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Moderators and mediators of behaviour change in a lifestyle program for treated hypertensives: a randomized controlled trial (ADAPT)

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Abstract

We aimed to examine moderators and mediators of behaviour change in a cognitive lifestyle program for drug-treated overweight hypertensives in Perth, Australia. We collected data at baseline, 4 months (post-intervention) and 1-year follow-up in a randomized controlled trial of a program that focused on weight loss, diet, and exercise. Mediation analysis used regression models that estimate indirect effects with bootstrapped confidence limits. Outcomes examined were saturated fat intake (% energy) and physical activity (hours per week). In total, 90/118 individuals randomized to usual care and 102/123 to the program-completed follow-up. Sex was a moderator of response post-intervention for diet and physical activity, with a greater response among women with usual care and among men with the program. Change in self-efficacy was a mediator of dietary change post-intervention [effect size (ES) −0.055, 95% confidence interval (CI) −0.125, −0.005] and at follow-up (ES 0.054, 95% CI −0.127, −0.005), and in physical activity post-intervention (ES 0.059, 95% CI 0.003, 0.147). These findings highlight different responses of men and women to the program, and the importance of self-efficacy as a mediator. Mediators for physical activity in the longer term should be investigated in other models, with appropriate cognitive measurements, in future trials.

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Introduction

Effective programs for lifestyle modification should be based on knowledge of factors that influence response (moderators), as well as possible mechanisms that bring about behaviour change (mediators). There is little information about these roles for cognitive variables in behaviour change [1, 2]. Kraemer *et al*. [3] have highlighted the potential for data from randomized controlled trials of behaviour modification programs to inform practice.

Moderators interact significantly with outcome but are uncorrelated with treatment [3]. Mediators have usually been identified according to the causal steps approach of Baron and Kenny [4]. This requires that treatment affects outcome, treatment affects the mediator, changes in the mediator are related to changes in outcome, and changes in the mediator remain associated with outcome after adjustment for treatment. This method lacks statistical power [5], partly arising from the need for a significant effect of treatment on the outcome, which may not be achieved without large samples and at least moderate effect sizes (ESs). More powerful statistical methods [5], do not have this requirement. These authors found the greatest power and lowest Type I error rates using the difference of coefficients or its equivalent, the product of coefficients [6]. Inaccessibility of appropriate statistical tables and the non-normal distribution of the test statistic

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have been practical issues in applying these methods. Preacher and Hayes [6] have published programs for use with standard statistical software which provide estimates of indirect effects of possible mediators along with bootstrapped 95% confidence limits and overcome these problems.

We examined mediators, assessed using the method of Preacher and Hayes [6], and moderators in a randomized controlled trial comparing usual care to a 4-month lifestyle program (ADAPT: activity, diet and blood pressure trial) for hypertensive patients, treated with antihypertensive drugs, with measurements at baseline, the end of the program and after an additional year of follow-up. Relative to usual care, scores for the importance of barriers to a healthy diet and barriers to physical activity fell both at the end of the program and 1 year later; dietary self-efficacy improved both at 4 months and 1 year later, while exercise self-efficacy was significantly greater in the program group after 4 months but not at follow-up [7]. External coping strategies decreased in the program group relative to usual care both at 4 months and at follow-up while consumption coping strategies also decreased at 4 months but not at follow-up. At follow-up, but not at the end of the program, beliefs about the benefits of a healthy diet and the benefits of physical activity increased with the program relative to usual care, as did social support from relatives.

At the end of 4 months, ambulatory blood pressure (ABP) was lower in the program group and a greater proportion of men, but not women, in that group had control of BP adequate for cessation of antihypertensive medication [8]. At follow-up 1 year later, groups did not differ significantly in ABP or in the proportion needing antihypertensive drugs. There was a greater decrease in weight and in central obesity in the program group at both time-points [9]. Relative to usual care, at the end of the program there was a decrease in dietary fat (total and saturated), sodium and energy intake; physical activity increased, as did consumption of fish and vegetables. One year later, dietary fat remained lower in the program group and intake of fish and vegetables was greater than with usual care. Blood levels of cholesterol and triglycerides showed a greater fall in the program group at the end of the 4-month program; at follow-up, high-density lipoprotein cholesterol was higher and insulin was lower in the program group.

