were female and were aged between 45 and 60 years of age.

Two hundred and forty women were randomly selected to take part in this present study from the 886 women who responded positively to the QMWHS. The representation from the six-selected postcodes was evenly distributed between high/low socio-economic and rural/metropolitan areas, suggesting good representation from the general population. The response rate was 55.4% which left 133 women to be randomised into the intervention and control groups. The 133 randomly selected women were mailed a consent form that included the following: a study description, the potential risks and benefits and the possibility of being selected to take part in the WWP. All cases and controls were randomly assigned into an intervention or control group. Randomisation was achieved by allocating the surveys to group 1 (intervention) or group 2 (control) sequentially as they were received. Of the 133 women, 67 (50%) were invited to take part in the intervention program and 66 (50%) were allocated to control. 47 (70%) of the selected intervention group accepted the invitation to undertake the program (see figure 1).

## Procedures

Intervention Group

The intervention group were invited to participate in a 12 week program incorporating cognitive-behavioural strategies to facilitate positive lifestyle changes for preventing CVD risk factors. Items of interest for these analyses are presented for the CVD risk factor variables. All the procedures and interventions in this study were approved by the Queensland University of Technology ethics committee prior to beginning the study.

The intervention group was provided with a 40 minute consultation with a registered nurse, which outlined the 12-week program, and included an individual health education and goal setting session. This was provided personally to each woman where biophysical measures of weight, height, blood pressure, waist and hip circumference, and heart rate were taken. Women received their results of these measures and together with the registered nurse set goals to achieve over the next three months. In the area of nutrition; participants were asked to increase water intake (6-8 glasses/day), minimise saturated fats and increase monounsaturated and polyunsaturated fats, increase fruit and vegetable intake (5-7 /day), increase calcium (1500mg/day) and increase phytoestrogen dietary intake (40mg/day).

Women were requested to increase their water intake to enhance weight loss/maintenance and improve hydration. This was because, we have found that women often mistake thirst for hunger (when the body is dehydrated) signalling women to eat when they really require water. Women were also requested to aim to increase their dietary phytoestrogen intake to 40mg/day. Women were recommended to consume whole foods that contain isoflavones, particularly for the cardiovascular benefits of these foods (The North American Menopause Society, 2000).

All the women received written health education material including a copy of the book 'The Menopause Made Simple Program' (Anderson & Graham, 2002), as well as receiving a Program Journal. The journal titled: 'The Women's Wellness Program Journal' included three sections. Section one titled; Your Personal Journal, was divided into twelve weeks and was designed to take women through each step of the program, giving them daily or weekly focus points. It encouraged the women to bring together the various components of the health education provided and put them into their life over a twelve week period. Section two titled: Your Weekly Exercise Planner included a weekly exercise planner, where women were encouraged to plan ahead for their exercise in the following week. Section three was titled: Your Daily Diet and Exercise Record, and was broken down into segments where women were encouraged to record the following daily measures in their journal: calcium foods (mg), phytoestrogen foods (mg), water intake (glasses per day) and exercise activities including: aerobic (mins), strength (mins) and pelvic floor exercises (minutes).

Women then received a second consultation at the end of the twelve weeks where biophysical measures were again recorded and the daily diet and exercise records were collected. All of the women also undertook a survey questionnaire at T2. Facilitative strategies promoting adherence to the intervention were education, monthly letters and a research study website. Participants were also welcome to phone or e-mail the registered nurse throughout the 12 weeks if they had any questions or concerns or wanted further information (refer to figure 2).

## Control Group

The women in the control group completed surveys at T1 and T2 and were encouraged to continue their normal daily activities.

#### Instruments

Women in both the intervention and control groups received pre and post assessments. These assessments were undertaken at T1 (prior to intervention) and T2 (12 weeks from commencement of the intervention). The women completed a questionnaire which included measures for socio demographic factors, menopausal status, height/weight ratios, mental health, vitality, social functioning, general health, physical functioning, bodily pain, diet, use of hormone replacement therapy, use of prescription and complementary medicines, smoking, alcohol and caffeine use, exercise and activity levels, co-morbidities, menopausal symptoms, previous health checks including pap smears, self and professional breast checks and urine control. Test re-test of the questionnaire demonstrated a high level of repeatability and a high reliability co-efficient (Cronbach's alpha 0.85). Items of interest for this analysis include menopausal status, socio demographic, smoking use and exercise and activity levels.

