Impact of Soy Foods on Physical and Cognitive Health in Children: The Plants Optimizing Development Study (PODS) Protocol

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INTRODUCTION

- Soy foods are rich in high-quality protein, micronutrients, and isoflavones that may contribute to numerous health benefits.
- Soy isoflavones (i.e., daidzein, genistein, glycitein) are phytoestrogens that function through binding to both estrogen receptors in the body.
- Previous studies have examined the effects of soy isoflavones in adults, but the effects remain unclear in children.
- The Plants Optimizing Development Study (PODS) seeks to address this significant gap in research.

HYPOTHESIS & AIMS

We hypothesize that greater soy isoflavone consumption will *not* alter sex steroid levels but will be associated with beneficial health outcomes on body composition, cognition, and metabolic health in pre- and early adolescents.

AIM 1. Randomized-Controlled Trial (RCT) of Soy Foods, Visits 1 – 6
Conduct a 3-month daily mixed-soy food intervention vs. a control group receiving isocaloric foods & measure effects on cognition, body composition, metabolic risk, fecal microbiota, and sex steroids.

AIM 2. Longitudinal Follow Up, Visits 7 – 8
Assess soy food intake and habitual diet immediately following participation at 3- and 6-months post RCT. Collect biological samples at 3- and 6- months post-RCT from those willing.

TABLE 1. Inclusion & Exclusion Criteria

Inclusion	Exclusion
1. Free of any food allergy	1. Presence of any food allergy
2. 8-11 years of age	2. Younger than 8 years or older than 11 years
3. Absence of specific neurological and genetic disorders (i.e., Autism, Cerebral Palsy, Multiple Sclerosis, Downs Syndrome)	3. Presence of specific neurological and genetic disorders (i.e., Autism, Cerebral Palsy, Multiple Sclerosis, Downs Syndrome)
4. Absence of endocrine, metabolic, and gastrointestinal disease e.g., hypertension, diabetes, celiac disease	4. Presence of endocrine, metabolic, and gastrointestinal disease e.g., hypertension, diabetes, celiac disease
5. Tanner scale score of ≤ 2	5. Tanner scale score of > 2
6. 20/20 or corrected vision	6. Not 20/20 or uncorrected vision
7. No antibiotic usage in the past 3 months	7. Antibiotic usage in the past 3 months
8. ≤1 serving/d of soy food that provides 9-13 g of soy protein and 33-40 mg of total soy isoflavones/d	8. >1 serving/d of soy food that provides 9-13 g of soy protein and 33-40 mg of total soy isoflavones/d

METHODS

Children ages 8 – 11 years will participate in a 3-month randomized-controlled clinical trial (N = 96).

The treatment group will receive mixed soy foods daily and the control group will receive isocaloric plant-based alternatives.

Cognitive measures include electroencephalographic activity, the Woodcock Johnson Tests of Cognitive Abilities and Academic Achievement, and a spatial reconstruction memory task.

Dual-energy X-ray Absorptiometry (DXA) will assess whole body Android:Gynoid ratio and bone mineral density (BMD).

Urinary samples will be analyzed for sex steroids, isoflavones, and creatinine. Blood and stool samples will be collected to evaluate metabolic markers and gut microbiota.

Pulse wave velocity and arterial stiffness will be assessed using waveform analysis.
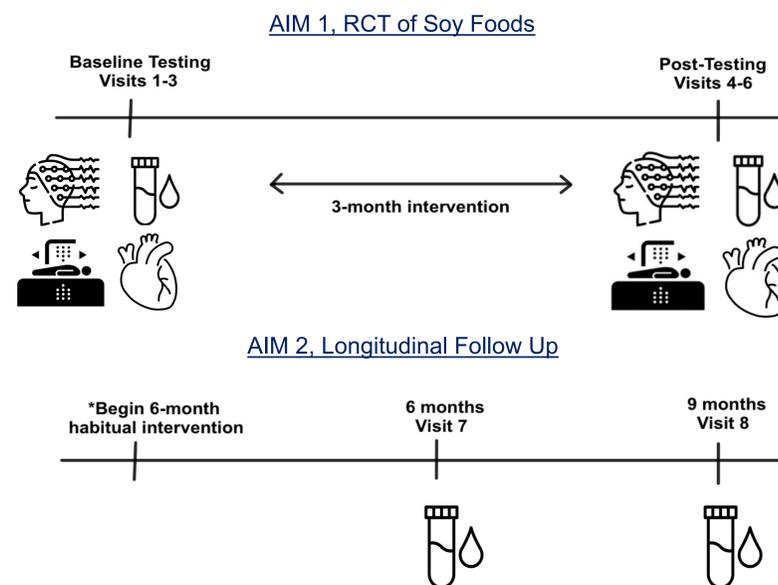
FIGURE 1. Timeline of Visits

AIM 1, RCT of Soy Foods
Baseline Testing Visits 1-3 — 3-month intervention — Post-Testing Visits 4-6

AIM 2, Longitudinal Follow Up
*Begin 6-month habitual intervention — 6 months Visit 7 — 9 months Visit 8

FIGURE 2. Electroencephalography Cap

FIGURE 3. DXA Scan

TABLE 2. Intervention Foods for Treatment and Control Group

Treatment Group Foods	Control Group Foods
Soy Milk	Pea Milk
Soy Yogurt	Almond Milk Yogurt
Edamame	Fava Bean Crisps
Soynuts	Roasted Chickpeas
Soy Protein Bar	Plant Protein Bar
Tofu	Lentil Chips
Tempeh	Chickpea Chips
Soy Based Meat Alternatives	Plant Based Meat Alternatives

CONCLUSION

Successful completion of the study will address important knowledge gaps regarding the effects of soy and plant-based food consumption on development and health outcomes in pre- and early adolescents.

FIGURE 4. Expected outcomes

Gut Health (+), Bone Health (+), Cardiovascular Health (+), Spatial Memory (+), Adiposity (−), Academic Testing (+)