Compliance to step count and vegetable serve recommendations mediates weight gain prevention in mid-age, premenopausal women: findings of the 40-Something RCT

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Highlights

- The RCT evaluated a 12 month obesity prevention intervention in mid-age women
- Compliance to 10 diet and exercise recommendations were measured at three months
- Compliance scores were assessed in mediation models for 12 and 24 month weight loss
- Compliance to the 10,000 steps/day guideline mediated 12 and 24 month weight loss
- Compliance to the five vegetables serve/day guideline mediated 24 month weight loss

Abstract

The 40-Something RCT aimed to determine if a 12-month health professional-led intervention could modify diet and physical activity behaviour for obesity prevention, in 44-50 year old, non-obese (BMI=18.5-29.9kg/m^2) premenopausal women. Women were monitored for an additional 12 months to determine if effects could be maintained. This paper aimed to explore dietary and physical activity behavioural mediators hypothesized to be causally associated with weight change. Fifty-four women were randomised to a Motivational Interviewing Intervention (MI) (n=28; five health professional consultations) or a Self-Directed Intervention (n=26; written advice). Compliance to 10 study recommendations was measured at three months by a four-day weighed food and physical activity record including pedometer-measured step counts, self-reported exercise minutes and sitting time. The 10 compliance scores were independently assessed in mediation models for 12- and 24-month weight change. The MI effect on step count was an increase of 0.99 points on the 10-point compliance scale (p≤0.01). This MI effect on step count significantly mediated the 12 and 24 month effect on weight (12 months AB=-0.74, 95%CI=-1.95, -0.14; 24 months AB=-1.06, 95%CI=-2.56, -0.36), accounting for 37.23% and 53.79% of the effect, respectively. The MI effect on vegetable serves was an increase of 1.50 points on the compliance scale (p=0.02). The MI effect on vegetable compliance significantly mediated the effect on weight at 24 months (AB=-0.54, 95%CI=-1.50, -0.04), accounting for 24.92% of the effect. The remaining

eight dietary and physical activity compliance scores did not significantly mediate weight loss. Encouraging women to take 10,000 steps and eat five vegetable serves per day may be a promising strategy to achieve long-term weight control at mid-life.

Key words: *nutrition, pedometer, mediator, obesity prevention, motivational interviewing*

Background

In the last few decades, there has been a strong interest in effective weight gain prevention strategies to combat rising obesity prevalence.[1-7] Not surprisingly, the worldwide weight gain trend correlates with decreasing levels of adherence to population diet and physical activity recommendations.[8, 9] Behavioural treatments that incorporate diet and physical activity lifestyle changes are recommended for weight control interventions.[10-12] Weight loss interventions have had small yet clinically important effects,[3-6] however, few interventions have been successful in facilitating weight loss beyond two years.[13]

In addition to evaluating whether an intervention is effective, it has been recognized that understanding how interventions achieve their results is important.[14] Understanding how 'successful' intervention participants achieve weight loss provides insight into effective weight control treatment.[15] Mediation analysis is emerging as an important statistical tool in weight loss research as it provides evidence on the mechanism of change in a behavioural intervention.[16] This provides an opportunity for researchers to understand associations between complying with diet, physical activity and sedentary behaviour recommendations and achieving weight loss.[17] Determining which intervention recommendations are more effective will enable the development and refinement of more targeted weight management programs[18, 19] and will enable researchers to modify intervention resources to support recommendations that are associated with weight loss success.[15]

The '40-Something' Randomised Controlled Trial (RCT) aimed to determine whether a 12-month health professional-led intervention, employing motivational interviewing as the counselling framework, could result in diet and physical activity behaviour change for weight control in non-obese, premenopausal mid-age women.[20] Weight gain prevention advice for all participants was based on 10 weight control recommendations. Seven recommendations

related to dietary intake for vegetable, fruit, meat, dairy, wholegrains and extras (non-discretionary food) serves as well as the number of meals eaten outside the home. Two recommendations related to physical activity for minutes of moderate-to-vigorous physical activity and step count, and one to sedentary behaviour (Figure 2). This paper aimed to examine whether compliance to the 10 weight control recommendations of the 40-Something study significantly mediated the long-term effect of the intervention on weight loss at 12 and 24 months. The 40-Something Study methods paper [20] and the 12-month weight outcomes paper (which also presents the waist circumference, percentage body fat, percentage lean muscle mass, blood cholesterol level, fasting glucose and blood pressure findings)[21] have been published. This paper presents the findings from our mediation analysis to determine how successful intervention women achieved weight gain prevention and provides evidence of the mechanism of behaviour change.