The questions determining menopausal status ask the women about their monthly period/menstruation, and lead to categorising women as pre-menopausal, menopausal and post menopausal. Postmenopausal women are determined from those women who have had no menstrual bleeding in the previous twelve months. Women who were defined as late peri menopausal were determined from women who have had a menstrual period in the previous twelve months but not in the previous three months. Early peri menopausal women are determined from those who have experienced irregularity in their periods over the previous twelve months, but have had a menstrual period in the previous three months. Premenopausal women were determined from those women who had reported no irregularity in their periods in the previous three months.

The women were asked the following questions in relation to smoking use; *do you smoke cigarettes at all*? Women had a choice of response as yes or no; and *if yes, how many cigarettes do you usually smoke per week*?, with women providing a response of number of cigarettes/week.

Exercise and activity levels were measured using two sets of questions, the first include questions used with permission from Woods and Mitchell, Seattle Mid-life Study, University of Washington, and included the questions: *General daily activity includes activities such as housework, caring for children, shopping, gardening or activity at work. It does not include exercising. How do you describe your current general daily activity level?* The women were given a choice of response as very active (involves strenuous labour), moderately active, mildly active (some walking/stair climbing) or sedentary (mostly sitting). The second question asked: *During the past month, how many times did you exercise for at least 15 minutes at a time? (Exercise includes activities such as callisthenics, jogging, racquet sports, team sports, dance classes, brisk walking, lifting weights, etc)*, women were given a choice of response including: daily, 5-6 times a week, 3-4 times a week, 1-2 times a week, none.

Section three of the journal provided specific pages to record adherence of the physical activity component of the intervention. All participants recorded in their journal frequency of performing aerobic exercise, with the goal being 5-7 exercise sessions per week.

Women in the intervention group only were assessed for biophysical measures including: height, weight, waist and hip circumference, blood pressure and heart rate.

Height in centimetres was measured at baseline only. Weight in kilograms was measured at baseline and at time 2. The same standing scale was used throughout the study. Women were dressed in light indoor clothing without shoes. Body Mass Index (BMI) was calculated as (weight [in kilograms]/height [in meters]<sup>2</sup>. The waist: hip ratio (WHR) was obtained by dividing the circumference of the waist, measured at the narrowest point superior to the hip, by the circumference of the hip, measured at the greatest gluteal protuberance. The blood pressure and heart rate were measured using the same sphygmomanometer (with heart rate monitor), with the women in the sitting position, at both time points.

# Theoretical Framework:

The multi-modal intervention targets the enhancement of self-efficacy in the women and is based on Bandura's Self-Efficacy model (Bandura, 1977). Self-efficacy is defined as; *"the belief in one's ability to successfully accomplish particular behaviours"*, and is seen as a major determinant of one's choice of activities, including the amount of time and effort that one devotes to the activity. The multiintervention program has endeavoured to utilise the dynamics that Bandura asserted to enhance self-efficacy in promoting positive lifestyle behaviours including: the behavioural techniques and cognitive strategies of goal setting and self-efficacy; health education to incorporate healthy choices and positive behaviours; and social support through registered nurse consultations, ongoing support and follow up.

# Statistical analysis:

Data entry and analysis was undertaken using the Statistical Package for the Social Sciences (SPPS) software (Version 11.5). During the data analysis phase, socio demographic and baseline variables for the intervention and control groups were analysed to ensure compatibility between the two groups. The potential confounding variables including age, country of birth, education level, employment and marital status were controlled for.

T-tests were used to calculate and compare smoking use, biophysical measures, adherence to exercise activity and current exercise and activity levels with the mean differences observed at each time point for the two groups. Repeated measure analysis were undertaken to explore the differences over the two time points. Efficacy analysis was designed to evaluate the changes in scores of the major dependent variables from Time 1 to Time 2 using analysis of covariance (ANCOVA) for exercise and activity levels and smoking use.

