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Does soy protein supplementation affect body composition in healthy exercising adults? A systematic review and meta-analysis of clinical trials

Running title: Effects of soy protein on body composition: A meta-analysis

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Conflict of interest

The authors declare that there is no conflict of interest with respect to this manuscript.

1 ABSTRACT

2 Background Objectives

3 The effects of soy protein supplementation on anthropometric parameters and body composition
4 indices of healthy adults is equivocal. The aims of this systematic review and meta- analysis were
5 to assess the effects of soy protein supplementation on weight and body composition of healthy
6 adults in clinical trial studies.

7 Methods

8 A systematic search of literature was carried out on clinical trial studies in PubMed, Scopus,
9 Cochrane's library and ISI Web of Science Direct up until November 2017. From 492 studies
10 initially retrieved, only 8 articles with 6, 5 and 4 arms included in the meta-analysis of the effects
11 of soy protein supplementation on body weight, Fat free mass and Fat mass, respectively, with
12 120 participants in the intervention group and 119 participants in the control group.

13 Results

14 Results of the fixed effect model meta-analysis showed that soy protein supplementation had no
15 significant effects on body weight (0.94 kg, 95% CI: -2.41, 4.30 kg; P=0.58), fat-free mass (0.6
16 kg, 95% CI: -0.21, 1.41; P=0.14) or fat mass (0.43 kg, 95% CI: -2.18, 3.03; P=0.74) in healthy
17 exercising adults.

18 Conclusions

19 Results of this meta-analysis study does not confirm any significant beneficial effects of soy
20 protein supplementation on weight and body composition in healthy adults.

21

22 **Keywords:** soy protein; weight; fat mass; fat-free mass; meta-analysis

23

24 **Introduction**

25 Soy is regarded a high quality protein source, with relatively abundant levels of essential amino
26 acids [1]. Epidemiological studies have confirmed the beneficial effects of soy-foods
27 consumption in lowering the incidence of several chronic diseases, including chronic heart
28 disease, osteoporosis, diabetes type 2 and various hormone-related cancers [2-5]. The protein
29 content of the soy bean comprises approximately 40% of its dried weight[6]; for this reason, soy
30 protein is one of the most popular supplements, alongside whey protein, for active and exercising
31 adults, and is used to facilitate a higher protein intake for the improvement of body composition
32 indices [7, 8]. One clinical trial study in non-resistance training men and women found that
33 consuming whey protein supplements could result in 3.6 Kg increases in lean body mass (LBM)
34 in compared to people consuming isocaloric carbohydrate containing supplements [9]. However,
35 the results of a systematic review and meta- analysis contended this, asserting that whey protein
36 supplementation could only modestly increase LBM, and has no significant effect on total fat
37 mass [10].

38 The effects of soy protein consumption on anthropometric parameters and body composition are
39 conflicting in several clinical trial studies, conducted on people undergoing physical exercise-
40 based interventions. One study showed that consuming a soy protein supplement, adjunct to non-
41 resistance-based training for 9 months, resulted in 2.6 kg increase in LBM [9]. Whilst further
42 work has shown that adding soy protein to normal milk consumption, in post-menopausal
43 women, combined with resistance training for 16 weeks, significantly increases muscle strength
44 in this population [11]. Contrastingly, Maesta et al concluded that soy protein supplementation
45 does not significantly influence the indices of body composition in post-menopausal women
46 undergoing resistance-based exercise [12]. Due to the equivocality in the literature regarding the

47 effect of soy protein consumption on body composition indices, and a dearth of meta-analytical
48 assessments, the aim of the present study was to systematically review and meta-analyze the
49 effects of soy protein supplementation on weight and body composition of healthy adults in
50 clinical trial studies

51

52 **Methods**

53 **Search strategy and study selection**

54 The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines
55 were adopted to perform this systematic review and meta-analysis. Initially, two independent
56 researchers conducted a systematic search of literature, using online databases; PubMed, Scopus,
57 Cochrane's library and ISI Web of Science Direct, with now lower date restriction, and an upper
58 date restriction of November 2017, with following terms, as contained in titles, abstracts and
59 keywords: "Obesity OR overweight OR LBM OR FFM OR lean mass OR fat free mass OR body
60 fat OR BMI OR body mass index OR body mass OR adiposity OR body composition OR body
61 size OR fat mass OR lean body mass OR body weight" and "Athlete OR elite OR exercise OR
62 training OR sport" and "Soy OR soya OR soy protein OR soybean". Language restriction was
63 not imposed. Manual search in reference list of relevant articles was also performed to
64 supplement the search process.