Methods

The detailed methods of the 12-month parallel-group 40-Something RCT have been reported elsewhere.[20] Briefly, non-obese pre-menopausal, healthy women aged 44-50 years were stratified by BMI group (18.5-24.9kg/m^2 and 25-29.9 kg/m^2) then randomised using a computer generated allocation sequence to one of two study arms: i) Motivational Interviewing Intervention (MI) or the ii) Self-Directed Intervention (SDI) (Figure 1). The study received institutional review and approval by the Human Research Ethics Committee of the University of Newcastle (H-2010-0030) and all participants provided signed consent before participating in the study. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12611000064909). Both interventions were based on Social Cognitive Theory (SCT)[22] and targeted the hypothesized behaviour change mediators of self-efficacy, perceived barriers, self-management and social support.

Self-Directed Intervention (control)

Print materials, including individualized written advice tailored according to the participant's assessments, were mailed to SDI women. Women in this group received the materials in two mail-outs. Participants received a weight control booklet that focused on either weight maintenance or weight loss strategies, depending on their baseline BMI. These booklets were constructed according to evidence on factors increasing the risk of weight gain in mid-age women and centred on the 10 weight control recommendations (Figure 2).

Motivational Interviewing Intervention

The MI group received the same print materials as the SDI group during four 60 minute consultations with an Accredited Practicing Dietitian (APD) and one with an Exercise Physiologist. The Dietitian and Exercise Physiologist delivered their consultations according to a documented protocol developed by researchers developed from the *Best Practice Guidelines for the Treatment of Overweight and Obesity in Adults[10]*, the *Australian Guide to Healthy Eating* (AGHE) [23], 10,000 steps Rockhampton community initiative[24] and the *Australian Physical Activity Guidelines*.[25] The motivational interviewing counselling style was adopted as the behaviour change counselling strategy for the health professional intervention as motivational interviewing has previously been shown to be effective in weight loss studies.[1, 26] The consultations adhered to the principles of motivational interviewing by supporting participant autonomy, encouraging collaboration and evoking intrinsic motivation.[27]

Weight control guidance

Within each intervention condition (MI and SDI), women with a healthy weight (BMI 18.5kg/m^2-24.9kg/m^2) were encouraged to maintain weight to within 1kg of baseline. They were encouraged to consume ≤8300kJ/day, the estimated requirement for women aged 51-70 years, mean height of 1.6 meters and a Physical Activity Level (PAL) factor of 1.6.

Overweight participants (BMI 25.0kg.m^2-29.9kg/m^2) were encouraged to lose sufficient weight to place them within the healthy weight range and then to maintain this for the study duration. They were encouraged to consume approximately 6300kJ/d, 2000kJ less than the estimated requirement for weight maintenance (8300kJ/d), resulting in a weight loss of approximately 0.5kg per week.[10]

The women also received guidance centred on the study's 10 weight control recommendations (Figure 2). The 10 weight control recommendations included seven dietary recommendations, two physical activity recommendations and one sitting time recommendation. More detail on how the recommendations were developed and pilot tested have been reported elsewhere.[20] Briefly, women were encouraged to consume food from each food group (fruit, vegetables, meat, dairy, wholegrains, and 'extra' foods) according to the AGHE recommendations[23] and compliance literature (Table 1).[18, 28-32] Women were also encouraged to meet the physical activity recommendations of at least 150 minutes/week of moderate-vigorous intensity physical activity for healthy weight women (250 minutes/week of moderate-vigorous intensity physical activity for overweight women)[25], to take 10,000 steps per day[24] and restrict sitting time to 3 hours/d or less.[29]

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Measures

Anthropometric measurements including height and weight were collected during the intervention at baseline and 12 months. Women completing the intervention to 12 months were invited to participate in the study for an additional 12 months to assess weight control maintenance, with measures taken at 24-months post-baseline (Figure 1).

Dietary intake was measured at three months using a four-day weighed food record (WFR). Participants were instructed on how to record their usual dietary intake by a Dietitian, for four consecutive days, including three weekdays and one weekend day. Participants were asked to record the weight of all food and beverages as well as any leftovers using electronic kitchen scales accurate to ±0.1g (Soehnle Siena Electronic Kitchen Scale; Soehnle, Germany) and to keep detailed descriptions of recipes, foods, snacks and drinks (including alcohol). Participants were also instructed to record cooking methods (e.g. deep frying, grilling or boiling), the brand names of packaged foods, and whether food was prepared inside or outside of the home.

Yamax SW200 pedometers (Yamax Corporation, Kumamoto City, Japan) were used to measure step counts, and are considered to be a valid and reliable measure of ambulatory physical activity.[33, 34] Participants were asked to maintain their usual exercise routine and record their daily step count, minutes of physical activity and minutes spent sitting for the same four consecutive days as their WFR in a written diary. Sedentary behaviour, including sitting time, was measured using a modified version of the sitting questionnaire.[35]

Data checking and analysis

Completed four-day WFRs and the physical activity records were checked for missing data and plausibility by a Dietitian. The total serves per day for each food group (fruit, vegetables,

meat, dairy, wholegrains, and 'extra' foods) were calculated according to the AGHE[23] serving sizes, rounding to the nearest 0.5 serve. The total number of meals eaten outside the home was summed for each day. The number of minutes spent doing vigorous, moderate and light physical activity each day was calculated according to the *2011 Compendium of Physical Activities*.[36] The step count and sitting time minutes per day were also calculated. For each of the 10 recommendations, the measures (serves/minutes/steps per day) over the four days were summed together and divided by four to calculate the daily average at each data collection point.

