Ovid: Search Form EMBASE
<1980 to 2004 Week 12>

#	Search History	Results
1	exp soybean protein/	1247
2	exp soybean/	4388
3	exp isoflavone/	815
4	exp casein/	3830
5	exp genistein/	4989
6	soy$.mp.	13750
7	tofu.mp.	133
8	tempeh.mp.	27
9	casein$.mp.	11015
10	isoflavone$.mp.	1962
11	genistein$.mp.	5759
12	daidzein$.mp. or exp DAIDZEIN/	1272
13	exp GLYCITEIN/ or glycitein$.mp.	102
14	aglycone$.mp.	1811
15	or/1-14	31218
16	limit 15 to human	10162
17	limit 16 to english language	9578
18	limit 17 to (adult <18 to 64 years> or aged <65+ years>)	1420
19	17 not 18	8158
20	limit 19 to (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)	839
21	17 not 20	8739
22	exp controlled study/	1724288
23	exp clinical study/	2696150
24	double blind procedure/	51005
25	single blind procedure/	4636
26	Crossover Procedure/	14692
27	or/22-26	3787687
28	21 and 27	4532
29	exp in vivo study/	3875902
30	28 not 29	2182
31	exp in vitro study/	2038097
32	30 and 31	1893
33	28 not 32	2639

Ovid: Search Form Ovid MEDLINE(R) <1966 to March Week 5 2004>

#	Search History	Results
1	exp soybean proteins/	2636
2	exp soybeans/	10386
3	exp isoflavones/	6991
4	exp caseins/	9648
5	exp genistein/	3130
6	soy.mp.	5149
7	soya.mp	1635
8	tofu.mp.	152
9	tempeh.mp.	32
10	casein$.tw.	14637
11	soybean$.mp.	17685
12	soyabean$.mp.	313
13	isoflavone$.mp.	3814
14	genistein$.mp.	5387
15	daidzein$.mp.	918
16	glycitein$.mp.	70
17	aglycone$.mp.	1890
18	or/1-17	48150
19	limit 18 to human	13705
20	limit 19 to english language	12541
21	limit 20 to all adult <19 plus years>	2516
22	20 not 21	10025
23	limit 22 to all child <0 to 18 years>	1262
24	20 not 23	11279
25	limit 24 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index)	400
26	24 not 25	10879
27	follow-up studies/	280686
28	(follow-up or followup).tw.	297836
29	exp Case-Control Studies/	250582
30	(case adj20 control).tw.	38163
31	exp Longitudinal Studies/	456180
32	longitudinal.tw.	54945
33	exp Cohort Studies/	487498
34	cohort.tw.	58541

Appendix A. Search Strategies (continued)

35	(random$ or rct).tw.	280359
36	exp Randomized Controlled Trials/	31513
37	exp random allocation/	50295
38	exp Double-Blind Method/	77373
39	exp Single-Blind Method/	7937
40	randomized controlled trial.pt.	186803
41	clinical trial.pt.	378381
42	(clin$ adj trial$).tw.	76518
43	((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).tw.	74006
44	exp PLACEBOS/	22848
45	placebo$.tw.	83019
46	exp Research Design/	177697
47	exp Evaluation Studies/	480708
48	exp Prospective Studies/	170854
49	exp Comparative Study/	1106306
50	or/27-49	2492656
51	26 and 50	2650

Ovid: Search Form Ovid MEDLINE(R) <1966 to March Week 5 2004>

#	Search History	Results
1	exp soybean proteins/	2644
2	exp soybeans/	10410
3	exp isoflavones/	7023
4	exp caseins/	9657
5	exp genistein/	3139
6	soy.mp.	5166
7	soya.mp	1637
8	tofu.mp.	152
9	tempeh.mp.	32
10	casein$.tw.	14662
11	soybean$.mp.	17720
12	soyabean$.mp.	315
13	isoflavone$.mp.	3839
14	genistein$.mp.	5402
15	daidzein$.mp.	923
16	glycitein$.mp.	70
17	aglycone$.mp.	1896
18	or/1-17	48260
19	limit 18 to human	13744
20	limit 19 to english language	12576
21	limit 20 to all adult <19 plus years>	2524
22	20 not 21	10052
23	limit 22 to all child <0 to 18 years>	1264
24	20 not 23	11312
25	limit 24 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index)	401
26	24 not 25	10911
27	follow-up studies/	281231
28	(follow-up or followup).tw.	298732
29	exp Case-Control Studies/	251543
30	(case adj20 control).tw.	38324
31	exp Longitudinal Studies/	457323
32	longitudinal.tw.	55119
33	exp Cohort Studies/	488857
34	cohort.tw.	58921

35	(random$ or rct).tw.	281428
36	exp Randomized Controlled Trials/	31687
37	exp random allocation/	50387
38	exp Double-Blind Method/	77581
39	exp Single-Blind Method/	7981
40	randomized controlled trial.pt.	187367
41	clinical trial.pt.	379438
42	(clin$ adj trial$).tw.	76848
43	((singl$ or doubl$ or trebl$ or tripl$) adj (blind$ or mask$)).tw.	74193
44	exp PLACEBOS/	22885
45	placebo$.tw.	83266
46	exp Research Design/	178254
47	exp Evaluation Studies/	482188
48	exp Prospective Studies/	178254
49	exp Comparative Study/	1109381
50	or/27-49	2499998
51	26 and 50	2663
52	miso.tw.	417
53	53 not 18	354
54	limit 53 to human	97
55	limit 54 to english language	84
56	limit 55 to (all adult <19 plus years> or adolescent <13 to 18 years>)	35
57	55 not 56	49
58	limit 57 to (all infant <birth to 23 months> or preschool child <2 to 5 years> or child <6 to 12 years>)	0
59	limit 58 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index)	1
60	55 not 61	83
61	60 and 50	47
62	misonidazole.tw	1196
63	61 not 62	10

Design

Submit This Section

Randomized? ☐ ND

- ○ Randomized
- ○ Non-randomized
- ○ Unclear (Explain:)

Multiple vs Single Cohorts ☐ ND

- ○ Multiple study arms/cohorts (Comment:)
- ○ Single study arm/cohort (Comment:)

Submit This Section

What is the specific study design? ☐ ND

- ○ Randomized Parallel
- ○ Randomized Cross-over
- ○ Randomized Factorial Design
- ○ Non-Randomized Controlled trial
- ○ Non-Randomized Non-Controlled trial -- Single soy cohort
- ○ Non-Randomized Non-Controlled trial -- Multiple cohorts (all soy)
- ○ Other or Mixed (Describe:)

Comments about Study Design:

Submit This Section

Blinding

Was study: ☐ ND

- ○ Not blinded
- ○ "Single Blind"
- ○ "Double Blind"
- ○ Other:

Comments about Blinding

Submit This Section

Randomization Quality

If "Randomized" Trial:

Did authors explicitly state that study was "randomized"? ☐ ND

- ○ Yes
- ○ No

What was method of randomization? ☐ ND

- ○ Not reported (only stated "randomized")
- ○ Reported (What was method?)

Submit This Section

Allocation Concealment Quality

If Randomized trial:

Allocation Concealment = Method by which allocation (which cohort a subject was assigned to) is concealed from subject, caretaker, and all others involved in study. The purpose is to prevent subjects being allocated to one or another cohort based on any subject or researcher characteristics or biases (such as peaking into envelope to give sicker patients active treatment because "they need it more.")

Examples (of both good and bad allocation concealment) = Central randomization site, Pharmacy-randomization, Opaque envelope, Alternating, List

What was method of Allocation Concealment? ☐ ND

- ○ None reported
- ○ Reported (What was method?)

Submit This Section

Overall Study Design Quality

Also consider reporting of drop-outs/withdrawals and actual drop-out rate.

Is overall quality of Study Design: ☐ ND

- ○ Good
- ○ Fair
- ○ Poor

Why?

Do you find substantial biases related to Study Design: ☐ ND

- Yes
- No

What?

Submit This Section

Characteristics

Submit This Section

Check all responses that apply. Complete all sections fully. Check ND if data not reported

Country in which study conducted (where subjects live) ND

- US
- Canada
- China
- France
- Germany
- Hong Kong
- Japan
- Netherlands
- UK (England, Scotland, Wales, Northern Ireland; NOT Ireland)
- Other(s) [Separate countries with commas]:
- ND

Number of Sites (enter # or "multiple"): ND

Funding source: ND

- Government
- Industry (specify which):
- Private -- non-industry (specify which):
- Hospital or University
- Unclear (specify which):
- ND

Duration of Intervention: Choose ND

Study Duration Range (if applicable) to ND

Submit This Section

Is overall quality of Study Characteristics: ☐ ND

- ○ Good
- ○ Fair
- ○ Poor

Why?

Do you find substantial biases related to Study Characteristics? ☐ ND

- ○ Yes
- ○ No

What?

Submit This Section

Eligibility

Submit This Section

Inclusion Criteria:

Exclusion Criteria:

Comment about Eligibility Criteria:

Submit This Section

At baseline, Were subjects...? ☐ ND

- ☐ Men
- ☐ Pre-menopausal Women
- ☐ Post-menopausal Women
- ☐ Women on Hormone Replacement Therapy (HRT)

☐ On hormone-blocking treatment (eg, for cancer)

At baseline, Were subjects...? ☐ ND

- ○ Women on Hormone Replacement Therapy (HRT)
- ○ On hormone-blocking treatment (eg, for cancer)
- ○ Neither

If necessary, for each condition, What was the reported definition?

Pre-Menopause?

Post-Menopausal?

Menopause

HRT

Hormone-blocking treatment

Comment about Definitions:

Submit This Section

Is overall quality of Eligibility: ☐ ND

- ○ Good
- ○ Fair
- ○ Poor

Why?

Do you find substantial biases related to Eligibility Criteria? ☐ ND

- ○ Yes
- ○ No

What?

Submit This Section

Population

Submit This Section

Subjects and Controls

(Provide largest #, if multiple analyses reported. If possible, number enrolled should be based on Intention-to-Treat principle: All subjects who were randomized or put into a treatment cohort)

Control (No intervention or Placebo) -- Number enrolled: ☐ ND

IGNORE NON-SOY, NON-CONTROL ARMS. ASK ETHAN OR JOSEPH IF UNCLEAR.

Treatment Arm 1 or Single Cohort -- Simple description: ☐ ND

Treatment Arm 1 or Single Cohort -- Number enrolled ☐ ND

Treatment Arm 2 -- Simple description: ☐ ND

Treatment Arm 2 -- Number enrolled: ☐ ND

Treatment Arm 3 -- Simple description: ☐ ND

Treatment Arm 3 -- Number enrolled: ☐ ND

Treatment Arm 4 -- Simple description: ☐ ND

Treatment Arm 4 -- Number enrolled: ☐ ND

More Arms: Number each arm, Describe, and give Sample Size

Were the number of enrolled subjects and drop-outs explicitly and clearly reported? ☐ ND

- ○ Yes
- ○ No

Were the reasons for drop-outs/withdrawals clearly stated? ☐ ND

- ○ Yes
- ○ No

Reason for dropouts, withdrawals, etc.

Comment about Number Enrolled etc.:

Submit This Section

Demographics etc.

(Choose one group of subjects to report on. Choose COMBINED over SINGLE soy cohort. If necessary, Choose LARGEST soy cohort.)

...

For each variable, answer whether there is a difference among treatment groups. If yes, describe in Comments box below.

Which cohort/group of subjects are baseline data reported for? ☐ **ND**

- ○ **Combined (all subjects)**
- ○ **Soy (only single soy cohort)**
- ○ **Largest (by N) Soy cohort**
- ○ **Specific (Other) Soy cohort (describe:)**

Are statistical analyses (eg, p-values) reported comparing cohorts at BASELINE?

- ○ **Yes**
- ○ **No**

AGE

Is there a Difference in Age among cohorts?

- ○ **Yes (describe below)**
- ○ **No**
- ○ **ND / NA / Unclear**

Mean/Median Age: Choose 1 ☐ **ND**

+/- SD/SE: Choose 1 ☐ **ND**

Age Range: **to** ☐ **ND**

SEX

Is there a Difference in Sex Ratio among cohorts?

- ○ **Yes (describe below)**
- ○ **No**
- ○ **ND / NA / Unclear**

Sex: Male (%): ☐ **ND**

SMOKING

Is there a Difference in Smoking Rates among cohorts?

- ○ **Yes (describe below)**
- ○ **No**
- ○ **ND / NA / Unclear**

Smokers (%): ☐ **ND**

WEIGHT/BMI

Is there a Difference in Body Weight (BMI, Kg) among cohorts?

- Yes (describe below)
- No
- ND / NA / Unclear

Mean Weight/BMI: [ ] Choose 1 ☐ ND

RACE

Is there a Difference in Race among cohorts?

- Yes (describe below)
- No
- ND / NA / Unclear

Race (%, Put Whole Number only in text box): ☐ ND

- ☐ White/European
- ☐ Black/African-American/etc.
- ☐ Asian
- ☐ Hispanic
- ☐ Other 1 (% here, describe below)
- ☐ Other 2 (% here, describe below)
- ☐ Other 3 (% here, describe below)
- ☐ ND

OTHER RELEVANT BASELINE DEMOGRAPHIC VARIABLES

Do Not Include Variable If It Is An Outcome Being Analyzed

VARIABLE 1

Variable

Is there a Difference in Variable 1 among cohorts?

- Yes (describe below)
- No
- ND / NA / Unclear

Variable 1 Data ☐ ND

+/- SD/SE [ ] Choose 1 ☐ ND

Variable 1 Range: [ ] **to** [ ] ☐ ND

VARIABLE 2

Variable

Is there a Difference in Variable 2 among cohorts?

- Yes (describe below)
- No

ND / NA / Unclear

Variable 2 Data ND

+/- SD/SE Choose 1 ND

Variable 2 Range: to ND

VARIABLE 3

Variable

Is there a Difference in Variable 3 among cohorts?

Yes (describe below)

No

ND / NA / Unclear

Variable 3 Data ND

+/- SD/SE Choose 1 ND

Variable 3 Range: to ND

COMMENTS

Comments about Demographics etc.:

Submit This Section

Is overall quality of Population data/reporting: ND

Good

Fair

Poor

Why?

Do you find substantial biases related to Population: ND

Yes

No

What?

Submit This Section

Confounders

Submit This Section

Other Confounders etc.

CONCOMITANT MEDICATIONS

Is there a Difference in Medication Use among cohorts?

- ○ Yes (describe below)
- ○ No
- ○ ND / NA / Unclear

If YES, What?

BASELINE DIET FACTORS

Difference in Baseline Diet among cohorts? ☐ ND

- ○ Yes (describe below)
- ○ No
- ○ ND / NA / Unclear

If Yes, What?

.....Type in All or Subgroup (check box also) ☐ ND

- ☐ High soy diet
- ☐ Low soy diet
- ☐ Vegetarian diet
- ☐ Low fat diet
- ☐ High fat diet
- ☐ Other1
- ☐ Other2
- ☐ Other3

Description of Baseline Diets:

Comments about Other Confounders:

Submit This Section

Is overall quality of Confounder data/reporting: ☐ **ND**

- ○ **Good**
- ○ **Fair**
- ○ **Poor**

Why?

Do you find substantial biases related to Confounders? ☐ **ND**

- ○ **Yes**
- ○ **No**

What?

Submit This Section

Applicability

Submit This Section

Sample representative of...

- ○ **Men**
- ○ **Both Men and Women (everyone)**
- ○ **Premenopausal Women**
- ○ **Postmenopausal Women**
- ○ **Both Pre- & Postmenopausal Women**
- ○ **Other**

that are ☐ **ND**

- ☐ **Representative of the General Population**
- ☐ **"Healthy"**
- ☐ **At Increased Risk of Bone Disease (or have disease)**
- ☐ **At Increased Risk of CVD (including BP,Chol or have CVD))**
- ☐ **At Increased Risk of DM (or have DM)**
- ☐ **At Increased Risk of Cancer**
- ☐ **Other**

If Other, or if a variant of above, Describe

Within Above Category, What is Applicability

- I: Sample representative of total population relevant to category
- II: Sample is an important sub-group of reference population
- III: Sample represents only a narrow, atypical subgroup of reference population
- ND: Cannot categorize because of incomplete demographic or other data

Other Comments about Applicability:

Submit This Section

Control Arm

Submit This Section

What was the authors' description of Control or Placebo

What was used as Control / "Placebo" ☐ ND

- ☐ Milk protein/Casein
- ☐ Non-fat Milk
- ☐ Other Milk, describe
- ☐ Other protein (non-fat), Which?
- ☐ Other protein (with fat), Which?
- ☐ Other, Which?

How much protein per day? ☐ ND

How much product per day (if necessary)? ☐ ND

Comments on Control/Placebo source:

Submit This Section

Is overall quality of Control data/reporting: ☐ ND

- Good

- Fair
- Poor

Why?

Do you find substantial biases related to Control/Placebo? ND

- Yes
- No

What?

Submit This Section

Soy Description

Submit This Section

DUPLICATE THIS SECTION FOR EACH TREATMENT ARM
Do Not Use The Template (titled Tx Arm No.) to Enter Data.
Title each new section by an appropriate Brief Description (eg, Soy Milk, ISP+Isoflavone,ISP-Isoflavone)
Also name Section ID the same

Treatment Arm Name

Submit This Section

What was the authors' description of Soy intervention?