65 **Inclusion and exclusion criteria**

66 To be included in the systematic review and meta-analysis, articles were required to meet the
67 following inclusion criteria; 1) studies were controlled clinical trials of oral supplementation of
68 soy protein, 2) studies reported mean or median values of body weight, fat mass and fat free

69 mass with standard deviation (SD), standard error of the measurement (SEM) or 95% confidence
70 intervals (CI) at the beginning and the end of the study, 3) the study was performed with healthy,
71 exercising adults. Additionally, articles were excluded if; 1) there was combined
72 supplementation of soy protein with other types of protein (whey, egg, etc.), 2) studies had no
73 control or placebo group, 3) studies did not have enough data at baseline and final value of body
74 weight, fat mass, fat free mass, 4) studies were observational.

75 **Data extraction and quality assessment**

76 Duplicated articles were first removed, then titles and abstracts screened by two independent
77 authors (OA, MZ) for relevance to the topic. Following this, full-texts of selected articles were
78 retrieved and assessed for eligibility. Any disagreement between two researches were discussed
79 and reconciled with the help of third author (EY). Quality assessment of trials was done by use
80 of Jadad scale, which scores trials for reporting randomization, blinding, number and reasons of
81 dropouts [13]. The characteristics of included studies were extracted in a tabulated spreadsheet
82 as; first author's name, year of publication, original country, sample size in intervention and
83 control groups, dosage and duration of soy protein supplementation and study design. The
84 extracted population characteristics were; sex, mean age, BMI, baseline and final value of body
85 weight, fat mass and fat free mass in control and supplementation groups. All anthropometric
86 values were reported as kg.

87 **Data synthesis and statistical analysis**

88 STATA version 12.0 (Stata Corporation, College Station, TX, USA) was used for all analyses in
89 this study. The mean and SD of anthropometric values at study commencement and post-
90 supplementation in control and intervention groups were used. The reported median values with

91 confidence intervals or ranges were converted to mean and SD using the Hozo et al method [14].
92 Heterogeneity was assessed using Cochran's Q-test (significance set at $P < 0.05$) and the I^2 test
93 were used for calculating the percentage of heterogeneity among studies. A fixed effects model,
94 or in the presence of heterogeneity random effects model, was conducted to calculate pooled
95 effect size. Beg test, Egger's regression test and funnel plot were used for assessment of
96 publication bias.

97 **Results**

98 **Search results and study selection**

99 In the literature search of PubMed, Scopus, Cochrane's library and ISI Web of Science, a total
100 of 492 articles identified. Following removal of 83 duplicated references, 409 articles were
101 included for title and abstract screening. Subsequently, 384 articles were excluded because they
102 did not meet the inclusion criteria, resulting 25 articles remaining for eligibility assessment.
103 After quality assessment, 8 articles were deemed suitable for inclusion in the meta-analyses of
104 the effect of soy protein supplementation on body weight (6 trials), Fat mass (4 trials) and Fat
105 free mass (5 trials). All of the included studies were randomized, controlled trials. Flowchart of
106 study selection of this meta-analysis is shown in Figure 1.

107 **Study characteristics**

108 Included studies were performed between the years of 2004 and 2017, of varying origin,
109 including; USA [15-17], Canada [18, 19], Germany[20], China[21], and Australia[22], with a
110 total of 120 participants in the intervention group and 119 participants in the control group. The
111 mean ages of participants ranged between 20.44 and 61.7 y and a mean BMI of 21.8 to 27.6
112 $\text{kg}\cdot\text{m}^2$. Intervention durations of trials were between 4 and 39 weeks, with the average of 12.5

113 weeks. All trials were designed as randomized, controlled clinical trials. The type and dose of
114 soy supplementation varied between studies. The characteristics of the included studies and
115 participants are depicted in Table 1.