As moderators of behaviour change we examined: sex, age, educational level and BP, number of antihypertensive drugs prescribed, social support, depression, anxiety, stress, coping mechanisms, stages of change and behaviour-specific self-efficacy at entry to the study. Mediation analysis focused on cognitive variables which were related to behaviour change as previously reported [7], namely, self-efficacy; barriers to behaviour change; beliefs about the benefits of behaviour change; support from relatives and the coping mechanisms of 'consumption' that included 'drank alcohol to help me forget my problems' and 'external' that included 'discussed my feelings with someone'.

Methods

Men and women aged 40–70 years with body mass index >25 kg m^{-2} and treated with one or two antihypertensive drugs for at least 3 months were recruited by advertisement [8]. All individuals were being currently treated with antihypertensive drugs at entry to the study. Exclusion criteria included clinic BP >160/90 mm Hg, consumption >2 fish meals or 4 fish oil capsules per week, alcohol intake >4 standard drinks per day for women and 6 standard drinks per day for men, drug- or insulin-treated diabetes, chronic renal failure (serum creatinine >120 μ mol l^{-1}), chronic liver disease, symptomatic cardiovascular disease <3 months, other chronic debilitating disease, the use of antihypertensive drugs for indications other than hypertension, such as the use of β-blockers for arrhythmias.

The population from which volunteers were recruited is predominantly Caucasian and all participants were Caucasian. After a 2-week baseline, participants were randomized to the program or to usual care by the biostatistician using computer-generated random numbers. Individuals in either group whose mean 24-hour ABP <130/85 mmHg at the end of 4 months had antihypertensive drugs withdrawn or the dosage reduced with careful monitoring. The study was approved by the Human Research Ethics Committee of the University of Western Australia and all participants provided written informed consent.

The program was based on cognitive models including the Theory of Planned Behaviour [10, 11], the Health Belief Model [12], the Transtheoretical Model [7], Social Cognitive Theory [13, 14, 15] and Decisional Balance [16] which address issues of knowledge, self-efficacy and barriers to behaviour change and maintenance. Participants were encouraged to achieve a low-sodium, low-fat diet, rich in fruit and vegetables, based on the principles of the Dietary Approaches to Stop Hypertension diet [17] but with energy intake reduced to achieve weight loss. The program also promoted increased fish consumption and increased physical activity. The program encouraged self-directed change and emphasized barriers, costs and benefits of a healthy lifestyle, goal setting, time management and social support.

During the year of follow-up, the program group attended the research unit on six occasions for measurement of weight and BP, and for six group sessions, where group and individual progress was discussed, held every second week for the first month, monthly for the next 2 months and then once every 3 months. A newsletter was issued every 3 months during follow-up. This group completed diet and physical activity calendars during the 4 months of the program and during the year of follow-up; these were collected during group sessions and feedback was provided.

For ethical reasons, we did not attempt to prevent the usual care group from making lifestyle changes. They were given generally available publications from the National Heart Foundation of Australia and the Health Department of Western Australia, but received no other advice from the program facilitators. Seminars on topics unrelated to the ADAPT program were held at 2, 7, 12 and 14 months after baseline. As in the program group, end-points were assessed at the end of 4 months and after a further year.

If antihypertensive drugs were withdrawn, participants reported BP, measured with a home monitor (A&D UA-767PC, A&D Medical, Thebarton, Australia), by telephone to the program staff every second day for the first month, then weekly until the end of follow-up.

Measurements

Measurements were recorded at baseline, at 4 months and at 1-year follow-up. The present analysis used as outcomes physical activity assessed by questionnaire that recorded hours per week spent in exercise of at least moderate intensity, and saturated fat intake calculated from diet records, using household measures, of 2 weekdays and one weekend day using the Foodworks program (Xyris, Brisbane, Queensland).

