

## **Effects of Tai Chi and Resistance Training on Cardiovascular Risk Factors in the Elderly: A 12 month Longitudinal, Randomised, Controlled Intervention Study**

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**Background:** Tai Chi is rapidly gaining in popularity, worldwide. This study was performed to assess its impact on cardiovascular risk factors in comparison with resistance training exercises in elderly Chinese subjects.

**Methods:** A total of 207 healthy elderly participants (65-74 years, 113/207 (55%) men) were randomly assigned to one of three intervention groups: 1) Tai Chi, three times/week for one hour/session (n=64); 2) Resistance training exercise, three times/week for one hour/session (n=65); 3) Usual level of physical activity control group (n=78). Anthropometric measures, dual x-ray densitometry body composition, blood pressure, lipids, glycaemic, and insulin sensitivity indices were measured at baseline, and 12 months. Repeated measures analysis of variance was used to assess the between-group changes using a last-observation-carried-forward intention-to-treat approach.

**Results:** A total of 180 (87.0%) subjects completed the study. No significant changes were identified in the Tai Chi group compared to the resistance training or control groups. Of the primary outcomes, only the improvement in the insulin sensitivity index differed being significantly greater in the resistance training than in the control group (mean difference 0.018 (95%CI 0.000, 0.037) mmol glucose/min,  $p=0.02$ ), and tending to be greater than in the Tai Chi group (mean difference 0.019 (95%CI 0.000, 0.038) mmol glucose/min,  $p<0.06$ ).

**Conclusion:** Tai Chi had no significant effect on any measure compared to the controls, whereas resistance training improved the insulin sensitivity index in this 12 month study.

## Introduction

Increasing age is associated with the development of chronic disease, such as the clustering of the cardiovascular risk factors hypertension, type 2 diabetes, obesity and dyslipidaemia which constitute the metabolic syndrome.<sup>1,2</sup> Healthy ageing is therefore a major goal for the medical community to limit age-related morbidity. Increasing physical activity has been shown to reduce cardiovascular risk factors and associated mortality. For instance, in a Chinese subjects with white coat hypertension treadmill-based moderate physical activity three times per week improved the blood pressure and lipid profile.<sup>3</sup> In epidemiological studies, a group of predominantly Caucasian males aged 45-84 years who started moderate physical activity lowered mortality by 23% than those who do not,<sup>4</sup> whereas in another US population males and females with low compared to high physical activity increased their risk by 52 and 110%, respectively.<sup>5</sup> Similar observations have also been described in elderly, mainly Caucasian, populations.<sup>6,7</sup>

Tai Chi, a set of Chinese systematic callisthenic exercises, became well established in the late Ming (1368–1644) and early Qing (1644–1911) dynasties. The circular movements are slow and require the muscles to remain relaxed whilst making a sustained even and continuous effort. Studies investigating Tai Chi have generally concentrated on the modulation of cardiorespiratory function, balance, flexibility and mental well-being, which were often reported to improve in the subjects participating in the Tai Chi intervention compared to the comparator group,<sup>8-14</sup> but not in all studies.<sup>12,14</sup> However, well-controlled trials assessing the effect of Tai Chi on cardiovascular risk factors are lacking.<sup>15,16</sup> Indeed, a recent systematic review found that of 743 abstracts describing Tai Chi only nine were randomised controlled trials and these were of a short duration of 8-16 weeks.<sup>14-17</sup> That review also suggested that bias in presentation of positive data and publication selection bias occurred.<sup>14</sup> The meditative component of the Tai Chi movements has the potential to reduce stress levels that can mediate a range of effects by attenuating the sympathoadrenal axis. Reductions in catecholamine levels can improve the lipid profile, the haemodynamic profile, including blood pressure, and coagulation profile.<sup>18</sup> Similarly, stress can activate the hypothalamic-pituitary-adrenal

axis increasing hypothalamic release of multiple corticotropin secretagogues, corticotropin-releasing hormone and arginine vasopressin.<sup>19</sup> Cortisol hypersecretion has been associated with hypertension, and the development of the constellation of cardiovascular risk factors, including diabetes, hypertension and dyslipidaemia, termed the metabolic syndrome, and associated cardiovascular comorbidities. (Rosmond, 2005 #5003; Bjorntorp, 1999 #3000)