# RESULTS

There were no statistical differences between the two groups in the socio demographic characteristics; menopausal status, exercise activity and smoking status. A significant difference was observed for marital status (P=0.05), with a higher percentage of the control group describing themselves as being widowed or never married. Most of the women were married (68%), Australian born (80.0%) and were aged between 55-60 years (61%), with family incomes of between \$20 – 60,000 (46.6%). The majority of women were educated to high school level <12 years education (60%) and were currently working, either in part-time (30%) or full-time (27%) employment. The menopausal status of the women included pre-menopausal (1%), peri-menopausal (13%) and post-menopausal (86%) women (refer to Table 1).

## Insert Table 1 here

Regarding exercise and smoking activity, 3% of the women identified themselves as sedentary, 27% as mildly active, 59% as moderately active with only 11% describing themselves as very active. Most of the women undertook some weekly aerobic activity lasting in duration for 15 minutes or more with 30% undertaking it 1-2 times per week; 23% 3-4 times per week and 13% 5-6 times per week. About one quarter (22%) of the women were doing no aerobic activity at all (refer to Table 2).

## Insert Table 2 here

## Exercise and Activity level and Smoking Use

The ANCOVA results indicate that the intervention was effective in increasing women's weekly aerobic exercise (p=0.00) and in decreasing their smoking use (P=0.02). General daily activity levels (excluding exercise [P=0.12]) did not show significant differences between the intervention and control group (refer to table 3).

#### Insert Table 3

#### Bio-physical cardio-vascular risk factor measures

Significant changes were seen in the intervention group between the following preand post-intervention bio-cardio-vascular risk factor measurements, including; waist to hip ratio (0.03), body mass index (0.02), diastolic blood pressure (0.02) and measured weight (0.02). Changes were also seen in the systolic blood pressure (0.08), however this did not reach significance. Changes in the resting heart rate (0.19), between T1 and T2 did not reach significance (refer to Table 4).

#### Insert Table 4

## Adherence to the Intervention Protocol

A high level of adherence to the intervention regimen was recorded in the women's logbooks. A total adherence score for the exercise component was calculated as the sum of the number of occurrences of each of the activities per week. The women were requested to aim to undertake 5-7 aerobic sessions per week; 2 strength training sessions per week and pelvic floor exercises daily. The mean adherence rates for weekly exercise activity included: aerobic activity (M = 4.35, SD=3.71); strength training (M=2.11, SD=1.86) and pelvic floor exercises (M=3.98, SD=2.52).

In the area of nutrition the adherence to the intervention was recorded as milligrams per day in the areas of calcium and phytoestrogen intake with the goals being 1500mg per day for calcium intake and 40mg per day for phytoestrogen intake. A high level of adherence to phytoestrogen intake was seen with the mean being 40.11mg/day (SD 24.01). The women's mean daily calcium intake was 730 mg/day (SD 463.62). Women were also requested to record their water intake by glasses of water per day with a goal of reaching 6-8 glasses per day. Women reported a high level of adherence to water intake with the mean being 5 glasses per day (SD 2.56)

## Drop Outs

Of the 113 women who began the study,10 of the controls and 11 of the intervention group failed to complete T2 questionnaires leaving 56 controls and 36 of the intervention group eligible for analysis Primary reasons for drop-outs were family

health priorities, planned recreational travel and a perceived lack of time to complete the program and maintain a journal.

#### DISCUSSION

These study findings suggest that a multi-modal intervention of health education, exercise and nutrition can improve menopausal and post-menopausal womens' cardio-vascular risk factors. The high level of adherence to the intervention suggests that women could comfortably incorporate this multi-modal intervention into their daily lives.