116 **Meta-analysis**

117 Meta-analysis of the effects of soy protein supplementation on body weight, fat free mass and fat
118 mass of healthy adults were carried out in 6, 5 and 4 studies, respectively. Results of the pooled
119 effects size, fixed effect model, meta-analysis showed that soy protein supplementation had no
120 significant effects on body weight (0.94 kg, 95% CI: -2.41, 4.30 kg; P=0.58; test for
121 heterogeneity: P=0.99 and $I^2=0.0\%$) (Figure 2), fat mass (0.43 kg, 95% CI: -2.18, 3.03; P=0.74;
122 test for heterogeneity: P=0.53 and $I^2=0.0\%$) (Figure 3) and fat-free mass (0.6 kg, 95% CI: -0.21,
123 1.41; P=0.14; test for heterogeneity: P=0.7 and $I^2=0.0\%$) (Figure 4) of healthy adults.

124 **Publication Bias**

125 No publication biases were seen by using Begg test (P = 0.18 for body weight, P = 0.32 for fat
126 free mass and P = 1.0 for fat mass) and Egger's regression tests (P = 0.34 for body weight, P =
127 0.41 for fat free mass and P = 0.32 for fat mass). The funnel plots are shown in Figure 5.

128 **Discussion**

129 Protein ingestion, especially after resistance training, can improve muscle protein synthesis in
130 exercising adults [23]. However, results of this meta-analytical study was revealed that the
131 consumption of soy protein supplements had no beneficial effects on weight and body
132 composition of healthy adults.

133 Several studies have sought to compare the effects of varying sources of protein
134 supplementation, particularly whey versus soy protein, on muscle mass and strength in response
135 to an exercise intervention. In this regard, the consumption of skimmed milk after resistance
136 exercise has been shown to result in gaining greater LBM in comparison to soy-based beverages
137 with equivalent protein, macronutrient and caloric content [18]; whilst Lacroix and colleagues
138 revealed greater capacity of milk protein in muscle accretion after resistance exercise [24]. This
139 phenomenon may be putatively attributed to the higher branched chain amino acids (BCAAs)
140 exit in milk protein, which can alter the flux of certain amino acids into muscles for protein
141 anabolism; where some empirical data exists to support the claim that adding BCAAs to soy
142 protein can improve muscle metabolism in healthy elderly subjects [25]. However, Haub et al., in
143 a study on older men, comparing different sources of animal and vegetable proteins concomitant
144 to resistance training, concluded that when protein intake is adequate, both meat- and soy-based
145 diets could facilitate a significant increase in strength, and induce muscle accretion through
146 sustaining a positive nitrogen balance [26].

147 Moeller et al., in a clinical trial study on post-menopausal women lasting 24 weeks, showed that
148 whilst soy protein supplementation could significantly increase hip lean mass, it cannot prevent
149 fat deposition in the abdominal cavity [27]. Whereas Thomson et al., showed that soy protein
150 ingestion during resistance exercise, in healthy older adults, could attenuate muscle strength, and
151 that this effect may be mediated through the isoflavone content of soy, which can reduce post-
152 exercise serum levels of testosterone [22]. The results of recent meta-analysis study assessing the
153 effects of whey protein supplementation on body composition parameters in women, showed that
154 this supplementation only can increase lean body mass as much as 370 gr, without conferment of

155 significant effects on fat mass. Additionally, the authors noted that energy restriction augmented
156 the beneficial effects of whey protein supplementation [10].

157 It is conceivable that free radicals produced during exercise could induce muscle damage and
158 limit the amount of fat-free mass gain during exercise. It is believed that the isoflavones,
159 saponins and other antioxidant content present in soy protein could neutralize free radicals
160 produced during exercise, and possibly, result in beneficial effects on body composition [28].

161 Another mechanism purportedly justifying the beneficial effects of soy protein consumption on
162 body composition is that isoflavone content of this protein can alter lipoprotein metabolism
163 through interacting with peroxisome-proliferator activated receptors (PPARs), which can affect
164 energy metabolism via influencing the expression of genes involved in metabolic pathways,
165 including fatty acids oxidation and glucose homeostasis [29, 30].