The benefits of resistance training in the elderly have been more widely investigated. Resistance training has been reported to preserve or increase skeletal muscle mass and functional status,<sup>6,21,22</sup> as well as improving memory and well-being.<sup>23,24</sup> However, the impact of physical activity on cardiovascular risk factors, particularly in the elderly, is less clearly understood. Although studies have reported beneficial effects of activity, especially for aerobic activity, on these parameters,<sup>6,25-27</sup> the findings for resistance training are not consistent.<sup>27,28</sup> The use of resistance training to improve skeletal muscle mass may improve insulin resistance,<sup>6,21,22</sup> a potentially important contributing factor to the metabolic syndrome, and thus improve the cardiovascular risk factor profile.<sup>1,2,29</sup>

Despite a lack of rigorous evidence, increasing interest has led to a rapid increase in the United States of America of those practicing Tai Chi to promote healthy ageing. In this study we compared the effects on cardiovascular risk factors over 12 months of Tai Chi in contrast to a resistance training group and a control group.

## **Methodology**

### *Study participants*

The study was approved by the Clinical Research Ethics Committee of the Chinese University of Hong Kong. A total of 225 participants (65-74 years) who gave written informed consent were recruited from community centres for the elderly. Subjects with impaired mobility, dementia, known cardiovascular disease or uncontrolled/newly diagnosed hypertension were excluded, as were those who were regularly performing exercise. After screening for uncontrolled diabetes (glycated haemoglobin >10%), or ongoing physical activity for at least 5 years, 207 Chinese subjects (55% men

(113/207)) were eligible for randomisation (92% (207/225)). A flow diagram of the study as outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement<sup>30,31</sup> is shown in the figure.

### *Primary outcomes*

Although a number of cardiovascular risk factors were investigated in the current study, the major components or determinants of the metabolic syndrome were identified outcomes of primary interest. The study power calculations were based on assumed changes in blood pressure and insulin sensitivity levels. The primary outcomes were; anthropometry: body mass index, waist circumference and dual x-ray densitometry percentage body fat; blood pressure: systolic and diastolic blood pressures; lipids: low- and high-density lipoprotein-cholesterol; insulin resistance: fasting glucose and short insulin tolerance test insulin sensitivity index. The remaining parameters were considered secondary.

### *Randomisation of subjects*

A computer generated randomisation list, stratified by sex, allowing for a 20% extra allocation of subjects to the control group (to allow for a greater expected drop-out rate) was produced. The list was held by one study member, and as the subjects were recruited they were allocated to the appropriate group by the study nurse. We randomised 64 to Tai Chi, 65 to resistance training and 78 to the control group (Figure)

### *Energy expenditure evaluation*

Evaluation of overall energy expenditure was based on the modified Yale Physical Activity Survey.<sup>32-35</sup> The questionnaire includes the duration and frequency of daily activities including occupational work, general (including household duties), sports and leisure time activities, sitting and sleeping. The structured questionnaire has been validated in this population,<sup>36</sup> has a broad coverage and uses intensity codes from existing studies.<sup>33-35</sup>

### *Exercise program*

The exercise interventions were carried out for 12 months, with a study log completed when the subjects attended each group exercise session to assess compliance. Those undertaking the exercise interventions attended a health centre, for one hour sessions three times each week.

The Tai Chi (n=64) was performed using the 24 forms or movements of the simplified Yang style. The Yang style is the most popular form of Tai Chi.<sup>14</sup> The standardized 24 forms were proposed by the Chinese National Council of Sports and Physical Education of the Government of the People's Republic of China in 1956. They have been adopted to reduce the complexity and time required to complete the forms. A 15 minute warm-up period followed by a 45 minutes period of the Yang style Tai Chi was performed, three times a week. The subjects were encouraged to practice the Tai Chi forms between classes. A registered Tai Chi master supervised the Tai Chi classes. The Tai Chi master explained how the forms should be performed and throughout each lesson directed the lesson by performing the forms and the subjects followed the motions.