The broad improvement shown by combining health education, nutrition and exercise suggest that multi-modal interventions warrant further study in helping women decrease their cardio-vascular risk factors. Our study found that women in the intervention group increased their aerobic exercise activity and decreased their smoking use significantly compared to those in the control group. Results also showed that all five biophysical outcome measures supported the efficacy of the intervention, with significant decreases seen in the women's waist-hip ratios, body mass index, blood pressure and measured weight. Kuller, Simkin-Silverman and Wing et al., (2001), undertook a case/control study on women assigning them to a lifestyle intervention program aimed at improving their diet and fitness habits and a control group who received no intervention. Their findings revealed at the end of the intervention, the women weighed less, had lower BMI's and had higher metabolisms. (Kuller, Simkin-Silverman and Wing et al., 2001). Brown et al, (2000) also found that physical activity had benefits for women in terms of lowering their blood pressure. and further studies have recognised that physical activity has a protective role for women in reducing the risk of cardiovascular disease (Kushi et al., 1997; Brown et al 2000)

The belief in ones' ability to accomplish behaviours successfully is seen as a major reason for choosing the amount, time and type of activity that women undertake. The positive results seen from this research may be linked to the use of Bandura's Self Efficacy framework in the design of this study (Bandura, 1977). This intervention used dynamics within the intervention to enhance self-efficacy in promoting positive lifestyle behaviours. Goal setting, positive discussion and social support through registered nurse consultations, support and follow up, and extensive health education was provided to promote healthy choices and positive behaviours. The relationship that developed between the registered nurse and participants might have also increased the participants' motivation.

There were some limitations in our study design which might have influenced the findings. This study determined the effect of a multi-modal program on CVD risk factors in post menopausal women. Further studies to assess the effectiveness of the three components separately, compared with the multi-modal approach are recommended in the future. Secondly the significant results reflect modest gains, however, the literature has reported that even modest improvements, if they are sustained, confer valuable benefits over time. Further studies would benefit from including further time points at 12 and 24 months post-intervention to measure the sustainability of the program.

In conclusion, the study found that the intervention was effective in improving women's aerobic exercise activity and decreasing smoking. Significant decreases were seen in the women's waist-hip ratios, body mass index, blood pressure and measured weight. The findings from the present study contribute significantly

towards providing an effective, clinically manageable therapy for women who prefer a self-directed approach to preventing and decreasing cardio-vascular risk factors.

Variable	Fieque	encies (percentage	=)		
	Whole Sample	Case	Control	Chi-square	
Age	N=90	N=36	N=54	P = 0.10	
50-54	27 (30.0%)	13 (36.1%)	14 (25.9%)		
55-60	55 (61.1%)	22 (61.1%)	33 (61.1%)		
61-65	8 ( 8.9%)	1(2.8%)	7 (13.0%)		
Marital Status	N=90	N=36	N=54	P=0.05	
Married	61 (67.8%)	27 (75.0%)	34 (63.0%)		
de facto	6 (6.7%)	3 ( 8.3%)	3(5.6%)		
Separated	3 (3.3%)	1 (2.8%)	2(3.7%)		
Divorced	6 (6.7%)	4 (11.1%)	2(3.7%)		
Widowed	0 (0%)	0	7 (13.0%)		
Never Married	7 (7.8%)	1 (2.8%)	6 (11.1%)		
Education level obtained	N=90	N=36	N=54	P=0.73	
Completed primary	11 (12.2%)	2 ( 5.6%)	9 (16.7%)		
Junior high School <10	30 (33.3%)	11 (30.6%)	19 (35.2%)		
High School 11-12	13 (14.4%)	8 (22.2%)	5 (9.3%)		
Trade, tech cert or dip	17 (18.9%)	10 (27.8%)	7 (13.0%)		
Uni or college	13 (14.4%)	4 (11.1%)	9 (16.7%)		
other	6 (6.7%)	1 (2.8%)	5 (9.3%)		
Total Annual Income	N=87	N=36	N=54	P=0.14	
<10,000	4 (4.4%)	0	4 ( 7.4%)		
10,001-20,000	15 (16.7%)	4 (11.1%)	11 (20.4%)		
20,000-40,000	21 (23.3%)	9 (25.0%)	12 (22.2%)		
40,000-60,000	21 (23.3%)	11 (30.6%)	10 (18.5%)		
60,000-80,000	8 (8.9%)	4 (11.1%)	4 (7.4%)		
>80,000	13 (14.4%)	6 (16.7%)	7 (13.0%)		
don't know	5 (5.6%)	2 ( 5.6%)	3 ( 5.6%)		
Current Employment Status	N=90	N=36	N=54	P=0.15	
Full time	24 (26.7%)	14 (38.9%)	10 (18.5%)		
Part time	27 (30.0%)	6 (16.7%)	21 (38.9%)		
Home duties	20 (22.2%)	11 (30.6%)	9 (16.7%)		
Full time student	1 (`1.1%)́	0` ´	1 ( 1.9%)		
Retired	15 (16.7%)	5 (13.9%)	10 (18.5%)		
Perm ill/unable to work	3 ( 3.3%)	0` ´	3 (5.6%)		
Country of Birth	N=90	N=36	N=54	P=0.53	
Australia	72 (80.0%)	30 (83.3%)	42 (77.8%)		
UK&Ireland	14 (15.6%)	5 (13.9%)	9 (16.7%)		
Netherlands	2 ( 2.2%)	0` ´	2 ( 3.7%)		
Other	2 ( 2.2%)	1 ( 2.8%)	1 ( 1.9%)		
Menopausal Status	N=90	N=36	N=54	P=0.44	
Pre-menopausal	1 ( 1.1%)	1 ( 2.8%)	0		
Peri-menopausal	12 (13.3%)	5 (13.9%)	7 (13.0%)		
Post-menopausal	77 (85.6%)	30 (83.3%)	47 (87.0%)		