Was Intervention a branded supplement? ND

- Yes
- No

If Yes, which? ND

- Abacor
- Supro
- SOYSELECT
- TakeCare
- Phytosoya

- ○ Other, which? [ ]

What was/were the source(s) of Soy? ☐ ND

- ☐ Soy-based Diet
- ☐ Whole Soybean (or equivalent)
- ☐ Tofu
- ☐ Textured Soy Protein (meat substitute)
- ☐ Soy Milk (not soy protein drink)
- ☐ Other Dietary Soy Product, Which? [ ]
- ☐ Isolated Soy Protein w/Isoflavones
- ☐ Isolated Soy Protein w/o Isoflavones
- ☐ Isolated Soy Protein, unclear re: Isoflavones
- ☐ Soy Isoflavones (without protein)
- ☐ Other Soy Product Supplement, Which? [ ]

Comments on Soy source:

[ ]

How many grams of Soy Protein per day? [ ]

How many mg of Genistein per day? [ ]

How many mg of Daidzein per day? [ ]

How many mg of Other Isoflavone per day? Name isoflavone below [ ]

How many mg of Total Isoflavones per day? [ ]

How many grams total soy product (dietary or supplement) per day, if different than above (eg, grams of tofu) [ ]

Submit This Section

For all interventions

Is overall quality of Intervention data/reporting: ☐ ND

- ○ Good
- ○ Fair
- ○ Poor

Why?

[ ]

Do you find substantial biases related to Treatments: ☐ ND

- ○ Yes
- ○ No

What?

Submit This Section

Outcomes

Submit This Section

Submit This Section

OUTCOME CATEGORY

What types of Outcomes are reported in study?

- ☐ **Clinical Outcome**
- ☐ **Intermediate Outcome**

Submit This Section

CLINICAL OUTCOMES

Check box and describe

- ☐ **Menopausal Symptoms** **Description:**
- ☐ **Clinical Outcome 1** **Description:**
- ☐ **Clinical Outcome 2** **Description:**
- ☐ **Clinical Outcome 3** **Description:**
- ☐ **Clinical Outcome 4** **Description:**

Comment about Clinical Outcomes

Submit This Section

INTERMEDIATE OUTCOMES

Include even if data not reported (eg," BP unchanged, data not reported)")

*CVD RELATED (*** = to be data extracted)*

Lipids:

- ☐ **Total Cholesterol *****
- ☐ **LDL *****
- ☐ **HDL *****
- ☐ **Triglycerides *****
- ☐ **Lp(a) *****
- ☐ **Apo A-1**
- ☐ **Apo B/B-100**
- ☐ **Apo C-III**
- ☐ **Apo E**
- ☐ **Remnant-Like Particles (RLP)**
- ☐ **Free or Non-Esterified Fatty Acids**

Blood Pressure:

- ☐ **Systolic (SBP) *****
- ☐ **Diastolic (DBP) *****
- ☐ **Mean Arterial Pressure (MAP) *** [if ND on SBP/DBP]**

Vascular Function

- ☐ **Peripheral Endothelial Function (Brachial artery/FMD/FBF) *****
- ☐ **Coronary Endothelial Function *****
- ☐ **Systemic Arterial Compliance *****

Miscellaneous CVD Risk Factors Being Included

- ☐ **C-reactive protein (CRP) *****
- ☐ **Homocysteine *****
- ☐ **Oxidized LDL/Lipids/Dienes/TBAR (Ask Ethan if unsure) *****

Other CVD Serum Markers:

- ☐ **E-Selectin**
- ☐ **Endothelin 1**
- ☐ **Factor VII (any type)**
- ☐ **Factor VIII (any type)**
- ☐ **Factor XII (any type)**
- ☐ **Fibrinogen**
- ☐ **ICAM**
- ☐ **Interleukin 2R**
- ☐ **Interleukin 6**
- ☐ **Nitrous Oxide (NO)**
- ☐ **P-Selectin**
- ☐ **Thrombomodulin**
- ☐ **VCAM**

- ☐ **von Willebrand Factor (vWF, Factor VIII:Ag) (any type)**
- ☐ **OTHER SERUM CVD MARKER 1** _____
- ☐ **OTHER SERUM CVD MARKER 2** _____
- ☐ **OTHER SERUM CVD MARKER 3** _____

Other Diagnostic Tests

- ☐ **Ankle Brachial Index**
- ☐ **Bleeding Time**
- ☐ **Carotid Doppler/Ultrasound**
- ☐ **Carotid Intima Media Thckness (IMT) aka Doppler**
- ☐ **Coronary Arteriography**
- ☐ **ECG parameters**
- ☐ **Echocardiography**
- ☐ **Exercise Tolerance Test (treadmill, bicycle)**
- ☐ **Heart Rate Variability**
- ☐ **Platelet Aggregation**
- ☐ **OTHER CVD TEST 1** _____
- ☐ **OTHER CVD TEST 2** _____
- ☐ **OTHER CVD TEST 3** _____

Diabetes related:

- ☐ **Hgb A1c (Glycohemoglobin) *****
- ☐ **Fasting Glucose/Blood Sugar (FBS) *****
- ☐ **Insulin:Glucose Ratio (not just insulin alone) *****
- ☐ **Insulin Sensitivity Measure (ask Athina, Joseph, or Ethan if unclear) *****
- ☐ **OGTT (oral glucose tolerance test) *****
- ☐ **Insulin [DO NOT EXTRACT Insulin or Insulin OGTT]**
- ☐ **Glucagon [DO NOT EXTRACT]**

Kidney Outcomes:

- ☐ **GFR or Creatinine Clearance**
- ☐ **Uric Acid clearance/metabolism**
- ☐ **Serum Creatinine**
- ☐ **Proteinuria**
- ☐ **Albuminuria**
- ☐ **BUN**
- ☐ **Other Kidney Outcome (enter):** _____

Osteoporosis:

- ☐ **Bone Mineral Density (BMD)**

- [ ] **Bone Mineral Content (BMC)**
- [ ] **Serum bone specific alkaline phosphatase (BAP)**
- [ ] **Serum osteocalcin (OC)**
- [ ] **Urine deoxypyridinoline (D-PYR)**
- [ ] **Urine pyridinoline (PYR)**
- [ ] **Type 1 Collagen cross-linked N-teleopeptide (NTx)**
- [ ] **Urine Calcium**
- [ ] **Bone Stiffness**
- [ ] **Other Bone Outcome (enter):**

Women's Health:

- [ ] **Menstrual Cycle Length**
- [ ] **Vaginal Cytology Maturation Index**
- [ ] **Endometrial Thickness**
- [ ] **Endometrial Histology**
- [ ] **Mammographic Density**
- [ ] **Other GYN Outcome (enter):**

SEX HORMONES:

Serum

- [ ] **SHBG (Sex Hormone Binding Globulin)**
- [ ] **LH**
- [ ] **FSH**
- [ ] **Estradiol**
- [ ] **Estrone**
- [ ] **Estrone Sulfate**
- [ ] **Progesterone**
- [ ] **Prolactin**
- [ ] **Testosterone**
- [ ] **Androstenedione**
- [ ] **DHEA/DHEAS**
- [ ] **Other Serum Sex Hormone Outcome (enter):**

Urine

- [ ] **2-hydroxyestrone**
- [ ] **16-alpha-hydroxyestrone**
- [ ] **Equol**
- [ ] **Other Urine Sex Hormone Outcome (enter):**

Cancer Intermediate Outcomes:

- [ ] **PSA levels**

- [ ] 5-OHmdU in DNA from nucleated blood cells
- [ ] Other Intermediate Cancer Outcomes (enter):

Other Endocrine:

- [ ] T3 (triiodothyroxine)
- [ ] T4 (thyroxine)
- [ ] Thryoid Binding Globulin (TBG)
- [ ] TSH
- [ ] Parathyroid Hormone
- [ ] Cortisol
- [ ] IGF-1
- [ ] Other Endocrine Outcomes (enter):

Any Other Outcomes:

Submit This Section

Comment about Intermediate Outcomes

Submit This Section

ADVERSE EVENTS/DRUG INTERACTIONS

Are Adverse Events, Side Effects, Complications DUE TO Soy Supplement or Diet Reported? ☐ ND

- ○ Yes
- ○ No

If YES, What was reported?

Are DRUG INTERACTIONS between soy and medications reported? ☐ ND

- ○ Yes
- ○ No

If YES, What was reported?

Submit This Section

Results TEMPLATE (continuous d

Submit This Section

Duplicate this section for each OUTCOME. Name and ID new section "Outcome". NO SPACES IN NAME.

Was this outcome reported as a Primary or Secondary Outcome? ☐ **ND**

- ○ **Primary Outcome**
- ○ **Secondary Outcome**
- ○ **Unclear (Desribe why below)**

Why unclear?

Description of Outcome (if necessary):

Outcome Units (type in if not in menu. Use Dichotomous form if N or % subjects) mg/dL ☐ **ND**

Submit This Section

Treatment Arms

Check box and describe

- ☐ **Tx Arm 1** **Description:**
- ☐ **Tx Arm 2** **Description:**
- ☐ **Tx Arm 3** **Description:**
- ☐ **Tx Arm 4** **Description:**

Submit This Section

Outcomes

The results reported for this outcome are the: ☐ **ND**

- ○ **Mean**
- ○ **Median**

The variance unit reported for this outcome is: ☐ **ND**

- ○ **SD**
- ○ **SE or SEM**
- ○ **Unclear SD or SE**

The ranges reported for this outcome are: ☐ **ND**

- ○ **95% CI (confidence interval)**
- ○ **Total Range**
- ○ **Inter-Quartile Range (IQR)**

Baseline Data

	n	Baseline Value	SD or SE Value
Tx Arm 1			
Tx Arm 2			
Tx Arm 3			
Tx Arm 4			
Control			

Comment about Baseline Data

Report number of FINAL subjects analyzed, even if the same as baseline (to avoid confusion)

Follow-up / Final Data or Clinical Event Data

	n	Final Value	SD or SE Value
Tx Arm 1			
Tx Arm 2			
Tx Arm 3			
Tx Arm 4			
Control			

Comment about Final Data

Submit This Section

Reported Within-Treatment Difference:

Reported data re: difference in outcome level between final and baseline times.
NOT differences between interventions.
Reported value for FINAL value minus BASELINE value.

Be Careful: Studies can report a decrease as either a positive or negative number (and vice versa).
Report Real change (FINAL - BASELINE).
No need to repeat P-value for within-treatment difference if reported in Final table.

Within-Treatment Difference Data

	Reported difference	SD or SE Value	Range
Tx Arm 1			
Tx Arm 2			
Tx Arm 3			
Tx Arm 4			
Control			

Comment about Within-Treatment Difference

----- ----- ----- ----- ----- -----

Submit This Section

Reported Difference of FINAL Treatment vs Control (Cross-over Studies ONLY):

Reported data re: difference between FINAL levels of intervention and control.
NOT net difference (see below)
Tx(final) - Control(Final)
ONLY FOR CROSS-OVER STUDIES

Reported Final difference

	Reported Difference	SD or SE Value	Range
Tx Arm 1 - Control			
Tx Arm 2 - Control			
Tx Arm 3 - Control			
Tx Arm 4 - Control			

Comment about Difference between Final Values

----- ----- ----- ----- ----- -----

Submit This Section

Reported NET Treatment vs Control Difference:

Reported data re: difference between CHANGE in outcome level between intervention and control.
NOT difference between final outcome levels.

[Tx(final) - Tx(baseline)] - [Control(Final) - Control(Baseline)]

Reported Net difference

	Reported Difference	SD or SE Value	Range
Tx Arm 1 - Control			
Tx Arm 2 - Control			
Tx Arm 3 - Control			
Tx Arm 4 - Control			

Comment about Between-Treatment Difference

----- ----- ----- ----- ----- -----

Submit This Section

Statistical Significance

Comment about Statistical Significances

----- ----- ----- ----- ----- -----

Submit This Section

Results TEMPLATE (dichotomous data or OR/RR)

Submit This Section

DUPLICATE THIS SECTION FOR EACH RESULT SECTION.
This will include both treatment and control arm
THERE SHOULD BE ONE NEW SECTION FOR EACH "OUTCOME."
Title each new Dichotomous Result section with "Outcome". NO SPACES IN NAME.

Submit This Section

Answer the following question Once only for each outcome

Was this outcome reported as a Primary or Secondary Outcome? ☐ **ND**

- ○ **Primary Outcome**
- ○ **Secondary Outcome**

Unclear (Desribe why below)

Why unclear?

Description of Outcome (if necessary):

Description of Tx Arm 1:

Description of Tx Arm 2:

Description of Tx Arm 3:

Description of Tx Arm 4:

Submit This Section

2x2 Data

PREFERABLY ENTER NUMBER OF SUBJECTS. IF NOT REPORTED ENTER % OF SUBJECTS IN SECTION BELOW.

NUMBER

Enter NUMBER of Subjects That Belong in Each Cell

Enter EITHER (number with outcome AND number w/o outcome) OR (number with outcome AND total (denominator

---

2 x 2 Number

	Number WITH Outcome	Number WITHOUT Outcome	Total N (Denominator)
Control			
Tx Arm 1			
Tx Arm 2			
Tx Arm 3			
Tx Arm 4			

2 x 2 Percent

	Percent WITH Outcome	Total N (Denominator)
Control		
Tx Arm 1		
Tx Arm 2		
Tx Arm 3		
Tx Arm 4		

------ ----- ----- -----

Comment about 2x2 Results

Submit This Section

Odds Ratio / Risk Ratio Data

If Results Presented in OR or RR format, Enter Here
There Are Separate Sections Below for UNADJUSTED and ADJUSTED OR/RR

UNADJUSTED OR/RR

Metric ☐ **ND**

- ○ **OR (odd ratio)**
- ○ **RR (Risk Ratio/Relative Risk)**
- ○ **Other** **Which?**

Tx 1 vs Control:
Tx 2 vs Control:
Tx 3 vs Control:
Tx 4 vs Control:

----- ----- ----- -----

ADJUSTED OR/RR

Variables Adjusted For:

Metric ☐ **ND**

- ○ **OR (odd ratio)**
- ○ **RR (Risk Ratio/Relative Risk)**
- ○ **Other** **Which?**

Tx 1 vs Control:
Tx 2 vs Control:
Tx 3 vs Control:
Tx 4 vs Control:

Comment about OR/RR

Submit This Section

Statistical Significance

For 2x2 data, OR, RR, etc.

p-value of UNADJUSTED Tx 1 vs Control ☐ ND

p-value of UNADJUSTED Tx 2 vs Control ☐ ND

p-value of UNADJUSTED Tx 3 vs Control ☐ ND

p-value of UNADJUSTED Tx 4 vs Control ☐ ND

p-value of ADJUSTED Tx vs Control ☐ ND

Comment about Statistical Significance

Submit This Section

Results TEMPLATE (Text)

Submit This Section

DUPLICATE THIS SECTION FOR EACH OUTCOME.
This will include both treatment and control arm
THERE SHOULD BE ONE NEW SECTION FOR EACH "OUTCOME."
Title each new Text Result section with "Outcome"

Description of Outcome (if necessary):

Describe Results:

Submit This Section

Appendix C. Evidence Tables

EvidenceTable (Part 1)

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
Adams 2003	Age (yr):65.1 (SD 7.9) Male%:85 Country: US Sites:2 BMI:29.1 Soy1 N:74 Soy2 N:76 Control N:0	Design:RCT Randomized: Yes Blinding: double Duration:12 mo	Undergoing colonoscopy, 50-80 y, adenomatous colorectal polyps on current or recent (within 12 mo) colonoscopy Excluded:HRT. Various GI and other medical conditions. Habitual soy food intake >= 4 servings/week. (Initially regualr NSAID use, lifted after 1 y enrollment to increase numbers.)	1. ISP without isoflavone Soy drink powder packets (DuPont Protein Technologies, St Louis). 2 packets/day = 58 g/d. Diet composition: 6240 kJ/d, carb 171 g/d, protein 61g/d, fat 59g/d 2. ISP with Isoflavone Soy drink powder packets (DuPont Protein Technologies, St Louis). 2 packets/day = 58 g/d Diet composition: : 6500 kJ/d, carb 175 g/d, protein 64.7g/d, fat 62g/d	No non-soy control	Insulin like growth factor (IGF-I) IGFBP-3 IGF-I/IGFBP-3	AE:no Drop out: 16 from Iso+: 7 health-related reasons; 7 logistical reasons; 2 unknown;11 from Iso-: 6 health-related; 3 logistical; 2 unknown. Comments: High proportion of women taking replacement estrogen and therefore ineligible, the majority of participants (85%) were men
Adams 2004	Age (yr):63.9 (SD 7.2) Male%:100 Country: US Sites:1 BMI:29.1 Soy1 N:61 Soy2 N:51 Control N:0	Design:RCT Randomized: Yes Blinding: double Duration:12 mo Duration:1 years	Subset of men from Soy Isoflavone prevention trial Undergoing colonoscopy, 50-80 y, adenomatous colorectal polyps on current or recent (within 12 mo) colonoscopy and consented to PSA Excluded:HRT. Various GI and other medical conditions. Habitual high soy food	1. Soy drink powder packets (DuPont Protein Technologies, St Louis). 2 packets/day = 58 g/d. ISP without isoflavone Diet composition: E 1528 kcal/d, Protein 61g/d, carb 170g/d, fat 37% 2. Soy drink powder packets (DuPont Protein Technologies, St Louis). 2 packets/day = 58 g/d ISP with Isoflavone Diet composition: E 1545 kcal/d, protein 64g/d, carb 171 g/d, fat 36%E	No non-soy control	PSA	AE:no Drop out: See Adams 12730416;In addition, only subset of men 34/51 in the isoflavone+ and 47/61 agreed to PSA test. Comment: Part of Soy Isoflavone prevention trial
Albert 2002	Age (yr): >45 Male%: 0 Country: Spain Sites:13	Design:NRNCT Randomized: No CohortSing	post-menopausal, > 45 y, at least one year amenorrhea, at least 6 moderate or severe daily hot flushes previous 15 day prior to inclusion	Soy Isoflavones without protein Phytosoya soy preparation rich in isoflavones, capsules containing 17.5 mg isoflavones	No control	Menopausal symptom hot flushes sleep disorder vaginal dryness loss of libido psychological	AE:yes AE Report:"No severe side-effects were reported and tolerance was excellent." Gastric disorders (1) and/or