Compliance score (CS)

Compliance with each of the 10 weight control recommendations was assessed based on the AGHE[23], physical activity guidelines[24, 37] and compliance literature (Table 1)[18, 28-32] and assessed using the 3-month diet and physical activity data. Scores between one and ten (to 1 decimal place) were assigned for each of the 10 weight control recommendations, with non-compliance indicated by a score of one and full compliance assigned a score of 10.

Statistical analysis

The mediation analysis was conducted in SPSS Statistics Version 21 (SPSS Inc, Chicago, Illinois, USA) to investigate whether the long-term (12-month and 24-month) weight loss outcomes were mediated by three-month compliance scores for each of the 10 weight control recommendations. To adjust for pre-treatment effects, baseline weight and baseline compliance scores were included as covariates in each model, with the exception of the variables 'meals eaten outside the home' (MEOH) and 'increasing wholegrain serves'. The compliance scoring system for MEOH at three months had already been calculated as a

212 Table 1. Protocol for evaluating compliance with each of the 10 weight control

213 recommendations.

Recommendation	Compliance score calculation	Evidence for calculation method
Eat 2 serves of fruit	For x≤0.2, y=1 For 0.2<x≤2, y=5x For x>2, y=10	AGHE recommends 2 serves/d of fruit[23, 31]
Eat at least 5 serves of vegetables	For x≤0.5, y=1 For 0.5<x≤5, y=2x For x>5, y=10	AGHE recommends ≥5 serves/d of vegetables[23, 31]
Eat 2-3 serves of dairy	For x≤0.3, y=1 For 0.33<x≤3, y=10x/3 (3.33x) For x>3, y=10	AGHE recommends consuming ≥3 serves/d of dairy[23, 31]
Choose wholegrain varieties of bread and cereal	For x<0.2, y=1 For 0.2<x≤50, y=0.2x For x≥50, y=10	Theoretical distribution based on calculation using the Maras et al method.[28] Full compliance classified as ≥50% of breads and cereals as wholegrain
Eat 1-1.5 serves of meat or meat alternatives	For 0.15>x>3, y=1 For x<1.5, y=(10/1.5)x For x≥1.5, y=(-6x + 19)	AGHE recommends 1-1.5 serves/d of meat and meat alternatives.[23, 31] Compliance based on the maximum intakes from the data. Therefore sliding scale used with non-compliance classified as 0 serves or ≥ 3 serves/d of meat or meat alternatives
Eat 2 (1.5 for weight loss) serves or less of extra foods	Weight maintenance For x≥5, y=1 For x<5, y=(-9x + 50)/5 Weight Loss For x≥3.75, y=1 For x<3.75, y=(37.5-9x)/3.75	Based on the maximum intakes from the data. Therefore non-compliance classified as ≥2.5x recommendation (eg. ≥3.75 serves extras/day for weight loss) Optimum intake (full compliance) classified as 0 serves/d.[23, 31]
Cut down on the meals eaten outside the home (MEOH)	For x>100, y=1 For x>50, y=(-9x + 950)/50 For x≤50, y=10	Full compliance classified as a reduction in total MEOH from baseline to three month intakes. Optimum intake (full compliance) classified as ≤50%.[32]
Engage in moderate to vigorous physical activity for 150 (WL 250) minutes per week	Weight maintenance For x≤2.1, y=1 For 2.1<x<21, y=(10/21)x For x≥21, y=10 Weight loss For x≤3.5, y=1 For 3.5<x<35, y=(10/35)x For x≥35, y=10	Theoretically derived from the National Physical Activity Guidelines (based on minutes/day).[37]
Sit for less than 3 hours each day (using average)	For x≥900, y=1 For 180<x<900, y=(-9x + 8820)/720 For x≤180, y=10	Based on the recommendation of ≤3 hours sitting time/day.[29]
Walk 10,000 steps/day	For x≤100, y=1 For 100>x<10,000, y=(x + 1000)/1100 For x≥10,000, y=10	Theoretically derived from the recommended ≥10,000 steps/d.[18, 24, 30]

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change score during the compliance scoring system (Table 1) as it measured a change in total from baseline to three months. Wholegrain serves were not calculated at baseline.