Table 1: Description of the Sample.Participants were 90 women aged between 50-65who participated in the Women's Wellness Program Study, 2003.

Table	2:	Exercise	Frequencies
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Variable	Freque			
	Whole Sample	Case	Control	Chi-square
General Daily Activity*	N=90	N=36	N=54	0.21
Sedentary	3 (3.3%)	1 (2.8%)	2 (3.7%)	
Mildly active	24 (26.7%)	14 (38.9%)	10 (18.5%)	
Moderately active	53 (58.9%)	17 (47.2%)	36 (66.7%)	
Very active	10 (11.1%)	4 (11.1%)	6 (11.1%)	
Weekly Aerobic Exercise	N=90	N=36	N=54	0.31
None	20 (22.2%)	6 (16.7%)	14 (25.9%)	
1-2 times a week	27 (30.0%)	14 (38.9%)	13 (24.1%)	
3-4 times a week	21 (23.3%)	11 (30.6%)	10 (18.5%)	
5-6 times a week	12 (13.3%)	4 (11.1%)	8 (14.8%)	
daily	10 (11.1%)	1 (2.8%)	9 (16.7%)	
Current Smoker	N=90	N=36	N=54	0.09
Yes	12 (13.6%)	2 ( 5.9%)	10 (18.5%)	
no	78 (86.4%)	34 (94.4%)	44 (81.5%)	