166 Although the results of present meta-analysis showed no heterogeneity between studies included
167 in the final analysis, we performed sub-group analysis based on duration of intervention. The
168 results revealed no significant differences in weight and body composition of healthy adults
169 when the duration of soy protein supplementation was less than 12 weeks, versus studies lasting
170 at least 12 weeks (data are not shown). One limitation of this study is the sparse number of
171 clinical trials that remained in the final step of quantitative synthesis, this was because of the
172 paucity of studies conducted on the topic. Small sample size of subjects in included studies is
173 another limitation of this meta-analysis which can probably justify these insignificant results.
174 Another limitation of our study is assuming lean body mass and fat-free mass are equivalent.
175 Although lean body mass is not the same as fat-free mass, and it have small percent of lipid as
176 essential fat ,which are necessary for normal body functioning [31], for purposes of statistical

177 analyses, we equated lean body mass to fat-free mass, this was due to the lack of standardized
178 reporting in the included studies.

179 **Conclusions**

180 The results of current meta-analysis study did not suggest any beneficial effects of soy protein
181 supplementation on weight and body composition components in healthy adults.

182 Notwithstanding, it is evident that more, well-controlled and randomized studies are needed in
183 order to better elucidate the effects of soy protein supplementation on body composition indices
184 in healthy adults.

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Table1. Characteristic of included studies in the meta-analyses

Author	Year	Country	Study design	participants	sex	Trial duration (week)	Type and Daily dose of soy supplementation	Placebo	Sample size in intervention group/control	Jaded score
Brown.EC ⁽⁴⁾	2004	USA	R/DB	healthy volunteers	M	9	protein bar 33 gr/day	none	9/9	4
Hartman.JW ⁽⁹⁾	2007	Canada	R/PC	healthy volunteers	M	12	soy protein drink 500 ml /day	maltodextrin	19/19	3
Berg.A ⁽²⁾	2012	Germany	R	healthy volunteers	M/F	6	soy supplementation 53.3 gr /day	none	15/15	3
Aristizabal.JC ⁽¹⁾	2014	USA	R/DB	healthy volunteers	M/F	39	soy supplementation 20 gr/day	carbohydrate	21/22	3
Candow.DG ⁽⁵⁾	2006	Canada	R/PC/DB	healthy volunteers	M/F	6	soy supplementation 1.2 gr/kg/day	maltodextrin	9/9	4
Liu.W ⁽¹⁴⁾	2013	China	R/PC	healthy volunteers	M	4	soy peptide 10 gr/day	placebo	6/7	2
Thomson.RL ⁽²⁹⁾	2016	Australia	R	healthy volunteers	M/F	12	soy supplementation 1.2 gr/kg/day	none	26/23	4
Mobley.CB ⁽¹⁸⁾	2017	USA	R/PC/DB	healthy volunteers	M	12	soy protein concentrate 78.4 gr/day	maltodextrin	15/15	4

Abbreviations: DB, double-blinded; PC, placebo-controlled; R, randomized; NR, not reported.