The muscle strength/resistance training (n=65) sessions were performed three times per week for 45 minutes supervised by a qualified trainer who directed each stage of the session instructing the subjects which action should be performed. Stretching of muscle groups for 15 minutes was performed as warm up, before the actual muscle strength training session. There were seven forms of motion (upper body strengthening: arm lifting; central body strengthening: hip adduction; lower body strengthening: heel raise, knee flexion, hip extension and ankle dorsiflexion). Each motion was repeated 30 times at each visit using a Theraband, a cloth-covered elasticated loop (Hygienic, Akron, Ohio), to provide the resistance. Additional Therabands were available to increase the resistance as required on an individual basis to progress the resistance training. Given the age of the subjects and the aim of assessing the intervention for long-term health improvements there was no forced progression of the resistance training, and although the subjects were encouraged, none of the participants wished to increase the level of resistance.

The volunteers in the non-intervention control group (n=78) were requested to maintain their usual levels of physical activity for the duration of the study.

### *Baseline and outcome measurements*

All subjects, including controls, had the physiological and clinical assessments measured at baseline, and 12 months after the initiation of the exercise program. Percentage body fat was measured by dual x-ray densitometry (Hologic QDR-4500, Waltham, Massachusetts). Fasting plasma parameters (Table 1) were measured as previously reported.<sup>1,37</sup> Blood pressure and pulse rate (mean of three readings taken one minute apart after five minutes seated rest) were measured with an automatic sphygmomanometer (Dinamap, Critikon, California). Hypertension was classified as systolic/diastolic blood pressure  $\geq 140/90$  mm Hg; dyslipidaemia as total cholesterol  $\geq 6.2$  or 5.2-6.2 mmol/L, if the total cholesterol-to-high-density lipoprotein-cholesterol ratio was  $\geq 5.0$ ; or triglycerides  $\geq 2.3$  mmol/L; impaired fasting glucose/diabetes as a glucose between 6-7.0/ $\geq 7.0$  mmol/L; or in each category the use of medications. Overweight or obesity were defined according to criteria for Asian populations as a body mass index  $\geq 23.0/25.0$  kg/m<sup>2</sup>.<sup>38</sup>

The short insulin tolerance test is a simple 20 minute protocol which assesses the glucose decay curve following an intravenous bolus of 0.1 U/kg insulin (Actrapid HM, Novo Nordisk, Bagsvaerd, Denmark) through a cannulated antecubital vein as previously reported.<sup>39</sup> The intra-subject coefficient of variation was 7-9% in normal controls.<sup>39</sup> Insulin sensitivity was determined from the slope of a least-squares linear regression performed on glucose concentrations obtained during the maximum response to insulin.

### *Statistical analyses*

Data from normally distributed parameters are presented as mean $\pm$ standard deviation. Skewed data were logarithmically transformed and expressed as geometric mean with 95% confidence intervals (95%CI). Baseline differences in the continuous variables were assessed using analysis of variance

with Bonferroni post hoc test to identify where possible differences may exist. Differences in non-continuous data between the groups were assessed using the  $\chi^2$ -test. Repeated measures analysis of variance was used to determine whether longitudinal changes in the parameters within-groups were significantly different between the three study groups, which are the primary endpoints for of the study. Data from all 207 subjects who were randomised were included in the analyses using last-observation-carried-forward intention-to-treat analyses. The Statistics Package for Social Sciences (SPSS, Chicago, Illinois) was used for the above analyses.

## **Results**

### *Subjects*

A total of 207 elderly participants (mean age  $68.8 \pm 2.9$  years, 55% men (113/207)) were randomised to one of three intervention groups: 1) Tai Chi, three times/week for 1 hour/session, 2) Resistance training exercise, three times/week for 1 hour/session, or 3) a control group who maintained their usual level of physical activity. The mean age and sex distribution of the three groups were similar, as were the other parameters (Table 1). There was a high prevalence of metabolic disorders found in each of these groups, with mean prevalence rates of 61% (126/207) for hypertension, 14% (29/207) impaired fasting glucose or diabetes, 59% (121/207) dyslipidaemia, and 65% (134/207) were overweight or obese (Table 1). There were no differences in the prevalence of treatments for these conditions (Table 1). Calcium channel blockers (55%),  $\beta$ -blockers (23%), and diuretics (20%) were the most commonly prescribed blood pressure-lowering treatments, whereas sulphonylureas were the most commonly prescribed glucose-lowering agent (90%), of which 42% were in combination with metformin. During the study only 12 subjects (5.8%) changed their medications, gemfibrozil was introduced in 1 patient; blood pressure treatment was changed or increased in 10 subjects, and glucose-lowering treatment changed or increased in 4 subjects, 3 of whom also had changes in antihypertensive therapy. However, when we repeated the analyses after excluding these subjects there was no difference in the relationship between the interventions and the outcome measures (data not shown)