not including planned aerobic exercise

Group		-		Change Mean	Score SD	Paired T- test	ANCOVA Significance#
Case (N=34)	2.68 0.63	3 2.76	0.55	0.09	0.71	0.47	0.12
Control (N=54)	2.85 0.6	5 2.80	0.76	0.06	0.59	0.49	
Case (N=33)	2.52 1.0	0 3.27	1.18	0.76	1.25	0.00	0.00
Control (N=54)	2.72 1.4	3 2.70	1.31	0.02	0.85	0.87	
Case (N=32)	5.56 1.	75 6.25	1.96	0.69	1.87	0.04	0.57
Control (N=53)	4.92 2.3	34 5.53	2.16	0.60	1.70	0.13	
Case (N=32)	1.94 0.	24 1.84	0.36	0.09	0.29	0.83	0.02
Control (N=54)	1.83 0.	37 1.81	0.39	0.02	0.23	0.56	
	Case (N=34) Control (N=54) Case (N=33) Control (N=54) Case (N=32) Control (N=53) Case (N=32)	Mean S   Case (N=34) 2.68 0.63   Control (N=54) 2.85 0.63   Case (N=33) 2.52 1.0   Control (N=54) 2.72 1.4   Case (N=32) 5.56 1.7   Control (N=53) 4.92 2.3   Case (N=32) 1.94 0.	Mean SD Mean   Case (N=34) 2.68 0.63 2.76   Control (N=54) 2.85 0.65 2.80   Case (N=33) 2.52 1.00 3.27   Control (N=54) 2.72 1.43 2.70   Case (N=32) 5.56 1.75 6.25   Control (N=53) 4.92 2.34 5.53   Case (N=32) 1.94 0.24 1.84	Mean SD Mean SD   Case (N=34) 2.68 0.63 2.76 0.55   Control (N=54) 2.85 0.65 2.80 0.76   Case (N=33) 2.52 1.00 3.27 1.18   Control (N=54) 2.72 1.43 2.70 1.31   Case (N=32) 5.56 1.75 6.25 1.96   Control (N=53) 4.92 2.34 5.53 2.16   Case (N=32) 1.94 0.24 1.84 0.36	Mean SD <t< td=""><td>Mean SD Mean SD Mean SD Mean SD Mean SD SD   Case (N=34) 2.68 0.63 2.76 0.55 0.09 0.71   Control (N=54) 2.85 0.65 2.80 0.76 0.06 0.59   Case (N=33) 2.52 1.00 3.27 1.18 0.76 1.25   Control (N=54) 2.72 1.43 2.70 1.31 0.02 0.85   Case (N=32) 5.56 1.75 6.25 1.96 0.69 1.87   Control (N=53) 4.92 2.34 5.53 2.16 0.60 1.70   Case (N=32) 1.94 0.24 1.84 0.36 0.09 0.29</td><td>Mean SD Mean SD Mean SD test   Case (N=34) 2.68 0.63 2.76 0.55 0.09 0.71 0.47   Control (N=54) 2.85 0.65 2.80 0.76 0.06 0.59 0.49   Case (N=33) 2.52 1.00 3.27 1.18 0.76 1.25 0.00   Control (N=54) 2.72 1.43 2.70 1.31 0.02 0.85 0.87   Case (N=32) 5.56 1.75 6.25 1.96 0.69 1.87 0.04   Control (N=53) 4.92 2.34 5.53 2.16 0.60 1.70 0.13   Case (N=32) 1.94 0.24 1.84 0.36 0.09 0.29 0.83</td></t<>	Mean SD Mean SD Mean SD Mean SD Mean SD SD   Case (N=34) 2.68 0.63 2.76 0.55 0.09 0.71   Control (N=54) 2.85 0.65 2.80 0.76 0.06 0.59   Case (N=33) 2.52 1.00 3.27 1.18 0.76 1.25   Control (N=54) 2.72 1.43 2.70 1.31 0.02 0.85   Case (N=32) 5.56 1.75 6.25 1.96 0.69 1.87   Control (N=53) 4.92 2.34 5.53 2.16 0.60 1.70   Case (N=32) 1.94 0.24 1.84 0.36 0.09 0.29	Mean SD Mean SD Mean SD test   Case (N=34) 2.68 0.63 2.76 0.55 0.09 0.71 0.47   Control (N=54) 2.85 0.65 2.80 0.76 0.06 0.59 0.49   Case (N=33) 2.52 1.00 3.27 1.18 0.76 1.25 0.00   Control (N=54) 2.72 1.43 2.70 1.31 0.02 0.85 0.87   Case (N=32) 5.56 1.75 6.25 1.96 0.69 1.87 0.04   Control (N=53) 4.92 2.34 5.53 2.16 0.60 1.70 0.13   Case (N=32) 1.94 0.24 1.84 0.36 0.09 0.29 0.83

## Table 3 Exercise and Smoking Activity: Total Means and ANCOVA Significance

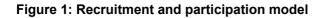
\*not including planned aerobic exercise #p-value for ANCOVA comparing post-test scores controlling for pre-test scores No significance found for the selected confounding variables including: age, country of birth,