Intention-to-treat principles were applied, using the expectation maximisation imputation technique in SPSS for weight and compliance scores in the mediation analysis except for MEOH (as this was calculated as a change score) and wholegrain serves (not calculated at baseline). In sensitivity analysis the mediation analysis was repeated using last observation carried forward (LOCF) to account for missing data (supplementary file 1) as this method was outlined a priori in the study methods paper.[20]

Each of the 10 compliance scores hypothesized to mediate the effect of weight change were independently assessed in single mediation models for 12-month and 24-month weight change. The INDIRECT SPSS Macro[38] was used to i) calculate the regression coefficients for the effect of the intervention on compliance score (inferential statistics provided for the measure of between group change in compliance scores) (Pathway A) ii) examine the association between changes in compliance and changes in weight, independent of group assignment (Pathway B) and iii) estimate the total (Pathway C), direct (Pathway C') and indirect (Pathway AB) intervention effects. To test the significance of the indirect effect, the macro generates bias-corrected bootstrapped 95% confidence intervals, which may be asymmetrical.[38] Significant mediation was established if the confidence intervals around the indirect effect did not include zero. Using the bias-corrected bootstrap procedure to test for mediation, the sample size provided sufficient power to detect medium-to-large mediation effects in the current analysis.[39] This method of bootstrapping is recommended for studies with small sample sizes.[40]

Results

Fifty-four women met the inclusion criteria and were enrolled (Figure 1) with 28 randomised to MI and 26 to SDI group. The women had a mean (SD) age of 47.3 (1.8) years, a weight of 68.7 (7.9) kg, BMI of 25.1 (2.4) kg/m^2 and percent body fat of 35.8 (5.6) % (Table 2). Ninety-one percent, 74% and 56% of the participants were retained at 3-, 12- and 24 months respectively. Two women completed the 3-month weight measurement but not the 3-month diet and physical activity measurements, giving a retention rate of 87% for 3-month diet and physical activity outcomes.

Mediation analysis

As the mediation analyses were conducted separately for each compliance score at 12 and 24 months, each model contained different covariates (i.e. baseline weight and the baseline score for the compliance area in the model). As such, the main effect of the MI intervention on weight change was slightly different in each model. However, a significant main effect of the MI intervention on weight change was observed at 12- and 24 months in all mediation analyses (all p≤0.05). The effect of the 40-Something RCT on the potential compliance score mediators (Table 3). At 12 months, significant group-by-time effects were observed for several of the hypothesised compliance score mediators, favouring the intervention group (Table 4; Path A). The associations between the changes in mediators and the changes in weight are shown in Table 4. After controlling for baseline values and changes in the SDI group, the MI intervention effect on step count compliance was an increase of 0.99 points on the 10 point compliance scale (p≤0.01), which represents an increase of 990 steps/day. There was a significant inverse association between the compliance score for steps taken and weight change at 12 and 24 months (p=0.02 and p≤0.01, respectively) demonstrating that increased compliance to the step count recommendation in the first three months was associated with greater weight loss at 12 and 24 months, regardless of group allocation. The MI intervention effect on step count compliance significantly mediated the effect on weight at both 12 and 24 months (12 months

AB=-0.74, 95%CI=-1.95 to -0.14; 24 months AB=-1.06, 95%CI=-2.56 to -0.36). The mediating effect of compliance to step count recommendations was found to account for 37.23% and 53.79% of the intervention effect on weight change at 12 and 24 months respectively. The effect of the MI intervention on compliance to the vegetable serve recommendation was an increase of 1.50 points on the compliance scale (p=0.02), which represents an increase of 0.75 serves of vegetables/day. The MI intervention effect on vegetable serve compliance significantly mediated the effect on weight at 24 months (AB=-0.54, 95%CI=-1.50 to -0.04), accounting for 24.92% of the intervention effect on weight change.

No other dietary or physical activity compliance scores significantly mediated weight loss. While there was a significant inverse association between dairy serves per day and weight change at 12 months (p=0.01) indicating that women who consumed at least three serves of dairy foods per day reduced their weight, compliance to the dairy serve recommendation did not mediate weight change in the MI intervention. After controlling for baseline values and changes in the SDI, the MI intervention effect on fruit serve compliance was an increase in 1.65 points on the 10 point compliance scale (p=0.02), an increase of one third of a serve of fruit. However this intervention effect on fruit compliance did not significantly mediate weight loss at 12 or 24 months (12 months AB=0.02, 95% CI=-0.94 to 0.76; 24 months AB=-0.15, 95% CI =-1.37, 0.61).