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI: Soy1 N: 190 Control N: 0	Blinding:No Duration:4 mo	Excluded:HRT during previous 6 wks, R\loxifen tx , and personal records of breast cancer	Diet composition:Detailed reporting of analyses of capsules		symptoms Bone pain	breast pain (2) precordial pain , and metrorrhagia. Drop out:LTF (19), protocol violations (11), intervention ineffective (9). 2 of which left study for AE Comment: Pilot clinical trial
Albertazzi 1998	Age (yr):53.3 (SD 0.45) Male%:0 Country: Italy Sites:2 BMI:25.9 Soy1 N:51 Control N:53	Design:RCT Randomized: Yes Blinding: double Duration:12 wks	Postmenopausal women, at least 6 mo since last menstrual period, or at least 6 wks since bilateral oophorectomy, at least 7 moderate or severe hot flushes, including night sweats per 24 hr during at least last 2 wks of 4-wk prestudy period, baseline FSH conc>50IU/L, sr estradiol conc<35pg/mL Excluded:HRT < 6 wks prior prestudy period, meds for climacteric symptoms (vit E, clonidine, , and veralipride)	soy 60 g of isolated soy protein in powder form, supplied by manufacturer as identically appearing, code Supro ISP with Isoflavone Diet composition: ND	60 g of casein powder Protein40 g Product60 g Diet composition: ND	Menopausal symptom hot flushes	AE: ND Drop out:yes Nausea (2), vomiting (1), bloating (13), constipation (52), other (11); LTF (4), 25 of 104 WD Comment: Two groups of 46 each with 12 more enrolled following reserve randomized list which had 1:1 treatment ratio
Albertazzi 1999	Age (yr):53.3 (SE 0.45) Male%: 0 Country: Italy Sites:2 BMI:25.9 Soy1 N:51 Control N:53	Design:RCT Randomized: Yes Blinding: double Duration:12 wks	Postmenopausal women, at least 6 mo since last menstrual period, or at least 6 wks since bilateral oophorectomy, 7 moderate or severe hot flushes, including night sweats per 24 hr during at least last 2 wks of 4-wk prestudy period, baseline FSH concentration > 50 IU/L & serum estradiol concentration < 35 pg/mL	soy Daily supplements of 60 g soy powder Supro ISP with Isoflavone Diet composition: ND	60 g of casein contained 40 g of proteins but no isoflavones. Total Protein 40 g Total Product60 g Diet composition: ND	Vaginal cell maturation index Equol	Adverse event: GI, constipation, bloating, nausea, vomiting (70) Drop out: 25 of 104 WD Comment: Originally 46 randomized to each group with 12 additional on reserve randomization list for total 104 Same cohort as #914 Albertazzi '98

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
			Excluded: ND				
Alekel 2000	Age (yr):50.2 Male%:0 Country: US Sites:1 BMI:24.0 Soy1 N:24 Soy2 N:24 Control N:21	Design:RCT Randomized: Yes Blinding: double Duration:24 wks	Perimenopausl women with vasomotor symptoms; nonsmoking premenopausal >10 hot flashes/night sweats/wk, irregular menstrual periods. had1 or both ovaries, BMI between 20-31, willing to be randomized. FSH >30 IU/L Excluded:Chronic disease: osteoporosis or CVD, no long-term meds, no HRT or ERT within past 12 mo, no excessive exercise	1. ISP with Isoflavone Jumbo muffins containing 80.4 mg glycosides Diet composition: ~2.09 MJ (500 kcal) and 650 mg Ca/d for the muffin 2. ISP with Isoflavone (low) Jumbo muffins containing 4.4 mg glycosides components Diet composition: ~2.09 MJ (500 kcal) and 650 mg Ca/d from the muffin	whey protein Total Protein: 40 g/day Total Product: ND Diet composition: ~2.09 MJ (500 kcal) and 650 mg Ca/d	Serum bone specific alkaline phosphatase Type 1 Collagen cross-linked N-teleopeptide Urinary calcium BMD BMC	AE:yes AE Report:6 drop outs due to "inability to tolerate treatment" Drop out: 22 did not meet criteria of FSH, 11 unable to tolerate tx, 1 death, 1 family member death, 2 medical condition preventing continuance, 1 noncompliant
Anderson 1998	Age (yr):64 (SD 6.5) Male%:100 Country: US Sites:1 BMI:35.1 Soy1 N:8 Control N:8	Design:Xover Randomized: Yes Blinding:No Duration:8 wks	Men with insulin-treated type 2 DM with fair glycemic control defined as glycohemoglobin concentrations of < 8%. They were free of significant medical illnesses or uncontrolled conditions, substantial proteinuria (>1000 mg/d) or proteinuria unrelated to DM or HTN Excluded:ND	Soy diet Soy-protein diet, which provided 1 g protein/kg BW and were weight maintaining. Diet composition:Standard diabetic exchange diet to maintain body wt, carb ~55% E, fat 30%E	Animal-protein diet, which provided 1 g protein/kg BW and were weight maintaining. 50% of the protein in the form of ground beef and cow milk Product:ND Diet composition: Standard diabetic exchange diet to maintain body wt, carb ~55% E, fat 30%E	Total Cholesterol LDL HDL Triglyceride glycohemoglobin GFR Sr creatinine serum urea	AE:ND Drop out:no Comment: Self-control study, compared Soy diet to animal protein diet.
Anderson 2002	Age (yr):24.0 (SD 1.1) Male%:0 Country: US Sites:1 BMI:62.4 Total:38	Design:RCT Randomized: Yes Blinding: double Duration:1 years	healthy women of any ethnic background 21-25 Excluded:pregnancy/lactation, use of oral contraceptive agents or steroid hormones, continuing longitudinal growth (height)	isoflavone enriched soy protein diet isoflavone-enriched soy protein isolate diet available in powder and as chocolate liquid. ISP with Isoflavone Diet composition:ND	soy protein isolates lacking isoflavones Protein64.5 g at baseline Product Diet composition:ND	Bone mineral density Bone mineral content BMC-lumbar	AE:No Drop out:10/38 subjects dropped out--4 began using disqualifying meds, 3 moved away, 3 were unspecified Comment: insufficient detail;small sample size, 26% drop out rate

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy1 N:15 Control N:13 (soy and control completers only)						
Arjmandi 2003	Age (yr):62.4 (SD 2.4) Male%:0 Country: US Sites:1 BMI:84.5 Total Enrol: 71 Soy1 N:20 Control N: 22 (soy and control only for completers)	Design:RCT Randomized: Yes Blinding: double Duration:3 mo	postmenopausal women Excluded:GI disorders, cancer, DM, hypo or hyperthyroidism, liver or kidney problems, pelvic inflammatory disease, endometrial polyps, heavy smokers	soy protein 40 g daily soy supplement provided in 2 packs, each containing 29 g powdered unflavored drink mix Soy diet Diet composition:protein 40g, carb 6 g, total fat 2g	milk-based protein Protein40 g Product Diet composition:protein 40g, carb 6 g, total fat < 1g	IGF-1 Serum bone specific alkaline phosphatase Urine deoxypyridinoline Urinary calcium Urine Phosphorus Estradiol	AE:yes AE Report:2 ISP, 1 control GI disturbances Drop out: 7 ISP, 6 control-lack of palatability of protein;7 ISP, 5 control=time constraints; 2 ISP, 1 MBP=GI disturbances, 1 SP personal Comments: women taking HRT and not taking HRT are included--subgroup analysis done on these groups. 41% attrition rate
Ashton 2000 10694766	Age (yr): 34-62 Male%:100 Country: Australia Sites:1 BMI:26.2 Soy1 N:45 Control N:meat diet--45	Design:Xover Randomized: Yes Blinding:other Duration: 4.3 wks	healthy male vounteers aged 34-62 yr, no symptoms or prior dx of CHD Excluded: meds that affect lipids or BP, BMI>35 kg/m2, Total Cholesterol >7.5 mmol/L, Triglyceride >6.0 mmol/L.	Tofu diet 90-100% animal protein with 290g/tofu Diet composition:energy 9.5 MJ; protein 16.9%E;carb 44%, total fat 32%, saturated fat 12.4%, MUFA 11.5%, PUFA 5.2% alcholo 5.4%, cholesterol 189.5 mg	Meat diet Total Protein: ND Total Product: ND Diet composition: subjects consumed 150g/d (raw weight) of cooked lean red meat, all visible fat removed + PUFA margarine 15g energy 9.6 MJ, protein 17.2%E, carb 43.7%, total fat 32.4%, saturated fat 12.9%, MUFA 11.9%, PUFA 4.8%, alcohol 4.9%, cholesterol 253.2 mg	Total Cholesterol LDL HDL Triglyceride LDL:HDL ratio	AE:No Drop out:3 Comment: To minimize the differences in MUFA, PUFA, and SAFA between the two diets 5g of butter, 5g of lard, and 8ml of olive oil were also prescribed daily on the tofu diet
Ashton 2000	Age (yr):45.8 (SD 7.8)	Design:Xover Randomized: Yes	Healthy males Excluded:Symptoms or prior diagnosis of CHD. Use of any medication that	Tofu diet Designed to replace 90-100% of animal protein with 290 g tofu. 5 g butter, 5 g	Lean meat diet: 150 g (raw weight) of cooked lean red meat, with all visible fat removed, each day. Total Protein: 32.4	Total Cholesterol HDL Triglyceride Lpa	AE:no Drop out: 3: non-compliance.

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
11194529	Male%:100 Country: Australia Sites:1 BMI:26.2 Soy1 N:45 Control N:45	Blinding:No Duration:4.2 wks	affects lipids or BP, BMI > 35, Total Cholesterol > 7.5 mmol/L, Triglyceride > 6.0 mmol/L.	lard, 8 g olive oil Diet composition: E 9.5 MJ, 16.9%E protein, 44%E carb, 32%E fat, 12.4%E sat fat, 11.5%E MUFA, 5.2%E PUFA, 189.5%E Cholesterol	Total Product: 150 g raw meat Diet composition: E 9.6 MJ, 17.2%E protein, 43.7%E carb, 32.4%E fat, 12.9%E sat fat, 11.9%E MUFA, 4.8%E PUFA, 253.2%E Cholesterol	Free or Non-Esterified Fatty Acids Oxidized LDL Factor VII Fibrinogen	Comment: Baseline data for outcomes ND
Azadbakht 2003	Age (yr):62.5 (SD 12.1) Male%:71% Country: Iran Sites:1 BMI:70.6 Soy1 N:14 Control N:14	Design:Xover Randomized: Yes Blinding:No Duration:7 wks	Type 2 DM patients who were free of any uncontrolled conditions or other renal disease. All subjects had proteinuria with total urine protein excretion between 300 and 1000 mg/da, serum creatinine between 1 and 2.5 mg/dl and blood urea nitrogen between 20 and 40 mg/dl Excluded:ND	Soy protein diet 0.8 g/kg protein containing 35% soy protein, 30% vegetable protein and 35% animal protein Soy diet Diet composition: E 2403 kcal/d, protein 54 g/d, fat 55 g/d, fiber 16.1g/d, SFA 6.8g/d, MUFA 10.2g/d, PUFA 14.2g/d	Animal protein diet, 0.8 g/kg total protein, including 70% animal and 30% vegetable protein Protein56 Product Diet composition: E 2396 kcal/d, protein 55.6 g/d, fat 57.6 g/d, SFA 10.2 g/d, MUFA 8.8 g/d, PUFA 11.3g/d	Total Cholesterol LDL HDL Triglyceride LDL:HDL	AE:ND Drop out:ND Comments:None
Baird 1995	Age (yr): 45-65 Male%:0 Country: US Sites:4 BMI: ND Total enrol:97 Soy1 N:66 Control N:25 (soy and control for only completers)	Design:RCT Randomized: Yes Blinding:No Duration:4 wks	postmenopausal, =< 65, => 2 yr after menses Excluded:Antibiotics or HRT in past 6 mo, meds known to affect outcomes measures	Soy diet soy diet group ate daily portions of soy foods provided by the study as a substitute for approximate Diet composition:ND	Usual diet Control group instructed to eat as usual during dietary intervention period Protein:ND Product:ND Diet composition:ND	Vaginal cell maturation index Sex Hormone Binding Globulin LH FSH Estradiol	AE:yes AE Report:1 could not tolerate soy food Drop out:3 found ineligible (1 premenopausal, 1 on corticosteriods, 1meds for DM), 3 WD (personal reasons 2, aversion for soy foods 1) Comments: 3:1 randomization; 18/66 lack of compliance in the soy arm

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
Bakhit 1994	Age (yr):43 (SD 12) Male%:100 Country: US Sites:1 BMI:27.1 Soy1 N:21 Soy2 N:21 Control1 N:21 Control2 N:21	Design:Xover Randomized: Yes Duration:4 wks	Males, Plasma Total Cholesterol > 5.7 mmol/L, able to eat samples of the study muffins. Excluded:Persons taking lipid altering medications, thryoid and liver disorders.	1. Isolated Soy Protein + Cellulose 4 Muffins daily with (total) 25 g isolated soy protein, and 20 g cellulose Supro Diet composition:Supro 610 Isolated Soy Protein, Protein Technologies International, St. Louis, MO 2. Isolated Soy Protein + Soy Cotyledon Fiber 4 muffins daily with (total) 25 g Isolated Soy Protein and 20 g Soybean Cotyledon Fiber. Supro Diet composition: E:10692kJ, protein 19.7%KJ, carb 98%KJ, Fat 26.7 KJ	1. Casein + Soy Cotyledon Fiber 4 muffins daily with (total) 25 g Casein and 20 g Soybean Cotyledon Fiber. 2. 4 Muffins daily with (total) Casein 25 g + cellulose 20 g cellulose Protein25 g Product Diet composition: 10225kJ, protein 19.2%KJ, carb 90.7%KJ, Fat 24.6 KJ	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 VLDL	AE:ND Drop out:10; 6 individuals could not comply with low fat, low cholesterol diet or could not consume required number of muffins on a daily basis(within first 4 week treatment block), 1 lost to follow-up, 3 left out of analysis
Balk 2002	Age (yr):56.8 (SD 5.9) Male%: Country: US Sites:1 BMI:ND Wt:154.5 lbs Soy1 N:13 Control N:14	Design:RCT Randomized: Yes Blinding: double Duration:6 mo	postmenopausal, omnivorous, intact uterus Excluded:H/o of tamoxifen use, endometrial cancer, soy allergy, HRT in past yr, current supplementation of isoflavones	Soy diet 100 mg per day of isoflavones via soy flour & corn cereal (Nutlettes by Dixie). Soy & Placeb Diet composition:ND	Placebo was wheat cereal, Grapenuts, that is low in isoflavones but similar in appearance & texture Protein:ND Product:ND Diet composition:ND	Menopausal symptom hot flushes vaginal dryness decreased libido depression urinary discomfort Additional outcomes: headache, palpitations, night sweats, insomnia	AE:yes AE Report:Flatus, breast tenderness, nausea, diarrhea with no difference between groups at baseline or final week Drop out:8 WD (2 from placebo because lack of effectiveness of cereal, taste of cereal (1); 6 from soy because of personal reasons (2), excess flatus (1), increase hot flush intensity (1), LTF(1))
Baum 1998	Age (yr):59.8 (SD 9.1)	Design:RCT Randomized:	Completion of menopause with >= 1 yr since the last menstrual period, plasma	1. ISP56 ISP with Isoflavone Basal diet + 40 g of soy	Casein and non fat dry milk (CNFDM, containing 0 mg total glycosides isoflavones/d; New	Total Cholesterol HDL Triglyceride	AE: ND Drop out:7 withdrew

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Male%:0 Country: US Sites:ND BMI:28.2 Soy1 N:23 Soy2 N:21 Control N:22	Yes Blinding: double Duration:24 wks	cholesterol concentration between 6.2 and 7.8 mmol/L. Excluded:Hormone Replacement Therapy, Any medications known to lower lipids, h/o of DM mellitus or thyroid disease, or chronic illness, allergies to soybean protein.	protein and 56 mg total glycosides isoflavones/day, Supro 675, Protein Techno Supro ISP90 ISP with Isoflavone Basal diet + 40 g of soy protein and 90 mg total glycosides isoflavones/day, Diet composition:ND	Zealand Milk Product) Protein40 g Product:ND Diet composition:ND	Apo A1 Apo B/100 Total chol:HDL HDL2, HDL3 Non-HDLc LDL receptor mRNA	during wks 1-4: 1 moved, 3 withdrew because of unrelated medical problems, 3 unable to comply with study protocol. Comment: Well Reported. Industry Supported
Bazzoli 2002	Age (yr):21 (SD 1.8) Male%:0 Country: US Sites:1 BMI:22.4 Soy1 N:9 Control N:9	Design:RCT Randomized: Yes Blinding: double Duration:4 wks	female students modrately active from an exercise standpoint Excluded:smoking, any soy product consumed>1 time/week, oral contraceptives	ISP w /isoflavones Soy Isolated Soy protein w isoflavones consumed as a mixture w/ water and an approved flavoring Supro Diet composition:ND	whey protein Protein40 g Product:ND Diet composition:ND	plasma lipid peroxides urinary 8- hydroxyl-2-deoxyguanosine Total antioxidant status	AE:no Drop out:No Comment: baseline dietary intakes not explicitly reported;not clear whether mean or median are given.
Blum 2003 12595862	Age (yr):55 (SD 5) Male%:0 Country: Israel Sites:1 BMI: Soy1 N:30 Control N:30	Design:Xover Randomized: Yes Blinding: double Duration:6 wks	Mildly hypercholesterolemic (LDL > 3.36 mmol/L), post-menopausal, women. (not aware of high cholesterol level). Excluded:HRT or vitamins A, C, or E, or lipid-lowering Tx in preceding 2 mo	soy supplement Diet packets with isolated soy protein with isoflavones. Fortified with vitamins and minerals, sugar ISP with Isoflavone Diet composition:Unclear what food was allowed or replaced.	Placebo of 25 g/day total milk protein in similar powder. Protein25 Product: ND Diet composition: ND:	Total Cholesterol, LDL, HDL, Triglyceride E-selectin ICAM-1 IL 2R P-selectin VCAM-1	AE:no Drop out: 6 (4 during placebo, 2 during soy) stopped treatment because of bad taste and nausea caused by the powder): Comment: Same study as Blum 2003 12659466 (Triglyceride reported both studies)
Blum 2003	Age (yr):55 (SD 5)	Design:Xover Randomized:	Mildly hypercholesterolemic (LDL > 3.36 mmol/L), post-menopausal, women. (not	soy supplement Diet packets with isolated soy protein with	Placebo of 25 g/day total milk protein in similar powder.	Total Cholesterol LDL HDL	AE:no Drop out:

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
12659466	Male%:0 Country: Israel Sites:1 BMI: Soy1 N:30 Control N:30	Yes CohortMult Blinding: double Duration:6 wks	aware of high cholesterol level). Excluded:HRT or vitamins A, C, or E, or lipid-lowering Tx in preceding 2 mo.	isoflavones. Fortified with vitamins and minerals, sugar ISP with Isoflavone Diet composition:Unclear what food was allowed or replaced.	Protein:25g Product: ND Diet composition: ND	Triglyceride Peripheral endothelial function	6 (4 during placebo, 2 during soy) stopped treatment because of bad taste and nausea caused by the powder) Comment: Same as 12595862
Bricarello 2004	Age (yr):56 (SD 1) Male%:25 Country: Brazil Sites:2 BMI:24.9 Soy1 N:60 Control N:60	Design:Xover Randomized: Yes Blinding: double Duration:6 wks	Recruited from dyslipidemia clinics. 20-70 years, Total Cholesterol 200-350 mg/dL, Triglyceride <400 mg/dL Excluded:Presence of CAD and other significant CVD, renal, hepatic, gastrointestinal, mental, and endocrine disorders, including DM and BMI >=30 kg/m2. Hypolipidemic drugs in previous 8 wk	Soy milk 1 L per day soy milk (flavored with vanilla) SoyMilk Diet composition: E 1580kcal, total fat 34%Unsat fat 39%, sat fat 20%, carb 45%, protein 21%, Cholesterol 113mg, fiber 16g	1 L per day non-fat cow milk nonfat mil1 Protein:27.5 Product:1 L Diet composition: E 1578kcal, total fat 25%Unsat fat 24%, sat fat 20%, carb 53%, protein 21%, Cholesterol 142mg, fiber 13g	Total Cholesterol LDL HDL Triglyceride Apo E Oxidized LDL	AE:no Drop out: ND
Brooks 2004	Age (yr):54.1 (SD 0.6) Male%:0 Country: Canada Sites:ND BMI:27.1 Soy1 N:15 Control N1:15 Control N2:16	Design:RCT Randomized: Yes Blinding: double Duration:16 wks	healthy, postmenopausal, => 1yr of natural menopause Excluded:active bowel disease, malabsorption syndrome, exogenous estrogens within past 3 mo, phytoestrogen supplements within past 1 month, thyroid disorder, oral or parenteral corticosteroids, antibiotic use in past 4 wks	Soy diet The study muffins for all 3 treatment groups contained similar ingredients flour Diet composition: E 7326 kJ/d, protein 67.7g/d, fat 58g/d, carb 242.9.1g/d, fiber 18.3g/d	1.Placebo muffin 2.Flaxseed muffin Protein7.5 Product:21g Diet composition: E 6933 kJ/d, protein 81.0g/d, fat 52.8g/d, carb 240.2g/d, fiber 18.3g/d	Urine deoxypyridinoline Bone specific alkaline phosphatase Estradiol Estrone Estrone Sulfate Urinary 2OHE Urinary 16aOHE	AE:no Drop out:2 WD from analyses for missing lab data Comment:99 enrolled in a separate study, 46 (selected for compliance)-formed this study subgroup
Brown 2002	Age (yr):27.6 (SD 0.12)	Design:Xover Randomized: Yes	Healthy premenopausal women with standard blood cell counts , and clinical	Soy Supro ISP with Isoflavone Diet composition: Standard	2 control diet 1. PUFA diet 2.control diet protein	Cortisol Menstrual cycle length Sex Hormone	AE:no Drop out: 47%(Pregnancy (1), antibiotics (1),

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Male%:0 Country: US Sites:1 BMI: Soy1 N:26 Control N:26	Blinding: single Duration:11 mo	chemistry determinations Excluded:Oral contraceptives < 6 mo, antibiotics < 3 mo, > 2 alcoholic drinks per day, irregular menstrual cycles, diets of high fiber(>25 g/day), high soy (>2 servings/wk), high fat (>35% kcal), or low fat (<25% kcal), vegetarianism,	diet from 2,000-2,800 kcal/day. 37% kcal fat, 48% carb, 15%protein	Protein: 15%E Product:ND Diet composition: Standard diet from 2,000-2,800 kcal/day. 37% kcal fat, 48% carb, 15%protein	Binding Globulin LH FSH Estradiol Estrone Estrone Sulfate Progesterone Prolactin Testosterone Androstenedione DHEA/DHEAS Urinary 2OHE Urinary 16aOHE	relocation (2), difficult study schedule/noncompliance (8) Comments: ND for baseline data for outcomes; but data reported for follicular and luteal phase
Bruce 2003	Age (yr):68.9 (SD 1.03) Male%: Country: US Sites:1 BMI:20.5 Total enroll:42 Soy1 N:22 Control N:16 (soy and control for completers)	Design:RCT Randomized: Yes Blinding: double Duration:6 mo	Postmenopausal, > 60 y Excluded:HRT, breast cancer h/o, BMI > 35	Isoflavones supplement Soy Isoflavones without protein Diet composition:ND	Maltodextrin Protein Product3 Diet composition:ND	T3 T4 TSH	AE:no Drop out:Personal reasons (3), LTF (1) Comments: vitamin/mineral supplementatioin incl 150 mg of iodine isoflavones supplied by funder
Burke 2001	Age (yr):59.3 Male%:55.6 Country: Australia Sites:1? BMI:76.2 Soy1 N:10	Design:RCT Randomized: Yes Blinding:No Duration:8 wks	Nonsmoking, men or women, at least 20 years old, currently on antihypertensive therapy for at least 6 mo with <=2 medications, SBP between 130 and 160 mm Hg, and alcohol intake <= 210 g alcohol/wk. Excluded:DM, renal disease (creatinine > 130	1. HighSoyProteinHighFi 66 g soy protein/d, 12 g soluble Fiber in the form of Psyllium husks Diet composition:E 8.1mJ/d, 23.7% E protein/day, 26.1%E fat,47.7%E carb. 2. HighSoyProteinLowFib 66 g soy Protein/day Diet composition: E	1.LowProteinHighFiber 15 g psyllium/day, 66 g maltodextrin powder/day. Diet composition: E 9.3mJ/d, 12.2% E protein/day, 25.1%E fat,59.4%E carb. 2.Low, Protein, Low Fiber arm. 66 g maltodextrin/day. Total Protein: 11.5% of energy Total Product: 66 g maltodextrin Diet composition: E 9.0mJ/d, 11.5%	SBP DBP heart rate	AE:yes AE Report:3 withdrawals related to dietary intolerance. Drop out: 3 withdrawals due to dietary intolerance, 1 due to a change in hypertensive medications.

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy2 N:13 Control1 N:9 Control2 N:9		mmol/L), symptomatic heart disease, regular use of NSAIDs, psychiatric illness, BMI > 33 kg/m2 for men and 37 kg/m2 for women	10.0mJ/d, 22.8% E protein/day, 26.5%E fat,49.9%E carb.	E protein/day, 22.8%E fat,62.2%E carb.		Comment: Data presented clearly.
Burke 2003	Age (yr):50.8 (SD 0.1) Male%:0 Country: US Sites:1 BMI:27.1 Soy1 N:70 Soy2 N:65 Control N:76	Design:RCT Randomized: Yes Blinding: double Duration:2 years	Perimenopausal women, 45 - 55 y, at least 1 vasomotor symptom @ day; surgical menopause subjects okay if all other inclusion/exclusion met Excluded:HRT < 3 mo, MI or stroke < 6 mo, h/o breast or endometrial cancer, invasive cancer < 5 y, active thromboembolic disease, hormonal meds for osteoporosis-related fractures, low basln bone density, prev exposure to diethylstibestrol, dyslipidemia, or endometrial biopsy with hyperplasia	1. High isoflavoneflavone 25 g ready-to-drink soy protein beverage ISP with Isoflavone Diet composition:ND 2. Med isoflavone 25 g ready-to-drink soy protein beverage ISP with Isoflavone Diet composition:ND	soy protein without isoflavones 25 g ready-to-drink beverage Protein25 g Product:ND Diet composition:ND alcohol washed to remove isoflavones (<= 4 mg/day)	Menopausal symptom vasomotor symptoms	AE:yes AE Report:? Soy protein supplementation was quite palatable , and extremely well-tolerated. Drop out:13% drop out from 241enrolled, 3 -no symptom diaries, 14 - no baseline symptom diaries, 11 - no fwup symptom diaries , 2 had baseline diary but no hot flashes; therefore 211 included for analyses of symptom diaries Comment: Breakdown of isoflavones not given
Carroll 1978	Age (yr):21 Male%:0 Country: Canada Sites:1 BMI:54.4 Soy1 N:10 Control N:10	Design: Xover Randomized: Unclear Blinding:No Duration:37 or 41 (each arm different) days	Healthy young women studying either food science or nutrition. Well nourished. Normal glucose, Triglyceride, Total Cholesterol, alkaline phosphatase, thyroxine, creatinine, calcium, sodium, potassium, chloride, bicarbonate, hematological and urine analyses, and chest X-ray. Excluded:Obese, metabolic or other disease, received any medication known to affect serum lipids or	Soy diet All meals provided on a 5 day rotation. Meats were replaced by soy protein meat analogues (textured Soy diet Diet composition: E 1880kcal, protein 75g, carb 242g, fat 68g	Mixed protein diet All meals provided on a 5 day rotation. Regular foods to maintain weight and adequate amounts of essential nutrients Protein:70 Product: Diet composition: E 1853 kcal, protein 70g, carb 238g, fat 69g	Total Cholesterol Triglycerides	AE:no No dropouts

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
			ingested > 30 g/day ethanol in previous 4 mo.				
Cassidy 1994	Age (yr):24 Male%:0 Country: UK Sites:1 BMI:61.59 Soy1 N:6 Control N:0	Design:NRNCT Randomized: No CohortSing Blinding:No Duration:1 month	Healthy, nonvegetarian women, normal menstrual cycle, no meds => 6 mo prior to record menses data Excluded:ND	soy diet During 2nd month, starting on 1st day of menses, appropriate modificatioins were made to the basal d ISP with Isoflavone Diet composition:Energy 8.5 with- 0.3 MJ, Total fat 60.0 with- 1.7g, Carb 260.3 with- 1.0g, Nonstarch polysaccharide 16.3 with- 0.7g, Starch 106.7 with- 2.7g, Nitrogen 2.10 with- 0.06 ug/g	First complete menstrual cycle served as control period, each Protein97.2 Product Diet composition:Energy 8.5 with- 0.1 MJ, Total fat 61.4 with- 0.7g, Carb 258.2 with- 1.9g, Nonstarch polysaccharide 16.0 with- 0.6g, Starch 108.3 with- 2.2g, Nitrogen 2.09 with- 0.03ug/g, Daidzein 0.76 with- 0.03 mg, Genistein 0.49 with- 0.03 mg	Total Cholesterol, but N<10 Menstrual cycle length Follicular Sex Hormone Binding Globulin FSH Estradiol Progesterone Testosterone	AE:no Drop out:None Comment: All subjects under 30;4 month prior study and several mo after, basal body temp monitored to determine menstrual cycle;1 month control diet followed by 1-4 month separation period before soy diet;Small sample size Same study as Cassidy 1995 Study 1
Cassidy 1995 7577895 study 1	Age (yr):20-29 Male%:0 Country: US Sites:1 BMI:61.6 Soy1 N:6 Control N:0	Design:NRCT Randomized: No CohortSing Blinding:No Duration:1 mo	non-vegetarian female students, regular menstrual cycles and no medication for 6 mo before the study. Excluded:ND	45 mg conjugated isoflavones ISP with Isoflavone Diet composition:ND.	No control	Follicular phase length Luteal phase length Total menstrual cycle length Total Cholesterol LDL HDL Triglyceride Sex Hormone Binding Globulin LH FSH Progesterone Oestradiol Urinary LH	AE:no Drop out:no Comments: no baseline data Same study as Cassidy 1994
Cassidy 1995 7577895 study3	Age (yr): Male%:0 Country: US Sites:1	Design:Xover Randomized: Yes Blinding:ND Duration:1	non-vegetarian female students, regular menstrual cycles and no medication for 6 mo before the study. Excluded:	isoflavones-free soyabean product ISP without isoflavone Diet composition:8MJ/d	Control diet	Follicular phase length Luteal phase length Total menstrual cycle length Total Cholesterol LDL	AE:no Drop out:no Comment: blinding is unclear and small numbers

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI: Soy1 N:5 Control N:5	mo				HDL Triglyceride Sex Hormone Binding Globulin LH FSH Progesterone Oestradiol Urinary LH	
Cassidy 1995 7577895 Study 4	Age (yr): Male%:0 Country: US Sites:1 BMI:57.0 Soy1 N:6 Control N:6	Design:NRCT Randomized: No CohortSing Blinding:No Duration:1 mo	non-vegetarian female students, regular menstrual cycles and no medication for 6 mo before the study. Excluded:	half-dose conjugated isoflavones 23 mg conjugated isoflavones ISP with Isoflavone Diet composition:ND	No control	Follicular phase length Luteal phase length Total menstrual cycle length Total Cholesterol LDL HDL Triglyceride Sex Hormone Binding Globulin LH FSH Progesterone Oestradiol Urinary LH	AE:ND Drop out:no Comments: no baseline data
Chen 2003	Age (yr):54.4 (SD 3.1) Male%:0 Country: HongKong Sites:1 BMI:57.9 Soy1 N:68 Soy2 N:68 Control N:67	Design:RCT Randomized: Yes Blinding: double Duration:1 years	age 48-62, postmenopausal women within 10 y of menopause Excluded:any meds known to affect bone or calcium metabolism, current use of or h/o of exogenous estrogens, corticosteroids, thiazine; soy allergic, any systemic endocrine disease; any surgery known to affect bone health (Ovariectomy, thryoid gland or intestin	1. high-dose soy isoflavones 80 mg soy isoflavones, calcium 500 mg, Vitamin D 125 IU Soy Isoflavones without protein Diet composition:E 5.49MJ/d, protein 68.2g/d 2. mid-dose soy isoflavones 40 mg soy isoflavones, 12.5 mmol calcium, 125 IU Vitamin D Soy Isoflavones without protein Diet composition: E	corn starch + calcium 500 mg + Vitamin D 125 IU Protein:0 Product:0.5g Diet composition: E 5.44MJ/d, protein 74.6g/d	Bone mineral density Bone mineral content	AE: ND Drop out:Isoflavone groups=14 cases abdominal distention, 6 constipation, 6 breast disorders, 3 menses-like bleeding, 12 misc. Comment: same trial as Chen 2004 RefID #5256--same design, characteristics, population etc etc etc. Differences are adverse events published in this paper

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
				5.38MJ/d, protein 71.3g/d			
Chen 2004	Age (yr):54.4 (SD 3.1) Male%:0 Country: HongKong Sites:1 BMI:57.9 Soy1 N:68 Soy2 N:68 Control N:67	Design:RCT Randomized: Yes Blinding: double Duration:1 years	age 48-62, postmenopausal women within 10 y of menopause Excluded:any meds known to affect bone or calcium metabolism, current use of or h/o of exogenous estrogens, corticosteroids, thiazine; soy allergic, any systemic endocrine disease; any surgery known to affect bone health (Ovariectomy, thryoid gland or intestin	1. high-dose soy isoflavones 80 mg soy isoflavones, calcium 500 mg, Vitamin D 125 IU Soy Isoflavones without protein Diet composition: Diet composition:E 5.49MJ/d, protein 68.2g/d 2. mid-dose soy isoflavones 40 mg soy isoflavones, 12.5 mmol calcium, 125 IU Vitamin D Soy Isoflavones without protein Diet composition: Diet composition: E 5.38MJ/d, protein 71.3g/d	corn starch + calcium 500 mg + Vitamin D 125 IU Protein:0 Product:0.5g Diet composition: Diet composition:E 5.49MJ/d, protein 68.2g/d	Bone mineral density Bone mineral content	AE:yes AE Report:14 cases: abdominal distension; 6 constipation; 6 breast disorders; 3 menses-like bleeding; 12 misc. "We did not observe a statistically higher incidence of any adverse effect in treatment groups compared to placebo arm." Drop out: 28/203 lost to follow up Comment: same trial as Chen 2004
Chiechi 2002 11836040	Age (yr):54.2 (SD 4.04) Male%:0 Country: Italy Sites:1 BMI:68.5 Soy1 N:58 Soy2 N:53 Control N:55	Design:RCT Randomized: Yes Blinding:No Duration:6 mo	All women in menopause as defined by 1) spontaneous menopause since at least 6 mo and with FSH >30 IU/L and E2 <20 pg/ml. 2) Bilateral ovariectomy. Excluded:age >60; drinking more than 14 standard alcoholic drinks weekly; hormonal replacement therapy or cholesterol lowering drugs in the previous 6 mo; h/o cancer; adherence to a vegetarian or macrobiotic diet or to any other medically prescribed diet; treatment for diabetes, presence of menopausal	Soy diet Diet intervention arm Women in the dietary intervention group were asked to add a soy food serving every day (e.g. soy milk, Soy bean,Tofu, SoyMilk) Diet composition:ND	Usual diet ProteinND ProductND Diet composition:No data available on the control arm	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 SBP DBP Total chol:HDL ApoA1:B Endometrial thickness Uterine artery resistance index	AE:no Drop out: 58 Diet group: Dislike of soy; lack of time/too difficult, side effects; family reasons; little conviction; menstruation; foods difficult to find; high cost of the foods; and other reasons Comment: Huge drop out and race, baseline CVD not reported.