Perceived barriers to positive health behaviours were recorded using a four-point scale; these used 18 items for dietary behaviour and 16 items for physical activity [7, 8, 18]. Self-efficacy was based on the instrument described by Plotnikoff and Higginbotham [19] with questions specific for diet or physical activity behaviours.

Beliefs about the benefits of health behaviours were elicited using a six-point scale. Six items for each behaviour addressed beliefs about associations between health behaviour and BP, cholesterol, risk of heart disease, longevity, general health and control of weight gain. For each item, a higher score indicated a stronger belief in the benefits of the behaviour.

Coping mechanisms were explored using the revised Ways of Coping Checklist [20]. Social support was assessed as described by Thoits [21] and included total support, as well as support from friends, relatives, spouses and co-workers. Depression, anxiety and stress were assessed using the Depression Anxiety Stress Scales (DASS) instrument [22].

Stages of change were assessed as previously described [18] based on a five-item algorithm [23] specific for each behaviour.

Statistical methods

Intention-to-treat analysis was used with intake of saturated fat to measure dietary behaviour, and time spent in exercise of at least moderate intensity for physical activity. A P value <0.05 was considered significant.

Assessment of moderators

Linear regression models (SPSS 12.1, Chicago, IL, USA) were used to examine possible moderators. Interactions between treatment and the following variables were examined: sex, age, educational level, BP, number of antihypertensive drugs prescribed, social support, depression, anxiety, stress, coping mechanisms, stages of change- and behaviour-specific self-efficacy. We examined the level of self-efficacy at entry to the study as a moderator while change in self-efficacy was examined as a potential mediator.

Assessment of mediators

Cognitive variables that changed significantly with the program were examined as potential mediators [7]. Change in self-efficacy was included as a potential mediator while self-efficacy at baseline was examined as a moderator. Other potential mediators included barriers to behaviour change, beliefs about the benefits of behaviour change, support from relatives and coping mechanisms. All variables were adjusted for baseline values and sex in linear regression and the residuals, which represent the dependent variable adjusted for covariates, were used in analysis. We used the program for SPSS, downloaded from www.psychonomic.org/archive/with 5000 bootstrap re-samples [6] to estimate the indirect effect of the intervening variable with the 95% confidence interval (CI). Mediation was considered significant if the 95% CI did not span zero.

Results

There were 118 individuals randomized to usual care (control group) and 123 to the program; 98 and 106, respectively, completed the 4-month visit (end of intervention); 90 and 102, respectively, attended follow-up. Table I shows characteristics of the participants at baseline. Mean values for cognitive variables examined as potential mediators are shown in Table II at baseline, post-intervention and follow-up.

Table I. *Baseline characteristics according to treatment groups*

Variable	Usual care group n = 118	Program group n = 123
Gender (M/F)	51/67	56/67
Body mass index (kg m^{-2})	29.7 (2.5)	30.4 (2.9)
Systolic BP (mmHg)	125 (10)	128 (10)
Diastolic BP (mmHg)	76 (8)	77 (7)
Saturated fat (% energy)	12.0 (5.8)	12.3 (5.5)
Hours of exercise per week	2.9 (1.8)	2.7 (2.2)
Smokers (%)	1 (1)	5 (5)

Continuous variables are shown as means (standard deviation).

Moderators of behaviour change

With intake of saturated fat (% energy) as the dependent variable, there was significant interaction between treatment and sex, coded as 0 for men and 1 for women, at post-intervention (regression coefficient, b = 2.18, 95% CI 0.24, 4.12; P = 0.03). Women showed greater improvement than men in the control group while men improved more than women with the program (Fig. 1). No significant interaction was seen at follow-up (b = 0.11, 95% CI −1.90, 2.12; P = 0.91). With time spent in physical activity, there was a significant interaction between sex and treatment group at post-intervention (b = −0.85, 95% CI −1.67, −0.04; P = 0.04) l. The interaction was not statistically significant at follow-up (b = −0.58, 95% CI −1.53, 0.37; P = 0.23). As for dietary behaviour, men showed less response than women with usual care and a greater response than women with the program (Fig. 1).