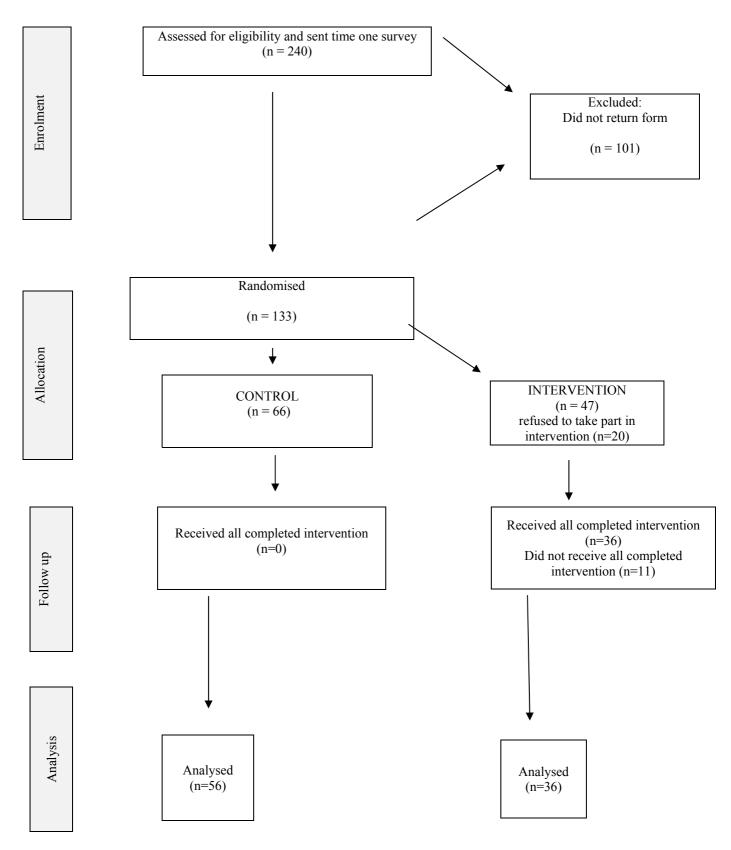
education level, employment status and marital status

+at Time 1, the control case and control group showed no significant differences in all variables.

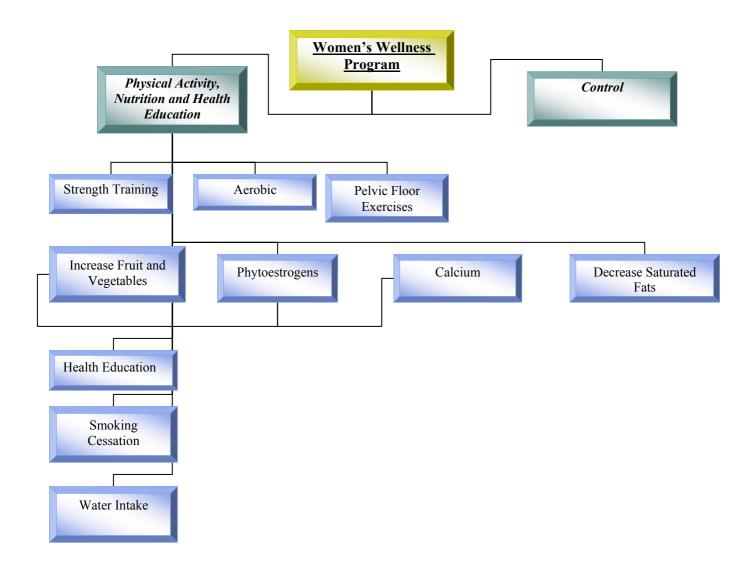
Biophysical	Time 1		Time 2		Change		Paired T-
Cardio-vascular risk factors	Mean	SD	Mean	SD	Mean	SD	test
Waist to Hip ratio (WHR) (N=36)	0.82	0.39	0.80	0.04	0.01	0.03	0.03
Body Mass Index (BMI) (N=35)	27.91	5.34	27.54	5.24	0.37	0.94	0.02
Systolic blood pressure (N=36)	137.91	18.43	133.21	22.21	4.70	15.20	0.08
Diastolic blood pressure (N=36)	79.24	10.44	75.33	10.22	3.91	10.27	0.02
Resting heart rate (n=31)	76.16	12.17	73.55	10.18	3 2.61	10.85	0.19
Measured weight (N=35)	71.66	12.53	70.66	12.1	1 1.00	2.46	0.02

Table 4: Bio-physical Cardio-Vascular Risk Factor Measures (Intervention Group)









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