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
			symptoms requiring therapy				
Chiechi 2002 12191852	Age (yr):54.2 (SD 4.04) Male%:0 Country: Italy Sites:1 BMI:68.5 Soy1 N:58 Soy2 N:53 Control N:55	Design:RCT Randomized: Yes Blinding:No Duration:6 mo	spontaneous menopause since 6 mo, FSH > 30 IU/I, E2 < 20 pg/ml, bilateral ovariectomy Excluded:age >60, drinking > 14 alcoholic drinks wkly, HRT or cholesterol lowering drugs within 6 mo, h/o of cancer or other chronic diseases, adherence to veg or macrobiotic diet, treatment for DM, presence of menopausal symptoms requeiring therapy	soy diet women were invited to continue usual diet, only adding soy food serving every day (soymilk, miso soup, tempeh, or soy beans) Diet composition:daily consumption of soy: 22.25 g soybeans, 33.3 g tofu, 299.06 soymilk, 8.6 g tempeh, 2.4 g miso	Usual diet Protein:ND Product:ND Diet composition:"usual diet"	Bone mineral density Bone mineral content Serum Osteocalcin Type 1 Collagen cross-linked N-teleopeptide FSH Estradiol Hydroxyproline/creatinine	AE:yes AE Report:1 (no reason stated) Drop out: diet group= 11 disliked soy, 7 too difficult, 1 side effect etc;HRT= 7 side effects; control= var reasons listed, seem unimportant to mention Comment: 3 arms: diet containing soy vs HRT vs control
Chiechi 2003	Age (yr):54.2 (SD 4.04) Male%:0 Country: Italy Sites:1 BMI:27.06 Soy1 N:53 Control N:58	Design:RCT Randomized: Yes Blinding: double Duration:6 mo	Asymptomatic postmenopausal women, 39-60 y, incl spontaneous menopause => 6 mo, FSH > 30 IU/1 and E2 < 20 pg/ml or with bilateral ovariectomy Excluded:>60 y, > 14 standard alcoholic drinks weekly, HRT, lipid-lowering, antiosteoporotic or other interfering drugs < 6 mo, DM, H/o cancer, vegetarian or macrobiotic diet, menopausal symptoms requiring tx	soy diet Continue usual diet & add soy food serving every day, to exchange 2 meals tice a week with meals Soy diet Diet intervention arm Women in the dietary intervention group were asked to add a soy food serving every day (e.g. soy milk, Soy bean,Tofu, SoyMilk) Diet composition:ND	Habitual diet of Southern Italy ProteinND ProductND Diet composition:No data available on the control arm	FSH Estradiol: Karyopycnotic index Maturation value	AE:no Drop out:no Comment: See Chiechi 2002, analyses on 166 of 187. PI spectulation for high dropout due to soy foods not common part of diet
Crisafulli 2004	Age (yr):52 (SD 0.5) Male%: Country: Italy Sites:1	Design:RCT Randomized: Yes Blinding: double Duration:1	Healthy, ambulatory women, 47-57 yr, FSH > 50 IU/L, serum E2 <= 100 pmol/L, > 5 hot flushes @ day Excluded:Sugical menopause, menstrual	Genistein Phytoestrogen genistein, 54 mg/day, or HRT, or placebo. All pills identical in appearance Soy Isoflavones without protein	Placebo pills identical in appearance to intervention. ProteinND ProductND Diet composition:ND	Endometrial thickness Menopausal symptom Hot flushes estradiol	AE:yes AE Report:Genistein generally well tolerated and ingested with high degree of compliance. No observed side effects after 1 year of genistein.

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI:24 Soy1 N:30 Control N:30	years	period in preceding year, clinical or lab abnormalities suggesting CVD, hepatic, or renal disorders, coagulopathy, oral or transdermal estrogen, progestin, androgen or other steroids in preceding year, >10 cigarettes/day	Diet composition:ND			Drop out: 7 WD from treatment but completed study Comment:Intention to treat analysis
Crouse 1999	Age (yr):52 Male%:60 Country: US Sites:1 BMI:26 Soy1 N:31 Soy2 N:31 Soy3 N:31 Soy4 N:31 Control N:31	Design:RCT Randomized: Yes Blinding:other Duration:9 wks	Mild cholesteremic (LDL 140-200 mg/dl) men and women after 1 month instruction in an NCEP Step 1 diet. Eligible individuals have to be 80% compliant with 25 g casein beverage run in 1 month period. Excluded:current use of lipid lowering medications, H/o CVD, current H/o DM or blood glucose levels higher than 6.94 mmol/L (125 mg/dl), uncorrected secondary causes of hypercholesterolemia, excessive alcohol consumption, triglyceride conc >4.52 mmol/L (>400 mg/dL), LDL cholesterol >5.17 mmol/L (>200 mg/dL), use of oral contraceptives or estrogen replacement, and usual consumption of high soy protein diet.	1) Isolated soy protein beverage ISP with Isoflavone (62 mg) 2) Isolated soy protein ISP without isoflavone 3) Isolated soy protein beverage ISP with Isoflavone (27 mg) 4) Isolated soy protein beverage ISP with Isoflavone (37 mg) Diet composition: ND	25 gram of casein Protein25 gram Product ND Diet composition: ND	Total Cholesterol LDL HDL Triglyceride Lpa SBP DBP	Adverse event: ND Drop out :12: 3 in the casein group, 4 in the 3mg isoflavone group and 5 in the 27 mg isoflavone group. 8/12 were lost to follow up. Among 4/12, 2 dropped out casein group- urticaria and exacerbation of asthma, 1 from the 3mg group-indigestion, 1 from the 27 mg group-chestpain and an abnormal exercise tolerance test. Comment: Baseline characteristics reported according to the gender and menopausal status;Divided at the median level for LDL into low group There is a discrepancy in the data between text and the table
Cuevas 2003	Age (yr):59 Male%:0 Country: Chile	Design:Xover Randomized: Yes Blinding:	Healthy, non-smoking, post menopausal women hypercholesterolemia (LDL 4.14 and 6.21 mmol/l and triacylglycerol <3.39	Soy 40 gram of isolated soy protein powder containing 80 mg isoflavones (60% genistein, 30% daidzein, 10	Caseinate powder Protein40 gram Product:ND Diet composition: NCEP step 1 diet; <30%E fat, <10%E sat fat,	Total Cholesterol LDL HDL Triglyceride SBP	AE:yes AE Report:Constipation, heart burn

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Sites:1 BMI:29.3 (0.81) Soy1 N:18 Control N:18	double Duration:8 wks	mmol/l). normal liver, kidney and thyroid functions and normal fasting glucose concentrations. No patients received vit, antioxidants, antilipemic agents, arginine, anti-HTN, soy foods Excluded:ND	ISP with Isoflavone Diet composition: NCEP step 1 diet; <30%E fat, <10%E sat fat, <300mg/day cholesterol	<300mg/day cholesterol	DBP Peripheral endothelial function other test:1 Nitroglyce FSH	Drop out:ND Comment: Small sample and drop out ND
Dalais 1998	Age (yr):54 Male%:0 Country: Australia Sites:0 BMI:26 Soy1 N:52 Control N:52	Design:Xover Randomized: Yes Blinding: double Duration:12 wks	45-65 yr; FSH>40 IU/ml, hot flush > 14 per wk; amenorrhea for 12 mos; no abx or HRT for preceding 3 mos., non-smoker, non-vegetarian Excluded:ND	Soy diet 45 grams per day of soy grits was achieved by using 3 different types of bread with the same backgro soy bread Diet composition:ND	45 grams/day of wheat kibble Protein without fat Protein:ND Product:45g/d Diet composition:ND	Menopausal symptom hot flushes Vaginal cell maturation index	AE: ND Drop out:52 enrolled, 44 completed the study, 7 drop-outs due to personal reason, 1 due to lack of compliance to study demands Comment: There is also a linseed and wheat arm reported in the paper.
Dalais 2003	Age (yr):60 (SD 1) Male%:0 Country: Australia Sites:1 BMI:24.9 Soy1 N:51 Control N:55	Design:RCT Randomized: Yes Blinding: double Duration:3 mo	Postmenopausal women between 50 and 75 years, nonsmokers, nonvegetarians, not on HRT for the previous 12 mo, not consuming isoflavones or soy-based products and not on any antibiotics for the previous 3 mo. None of the study participants were cons Excluded:None	Soy protein Soy protein, powder form (St Louis, MO, USA) ISP with Isoflavone Diet composition: E 2228 kcal; protein 109g	Placebo Protein40 ProductND Diet composition: E 2211kcal; protein 112 g	Urine deoxypyridinoline Urine pyridinoline	AE:yes AE Report:Low incidence of mild GI side-effects Drop out:13 withdrew from the soy group and 15 from the placebo group, primarily due to difficulty consuming the bulk of product provided each day. Comment: This study was part of a larger trial in men and women examining the role of soy protein on cardiovascular end points Teede, 2001
D'Amico	Age (yr):41	Design:NRNCT	Patients with biopsy-proven glomerular disease.	Vegtarian soy diet Vegtarian soy diet, low in	No control	Total Cholesterol LDL	AE:no

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
1992	(SD 18) Male%:65% Country: Italy Sites:1 BMI:22.7 Soy1 N:20 Control N:0	Randomized: No CohortSing Blinding:No Duration:8 wks	Consistent proteinuria of > 1.5 g/24 h for a mean of 25 mo (range 3-95]; serum creatinine < 220 umol/l; hyperlipidaemia (fasting serum cholesterol > 5.95 mmol/l); no treatment with steroids or c Excluded:ND	fat, moderately low in protein, and rich in PUFA and MUFA and fiver Soy diet Diet composition: 11% E protein, 28% E fat, carb 46%		HDL Triglyceride Apo A1 Apo B/100 SBP DBP GFR	Drop out:no dropout Comment: Lipid and kidney outcomes excluded from the report (NRCT)
Davis 2001	Age (yr):25-40 Male%:100 Country: US Sites:1 BMI:ND Soy1 N:6 Control N:0	Design:NRNCT Randomized: No CohortSing Duration:3 wks	Healthy male employees of Barbara Ann Karmanos Cancer Institute No H/o of health problems, no medications, vitamins or hebal supplements taken Excluded:none reported	Soy isoflavone mixture the tablets contain genistein, daidzein, and glycetin (1.3:1:0.3), which is estimated to contain 24% Diet composition:ND	No control	5-OHmdU NF-kB	AE:ND Drop out:no Comment:No baseline data
Dent 2001	Age (yr):50.2 (SD 3.6) Male%:0 Country: US Sites:1 BMI:24.1 Soy1 N:24 Soy2 N:24 Control N:21	Design:RCT Randomized: Yes Blinding: double Duration:24 wks	Perimenopausal women experiencing >=10 hot flashes and/or night sweats per week, had irregular menses or cessation of menses for <1 yr, had one or both ovaries remaining, had a BMI between 19-31kg/m2 and were willing to be randomized Excluded:women with chronic disease (ie heart disease or osteoporosis), on medications chronically, sex hormone treatment during the past 12 mo, h/o of an eating disorder or menstrual disorder and/or were excessive exercisers	1. Isoflavone poor soy protein isolate isoflavone poor soy protein isolate with 4.4 mg/d glycosides component ISP without isoflavone Diet composition:ND. 2. Isoflavone +ve soy protein SPI+ (80.4 mg/d glycosides components) Name ISP with Isoflavone Diet composition: ND	Whey protein Total Protein: 40 gram/day Total Product: ND Diet composition: ND	Total Cholesterol LDL HDL Triglyceride Lpa Factor VII Fibrinogen Plasminogen activator inhibitor	AE:no Drop out: inability to tolerate treatment (n=6), medical conditions preventing continuance (n=2), death (n=1), death in the family (n=1) Comment: Soy protein source not clear; outcomes assessed from figures

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
Dewell 2002	Age (yr):69 (SD 1) Male%:0 US:1 Country: US Sites:1 BMI:25 (18-32) Soy1 N:20 Control N:16	Design:RCT Randomized: Yes Blinding: double Duration:2 mo (HDL, non-HDL) , and 6 mo (Total Cholesterol, Triglyceride)	Healthy, moderately hypercholesterolemic postmenopausal women not receiving HRT. Excluded:Clinical or biochemical evidence of DM or renal, hepatic, or CV disease	150 mg soy-derived isoflavones. Tablet. Sermipurified extract. Exclude soy-containing foods from die Soy Isoflavones without protein Diet composition: E 6958 kJ, protein 17%, fat 34%, SFA 11% carb 48%	150 mg maltodextrin with 10% caramel color. Tablet. Exclude soy-containing foods from diet. Other control: Maltodextr Protein0 Product150 mg Diet composition: E 6460 kJ, protein 15%, fat 34%, SFA 10% carb 50%	Non-HDL cholesterol measured (=Total Cholesterol-HDL) Total Cholesterol HDL Triglyceride	AE:no No dropouts Comment: Distinction between eligibility criteria and sample description unclear."Subjects were recruited initially as part of a larger randomized trial.
Djuric 2001	Age (yr):32 (SD 12) Male%:50 Country: US Sites:1 BMI:~80 Soy1 N:6 Soy2 N:6 Control N:0	Design:NRNCT2 Randomized: No CohortMult Duration:3 wks	healthy male and female volunteers from Karmanos Cancer Institute staff Excluded:none reported	Soy extract pills supplements contain equal amounts of genistein and daidzein and lesser amounts of glycitein (1:1:0.2 Soy Isoflavones without protein Diet composition:	No control	5-OHmdU	AE:ND Drop out: no Comment: not explicitly stated that all women were pre-menopausal;sample size was too small for each cohort;non controlled trial
Duffy 2003	Age (yr):58.8 (SD 1.1) Male%:0 UK:1 Country: Sites:1 BMI: Soy1 N:18	Design:RCT Randomized: Yes Blinding:other Duration:12 wks	Postmenopausal women aged 50-65. All subjects were healthy and nonsmokers. Excluded:Use of HRT in the previous 12 mo, use of antibiotics in the previous 3 mo, current illness or use of psychoactive medication.	Soy Isoflavones without protein Solgen Soya isoflavone supplement Diet composition: E 7.8MJ, Fat 34.3%E, MUFA 10.4%E, PUFA 5.2%E, SFA 12.7%E, Protein 15%E, carb 47.4%E	lactose placebo Protein0 Product:2 capsules per day Diet composition: E 7.0MJ, Fat 31.9%E, MUFA 10.3%E, PUFA 6.1%E, SFA 11.1%E, Protein 15%E, carb 45.3%E	Tests of frontal lobe function Episodic memory Sustained attention Menopausal symptoms Sleepiness Mood ratings	AE: AE Report: Drop out: 3 excluded because treatment with amitryptiline and one because HRT. All excluded subjects came from the placebo group. Comment: Subjects were recruited by circular email at King's College London or from a database of

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Control N:18						those who had previously participated in a study on bone mieral density at Guy's Hospital. In the Soy group, 78% of subjects were naturally menopausal and 22% were surgically menopausal
Duncan 1999 10522983	Age (yr):56.9 (SD) 5.8 Male%:0 Country: US Sites:mutiple BMI:25.2 Soy1 N:23 Soy2 N:23 Control N:23	Design:Xover Randomized: Yes Blinding: single Duration: 13wks	Healthy postmenopausal women Excluded:strict vegetarian, high fiber, high soy, or low fat diets; regular vitamin and mineral supplementation >Recommended Dietary Allowances; athleticism; cigarette smoking; antibiotic or hormone use within six mo; bleeding within 12 mo; hysterectomy or oopherectomy; FSH concentration of less than 25 IU/L; history of chronic disorders, endocrine or gynecological diseases; benign breast disease; regular use of medication known to interfere with study endpoints (including aspirin); less than 90% or more than 120% ideal body weight; weight change >10 lb within the previous year, and inability to abstain from alcololic beverages duing the study.	1. Soy protein powders ISP with Isoflavone (high) Diet composition: E 1783kcal, protein 114g, carb 233g, fat 48g, fiber 13g 2. Soy protein powders with ISP with Isoflavone (low) Diet composition: E 1755kcal, protein 114g, carb 232g, fat 45g, fiber 13g	Soy protein powders with very low isoflavones Total Protein: ND Total Product: ND Diet composition: E 1799kcal, protein 111g, carb 242g, fat 46g, fiber 13g	T3 T4 TBG TSH Cortisol Sex Hormone Binding Globulin LH FSH Estradiol Estrone Estrone Sulfate Prolactin Testosterone Androstenedione DHEA/DHEAS Insulin	AE:ND Drop out=4 due to inability to comply with the study protocol, and one for not postmenopausal. Comment:none
Duncan	Age (yr):26.5	Design:Xover Randomized:	Premenopausal women Excluded:vegetarian, high	1. Soy protein powders ISP with Isoflavone (high)	Soy protein powders with very low isoflavones	T3 T4	AE:no