### *12 month follow-up*

A total of 180 subjects completed the study, 60 in each group, and in those subjects the proportion of classes attended over the 12 month study period, which was used to assess compliance, was high in both intervention groups being  $81\pm 16\%$  in the Tai Chi, and  $76\pm 19\%$  in the resistance training group. Using last-observation-carried-forward intention-to-treat analysis, those participants randomised to the Tai Chi ( $p=0.11$ ) or resistance training ( $p=0.06$ ) groups tended to increase their energy expenditure related to the controls (Table 2). However, exercise-related energy expenditure was a relatively small proportion of the weight-adjusted daily total energy expenditure, which remained unchanged.

### *Within-group analyses*

The glycaemic indices, glucose and glycated haemoglobin A1c improved significantly in all three groups. Furthermore, in the intervention groups, waist circumference and heart rate were reduced, exercise and daily energy expenditures increased, but not significantly compared to the control group (Table 2).

### *Between-group analyses*

When the longitudinal changes in the intervention groups were compared relative to the control group, the insulin sensitivity index was the only primary outcome for which a significant between-group difference was identified. The resistance training group was found to have a significantly greater increase in sensitivity to insulin than the control group (mean difference 0.018 (95%CI 0.000, 0.037) mmol glucose/min,  $p<0.05$ ). There was also a tendency for the resistance training group to have a greater increase in insulin sensitivity than the Tai Chi group (mean difference 0.019 (95%CI 0.000, 0.038) mmol glucose/min,  $p<0.06$ ). There was no evidence of a potential difference between the groups with the other primary outcome variables.

## Discussion

The strive for healthy ageing is leading to increases in the utilization of alternative therapies, but the purported benefits of Tai Chi have yet to be validated in controlled trials. The study subjects were found to have similar prevalence rates of metabolic disorders as those of the age-matched general population.<sup>40,41</sup> The compliance to the study interventions of the randomised subjects was high at 81 and 76% for the Tai Chi and resistance training groups respectively. The subjects were encouraged to increase their level of exertion throughout the study, and tended to increase the exercise related energy expenditure in the intervention groups. However, relative to the total energy expenditure these energy expenditure changes were small, but are likely to be representative of levels of activity that can be maintained in similarly aged populations. It is possible that the subjects modified other daily activities to compensate for their increased energy expenditures during exercise, and this could have negated some of the beneficial effects of the exercises. Maintenance of other activities should be encouraged in such intervention studies. Limited total energy changes in response to exercise intervention have been reported in other populations.<sup>42</sup> This may, in part, explain the minimal significant improvements in the parameters in the intervention groups compared to the controls, as has been reported in other studies.<sup>27,28</sup>

The between-group analyses found the insulin sensitivity index was improved more in the resistance training group compared to the controls, and the time to reduce glucose levels by an equivalent to baseline tended to be lower. It had been envisaged that resistance training may improve insulin sensitivity.<sup>26,43</sup> Peripheral insulin resistance has been purported to be a major risk factor for the development of the metabolic syndrome.<sup>29</sup> However, in Chinese it is unlikely to be a major determinant independent of obesity.<sup>1,2</sup> Resistance training has been reported to improve the performance/mass of skeletal muscle,<sup>6,21,22</sup> the major site of insulin resistance in metabolic syndrome patients.<sup>29</sup> The absence of a significant difference may in part be due to the large variability in these parameters or insufficient intervention intensity. Additionally, the short insulin tolerance test may also measure hepatic rather than skeletal muscle sensitivity and so may not be sensitive to this change.