There was no significant interaction between stage of change and treatment for saturated fat intake at post-intervention (b = 0.44, 95% CI −1.54, 2.42; P = 0.66) or follow-up (b = −0.64, 95% CI −2.67, 1.39, P = 0.53) or for physical activity (b = 0.28, 95% CI −0.40, 0.95; P = 0.37 at post-intervention; b = 0.06, 95% CI −0.89, 1.01; P = 0.90 at follow-up). Baseline values of age, educational level, systolic BP, the number of

Table II. *Cognitive variables significantly associated with treatment group (means and standard deviations) at baseline, end of intervention and 1-year follow-up*

Variable	Baseline	End of intervention	Follow-up
Diet barriers			
Control	25.1 (6.6)	24.8 (7.7)	24.3 (7.7)
Program	26.2 (8.8)	23.4 (7.1)	23.2 (7.4)
Diet beliefs			
Control	22.4 (2.6)	24.6 (2.7)	26.4 (2.2)
Program	22.6 (2.2)	23.0 (2.8)	23.4 (1.5)
Diet self-efficacy			
Control	11.0 (1.2)	10.8 (1.5)	10.9 (1.5)
Program	11.0 (1.1)	11.3 (1.2)	11.2 (1.3)
Physical activity barriers			
Control	25.0 (8.0)	24.4 (8.4)	24.0 (7.4)
Program	26.0 (7.9)	23.4 (7.7)	22.2 (7.6)
Physical activity beliefs			
Control	22.4 (2.6)	23.1 (2.1)	23.1 (2.2)
Program	22.6 (2.2)	25.0 (2.6)	25.2 (2.5)
Physical activity self-efficacy			
Control	10.3 (1.9)	10.6 (1.8)	10.8 (1.9)
Program	10.4 (1.7)	11.6 (1.4)	11.1 (1.4)
Support from relatives			
Control	26.4 (6.5)	26.1 (6.6)	26.6 (6.5)
Program	24.9 (6.8)	25.4 (6.4)	25.6 (6.3)
Coping external			
Control	14.7 (3.0)	15.0 (2.9)	15.0 (3.0)
Program	15.6 (2.5)	14.9 (2.9)	14.8 (3.2)
Coping consumption			
Control	7.8 (1.5)	7.7 (1.1)	7.7 (1.4)
Program	8.1 (1.6)	7.6 (1.0)	7.8 (1.5)

antihypertensive drugs prescribed, depression, anxiety or stress, self-efficacy, coping strategies and any dimension of social support showed no significant interactions with treatment for intake of saturated fat or time spent in physical activity at post-intervention or at 12-month follow-up.

Mediators of behaviour change

Reduction in saturated fat consumption at post-intervention was significantly associated with change in self-efficacy during the intervention (ES −0.055, 95% CI −0.125, −0.005). The association was similar at follow-up with an ES −0.054 (95% CI −0.127, −0.005). There were no statistically significant mediating effects of barriers, beliefs, social support from relatives or coping strategies (Table III).

Change in time spent in exercise of at least moderate intensity was significantly related to self-efficacy for exercise at post-intervention (ES 0.059, 95% CI 0.003, 0.147) but not at follow-up. Barriers, beliefs, social support from relatives and coping strategies were not statistically significant mediators at post-intervention or at follow-up (Table IV).

Discussion

In this randomized controlled trial of a program for lifestyle modification in hypertensive patients, the effect on intake of saturated fat and physical activity at post-intervention was moderated by the sex of the participants. Change was greater in women in the usual care group and in men in the program group. Stage of change at entry to the study was not a moderator of response. Self-efficacy was the only cognitive measure that fulfilled the criteria for mediation, using the program complied by Preacher and Hayes [6]. Behaviour-specific self-efficacy was related to a decrease in saturated fat intake both at post-intervention and at follow-up and increased physical activity at post-intervention. No moderators or mediators of change were associated with physical activity after 1 year of follow-up.