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
1999 9920082	(SD 4.7) Male%:0 Country: US Sites:1 BMI:23 Soy1 N:14 Soy2 N:14 Control N:14	Yes Duration:3 mo	fiber, high soy, or low fat diets; regular consumption of vitamin and mineral supplementation greater than the recommended dietary allowances; athleticism; cigarette smoking; antibiotic or hormone use within 6 mo; h/o of chronic dis , endocrine or gynecological diseases; benign breast disease; regular use of medication known to interfere with study endpoints (including aspirin); less than 90% or more than 120% ideal body weight; weight change >10 lb within the previous year, and inability to abstain from alcololic beverages duing the study.	Diet composition: E 2221kcal, protein 116g, carb 293g, fat 67g, fiber 8.2g 2. Soy protein powders with ISP with Isoflavone (low) Diet composition: E 2272kcal, protein 113g, carb 296g, fat 74g, fiber 8.8g	Total Protein: ND Total Product: ND Diet composition: E 2294kcal, protein 115g, carb 297g, fat 76g, fiber 8.7g	TBG TSH Insulin PRL Sex Hormone Binding Globulin LH FSH Estradiol Estrone Estrone Sulfate Progesterone Testosterone Androstenedione DHEA/DHEAS cortisol	Drop out:no Comment: All samples taken from days 2-5 of menstrual cycles 3 and 4. Data came from early follicular days 2 and 4.
Faure 2002	Age (yr):53.0 (SD 5.6) Male%:0 Country: France Sites:multiple BMI:24.9 Soy1 N:39 Control N:36	Design:RCT Randomized: Yes Blinding: double Duration:14 wks	Postmenopausal -natural or surgical, >= 6 mo since last period, 7 or more moderate to severe hot flashes including nightsweats per 24 hr during 2 week prestudy, FSH > 40 IU/L, E2 < 35 pg/mL Excluded:HRT < 6 wk, vitamin E, clonidine	isoflavones Phytosoya is standarized isoflavone supplement prepared from soy extract in 325 mg capsule Phytosoya Soy Isoflavones without protein Diet composition:	Placebo capsule was formulated with similar appearance and state...capsule contained cellulose micro cellulose Protein:ND Product:ND Diet composition:ND	Menopausal symptom hot flashes hot flashes night sweats SBP DBP	AE:yes AE Report:WD due to adverse drug reactions, 2 in placebo group Drop out:Inefficacy (15), adverse drug reaction (2), LFU (2), other (1) Comment: Not explicit on duration of intervention, first 2 wks assessments preceding randomization, unclear intervention between 14-16 weeks
File 2001	Age (yr):27.1 (SD 3.2)	Design:RCT Randomized:	Student volunteers were reruited by circular email at King's College London. All	1. high soya diet (100 mg total isoflavones/day) Soy diet	No soy control	tests of memory tests of frontal lobe function	AE:ND Drop out:no

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Male%:56 (based on the total sample) Country: UK Sites:1 BMI:ND Total:27 Soy1 N:~13-14 Soy2 N:~13-14	Yes Blinding:No Duration:10 wks	subjects were healthy and medication free throughout the trial, and all were non-smokers. Excluded:ND	2. low soya diet (0.5 mg total isoflavones/day) Total Protein: 16% of total energy TotalProduct: ND Diet composition: The high soya and low soy diets provided approximately equivalent amounts of energy (~1550 kcal/day) and equivalent proportions of energy as fat (~37%), carb (~47%) and protein (~16%)		mood ratinings	Comment: Number of subjects in each group was not reported
Foth 2003	Age (yr):56.21 (SD 5.01) Male%: 0 Country: Germany Sites:1 BMI:>25 Soy1 N:16 Control N:0	Design:NRNCT Randomized: No CohortSing Blinding:No Duration:24 wks	Postmenopausal, FSH serum level > 40 mIU/ml or last period > 12 mo Excluded:HRT < 3 mo or prolactin metabolism meds, strict vegetarian, high-fiber, high-soy, low-fat diet, withphenylketonuria, BMI>25, tx for climateric disorders	Soy ISP with Isoflavone Soy supplementation was provided as tasteless soluble powder in daily dosage packets ingested once Diet composition:ND	No control	LH FSH Estradiol Prolactin Testosterone DHEA/DHEAS	AE:yes AE Report:Flatulence , and heartburn (2) Drop out:none Comment: selection enrollment unclear
Gallagher 2004	Age (yr):54.6 (SD 0.9) Male%:0 Country: US Sites:1 BMI:70.2 Soy1 N:~22 Soy2 N:~24	Design:RCT Randomized: Yes Blinding: double Duration:9 mo	Postmenopausal women between the ages of 40 and 62 years, with femoral neck density within the normal range (+- 2 SD) for their age and Urine N-telopeptidelopeptide excretion in the upper half of the normal, premenopausal range. Excluded:Severe chronic illness, primary	1. SPI 96 40 g soy protein isolate with isoflavones isolate with 96 mg/day isoflavones ISP with isoflavone Diet composition: 2. SPI 52 40 g soy protein isolate with 52 mg/day isoflavones ISP with Isoflavone Diet composition: ND 3. SPI 4	No control	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 Bone mineral density Serum Osteocalcin Urine N-telopeptide	AE:ND Drop outs:15; 4 stopped becasue they had to begin hormone therapy for atrophic vaginitis or for hot flashes. 4 stopped because of noncompliance. 4 because of severe constipation or stmach irritation. 1 because of chest pain. 1 because of

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy3 N or Control N::~19		hyperparathyroidism or active renal stone disease, or on certain medications, such as bisphosphonates, anticonvulsants, estrogen, fluoride, or thiazide diuretics in the past 6 mo.	40 g soy protein isolate without isoflavones ISP without isoflavone Diet composition			hypertension and 1 stopped because of breast cancer Comment: Values were estimated from Figures
Gardner 2001	Age (yr):58.4 (SD 7.2) Male%:0 Country: US Sites:1 BMI:25.4 Soy1 N:34 Soy2 N:33 Control N:32	Design:RCT Randomized: Yes Blinding: double Duration:12 wks	Post-menopausal women, age < 80 years, BMI 20-31 kg/m2. LDL 130-190 mg/dL and Triglyceride <250 mg/dL. Excluded:Smokers, taking HRT or lipid-lowering medication during previous 3 mo, h/o CVD, DM, breast CA, endometrial CA, ovarian CA in previous 10 years.	1. Soy+Isoflavone Same as control except that protein = an isolated soy protein containg 80 mg glycosides isoflavones. ISP with Isoflavone Diet composition:287 Kcal (1200 kJ) 2. Soy-Isoflavone Same as control, except protein = ethanol-extracted isolated soy protein with trace amounts of isofl ISP without isoflavone Diet composition:287 Kcal (1200 kJ), 40 g protein	Milk protein supplement. Mixure of protein, carb, and calcium in a powder form. 42 g protein Protein42 g Product2 packets Diet composition: 287 Kcal (1200 kJ), 40 g protein	Total Cholesterol LDL HDL Triglyceride FSH Estradiol Estrone Androstenedione	AE:yes AE Report:One from the Soy+Isoflavone group due to increased number of hot flashes. Drop out:1 each arm (3): bloating/constipation; 1 soy+iso: lost to follow-up; soy+iso: increased number of hot flashes; 1 milk: too much stress in her life Comment: Low calorie and low protein trial
GardnerThorpe 2003	Age (yr):35.6 (SD 11.2) Male%:100 Country: UK Sites:1 BMI:25.6 Soy1 N:20 Control N:20	Design:Xover Randomized: Yes Blinding: double Duration:6 wks	volunteers, omnivorous, healthy, non-smokers. Excluded:obese (body mass index (BMI) > 30kg/m2) or had taken any antibiotics or vitamin supplements within the previous month.	Soy diet soy flour soya scones the additional daily intake of isoflavones. Diet composition: E9238 kj, carb 223g, protein 71, total fat 74g, sat fat 24g, MUFA 26g, PUFA 10.8g	wheat flour Protein Product3 wheat scones Diet composition: E9600 kj, carb 250g, protein 85, total fat 86g, sat fat 31g, MUFA 30g, PUFA 16.2g	Total Cholesterol LDL HDL Triglyceride Oxidized LDL markers of oxidative stress Sex Hormone Binding Globulin Testosterone oestradial	AE:ND Drop out:personal reasons Comment: Most volunteers ate their scones in a semi-supervisedd manner; not clear about the race
Gentile 1993	Age (yr):45.4 (SD 4.5) Male%:45%	Design:NRNCT Randomized: No	Patients with biopsy-proven glomerular disease. Proteinuria of > 2.5 g/24 h for a mean of 24 mo (range 3-90]; hyperlipidemia	Veg soy diet Vegtarian soy diet, low in fat, moderately low in protein, and rich in PUFA and MUFA and fiver	No control for the soy arm	Total Cholesterol LDL HDL Triglyceride Apo A1	AE:no Drop out:no Comment: Lipid and kidney outcomes

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Country: Italy Sites:1 BMI:22.1 Soy1 N:20 Control N:0	CohortSing Blinding:No Duration:2 mo	(fasting serum cholesterol >250 mg/dl); no treatment with steroids or cytotoxic, non-steroidal anti-inflammatory, or lip Excluded:ND	Soy diet Diet composition: 11% E protein, 28% E fat, carb 46%		Apo B/100 SBP DBP GFR Urinary Protein	excluded from the report as no control for soy arm.
Goldberg 1982	Age (yr):44 Male%:58 Country: US Sites:1 BMI:103% IBW Soy1 N:12 Control N:12	Design:Xover Randomized: Yes CohortMult Blinding: single Duration:6 wks	Patients with primary hypercholesterolemia. Total Cholesterol and LDL > 95 %ile after being on NIH-type IIA diet for 6 wks. Excluded:Hypertriglyceridemia, secondary cause for hyperlipidemia such as DM, thyroid disease, liver or renal dysfunction. Abnormal hematological or urine parameters. Pregancy. Estrogen containing medication.	Soy_Diet 75% of protein Kcal (15% of total Kcal) was derived from soy protein.25% from a variety of vegetable SoyMilk Unclear1 Diet composition: Calculated to keep subjects' weights stable. E 2458 Kcal; Protein 19.8%; carb 32.0%; Fat 43	75% of protein Kcal (15% of total Kcal) was derived from animal Diet composition:s and 25% from a variety of ve OP fat1 Animal pro Protein20.4% of Kcal Product Diet composition:Calculated to keep subjects' weights stable. 20% protein, 40% fat, 40% carb. 2460 Kcal; Protein 20.4%; carb 32.2%; Fat 43.2%; Sat fat 29.3 g; PUFA 49.2 g; PUFA:SFA 1.71; Cholesterol 215 mg; Alcohol 4.1% Kcal	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 Apo E VLDL, LDL:HDLtio, Apo A-II, LDL/Apo B ratio.	AE:no No dropouts Comments:subjects with type II a hypercholesterolemia
Habito 2000	Age (yr):45.7 (SD 7.6) Male%:100 Country: Australia Sites:1 BMI:26.2 Soy1 N:42 Control N:42	Design:Xover Randomized: Yes Blinding:No Duration:4 wks	Healthy males, 35-62 y Excluded:Symptoms or previous diagnosis of prostate disease or other illness, alcohol intake >10% of total daily energy, long-term meds affecting sex hormone concentrations, training athletes, obesity withBMI >35 kg/m2	soy diet tofu diet contained 290 g tofu/d (raw wt), containing about 3 g soybean protein, Diet composition: E 9.5 MJ, Protein 16.9%E, Fat 31.9%E, SF 12.4%E, MF 11.5%E, PF 5.1%E	Lean meat diet Total Protein: ND Total Product: 150g Diet composition: E 9.6 MJ, Protein 17.2%E, Fat 32.4%E, SF 12.9%E, MF 11.8%E, PF 4.8%E	Sex Hormone Binding Globulin Estradiol Testosterone Dihydrotestosterone Androstenediol Free androgen index Estradiol Testosterone:estradiol	AE:no Drop out: 3 didn't complete prescribed diets Comments: Randomized to two 4 week diets with 2 week wash-out consisting of individual's usual diet
Ham 1993	Age (yr):61 (SD 6.7)	Design:Xover Randomized: Yes	hypercholesterolemic men admitted to VA, 2 or more risk factors for CHD. Willingness to reside and	1. soy flour partially defatted extruded soy flour 6.5% fat Diet composition: E ND,	2. nonfat dry milk Diet composition: E ND, protein 20%E, carb 55%E, Fat 25%E	T3 T4 TSH Total Cholesterol	AE:yes AE Report:"baked products were well

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Male%:100 Country: US Sites:1 BMI:28 Soy1 N:17 Soy2 N:17 Control 1 N:17 Control 2 N:17N:	Blinding:other Duration:4 wks	consume all meals at VA. Excluded:Those taking meds that altered lipid metabolism, those who suffered from secondary hypertriglyceridemia, renal or hepatic disease.	protein 20%E, carb 55%E, Fat 25%E 2. soy protein isolate 50 g daily Supro 610 ISP without isoflavone Diet composition: E ND, protein 20%E, carb 55%E, Fat 25%E 3. ISP with cellulose 20 g dietary fiber (cellulose) Diet composition: E ND, protein 20%E, carb 55%E, Fat 25%E		LDL HDL Triglyceride	tolerated..with the exception of fruit bars." Drop out:No dropouts Comment:None
Han 2002	Age (yr):48 (SD 1.1) Male%:0 Country: Brazil Sites:1 BMI:25.6 Soy1 N:40 Control N:40	Design:RCT Randomized: Yes Blinding: double Duration:4 mo	women in menopause at least 12 mo, not on any type of hormonal tx during previous 12 mo, not using lipid lowering drugs, antidiabetic meds, soybean derived products, or herbal supplements. Intact utreus, FSH > 25 U/L, estradiol < 20 pg/ml, hot flashes. Excluded:h/o of uncontrolled HTN, stroke or TIA, dx of cancer within 5 y, MI	1. isoflavones (insignificant amount of soy protein) 100 mg soy isoflavone capsules TID ISP with Isoflavone Diet composition:ND	2. insignificant amount of soy without any kind of isoflavones (and glucose) TID ISP without isoflavone Diet composition: ND No control Protein Product Diet composition: NA	Total Cholesterol LDL HDL VLDL Triglyceride SBP DBP Glucose Endometrial thickness LH FSH Estradiol FBS Menopausal Kupperman index (hot flash score)	AE:yes AE Report:1 nausea (tx arm not specified) Drop out:1 for poor response, 1 for nausea Comment: The control is Placebo due to an insignificant amount of soy in the capsules (50 mg).
Hargreaves 2005	Age (yr):32 (SD 8) Male%:0 Country: UK Sites:1 BMI:ND Soy1 N:28	Design:RCT Randomized: Yes Blinding: None Duration:14 days	Patients attending symptomatic breast clinics at University hospital and due to undergo breast biopsy or definitive surgery for breast cancer Excluded: Menopausal, on chemotherapy, steroid or OCD therapy, non compliant for soy treatment	60g soy in the form of ground textured vegetable protein ISP with isoflavone 45mg Diet composition:ND	Normal unsupplemented diet	NA ApoD/pS2 TLI Ki67 ER labeling index PR labeling index Apoptotic index Mitotic index Bcl-2 MOD	AE:none Drop out: 6 from the soy group and 4 from the control group Comment: The control data also included 33 patients with tissue from local institute

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Control N:23 Control N2:33						
Hermansen 2001	Age (yr):63.6 (SD 7.5) Male%:70% Country: Norway Sites:1 BMI:30 Soy1 N:20 Control N:20	Design:Xover Randomized: Yes Blinding: double Duration:6 wks	Healthy Type 2 diabetics with normal liver and renal function Excluded:Insulin, hypolipidemic agents, BBs, aspirin	soy ISP 50 g/d + 20 g soy cotyledon fiber (Supro) ISP with Isoflavone Diet composition:total energy 2040 kcal/d, carb 47E, fat 30% enregy, protein 19%, alcohol 4%, fiber 26%, cholesterol 290 mg/d	50 g casein + 20 g cellulose Total Protein: ND Total Product: ND Diet composition: total energy 2021 kcal/d, carb 48E, fat 30% enregy, protein 19%, alcohol 4%, fiber 27%, cholesterol 327 mg/d	Total Cholesterol LDL HDL Triglyceride Lpa Apo B/100 SBP DBP Homocysteine Factor VII Fibrinogen von Willebrand Factor, Factor VIII:Ag PAI-1 HgbA1c FBS	AE:yes AE Report:control: 1 headache and vertigo, 1 did not tolerate phlebotomia; soy: 1 diarrhea, 1 previously undetected brain metastases, 1 liver metastases Drop out: 5/25 did not complete the study Comment:none
Hill 2004	Age (yr):21.8 (SD 2.0) Male%:100 Country: US Sites:1 BMI:25.3 Soy1 N:9 Control N:9	Design:RCT Randomized: Yes Blinding: double Duration:4 wks	"recreationally trained young adult men";active life style incorporating resistance training for 6 mo Excluded:smoking, soy consumption > 1/wk, competitive lifters and athletes	ISP Supro ISP with Isoflavone Diet composition:soy protein daily service contained 88 mg naturally occurring isoflavones(glycosides weight)/53 mg genistein, OR 151 mg total isoflavones (conjugated weight)/90 mg genistien	antioxidant poor whey protein Protein39 g Product:ND Diet composition:ND	Oxidized LDL IL-8	AE:no Drop out:no Comment: Data derived from Figure 1 and illegible Figure 1
Hsu 2001	Age (yr):51.4 (SD 4.3) Male%:0 Country: Taiwan Sites:1	Design:NRNCT Randomized: No CohortSing Blinding:No	healthy postmenopausal women Excluded:no meds for 6 mo before study	isoflavone isoflavone supplements Soy Isoflavones without protein Diet composition:	No control	Total Cholesterol LDL HDL HDL/LDL Triglyceride Bone mineral density Estradiol	AE:no Drop out:no Comment:None