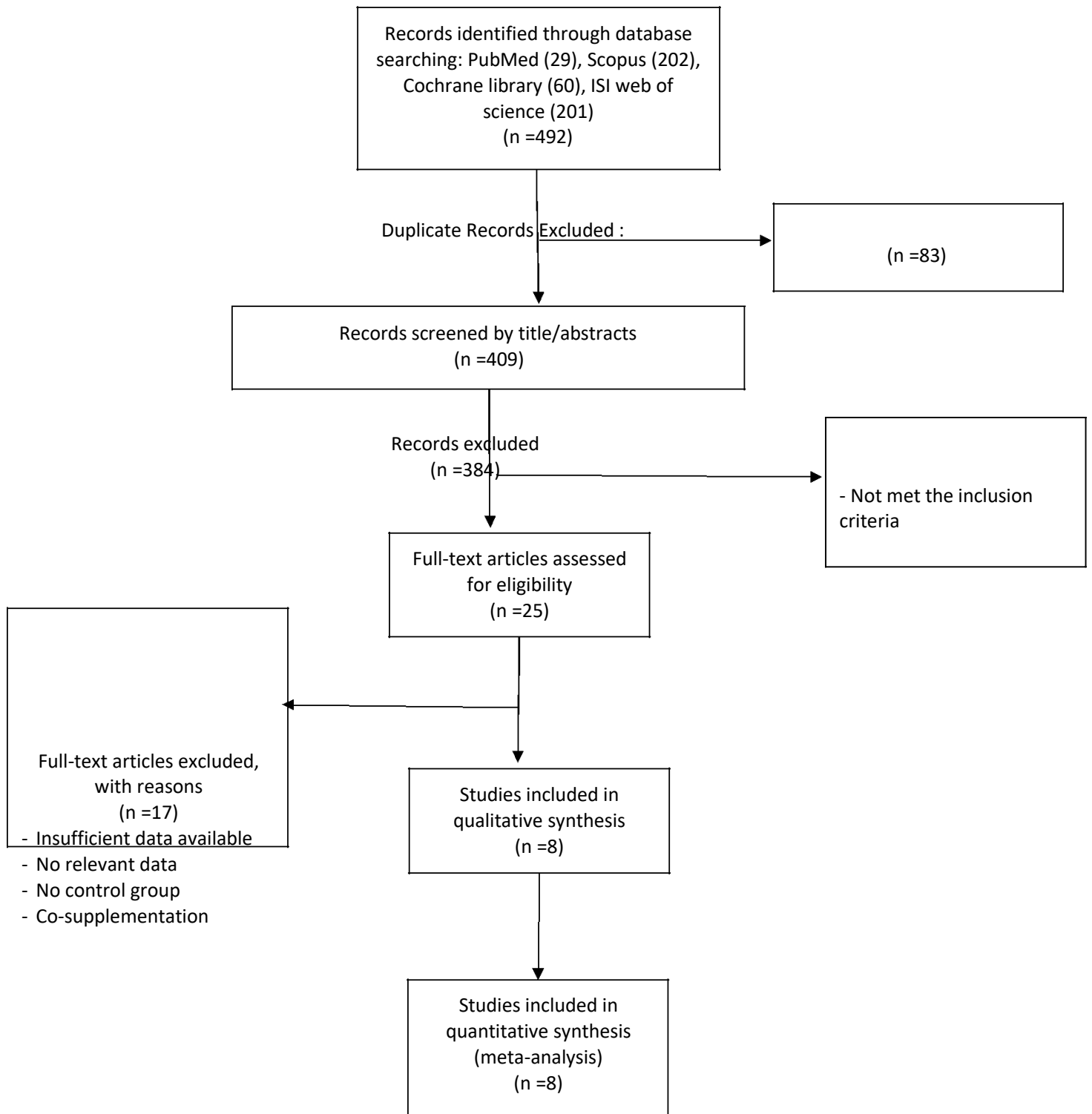


Figure 1. Flowchart of study selection for inclusion trials in the systematic review.