In the program group, men were more successful than women at decreasing intake of saturated fat and increasing physical activity. All the program facilitators were women and it is possible that this influenced responses. With usual care, outcomes were better among women than men, possibly related to women's higher ratings for cognitive variables, particularly in relation to diet [24]. Because of the possible associations between the outcomes in men and the staffing of the program, it is not appropriate to generalize the observed moderating effect of the sex of participants in our study to other programs, although no interaction between the sex of the instructor and participants was found in a physical activity program [25]. However, the interaction between treatment group and sex in our trial suggests that it may be useful to consider this

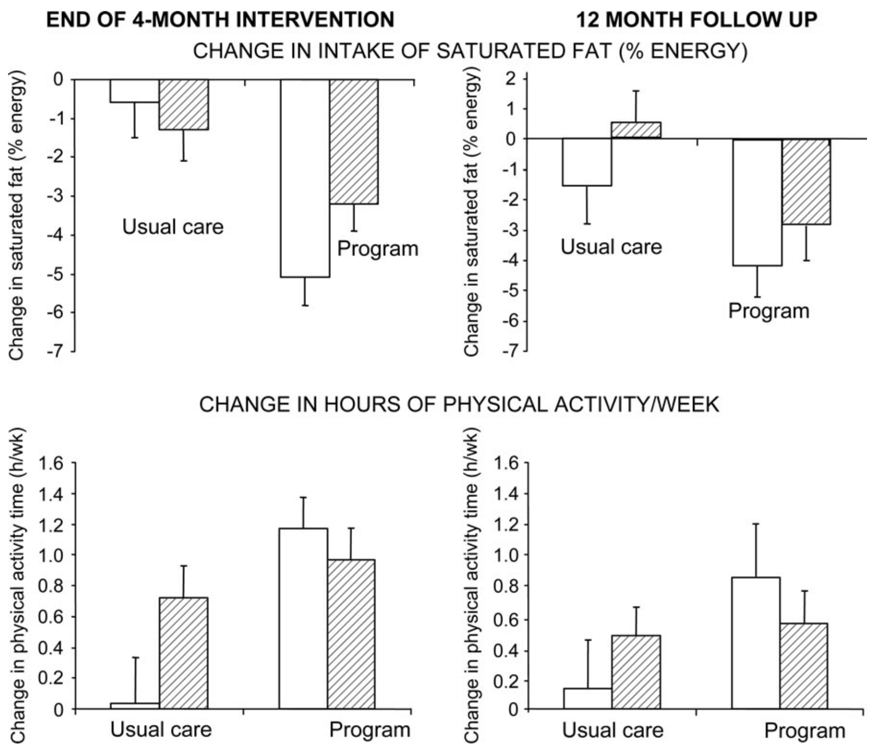

Fig. 1. Change in saturated fat intake and physical activity at post-intervention and at 1-year follow-up in men (clear bars) and women (hatched bars) according to treatment group.

Table III. *Assessment of possible mediators of change in dietary behaviour at post-intervention and at follow-up, using change in saturated fat intake as the outcome, showing estimated ES and 95% CIs*

Possible mediator of dietary behaviour	End of intervention		Follow-up	
	ES	95% CI	ES	95% CI
Self-efficacy	−0.055	−0.125, −0.005	−0.054	−0.127, −0.005
Barriers to prudent diet	−0.022	−0.056, 0.008	−0.019	−0.083, 0.027
Beliefs about benefits of prudent diet	−0.003	−0.026, 0.016	−0.024	−0.085, 0.009
Social support from relatives	−0.004	−0.036, 0.017	−0.001	−0.044, 0.043
Coping strategy				
External	0.014	−0.023, 0.072	0.003	−0.029, 0.037
Consumption	0.002	−0.047, 0.038	0.002	−0.023, 0.036

moderator as a stratification variable in future studies, as suggested by Kraemer *et al.* [3].