289 Table 2: Baseline characteristics of the 40-Something Study participants

Characteristics	Total (n=54) Mean (SD)	Motivational Interviewing Intervention (MI) (n=28) Mean (SD)	Self-directed Intervention (SDI) (n=26) Mean (SD)	p-value for difference between MI and SDI groups	Healthy weight (HW) (n=27) Mean (SD)	Overweight (OW) (n=27) Mean (SD)	p-value for difference between HW and OW groups
Age (years)	47.3 (1.8)	47.6 (1.9)	46.9 (1.6)	0.189	47.41 (1.74)	47.11 (1.89)	0.551
Weight (kg)	68.7 (7.9)	68.7 (8.9)	68.6 (6.7)	0.982	62.91 (5.30)	74.38 (5.49)	<0.001
Height (m)	1.65 (0.06)	1.66 (0.06)	1.65 (0.05)	0.600	1.65 (0.06)	1.66 (0.6)	0.790
BMI (kg/m^2)	25.1 (2.4)	24.9 (2.5)	25.2 (2.4)	0.641	23.03 (1.46)	27.08 (1.16)	<0.001
Body fat (%)[1]	35.8 (5.6)	35.6 (5.8)	36.2 (5.4)	0.703	31.52 (4.37)	40.06 (2.49)	<0.001
Lean muscle (%)[2]	27.4 (2.7)	27.5 (2.8)	27.2 (2.5)	0.649	29.02 (2.49)	25.70 (1.59)	<0.001
Waist circumference (cm)	83.1 (7.6)	83.3 (8.2)	83.0 (7.0)	0.905	77.65 (5.66)	88.62 (4.79)	<0.001
Fruit (serves/d) [3]	1.30 (0.79)	1.40 (0.82)	1.20 (0.75)	0.438	1.42 (0.85)	1.18 (0.71)	0.288
Vegetable (serves/d) [3]	2.72 (1.26)	3.05 (1.40)	2.40 (1.03)	0.083	2.99 (1.49)	2.45 (0.93)	0.126
Meat/meat alternatives (serves/d) [3]	1.82 (0.71)	1.89 (0.75)	1.74 (0.67)	0.451	1.78 (0.65)	1.85 (0.78)	0.729
Dairy (serves/d) [3]	1.70 (0.81)	1.82 (0.84)	1.57 (0.77)	0.257	1.79 (0.80)	1.60 (0.83)	0.417
Breads/cereals (serves/d) [3]	2.25 (0.62)	2.28 (0.64)	2.22 (0.60)	0.742	2.31 (0.65)	2.18 (0.59)	0.441
'Extra' foods (serves/d) [3]	3.12 (1.35)	3.28 (1.41)	2.95 (1.29)	0.396	3.00 (1.21)	3.23 (1.50)	0.540
Vig. mins PA (mins/4 days) [3]	43.57 (82.31)	38.52 (96.97)	48.81 (65.24)	0.654	61.81 (102.95)	24.62 (48.33)	0.100
Mod. mins PA (mins/4 days) [3]	57.81 (125.16)	63.11 (161.69)	52.31 (73.01)	0.757	82.96 (165.34)	31.69 (52.51)	0.137
Steps count (steps/d) [2]	9384.66 (3442.74)	10221.15 (3888.61)	8548 (2757.24)	0.103	10111.57 (3335.04)	8657.75(3457.96)	0.416
Sitting time (mins/d) [3]	422.72 (146.15)	410.65 (151.24)	435.25 (142.54)	0.545	406.53 (149.91)	439.53 (143.11)	0.129

290 Note. SD = Standard Deviation; d = day; BMI = Body Mass Index; PA = physical activity; mins = minutes; vig = vigorous; mod = moderate.
291 [1] N=53 (Total), n=27 (Motivational interviewing intervention), n=26 (Self-directed intervention); n=26 (Healthy weight), n=27 (Overweight)
292 [2] N=52 (Total), n=26 (Motivational interviewing intervention), n=26 (Self-directed intervention); n=26 (Healthy weight), n=26 (Overweight)
293 [3] N=53 (Total), n=27 (Motivational interviewing intervention), n=26 (Self-directed intervention); n=27 (Healthy weight), n=26 (Overweight)

294 Table 3. Mean participant compliance scores for the 10 weight control recommendations at

295 baseline and three months

Variables	Motivation Interviewing intervention (n = 28)		Self-directed Intervention (n = 26)	
	Baseline Mean (SD)	3 months Mean (SD)	Baseline Mean (SD)	3 months Mean (SD)
Fruit	6.60 (3.05)	8.07 (2.09)	5.57 (2.86)	6.13 (2.94)
Vegetable	5.96 (2.50)	6.28 (2.03)	4.77 (2.05)	4.75 (2.17)
Dairy	5.88 (2.39)	5.68 (2.23)	5.27 (2.48)	5.33 (2.24)
Meat	6.11 (2.57)	6.71 (1.88)	6.68 (2.78)	6.36 (2.15)
Extras	3.82 (2.03)	5.64 (1.84)	4.10 (2.28)	5.18 (2.23)
PA minutes	3.87 (3.13)	6.31 (3.78)	4.96 (3.76)	6.05 (3.71)
Sitting time	7.10 (1.84)	6.90 (2.02)	6.81 (1.78)	6.60 (2.05)
Steps	8.66 (1.69)	9.33 (1.14)	8.19 (1.76)	8.27 (1.43)
Wholegrain	-	8.23 (3.00)	-	7.21 (3.10)
MEOH	-	6.92 (4.03)	-	7.50 (3.70)

MEOH: Meals eaten outside the home
Possible range of 1-10 for each compliance score.