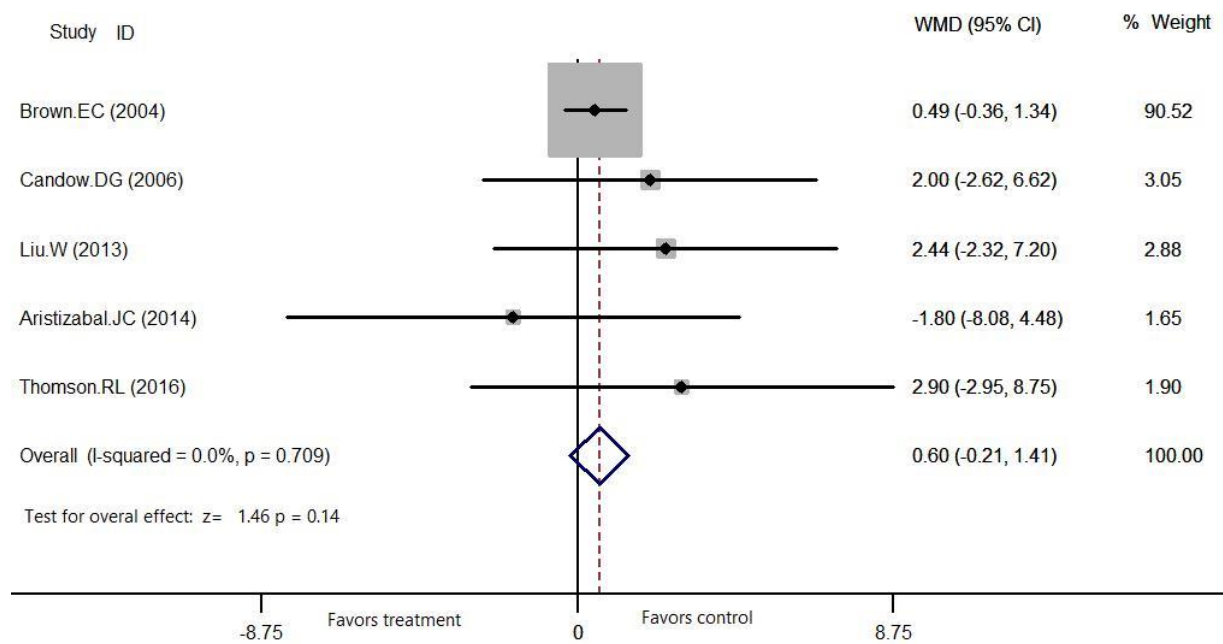


Figure 4. Pooled effect size of fixed effect model of soy protein supplementation on fat free mass (kg).

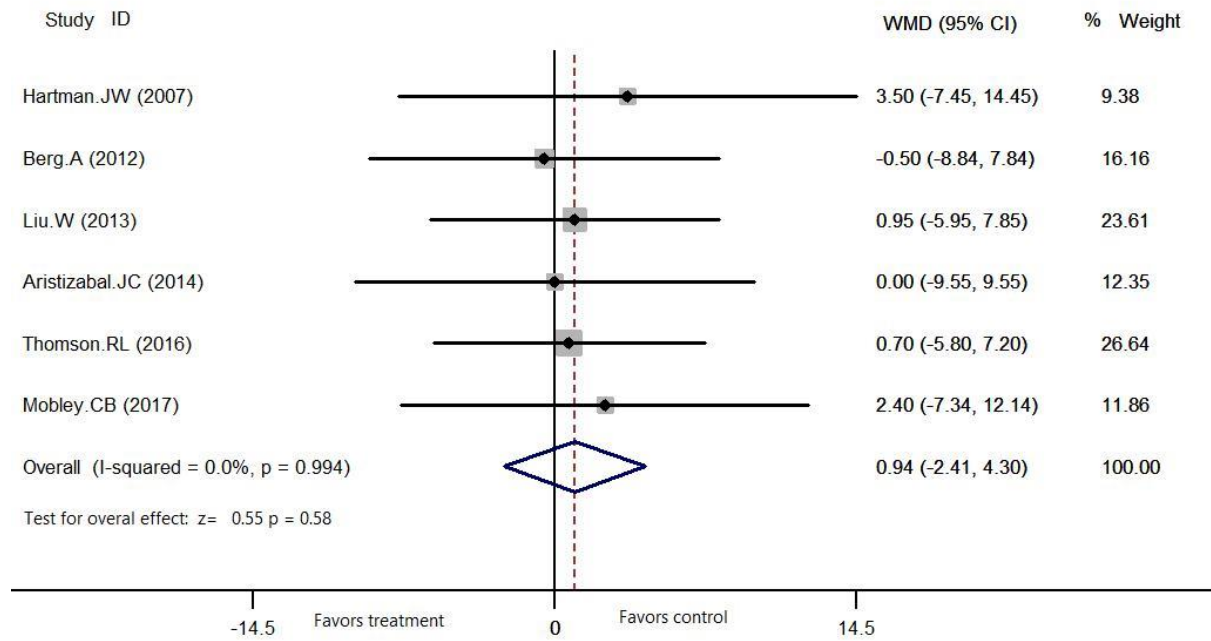


Figure 2. Pooled effect size of fixed effect model of soy protein supplementation on body weight (kg).

