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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
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ABSTRACT

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

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

Results
Results of the fixed effect model meta-analysis showed that soy protein supplementation had no significant effects on body weight (0.94 kg, 95% CI: -2.41, 4.30 kg; P=0.58), fat-free mass (0.6 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 exercising adults.

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

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

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

The effects of soy protein consumption on anthropometric parameters and body composition are conflicting in several clinical trial studies, conducted on people undergoing physical exercise-based interventions. One study showed that consuming a soy protein supplement, adjunct to non-resistance-based training for 9 months, resulted in 2.6 kg increase in LBM [9]. Whilst further work has shown that adding soy protein to normal milk consumption, in post-menopausal women, combined with resistance training for 16 weeks, significantly increases muscle strength in this population [11]. Contrastingly, Maesta et al concluded that soy protein supplementation does not significantly influence the indices of body composition in post-menopausal women undergoing resistance-based exercise [12]. Due to the equivocality in the literature regarding the
effect of soy protein consumption on body composition indices, and a dearth of meta-analytical assessments, the aim of the present study was to systematically review and meta-analyze the effects of soy protein supplementation on weight and body composition of healthy adults in clinical trial studies

Methods

Search strategy and study selection

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

Inclusion and exclusion criteria

To be included in the systematic review and meta-analysis, articles were required to meet the following inclusion criteria; 1) studies were controlled clinical trials of oral supplementation of soy protein, 2) studies reported mean or median values of body weight, fat mass and fat free
mass with standard deviation (SD), standard error of the measurement (SEM) or 95% confidence intervals (CI) at the beginning and the end of the study, 3) the study was performed with healthy, exercising adults. Additionally, articles were excluded if; 1) there was combined supplementation of soy protein with other types of protein (whey, egg, etc.), 2) studies had no control or placebo group, 3) studies did not have enough data at baseline and final value of body weight, fat mass, fat free mass, 4) studies were observational.

**Data extraction and quality assessment**

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

**Data synthesis and statistical analysis**

STATA version 12.0 (Stata Corporation, College Station, TX, USA) was used for all analyses in this study. The mean and SD of anthropometric values at study commencement and post-supplementation in control and intervention groups were used. The reported median values with
confidence intervals or ranges were converted to mean and SD using the Hozo et al method [14].

Heterogeneity was assessed using Cochran’s Q-test (significance set at P<0.05) and the $I^2$ test were used for calculating the percentage of heterogeneity among studies. A fixed effects model, or in the presence of heterogeneity random effects model, was conducted to calculate pooled effect size. Beg test, Egger’s regression test and funnel plot were used for assessment of publication bias.

**Results**

**Search results and study selection**

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

**Study characteristics**

Included studies were performed between the years of 2004 and 2017, of varying origin, including; USA [15-17], Canada [18, 19], Germany[20], China[21], and Australia[22], with a total of 120 participants in the intervention group and 119 participants in the control group. The mean ages of participants ranged between 20.44 and 61.7 y and a mean BMI of 21.8 to 27.6 kg m$^2$. Intervention durations of trials were between 4 and 39 weeks, with the average of 12.5
weeks. All trials were designed as randomized, controlled clinical trials. The type and dose of soy supplementation varied between studies. The characteristics of the included studies and participants are depicted in Table 1.

**Meta-analysis**

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

**Publication Bias**

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

**Discussion**

Protein ingestion, especially after resistance training, can improve muscle protein synthesis in exercising adults [23]. However, results of this meta-analytical study was revealed that the consumption of soy protein supplements had no beneficial effects on weight and body composition of healthy adults.
Several studies have sought to compare the effects of varying sources of protein supplementation, particularly whey versus soy protein, on muscle mass and strength in response to an exercise intervention. In this regard, the consumption of skimmed milk after resistance exercise has been shown to result in gaining greater LBM in comparison to soy-based beverages with equivalent protein, macronutrient and caloric content [18]; whilst Lacroix and colleagues revealed greater capacity of milk protein in muscle accretion after resistance exercise [24]. This phenomenon may be putatively attributed to the higher branched chain amino acids (BCAAs) exit in milk protein, which can alter the flux of certain amino acids into muscles for protein anabolism; where some empirical data exists to support the claim that adding BCAAs to soy protein can improve muscle metabolism in healthy elderly subjects [25]. However, Haub et al., in a study on older men, comparing different sources of animal and vegetable proteins concomitant to resistance training, concluded that when protein intake is adequate, both meat- and soy-based diets could facilitate a significant increase in strength, and induce muscle accretion through sustaining a positive nitrogen balance [26].

Moeller et al., in a clinical trial study on post-menopausal women lasting 24 weeks, showed that whilst soy protein supplementation could significantly increase hip lean mass, it cannot prevent fat deposition in the abdominal cavity [27]. Whereas Thomson et al., showed that soy protein ingestion during resistance exercise, in healthy older adults, could attenuate muscle strength, and that this effect may be mediated through the isoflavone content of soy, which can reduce post-exercise serum levels of testosterone [22]. The results of recent meta-analysis study assessing the effects of whey protein supplementation on body composition parameters in women, showed that this supplementation only can increase lean body mass as much as 370 gr, without conferment of
significant effects on fat mass. Additionally, the authors noted that energy restriction augmented
the beneficial effects of whey protein supplementation [10].

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

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

Although the results of present meta-analysis showed no heterogeneity between studies included
in the final analysis, we performed sub-group analysis based on duration of intervention. The
results revealed no significant differences in weight and body composition of healthy adults
when the duration of soy protein supplementation was less than 12 weeks, versus studies lasting
at least 12 weeks (data are not shown). One limitation of this study is the sparse number of
clinical trials that remained in the final step of quantitative synthesis, this was because of the
paucity of studies conducted on the topic. Small sample size of subjects in included studies is
another limitation of this meta-analysis which can probably justify these insignificant results.

Another limitation of our study is assuming lean body mass and fat-free mass are equivalent.
Although lean body mass is not the same as fat-free mass, and it have small percent of lipid as
essential fat ,which are necessary for normal body functioning [31], for purposes of statistical
analyses, we equated lean body mass to fat-free mass, this was due to the lack of standardized reporting in the included studies.

Conclusions

The results of current meta-analysis study did not suggest any beneficial effects of soy protein supplementation on weight and body composition components in healthy adults. Notwithstanding, it is evident that more, well-controlled and randomized studies are needed in order to better elucidate the effects of soy protein supplementation on body composition indices in healthy adults.
References


Table 1. Characteristic of included studies in the meta-analyses

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

Abbreviations: DB, double-blinded; PC, placebo-controlled; R, randomized; NR, not reported.
Records identified through database searching: PubMed (29), Scopus (202), Cochrane library (60), ISI web of science (201) (n =492)

Duplicate Records Excluded: (n =83)

Records screened by title/abstracts (n =409)

Records excluded (n =384)
- Not met the inclusion criteria

Full-text articles assessed for eligibility (n =25)

Full-text articles excluded, with reasons (n =17)
- Insufficient data available
- No relevant data
- No control group
- Co-supplementation

Studies included in qualitative synthesis (n =8)

Studies included in quantitative synthesis (meta-analysis) (n =8)

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**

![Funnel plot with pseudo 95% confidence limits](image)

**Fat free mass**

![Funnel plot with pseudo 95% confidence limits](image)

**Fat mass**

![Funnel plot with pseudo 95% confidence limits](image)

Figure 5. Funnel plots