Although studies suggest that Tai Chi improves cardiorespiratory function, balance, flexibility and mental well-being,<sup>8-13</sup> only minimal data describe its effects on cardiovascular risk. One report suggested that Tai Chi reduced blood pressure to a similar extent as aerobic exercise,<sup>15</sup> but no non-intervention control group was included, so conclusions cannot be drawn. Similarly in another study in patients post myocardial infarction, blood pressure fell in the Tai Chi and aerobic exercise groups, but the authors could not compare with the non-exercise support group as only 8% (4/47) of the group completed the study.<sup>16</sup> The lack of a satisfactory non-intervention control group means the confounding placebo or “Hawthorne” effect cannot be excluded, and may contribute to the conflicting nature of the literature,<sup>14</sup> as may have been the case in the present study had we not included a control group. A limitation of the current study is the lack of data describing life style factors such as alcohol consumption and smoking history in these subjects. Furthermore, 12 subjects (5.8%) changed their medications during the study, although repeating the analyses without those subjects did not affect the findings. Medications may have attenuated the changes associated with the physical activity interventions, but are representative of those that would be seen in older populations, and thus investigation of the interventions in subjects receiving common treatments is appropriate. Although the majority of the subjects had at least one metabolic abnormality, it is possible that a population with all the subjects having more abnormal metabolic profiles may have responded to a greater extent to the activity interventions.

In summary, we found that despite apparent within group improvements in a number of anthropometric and metabolic parameters, intervention with Tai Chi or resistance training did not significantly improve those parameters relative to the control group, except for resistance training which improved the insulin sensitivity index from the short insulin tolerance test.

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**Table 1. Baseline characteristics of the three study groups.**

Characteristic	Controls (n=78)	Tai Chi (n=64)	Resistance training (n=65)
	Number (%), Mean $\pm$ standard deviation, or Geometric mean (95% confidence interval)		
Age (years)	69 $\pm$ 3.0	68.9 $\pm$ 2.8	69.1 $\pm$ 3.2
Male sex	44 (56)	34 (53)	35 (54)
Body mass index (kg/m <sup>2</sup> )*	24.2 $\pm$ 3.0	23.8 $\pm$ 3.9	24.2 $\pm$ 3.8
Waist circumference (cm)*	86.5 $\pm$ 7.3	84.9 $\pm$ 11.0	86.9 $\pm$ 10.3
Dual x-ray densitometry body fat (%)*	31.0 $\pm$ 7.0	29.6 $\pm$ 7.6	29.4 $\pm$ 7.1
Systolic blood pressure (mm Hg)*	140 $\pm$ 20	142 $\pm$ 17	142 $\pm$ 23
Diastolic blood pressure (mm Hg)*	71 $\pm$ 12	72 $\pm$ 13	72 $\pm$ 14
Pulse (beats per min)	67 $\pm$ 11	70 $\pm$ 11	67 $\pm$ 9
Total cholesterol (mmol/L)	5.5 $\pm$ 0.9	5.4 $\pm$ 1.0	5.5 $\pm$ 0.9
Low density lipoprotein-cholesterol (mmol/L)*	3.6 $\pm$ 0.9	3.4 $\pm$ 0.9	3.6 $\pm$ 0.8
High density lipoprotein -cholesterol (mmol/L)*	1.3 $\pm$ 0.3	1.4 $\pm$ 0.35	1.3 $\pm$ 0.4
Triglycerides (mmol/L)	1.4 (1.3-1.5)	1.2 (1.1-1.4)	1.2 (1.1-1.4)
Glucose (mmol/L)*	5.1 $\pm$ 0.9	5.0 $\pm$ 0.9	5.1 $\pm$ 0.9
Glycated Haemoglobin A1c (%)	5.9 $\pm$ 0.8	5.8 $\pm$ 0.6	5.8 $\pm$ 0.7
Insulin sensitivity (mmol glucose/min)* <sup>†</sup>	0.138 $\pm$ 0.051	0.141 $\pm$ 0.045	0.157 $\pm$ 0.065
Glucose decrement (%) <sup>†</sup>	34.8 $\pm$ 9.8	33.6 $\pm$ 10.5	34.6 $\pm$ 11.3
Exercise energy expenditure (Kcal)	592 $\pm$ 783	497 $\pm$ 550	581 $\pm$ 713
Total daily energy expenditure (Kcal)*	2206 $\pm$ 397	2071 $\pm$ 378	2108 $\pm$ 425
Prevalence of hypertension (Rx, %)	57.7 (30.8)	70.3 (37.5)	55.4 (23.1)
Prevalence of dyslipidaemia (Rx, %)	55.1 (1.3)	62.5 (1.6)	58.5 (1.5)
Prevalence of impaired fasting glucose/diabetes (Rx, %)	4.0/8.0 (10.3)	7.8/10.9 (12.5)	3.2/9.7 (7.7)
Prevalence of obesity (%)	37.2	40.6	40.0