Table 4. Effect of the intervention on potential mediators and the association between changes in mediators and changes in weight (using imputation for missing data).

Hypothesized mediators	Month	Direct effect of intervention on weight		Intervention effect on potential mediators		Association between potential mediators and weight		Mediated effect		
		C' (SE)[a]	p	A (SE)[b]	p	B (SE)[c]	p	AB (SE)[d]	95% CI[e]	AB/(C' + AB)[f]
Fruit[g]	12	-2.05 (0.86)	0.02	1.65 (0.64)	0.01	0.05 (0.18)	0.77	0.02 (0.42)	-0.94, 0.76	1.18%
	24	-1.81 (0.96)	0.07			-0.05 (0.20)	0.82	-0.15 (0.48)	-1.37, 0.61	7.60%
Vegetable[g]	12	-1.82 (0.89)	0.05	1.50 (0.60)	0.02	≤0.01(0.20)	0.98	≤-0.01 (0.28)	-0.63, 0.58	0.49%
	24	-1.62 (0.95)	0.09			-0.35 (0.21)	0.10	-0.54 (0.35)	-1.50, -0.04	24.92%
Dairy[g]	12	2.05 (0.77)	0.01	-0.03 (0.47)	0.95	-2.05 (0.77)	0.01	≤0.01 (0.16)	-0.26, 0.44	0.21%
	24	-1.96 (0.90)	0.03			0.03 (0.27)	0.93	≤-0.01 (0.12)	-0.33, 0.22	0.48%
Meat[g]	12	-1.69 (0.79)	0.04	0.37 (0.55)	0.51	0.13 (0.20)	0.53	0.08 (0.16)	-0.11, 0.59	5.05%
	24	-1.90 (0.90)	0.04			-0.03 (0.23)	0.89	0.03 (0.15)	-0.44, 0.18	1.85%
Extras[g]	12	-1.71 (0.75)	0.03	0.56 (0.52)	0.29	0.13 (0.24)	0.59	0.06 (0.19)	-0.17, 0.75	3.83%
	24	-2.00 (0.90)	0.03			0.13 (0.24)	0.59	0.09 (0.21)	-0.18, 0.80	4.83%
PA minutes[h]	12	-1.35 (0.80)	0.10	1.07 (0.74)	0.16	-0.23 (0.15)	0.13	-0.23 (0.29)	-1.36, 0.07	14.75%
	24	-1.55 (0.89)	0.09			-0.32 (0.17)	0.06	-0.33 (0.36)	-1.44, 0.07	17.63%
Sitting time[g]	12	-1.91 (0.77)	0.02	0.06 (0.31)	0.85	-0.45 (0.35)	0.21	<-0.01 (0.20)	-0.64, 0.30	0.65%
	24	-2.10 (0.86)	0.02			-0.01 (0.39)	0.97	<0.01 (0.16)	-0.37, 0.33	0.18%
Steps[h]	12	-1.25 (0.81)	0.13	0.99 (0.35)	<0.01	-0.75 (0.30)	0.02	-0.74 (0.44)	-1.95, -0.14	37.23%
	24	0.91 (0.88)	0.30			-1.10 (0.33)	<0.01	-1.06 (0.51)	-2.56, -0.36	53.79%
MEOH[i]	12	-1.77 (0.80)	0.03	-0.58 (1.06)	0.58	0.05 (0.11)	0.63	-0.02 (0.13)	-0.44, 0.13	0.97%
	24	-2.03 (0.88)	0.02			-0.12 (0.12)	0.31	0.09 (0.21)	-0.15, 0.89	4.72%
Wholegrain[i]	12	-1.93 (0.81)	0.02	1.07 (0.84)	0.21	0.12 (0.13)	0.39	0.17 (0.28)	-0.11, 1.15	9.96%
	24	-1.95 (0.90)	0.04			-0.01 (0.15)	0.92	0.07 (0.29)	-0.54, 0.46	3.90%

Table design adapted from Lubans et al[17]

[a] C' = unstandardized regression coefficient of the intervention predicting change in weight with mediator in the model (SE – standard error)

[b] A = unstandardized regression coefficient of the treatment condition predicting hypothesized mediators

[c] B = unstandardized regression coefficient of the hypothesized mediator predicting weight with treatment condition included in the model