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI:ND Weight:53.0 Soy1 N:37 Control N:0	Duration:6 mo					
Huff 1984	Age (yr):49 (SD 5) Male%:100 Country: Canada Sites:1 BMI:82 Soy1 N:5 Control N:5	Design:Xover Randomized: Yes Blinding: double Duration:6 wks	5 male outpatients withfasting cholesterol exceeding normal, LDL >190 mg/dl, fasting Triglyceride <200 Excluded: ND	soybean diet whole soybean protein diet, all-plant protein in which meat and dairy protein was replaced by soybea Soy bean Diet composition:protein 81 g/d, carb 291g/d, fat 99 g/d, cholesterol 173 mg/day	high polyunsaturated fat, low cholesterol diet containing mixed protein from meat, dairy, plant sour Other control: various Protein41 g Product Diet composition:protein 82 g/d, carb 287g/d, fat 95 g/d, cholesterol 133 mg/day	VLDL IDL LDL HDL Total Cholesterol Triglyceride FBS	AE: AE Report: Drop out:0 Comment: Too selective a group of 5 individuals
Jayagopal 2002	Age (yr):62.5 (SD 6.77) Male%:0 Country: UK Sites:1 BMI:32.2 Soy1 N:33 Control N:33	Design:Xover Randomized: Yes Blinding: double Duration:12 wks	Postmenopausal women with type 2 DM Excluded:Any secondary cause of hyperglycemia, current or previous (in the preceding 6 mo) use of estrogen therapy, treatment with insulin or oral hypoglycemic agents, untreated hypothyroidism, h/o of drug or alcohol abuse, and h/o of breast or uterine cancer	Soy isolated soy protein with isoflavones (Essential Nutrition, Brough, U.K.). The product was completel ISP with Isoflavone Diet composition: ND	Placebo Protein:ND Product:ND Diet composition:No significant calorific content	Total Cholesterol LDL HDL Triglyceride SBP DBP HgbA1c FBS Insulin sensitivity measure Sr creatinine T3 T4 TSH Sex Hormone Binding Globulin LH FSH Testosterone Androstenedione DHEA/DHEAS catradiol	AE Report:Side effects were similar during both treatment phases and were predominantly gastrointestinal. Hearburn developed in 3 subject during the study 2 in the soy phase and 1 while on placebo. 6 subjects complained of feeling bloated on both soy and placebo. Drop out:1 subject was withdrawn after MI, 1 for statin Rx, 3 for BP analysis Comment: 1 for statin Rx from lipid analysis, 3 for BP analysis

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
Jenkins 1999	Age (yr):56.5 (SD 9.0) Male%:61 Country: Canada Sites:1 BMI:24.6 Soy1 N:31 Control N:31	Design: Xover Randomized: Yes Blinding:other Duration: 4.2 wks	19 hyperlipidemic men, 12 postmenopausal women--all with LDL >4.1 mmol/L, Triglyceride <4.0. Excluded: withclinical or biochem evidence of DM or liver or renal disease, on hypolipidemic agents	Soy-containing diet 93% animal protein replaced with vegetable protein from soy Diet composition:energy 2341 kcal/d;total protein 118 g/d 20.2%; 110 g/d vegetable protein 18.8%; carb 318 g/d 54.3%;total fat 66 25.5%;SFA 16 g/d 6%;MUFA 22 g/d 8.4%; PUFA 25 g/d 9.6%; dietary chol 77 mg/d 33%, alcohol 0	lacto-ovo vegetarian diet Total Protein: ND Total Product: ND Diet composition: Energy 2519 kcal/d; total protein 121 g/d 19.2%;27 g 4.3%;carb 343 54/6%;total fat 71 25.5%; SFA 18 g/d 6.5%, MUFA 24 8.4%, PUFA 24 g/d 8.7% cholesterol 76 30.2% alcohol 0	Total Cholesterol LDL HDL Triglyceride Lpa Apo A1 Apo B/100 SBP DBP Oxidized LDL Thiobarbituric reactive substances Total:HDL cholesterol LDL:HDL cholesterol Apo B:A-1	Report:"compliance was good" Drop out:no Comment: Same paper as Jenkins 2000 Ref ID #666 Isoflavones: no data
Jenkins 2000 10647066	Age (yr):56 (SD 2) Male%:75 Country: Canada Sites:1 BMI:24.2 Soy1 N:20 Control N:20	Design:Xover Randomized: Yes Blinding:No Duration:8 wks	Hyperlipidemia (LDL > 4.1 mmol/L, Triglyceride < 4.0 mmol/L), Inclusion in prior study. Excluded:Clinical or biochemical evidence of DM or liver or kidney disease.	Vegetable protein foods derived from soy, legumes, cereal foods, Diet composition:1795 Kcal; Protein 83 g/day, 18.5%; carb 254 g/d, 57.3%; Fiber, total 38 g/d; Fiber, soluble 11 g/d (sig higher); Fat 49 g/d, 23.6%; SFA 11 g/d, 5.5%; MUFA 18 g/d, 8.7%; PUFA 16 g/d, 7.7%; Cholesterol 74 mg/d (NS); EtOH 2 g/d, 0.7%	Low-fat, low-cholesterol milk and egg products, soups, and low-fat, low soluble fiber dishes (Lean Cuisine and Weight Watchers). Total Protein: 89 Total Product: ND Diet composition: 1 g/day of soy protein 1901Kcal; Protein 89 g/day, 18.7%; carb 270 g/d, 57.2%; Fiber, total 30 g/d; Fiber, soluble 7 g/d (sig lower); Fat 49 g/d, 23.1%; SFA 14 g/d, 6.9%; MUFA 17 g/d, 8.1%; PUFA 13 g/d, 6.0%; Cholesterol 104 mg/d (NS); EtOH 2 g/d, 0.7%	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 Oxidized LDL Total:HDL LDL:HDL Apo B:Apo A-1	AE:no No dropouts Comments: Unclear what exact sources of protein Same subjects, different study, as Jenkins 10381159 (RefID 747) and 10778882 (666)
Jenkins 2000 10778882	Age (yr):56.5 (SD 9.0) Male%:61 Country: Canada Sites:1	Design: Xover Randomized: Yes Blinding:other Duration: 4.2 wks	19 hyperlipidemic men, 12 postmenopausal women--all with LDL >4.1 mmol/L, Triglyceride <4.0. Excluded: withclinical or biochem evidence of DM or liver or renal disease, on hypolipidemic agents	Soy-containing diet 93% animal protein replaced with vegetable protein from soy Diet composition:energy 2341 kcal/d;total protein 118 g/d 20.2%; 110 g/d vegetable protein 18.8%;	lacto-ovo vegetarian diet Total Protein: ND Total Product: ND Diet composition: Energy 2519 kcal/d; total protein 121 g/d 19.2%;27 g 4.3%;carb 343 54/6%;total fat 71 25.5%; SFA 18 g/d 6.5%, MUFA 24 8.4%, PUFA 24	Oxidized LDL	Report:"compliance was good" Drop out:no Comment: Same paper as Jenkins 2000 10381159

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI:24.6 Soy1 N:31 Control N:31			carb 318 g/d 54.3%;total fat 66 25.5%;SFA 16 g/d 6%;MUFA 22 g/d 8.4%; PUFA 25 g/d 9.6%; dietary chol 77 mg/d 33%, alcohol 0 Isoflavones: no data:	g/d 8.7% cholesterol 76 30.2% alcohol 0		
Jenkins 2002 12077742	Age (yr):62 (SD 2) Male%:56 Country: Canada Sites:1 BMI:25.3 Soy1 N:55 Soy2 N:55 Control N:55	Design:Xover Randomized: Yes Blinding:No Duration:1 mo	Healthy hyperlipidemic men, postmenopausal women Excluded:ND	1.High isoflavone group 2. Low isoflavone group Self-selected National Cholesterol Education Program step 2 diets Soy diet:Tofu, low fat soyMilk, soy hot dogs,breakfast links, soy burgers, cold cuts and tofu nuggets Diet composition: 2000kcal diet; 92%E protein, 59%E carb, 18%E fat, SFA 4%E, MUFA 13-15%E, PUFA 6.4-6.9%E	Low fat dairy food replaced protein in NCEP step 2 diet Protein:88g Product:ND Diet composition: 2000kcal diet; 88%E protein, 60%E carb, 16%E fat, SFA 7%E, MUFA 12%E, PUFA 5.9%E	C-reactive protein IL 6 serum amyloid Tumor necrosis factor-α	AE:no Drop out:18 WD before diet phase, 14 WD after 1-2 phases, 1 WD - didn't like dairy foods, soy arm: 1 dislike, 1 tired of eating soy, 1 bladder irritation, 1 constipation Comments: Demographic data for 41 who completed study. Same study as Jenkins 2002; 12145008
Jenkins 2002 12145008	Age (yr):62 (SD 2) Male%:56 Country: Canada Sites:1 BMI:25.3 Soy1 N:55 Soy2 N:55 Control N:55	Design:Xover Randomized: Yes Blinding:No Duration:1 month	Hyperlipidemic men, postmenopausal women Excluded:ND	1.High isoflavone group 2. Low isoflavone group Self-selected National Cholesterol Education Program step 2 diets Soy diet:Tofu, low fat soyMilk, soy hot dogs,breakfast links, soy burgers, cold cuts and tofu nuggets Diet composition: 2000kcal diet; 92%E protein, 59%E carb, 18%E fat, SFA 4%E, MUFA 13-15%E, PUFA 6.4-6.9%E	Low fat dairy food replaced protein in NCEP step 2 diet Protein:88g Product:ND Diet composition: 2000kcal diet; 88%E protein, 60%E carb, 16%E fat, SFA 7%E, MUFA 12%E, PUFA 5.9%E	Total Cholesterol LDL HDL Triglyceride Lpa Apo A1 Apo B/100 SBP DBP Homocysteine IL 6 Total:HDL cholesterol LDL:HDL cholesterol Apo B:A-1 Oxidized LDL Coronary artery disease risk 10yr	AE:no Drop out:18 WD before diet phase, 14 WD after 1-2 phases, 1 WD - didn't like dairy foods, soy arm: 1 dislike, 1 tired of eating soy, 1 bladder irritation, 1 constipation Comments: Demographic data for 41 who completed study. Same study as Jenkins 2002; 12077742

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
Jenkins 2003 EMB20030 48927	Age (yr):57 (SD 2) Male%:100 Country: Canada Sites:1 BMI:25.3 Soy1 N:46 Control N:46	Design:Xover Randomized: Yes Blinding:ND Duration:3-12 wks	Men participated in 1 or more of 4 studies designed to assess the effect of soy protein on blood lipids. They were selected either by news paper ads or from patients already attending the Clin Nutr and RF Modific Clinics (increased LDL>4.1 mmol/L). None had clinical or biochemical evidence of DM, liver or renal disease Excluded:ND	1. ISP w/isoflavone (116mg) 2. ISP w/isoflavone (166mg) 3. ISP w/isoflavone (82 mg) Diet composition: E 2208, protein 111g/d, carb 300g/d,total fat 57g/d, cholesterol 113mg/d	Study 1: low fat diary foods, egg substitutes, additional soluble fiber; Study 2:starch based cereal low fat diet Protein106 Product:ND Diet composition: E 2276, protein 106g/d, carb 315g/d,total fat 58g/d, cholesterol 108mg/d	PSA	AE:no Drop out:ND
Jones 2003	Age (yr):16.7 (SD 0.78) Male%:100 Country: Australia Sites:1 BMI:73.4 Soy1 N:69 Control N:59	Design:RCT Randomized: Yes Blinding: double Duration:6 wks	Male students aged 16-18 years old Excluded:ND	Isoflavones Novasoy Diet composition:ND	Placebo tablet Protein:ND Product:ND Diet composition:ND	Serum bone specific alkaline phosphatase Urine pyridinoline Pyridinoline creatinine ratio	AE:no Drop out:4 subjects withdraw; Outside age limits Comment: Adloscent boys
Kanazawa 1995	Age (yr):54.2 (SD 13) Male%:53 Country: Japan Sites:1 BMI:ND Soy1 N:15 Control1N:10	Design:NRCT Randomized: No CohortMult Blinding:No Duration:6 mo	outpatients who did not use hypolipemic agents--healthy patients and those with CVD identified by clinical sumptoms, carotid angiography, CT. Excluded:as above	soycreme extract of soybeans containing 62% water, 10.6% protein, 8.2% lipid, 16.8% carb Diet composition:ND	no soycreme ProteinND Product0 Diet composition:ND	Oxidized LDL	AE:no Drop out:no Comment: Results are given after 6 h, 24 h, 48 h, 72 h.

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Control2 N:11						
Katsuyama 2004	Age (yr):30.4 (SD 9.8) Male%:0 Country: Japan Sites:1 BMI:22.1 Soy1 N:21 Soy2 N:16 Soy3 N:18 Control N:18	Design:RCT Randomized: Yes Blinding:No Duration:12 mo	Healthy female hospital workers. Excluded:Dropping out, menopause, pregnancy, CVD, oopherectomy, anticoagulant use, protocol neglect.	Natto: soybeans fermented by Bacillus natto, a traditional Japanese food. 30 g natto at lunchtime I 1. One/mo Diet composition:E 1787 kcal/d, protein 63.2g/d 2. Served 1/week at lunch Diet composition:E 1740 kcal/d, protein 59.3g/d 3. 3/wk Diet composition:E 1799 kcal/d, protein 69.4g/d	Regular diet. No natto intake Protein Product Diet composition: Diet composition:E 1736 kcal/d, protein 62.7g/d	Serum bone specific alkaline phosphatase Serum Osteocalcin Type 1 Collagen cross-linked N-teleopeptide Urinary calcium Stiffness	AE:no Drop out:no Comment: Poor description of methods
Khalil 2002	Age (yr):58.8 (SD 2.5) Male%:100 Country: US Sites:1 BMI:ND Soy1 N:32 Control N:32	Design:RCT Randomized: Yes CohortMult Blinding: double Duration:3 mo	Men with no known h/o of osteoporosis, cancer, insulin-dependent DM, liver and kidney diseases, thyroid and parathyroid disorders, chronic GI disorders or allergy to milk or soy protein Excluded:Current use of any prescription medications known to alter bone and calcium metabolism	Soy protein isolate ISP with Isoflavone Diet composition:ND	Milk-based protein (MP) Protein40 Product58 Diet composition:ND	IGF-1 Serum bone specific alkaline phosphatase U-pyr	AE:no Drop out:Milk-based protein group: 2 GI disturbances, 4 lack of palatabilaty; 4 lack of adherence. SPI group: 2 lack of palatabilaty; 4 lack of adherence.
Knight 2001	Age (yr):52.3 (SD 3.7) Male%: 0 Country: Australia Sites:2 BMI:69.9	Design:RCT Randomized: Yes Blinding: double Duration:12 wks	Postmenopausal, symptomatic with > 3 flushes @ day Excluded:HRT < 6 wks, h/o active bowel, liver, gall-bladder disease; tx for DM, malignancy, vegetarians, regular soy-product users	Soy Isoflavones without protein The isoflavone powder, TakeCare, was packaged in sachets to be used daily. Diet composition:	The placebo was an isocaloric casein-based beverage used daily ProteinND Product 60g Diet composition:ND	Green menopause score: Menopausal symptom Flushing Vaginal maturation index Sex Hormone Binding Globulin FSH	AE:yes AE Report:Adversion to taste (6), bloating (4), nausea (3), wt gain (2), change in bowel function (2) Drop out: Dislike soy taste (3), LTF (1) Comment: Possible with