No significant differences between the three groups were identified. \*primary outcomes; <sup>†</sup>data generated from the short insulin tolerance test; <sup>‡</sup>adjusted for body weight

**Table 2. Absolute changes in group characteristics over the 12 month study period and repeated measures analysis of variance analysis of relative changes between the three study groups.**

Characteristics	Controls	Tai Chi	Resistance training	Repeated measures analysis of variance between group p values
	Mean absolute change over 12 months (95% confidence intervals)			
Body mass index (kg/m <sup>2</sup> )*	0.1 (-0.0, 0.3)	0.3 (-0.0, 0.5)	0.1 (-0.1, 0.2)	0.82
Waist circumference (cm)*	-0.1 (-0.9, 0.7)	-1.5 (-2.5, -0.5) <sup>§</sup>	-1.7 (-2.6, -0.8) <sup>§</sup>	0.35
Dual x-ray densitometry body fat (%)*	-0.4 (-0.7, -0.1) <sup>§</sup>	-0.1 (-0.5, 0.4)	-0.2 (-0.6, 0.2)	0.43
Systolic blood pressure (mm Hg)*	-0.3 (-3.8, 3.2)	-1.0 (-3.7, 1.6)	-5.2 (-9.9, -0.5) <sup>§</sup>	0.78
Diastolic blood pressure (mm Hg)*	1.1 (-0.7, 2.9)	2.2 (0.1, 4.2) <sup>§</sup>	-0.1 (-2.2, 2.0)	0.53
Pulse (beats per min)	-2 (-4, 0)	-3 (-5, -1) <sup>§</sup>	-2 (-3, -0) <sup>§</sup>	0.29
Total cholesterol (mmol/L)	-0.0 (-0.2, 0.1)	-0.0 (-0.2, 0.2)	0.0 (-0.2, 0.2)	0.56
Low density lipoprotein-cholesterol (mmol/L)*	-0.1 (-0.2, 0.0)	-0.1 (-0.2, 0.1)	-0.1 (-0.2, 0.1)	0.26
High density lipoprotein -cholesterol (mmol/L)*	0.1 (0.0, 0.1)	0.1 (-0.0, 0.1)	0.1 (0.01, 0.1) <sup>§</sup>	0.24
Triglycerides (mmol/L)	0.0 (-0.2, 0.2)	-0.0 (-0.2, 0.2)	-0.2 (-0.4, 0.1)	0.15
Glucose (mmol/L)*	-0.3 (-0.5, -0.1) <sup>§</sup>	-0.5 (-0.7, -0.2) <sup>§</sup>	-0.5 (-0.8, -0.3) <sup>§</sup>	0.47
Glycated haemoglobin A1c (%)	-0.3 (-0.3, -0.2) <sup>§</sup>	-0.3 (-0.4, -0.2) <sup>§</sup>	-0.3 (-0.4, -0.2) <sup>§</sup>	0.43
Insulin sensitivity (mmol glucose/min) * <sup>†</sup>	0.000 (-0.011, 0.012)	-0.007 (-0.022, 0.007)	-0.003 (-0.020, 0.013)	0.02
Glucose decrement (%) <sup>†</sup>	-0.5 (-3.1, 2.2)	0.0 (-3.5, 3.6)	4.5 (1.5, 7.5) <sup>§</sup>	0.11
Exercise energy expenditure (Kcal)	-15 (-184, 152)	351 (184, 519) <sup>§</sup>	246 (38, 453) <sup>§</sup>	0.11
Total daily energy expenditure (Kcal) <sup>‡</sup>	-89 (-139, -40) <sup>§</sup>	74 (10, 138) <sup>§</sup>	140 (74, 207) <sup>§</sup>	0.62

Analyses performed using last-observation-carried-forward intention-to-treat analysis in all 207 randomised subjects. \*primary outcomes; <sup>†</sup> data generated

from the short insulin tolerance test; <sup>‡</sup>adjusted for body weight. <sup>§</sup>significant within-group differences by paired-t-test.

**Figure. Flow diagram describing subject enrolment, intervention allocation, follow-up and data analysis at 12 months as outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement.**<sup>30,31</sup>