[d] 95% CI = 95% confidence interval; AB = product-of-coefficients estimate

[e] Bootstrap bias corrected 95% confidence intervals of the mediated effect

[f] Proportion of intervention effect that was mediated

[g] n = 53

[h] n = 52

[i] n = 47

MEOH = meals eaten outside of the home

Discussion

This paper has revealed the potential dietary and physical activity behavioural mediators causally related to weight change at 12- and 24 months in healthy weight and overweight premenopausal women participating in the 40-Something RCT. The findings from the main analysis using the imputation mediation model (Table 4) are primarily consistent with the sensitivity analysis mediation model using LOCF (supplementary file 1). In both analyses, increased compliance to the 10,000 step count recommendation by the MI intervention mediated weight loss at the conclusion of the intervention phase (12 months), with compliance to step count also found to mediate the effect of long-term weight loss following a maintenance phase (24 months). Compliance to the vegetable serve recommendation was not found to mediate weight loss in the sensitivity analysis using LOCF to account for missing values. However, using a more robust approach to address the issue of missing data called expectation maximisation, compliance to the vegetable serve recommendation mediated longer term weight loss at 24 months. Expectation maximisation is an iterative approach to imputation that uses all available information to model values for the missing data. No other variables satisfied the criteria for mediation in either analysis.

The results are important given a rigorous mediation method was employed and the causal mechanism was explored in a sub-group of the population who despite being at high risk of weight gain (particularly abdominal obesity)[41], metabolic syndrome[42] and cardiovascular disease[42], are relatively under-studied. Whilst the link between physical activity and achieving and maintaining a healthy weight is well established [43-45], the findings from this study highlight the importance of physical activity in weight gain prevention at this life-stage. Despite finding that compliance to pedometer step recommendations mediated weight loss in mid-age women, compliance to the recommendation of ≥150 minutes per week (healthy weight women) or ≥250 minutes per week (overweight women) of moderate or vigorous physical activity was not found to be a mediator. Current recommendations indicate that 150-

250 minutes per week of moderate intensity physical activity is needed for both weight gain prevention and modest weight loss, however larger amounts in excess of 250 minutes per week may be required for long term weight loss maintenance.[46] One study conducted in the United States (US) found that 150 minutes of physical activity may be insufficient to prevent weight gain, particularly in middle aged women.[47] Studies conducted in the US[18, 48] and Australia[18, 48] have found that sedentary mid-age women are more likely to engage in physical activity when the recommendation is to walk 10,000 steps per day, rather than to walk for 30 minutes per day, possibly because the pedometer may have also motivated the women to increase their step count to meet their 10,000 step recommendation.[18, 48] However, the 10,000 step weight control recommendation does not address the issue of exercise intensity.[48] Women in the 40-Something study may have either increased incidental physical activity or non-brisk structured forms of physical activity which would increase step count but not moderate or vigorous physical activity minutes. Pedometers may therefore be a relatively objective measure of increasing incidental physical activity.

Despite recent interest in mediation analyses[16] and the benefits of investigating behavioural mediators of weight loss, the focus has been on psychosocial mediators and there are few studies of behavioural mediators with which to compare these results.[15, 49] Lubans and colleagues[17] conducted a mediation analyses to determine the behavioural mediators of weight loss in the Healthy Dads, Healthy Kids (HDHK) intervention for overweight fathers and similarly found that steps/day was a significant weight loss mediator. Despite assessing numerous dietary measures (such as portion size, fruit serves/day, vegetable serves/day, percent energy from alcohol/day, percent energy from fat/day and total energy (kcal)/day) none mediated weight loss.[17] Coughlin and colleagues[50] did find a significant dietary mediation effect in their study of behaviour mediators of weight loss maintenance in overweight and obese adults participating in either an individual contact

intervention, interactive technology intervention or a self-directed intervention. Increased fruit and vegetable intake and more frequent self-weighing mediated the effect of the individual contact intervention on weight loss maintenance in comparison to both the interactive technology intervention and the self-directed intervention.[50] A higher level of physical activity was also found to mediate the difference in weight loss maintenance between the individual contact intervention and interactive technology intervention on weight loss maintenance.[50] However the authors were unable to quantify the effect of the intervention on behaviour change as the diet, physical activity and behaviour change mediators were measured as a self-report binary categorical measure (yes/no answers).