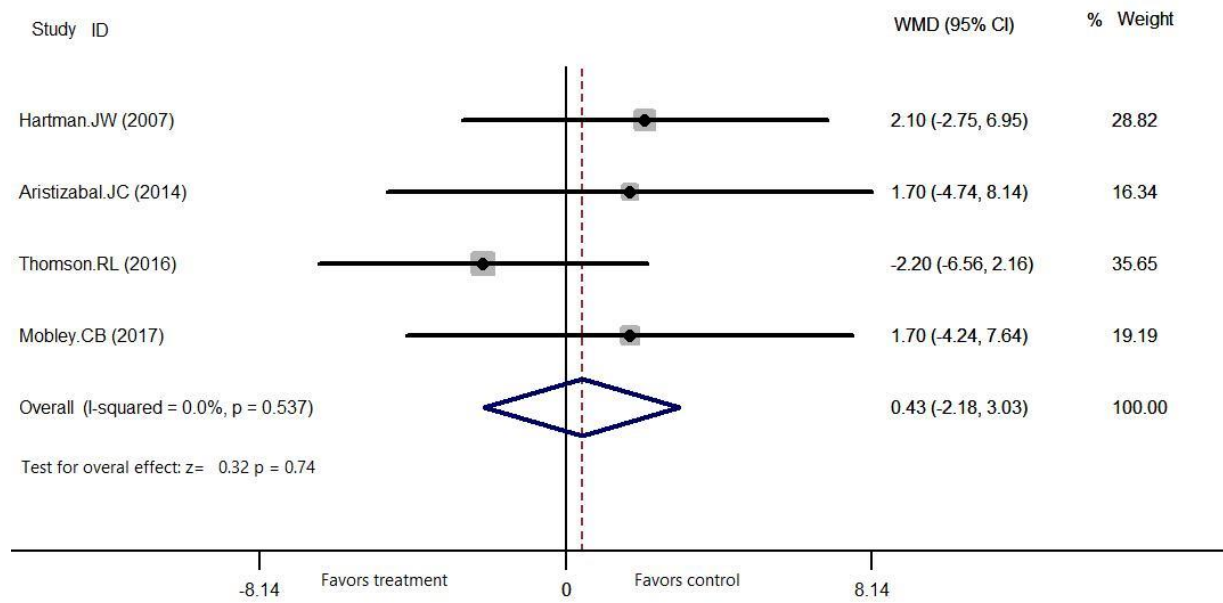


Figure 3. Pooled effect size of fixed effect model of soy protein supplementation on fat mass (kg).

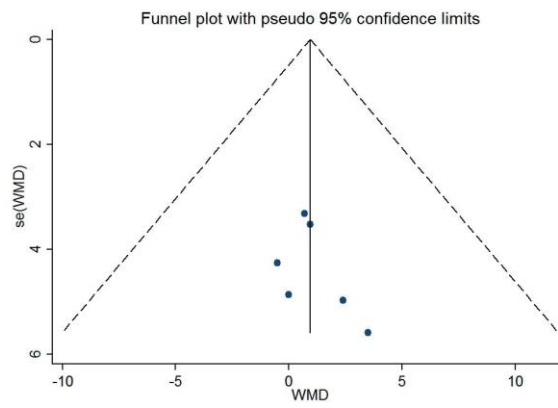
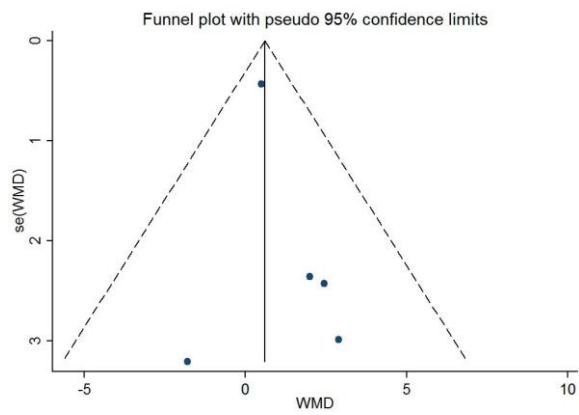
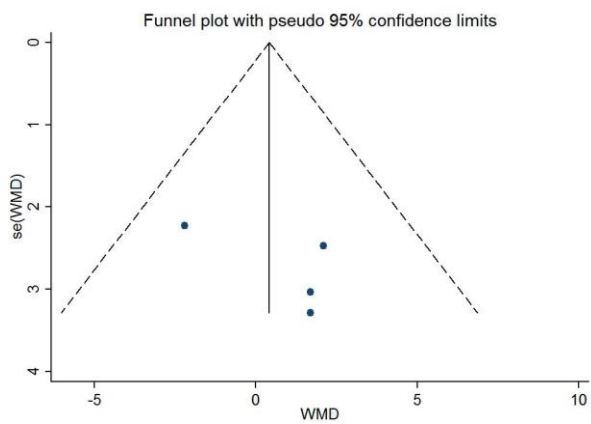
Body weight**Fat free mass****Fat mass**

Figure 5. Funnel plots