The Transtheoretical Model has been widely used in health promotion programs, often with a stage-specific approach [26], but the benefits of tailored interventions, at least for physical activity, have been questioned [27]. Because of additional costs we did not use a tailored program, but found no moderating effect of stage of change at baseline on diet or physical activity behaviours. However,

Table IV. *Assessment of possible mediators of change in physical activity at post-intervention and at follow-up, using change in hours per week of at least moderate activity as the outcome, showing estimated ES and 95% CIs*

Possible mediator of physical activity behaviour	End of intervention		Follow-up	
	ES	95% CL	ES	95% CL
Self-efficacy	0.059	0.003, 0.147	0.022	−0.020, 0.078
Barriers to physical activity	0.026	−0.008, 0.079	0.043	−0.008, 0.118
Beliefs—benefits of physical activity	0.038	−0.009, 0.109	0.008	−0.021, 0.042
Social support from relatives	−0.002	−0.029, 0.018	0.028	−0.008, 0.082
Coping strategy				
External	−0.008	−0.044, 0.029	−0.001	−0.035, 0.030
Consumption	0.006	−0.024, 0.049	−0.001	−0.021, 0.026

the participants in our study did not include pre-contemplators. They were motivated by the prospect of withdrawal of antihypertensive drugs, an incentive that influenced outcome in hypertensive patients in the Trial of Nonpharmacologic Intervention in the Elderly (TONE) study [28]. At-risk groups also more readily adopt lifestyle modification [29]. Our results suggest that stage-based programs may be unnecessary with a motivated group.

Self-efficacy has been associated with health behaviours [2, 7, 8, 18, 30]. Improvements in health behaviours have followed interventions that improve self-efficacy [13] and self-efficacy was a mediating variable in dietary interventions [21, 31], consistent with our findings.

Lewis *et al.* [32], in examining studies that reported mediational analysis in relation to physical activity behaviours, found inconsistent results. Assessment periods were often relatively short (up to 6 months) and some studies used the Baron and Kenny criteria for mediation, known to lack statistical power [5]. In our study, self-efficacy was a mediator only in the shorter term, as previously reported [33]. These authors suggest that self-efficacy may be phase specific and that action self-efficacy in the initial phase should be distinguished from the maintenance phase where different strategies are needed. Our findings and these reports suggest that examination of other cognitive processes is needed to provide a basis for achieving changes in physical activity in the longer term, as recommended by Lewis *et al.* [32].

Social support was emphasized in the program and support from relatives increased significantly in the program group at follow-up. However, we found no mediating effect of social support. Reports that examine social support in relation to behaviour change have been inconsistent [32] and few studies have adequately described social support or assessed its potential role [34].

Previous trials have shown a weak relationship between health beliefs and behaviour change [35, 36] and a systematic review has confirmed that effects are small [10]. We found no evidence of a mediational effect of change in health beliefs on dietary or physical activity outcomes, consistent with these reports.

Barriers to behaviour change decreased significantly with the program, but we did not find them to be mediators of dietary or physical activity behaviour change. Reports examining barriers to change in physical activity behaviours have been inconsistent and the role of changes in barriers, possibly affecting decisional balance, is unclear [32].

In reporting these findings, which required multiple statistical tests, we have not used procedures such as Bonferroni adjustments to modify overall significance levels. As pointed out by Perneger [37], such adjustments increase the probability of Type II error, so that clinically relevant differences may be unrecognized. We consider that reporting our findings is important in generating hypotheses that can be tested in larger trials where outcomes could contribute substantially to informing practice in the area of health education. We have therefore reported all differences that were significant at the 5% level but acknowledge that, as with all statistical tests, there is the possibility that these are chance findings.

Conclusions

Our analysis has highlighted differences in response between men and women and the importance of self-efficacy as a mediator of behaviour change in hypertensive patients. Confirmation of a moderating effect of sex is needed before this finding can be generalized to other settings. Our focus on strategies to improve self-efficacy is justified by our findings, particularly in regard to dietary outcomes. No mediators were identified that contributed to change in physical activity in the longer term indicating the need for other models, with appropriate cognitive measurements, in future trials.

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Conflict of interest statement

None declared.

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