Compliance to the vegetable serve recommendation mediated 24-month weight loss in the 40-Something RCT. At baseline MI and SDI women consumed 3.05 and 2.40 serves/day of vegetables, respectively, well below AGHE[23] recommendation of five serves/day. Vegetables are high in fibre and water and low in energy density thus increasing vegetable intake can lead to higher satiety levels, reduced hunger and lower energy intakes.[51] Many studies have found an association between higher vegetable intakes and weight loss.[52, 53] The frequency and variety of fruit and vegetable intake has been found to inversely predict six year weight gain in a sample of young women (n=4287, mean (SD) age = 27.6 ± 1.5) from the Australian Longitudinal Study on Women's Health.[52] Norman et al[53] conducted an RCT testing the effectiveness of a text message based weight loss intervention (2-5 diet and physical activity, weight management text messages per day) in comparison to a usual care group (print material) in overweight and obese adults. Collective fruit and vegetable intake (measured through multiple 24 hour food recalls) and Eating Behaviour Inventory mediated the effect of weight change (weight change=-3.17lb, p=0.014) at 4 months, accounting for 82.6% of the total effect of the intervention on weight change (31% and 69% respectively).[53] Despite evidence indicating the importance of consuming a high vegetable intake for weight management, the 2011-12 Australian Health Survey found that 90% of mid-

age Australian women (45-54 years old) reported consuming inadequate serves of vegetables[54] according to the Australian Guide to Healthy Eating recommendations of five serves/day.[23] This finding is comparable to the 40-Something study, with 94% of women reported consuming less than five serves/day at baseline More emphasis may need to be placed on supporting mid-age women to consume higher vegetable intakes in future weight control interventions.

There are many possible explanations for the relative lack of dietary mediators of weight loss in the 40-Something RCT. Firstly, it is possible that adherence to each individual dietary recommendation was responsible for some effect on weight, but these subtle contributions could not be identified as the current study was only powered to detect medium-to-large mediation effects. Another potential reason for lack of other dietary effects is possible misreporting of dietary intake. Although WFRs aim to reduce recall bias, they rely on self-reported data and therefore the reliability and validity of WFRs may be influenced by misreporting[55] or a social desirability bias,[56] unlike pedometer steps, which are an objective measure.[57] Whilst there is evidence that WFRs are an accurate tool to measure compliance amongst middle-aged women[58-60], and detailed instructions were provided by a Dietitian to increase the internal validity, the method could have been further strengthened by validation using biomarkers in urine or blood.

Alternatively, as dietary change for weight loss is quite complex, women may have complied with different combinations of the dietary recommendations to achieve weight loss, rather than each woman following the same standardized approach. Since weight loss occurs when energy expenditure exceeds energy intake[61] and the dietary compliance scores measures food group intake, it is possible that some women may have reduced their servings of meat and meat alternatives whilst others may have reduced extra foods servings to comply with recommendations. Both types of diet modifications may have resulted in weight loss but the

compliance instrument was not sensitive enough for the mediation analysis to detect dietary changes. Dietary change is thus more complex than step count, which measures most forms of modifiable physical activity, excluding times when the participant is in water or when playing contact sport, in one compliance score.

This study has some limitations which need to be acknowledged. As previously mentioned the WFR lacked biomarker validation. It was not possible to achieve participant blinding which increases the risk of bias. Efforts were made to achieve researcher blinding, with all but one researcher remaining blinded to participant's group allocation. This mediation analysis was exploratory. As such, the study was only powered to detect medium-to-large mediation effects and was unable to identify more nuanced effects. We were also unable to perform multiple-mediator models to identify the unique contributions of each compliance score to changes in weight. While a multiple mediator model would have allowed us to investigate the unique contribution of each variable to weight change, we were unable to perform this analyses given our sample size limitations. Despite this, simple, single-mediator models are still recommended in the literature.[62] In addition, the bias-corrected bootstrapped procedure we used in this study has been recommended as appropriate for studies with small sample sizes [63] and aligns with recent mediation papers published in the field.[17, 64-66] Although participant dropout would also have affected study power, the intention-to-treat imputation approach would have minimised these effects, given that estimates are provided for missing data and all participants are essentially retained in the final analysis. Due to sample size constraints, we were unable to validate the compliance score in mid-age women, however this will be addressed in future research. This study and analysis has several strengths. The analysis investigated a comprehensive list of evidenced-based diet and physical activity variables hypothesized to be casually related to weight change. The study design was of two years duration with a 12-month intervention period and an additional 12 months of monitoring to determine weight control maintenance. The study

investigated the mediators of weight loss in an under-reported, at-risk sub group of the population.

Conclusion

Encouraging mid age, pre-menopausal women to take at least 10,000 steps and consume five serves of vegetables per day may be a promising strategy to facilitate successful maintenance of weight loss up to 12 months following a health professional weight control intervention based on motivational interviewing counselling principles.

Conflict of interest

The authors declare that they have no competing interests.

Authors' contributions

All authors made contributed to the interpretation of the results and the drafting and revision of this manuscript. JLH, LTW, CEC and PJM were responsible for the design of the study. JLH completed the literature review, data entry, calculated the compliance score and drafted the initial paper. LTW, KTP and JLH developed the compliance scoring system. MDY conducted the statistical analysis.

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626 Figure 1. Flowchart outlining phase one (12-month intervention period) and phase two (12
627 months follow-up to assess effect maintenance) of the 40-Something study.

628 Figure 2. The 10 weight control recommendations provided to both Motivational Interviewing
629 and Self-Directed Intervention participants.