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy1 N:12 Control N:12					TBG Alkaline phosphatase Pyridinium cross links Gamma linoleic acid	industry funding
Kotsopoulos 2000	Age (yr):59 (SD 1) Male%:0 Country: Australia Sites: BMI:25 Soy1 N:44 Control N:50	Design:RCT Randomized: Yes Blinding: double Duration:3 mo	Postmenopausal, 50-75 yr Excluded:Smoker, vegetarian, HRT past 12 mo, ingesting phytoestrogens or soy-based products, antibiotics past 3 mo	soy Soy dietary supplement supplied in powder form in sachets, ingested twice daily ISP with Isoflavone Diet composition:ND	Identically presented placebo (casein) supplied in powder form in sachets ProteinND Producttwice daily Diet composition:ND	Menopausal symptom flushes vaginal dryness Various psychological outcomes hair, skin outcomes Musculoskeletal outcomes - joint, muscle pain, backache; genitourinary outcomes - libido, dyspareunia	AE:yes AE Report:Dislike taste (13), constipation (2), allergies (1), wt gain (1), menopausal symptoms (1), unrelated (1) Drop out:Dislike taste (13), constipation (2), allergies (1), wt gain (1), menopausal symptoms (1), unrelated (1) Comment: Limited data on quantity of protein, breakdown on isoflavones
Kreijkamp Kaspers 2004	Age (yr):66.5 4.7 Male%:0 Country: Netherland Sites:1 BMI:26.4 Soy1 N:100 Control N:102	Design:RCT Randomized: Yes Blinding: double Duration:12 mo	Women aged 60 to 75 years identified via the database of a breast cancer screening program Excluded:Active liver disease, impaired renal function, h/o of breast cancer or other malignancy, h/o of thromboembolism or deep venous thrombosis, endometrial thickness of more than 4 mm, estrogen users within past 6 mo, and known allergy or hypersensitivity to cow or soy milk	SP isoflavone-ruch Soy protein ISP with Isoflavone Diet composition: E 1887kcal, 82.5g protein, 69.5 g fat, 28.8 g sat fat, 25.1 g MUFA, 15.5 g PUFA, 213g carb	Milk protein powder Protein25.6 Product36.5 Diet composition: E 1862kcal, 81.3g protein, 71.91 g fat, 31.8 g sat fat, 26.2 g MUFA, 13.5 g PUFA, 206 g carb	Total Cholesterol LDL HDL Triglyceride Lpa Bone mineral density Serum bone specific alkaline phosphatase Plasma cal Cognitive: Short and long-term verbal and visual memory, tests	AE:yes AE Report:GI complaints (eg, obstipation and gastric complaints), musculoskeletal complaints, lower and upper airway complaints (including ear, nose, and throat), urogenital complaints (eg, urinary tract infectionsor vaginal infections), skin complaints Drop out:24% participants withdrew from the study; no difference in dropout rate between the 2 groups (24 placebo, 25

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
							soy) Comment: None
Kreijkamp Kaspers 2005	Age (yr):66.5 4.7 Male%:0 Country: Netherland Sites:1 BMI:26.4 Soy1 N:100 Control N:102	Design:RCT Randomized: Yes Blinding: double Duration:12 mo	Women aged 60 to 75 years identified via the database of a breast cancer screening program Excluded:Active liver disease, impaired renal function, h/o of breast cancer or other malignancy, h/o of thromboembolism or deep venous thrombosis, endometrial thickness of more than 4 mm, estrogen users within past 6 mo, and known allergy or hypersensensitivity to cow or soy milk	SP isoflavone-ruch Soy protein ISP with Isoflavone Diet composition: E 1887kcal, 82.5g protein, 69.5 g fat, 28.8 g sat fat, 25.1 g MUFA, 15.5 g PUFA, 213g carb	Milk protein powder Protein25.6 Product36.5 Diet composition: E 1862kcal, 81.3g protein, 71.91 g fat, 31.8 g sat fat, 26.2 g MUFA, 13.5 g PUFA, 206 g carb	SBP DBP Endothelial function	AE:yes AE Report:GI complaints (eg, obstipation and gastric complaints), musculoskeletal complaints, lower and upper airway complaints (including ear, nose, and throat), urogenital complaints (eg, urinary tract infectionsor vaginal infections), skin complaints Drop out:24% participants withdrew from the study; no difference in dropout rate between the 2 groups (24 placebo, 25 soy) Comment: None
KritzSilverstein 2003	Age (yr):61 (SD 5) Male%:0 US:1 Country: Sites:1 BMI:ND Soy1 N:28 Control N:28	Design:RCT Randomized: Yes Blinding: double Duration:6 mo	Women who were in good health, postmenopausal for at least 2 years, and were not using ERT Excluded:ND	Soy isoflavones Soy-extracted isoflavone (Healthy Woman: Soy Menopause Supplement, Personal Products Company, McNeil Soy Isoflavones without protein Diet composition:ND	Placebo pills identical-appearing pills that contained inert ingredients (<1mg isoflavones per day) ProteinND Product2 pills Diet composition:ND	Cognitve function	AE:ND Drop out: 2 placebo and 1 in soy Comment: SOPHIA study 11 and 12 women in placebo and soy group respectively were past estrogen users
Kumar	Age (yr):41.3	Design:RCT Randomized:	healthy, pre-menopausal, omnivorous (including	Soy protein supplement Soy protein supplement	isocaloric placebo supplement of identical appearance w/ Tx using	Menstrual cycle length	AE:yes AE Report:bloating,

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
2002	(SD 1.03) Male%:0 Country: US Sites:1 BMI:24.2 Total:97 Soy1 N:33 Control N:33 (Soy and control completers)	Yes Blinding: double Duration:12 wks	nonvegan vegeterians) of all races and ethnicities, between the ages 25-55 y at first screening, admitted consecutively Excluded:H/o of any type of cancer, prgnancy or breast feeding within 12 mo preceding the study; current use of hormones including birth control pills or HRT; perimenopausal status; irregular menstrual cycles; body mass index>38; antibiotic use within a 3 mo period and vegans	containing 40 mg of genistein (20 mg per dose) Diet composition:E 1967kcal, protein 110gm, fat 63.8 gm, carb 228.9gm, chol 221mg	milk protein ProteinND ProductND Diet composition:E 1810kcal, protein 97.2gm, fat 56.1 gm, carb 220gm, chol 188mg	follicular Sex Hormone Binding Globulin Estradiol Estrone anthropometric measurements (height, weight, skin fold, circumference)	nausea, feeling sick, constipation Drop out:31; unable to comply; intolerance to product; constipation; taste intolerance; pregnancy or birth control pill after starting the study; weight gain; no reason Comments: randomization and allocation concealment; how much soy protein was in tb unclear
Kurowska 1997	Age (yr):55 (SD 11) Male%:50 Country: UK Sites:3 BMI:80 Soy1 N:34 Soy2 N:34 Control N:34	Design:Xover Randomized: Yes Blinding:other Duration:3 X 4 wks	healthy volunteers with hypercholesterolemia= total cholesterol 5.8-5.9 mmol/L, LDL 3.5-5.4 mmol/L. Initial Triglyceride 0.8-3.7 mmol/L, habitual milk drinkers (>2 glasses/d) Excluded:thyroid disroders, kidney diseases, DM, alcohol intake >2 drinks/d, cholesterol lowering meds	1. soybean diet 3 cups soybean milk/d, 1/2 cup soybean dessert/d Soy diet 16 g soybe Diet composition:1996 kcal energy; protein 19% total energy, 96 g protein, carb 51% total energy, fat 29% total energy, 17.8 g SFA, 16.7 g PUFA, 22.4 g MUFA	3 cups 2% cows' milk/d (each containing 3.6% protein) + 1/2 cup low-fat milk dessert/d (containing nonfat milk Protein31 g Product Diet composition:2014 kcal energy; protein 19% total energy, 98 g protein, carb 51% total energy, fat 29% total energy, 24.7 g SFA ($p<0.0001$) , 9.2 g PUFA, 23.6 g MUFA	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 SBP DBP Oxidized LDL	AE:no AE Report: Drop out:no Comment: Soy arm 2-. milk/soy oil; so arm1 and control compared for the report
Laskowski 2003	Age (yr):16.24 Male%:ND Country: Poland Sites:1 BMI:64.9 Soy1 N:6	Design:NRCT Randomized: Unclear Blinding:No Duration:4 wks	Young healthy judo athletes who won medals in National Championships. Excluded: ND	soy protein supplement 0.5 g/Kg/day of soy protein supplement Diet composition: E 4000 kcal/day, protein 100g/d, fat 170g/d, carb 510g/d	no soy protein supplement Protein:0 Product:same amount as soy supplement as liquid orange juice Diet composition: same as soy arm	Max Oxygen uptake $VO_{2\ max}$ Total Work Peak Power and Total Work Output measured by the Wingate test.	AE:ND Drop out:ND Comment: only graphical depiction of results.Graph values do not match the text reports.Unclear study design

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Control N:6						
Lenn 2002	Age (yr):23.4 Male%:59 Country: US Sites:1 BMI:23.9 Soy1 N:7 Soy2 N:8 Control N:7	Design:RCT Randomized: Yes Blinding:ND Duration:5 wks	men and women from University of Kentucky Excluded:h/o of significant pain/fx in arms or shoulders within past 3 years; strength training within 60 days before study; applicances in arms or shoulders; pacemaker; pregnancy; acute trauma or inflammation; bleeding disorders;infection, severe ischemia, poor	ISP with Isoflavone isoflavone+Western fat blend 120 mg of soy isolate(1.3:1 genistein:daidzein)/day and Western fat blend (fish oil control) Diet composition:ND	received comparable amounts of Western fat blend and/or wheat flour Protein:ND Product:ND Diet composition:ND	Relaxed arm angle; Arm circumference; Strength parameters; muscle soreness Delayed Onset Muscle Soreness (DOMS) Sr total iron CK Cortisol IL-6 TNF-α	AE:ND Drop out:3men and 3 women did not complete Comment: incomplete data; values estimated from graph
Lichtenstein 2002	Age (yr):62.7 (SD 8.8) Male%:43% Country: US Sites:1 BMI:26.6 Soy1 N:57 Soy2 N:57 Soy3 N:57 Control N:57	Design:Xover Randomized: Yes Blinding:other Duration:42 days	men and women > 50 y withcholesterol >3.36mmol/L; women were postmenopausal Excluded:meds known to affect blood lipid levels	1. soy diet with isoflavones isolated soy protien , enriched with isoflavones ISP with Isoflavone Diet composition:carb 46E, protein 16%, fat 37%, saturated fat 11.3, MUFA 14.4, PUFA 6.1, cholesterol 150 per 4.2 MJ 2. soy diet without isoflavones protein component was contributed by specially prepeared isolated soy protein, this specific one dep ISP without isoflavone Diet composition:carb 45%, protein 17%, saturated fat 12.7, MUFA 14.7, PUFA 6.1, chol 151 per 4.2 MJ	1. animal diet with isoflavones The variable protein component was contributed by dairy and meat.Isoflavones, in the form of a powde Diet composition:carb 48E, protein 15, fat 36, saturated fat 11.8, MUFA 14.3, PUFA 5.7, chol 168 per 4.2 MJ 2. animal diet without isoflavones This diet was designed to mimic a nonoptimal diet of a hypercholesterolemic subject. The variable pr Diet composition:Bascially this is the control arm. carb 47E, protein 17%, fat 36%, saturated 12%, MUFA 14.2, PUFA 5.6, cholesterol 154 per 4.2 MJ	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 TC:HDL LDL:apoB HDL:apoA-1	AE:no Drop out:1 female , and 8 males dropped:1 change in employment, 3 change in med status, 3 change in family member's med status, 2 disliked study food;subjects that dropped out were replaced Comment: Further subgroup analysis: benefit attributed to soy with respect to total cholesterol was limited to those with LDL >4.14 mmol/L
Lissin 2004	Age (yr):61.7 8.8 Male%:0	Design:RCT Randomized: Yes	post menopausal status as defined by absence of menses prev 12 mo, or if surgically menopausal, age >55; hypercholesterolemic:	phytoestrogens isoflavone tablets Soy Isoflavones without protein 2 tablets/d	placebo Protein ND Product2 tablets/d Diet composition:ND	Total Cholesterol LDL Peripheral endothelial function	AE:no Drop out:no Comment: Baseline data

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Country: US Sites:1 BMI:25.3 Soy1 N:20 Control N:20	Blinding: double Duration:6 wks	total chol >200 mg/dl or 5.2 mmol/l , and LDL >125 mg/dl or 3.2 mmol/l and not receiving lipid lowering meds Excluded:current or recent use of ERT (within 2 mo); h/o of breast cancer, known atherosclerotic disease; current smoking; more than 6 servings of soy/wk	Diet composition:ND			given in percentages, no actual data
Lu 1996	Age (yr): Male%:0 Country: US Sites:1 BMI:ND Soy1 N:6 Control N:0	Design:NRNCT CohortSing Duration:1 mo	healthy nonvegeterian women with regular menstrual cycles Excluded:ND	Soy milk 3 12-oz portions of soy milk (one w/ each meal) daily for 1 mo under the supervision of dietary staf Diet composition:	No control	Menstrual cycle length Progesterone DHEA/DHEAS 17 b estradiol	AE:ND Drop out:yes Comment: sample size too small;baseline diet is not reported;eclusion criteria not explicitly described;% change given (not applicable in the tables)
Lu 2000	Age (yr):32.7 (SD 6.6) Male%: 0 Country: US Sites:1 BMI:71.5 Soy1 N:26 Control N:0	Design:NRNCT Randomized: No Blinding:No Duration: 4.2 wks	Healthy premenopausal Excluded:Smoker, vegetarian, intake > 2 alcohol drinks/week, significant change in wt or eating habits, antibiotics taken preceding 3 mo, irregular menstrual cycles, on contraceptives preceding 6 mo	1. Soya-containing diet for one menstrual cycles on site. 2. SoyMilk Diet composition: E 2341, Fat 35.5%E, carb 50.1%E, protein 14.0%E	No control	Menstrual cycle length LH FSH Estradiol Progesterone Total Cholesterol LDL HDL Triglyceride	AE:no Drop out: 16/26"Main reason for dropouts was frequency of blood drawing" Comment:Lipids not data extracted due to NRNCT
Lu 2001	Age (yr):34.4 (SD 5.1) Male%: 0 Country: US	Design:NRNCT Randomized: No	Healthy premenopausal Excluded:Smoker, vegetarian, intake > 2 alcohol drinks/week, significant change in wt or	1. Soya-containing diet for one menstrual cycles on site. 2. SoyMilk without isoflavones Diet composition: E 2352, Fat 35.9%E, carb 49.8%E,	No control	LH FSH Estradiol Progesterone	AE:ND Drop out: ND Comment:Lipids not data extracted due to NRNCT

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Sites:1 BMI:25.8 Soy1 N:9 Control N:0	Blinding:No Duration: 3 wks	eating habits, antibiotics taken preceding 3 mo, irregular menstrual cycles, on contraceptives preceding 6 mo	protein 14.0%E			
LydekingOlsen 2004	Age (yr):57.8 (SD 8.4) Male%:0 Country: Denmark Sites:1 BMI:24.0 Soy1 N:26 Control N:28	Design:RCT Randomized: Yes Blinding: Duration:2 years	At least 1 year postmenopausal, with a maximum age of 75 years, had not received any bone-active medication for at least 2 years previously and had at least 3 risk-criteria for osteoporosis: early menopause < 45 years of age, low-energy bone-fractures Excluded:drug or alcohol addition, malignant disease, immobility, current steroid treatment, osteomalacia, DM, unstable thyroid disease, severe osteoarthritis in lumbar spine/kip, chronic inflammatory diseases, active liver and kidney disease	1. Soy milk rich in isoflavones Soymilk rich in isoflavones Diet composition:ND 2. Soymilk w/o isoflavones Soymilk produced by alsohol washed soy concentrate with only 1.0 mg isoflavones /day Diet composition:ND	No non soy control	Bone mineral density Bone mineral content serum-type Equol Type-I C-terminal telopeptide Type-I procollagen N-terminal peptide	AE:yes AE Report:29% experienced milk and temporary side effects dur to soymilk, not leading to cessation: mild digestive trouble (nausea, bloating, flatulence 23%), undesired weight gain (fluid retention, 9%), milk throat irritation (4%), milk hot flushes (2%) and tempor Drop out:lost to followup (n=3 in soymilk witho isoflavones group); soy intolerance (n=3 and n=2 in soymilk with and witho isoflavones groups respectively); Aversone (n=1 in soymilk witho isoflavones group) Comment: There are one transdermal progesterone (TDP) group (n=27); combine TDP and soymilk group (n=26)
Mackey 2000 11216493_study1	Age (yr):56.40 (SD 4.92) Male%:0 Country:	Design:RCT Randomized: Yes Blinding: double	postmenopausal women, 45-65.. Fasting cholesterol >5.5 mmol. Excluded:H/o of allergy to soy, or taking any	1. ISP- and NHF diet soy protein isolate with content of 4 mg isoflavones/d ISP without isoflavone Diet composition:ND	No control (compared between soy 1 and soy 2)	TSH Total Cholesterol LDL HDL Triglyceride Serum bone specific	AE:no Drop out: 54 women randomized, 46 completed. 3 discontinued and were not contactable, 5

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Australia Sites:1 BMI:68.88 Soy1 N:22 Soy2 N:24 Control N:0	Duration:12 wks	cholesterol lowering drug.	2. ISP+ and NHF diet soy protein with isoflavone content of 65 mg isoflavones/d ISP with Isoflavone Diet composition:ND		alkaline phosphatase Serum Osteocalcin Urine deoxypyridinoline "menopause Sex Hormone Binding Globulin LH FSH	dropped out Comment:For lipids no data on what n= for baseline and final
Mackey 2000 11216493_study2	Age (yr):51.5 Male%:100 Country: Australia Sites:1 BMI: Soy1 N:27 Control N:0	Design:NRNCT CohortSing Blinding:No Duration:12 wks	Males over 40; fasting total cholesterol >5.5 mmol/L Excluded:H/o of allergy to soy or if taking cholesterol lowering agents	1. ISP+ 28 g ISP with isoflavone content of 65 mg/d ISP with Isoflavone Diet composition:ND 2. ISP- soy protein isolate with content of 4 mg isoflavones/d ISP without isoflavone Diet composition:ND	No control	TSH Total Cholesterol LDL HDL Triglyceride Sex Hormone Binding Globulin LH FSH Testosterone Androstenedione DHEA/DHEAS	AE:no Drop out:no Comment: open prospective observational pilot study
Martini 1999	Age (yr):25.5 Male%:0 Country: US Sites:1 BMI:21.2 Soy1 N:40 Control N:40	Design:Xover Randomized: Yes Blinding: ND Duration: 8.5 wks	Women 18-40 years from the University community, screened initially by phone in response to advertising in university newspapers and fliers Excluded: ND	Soy diet Soy diet composition: Each serving provided 104 kcal, 20 g protein, 6 g carb,	10 fluid oz of skim milk Total Protein: ND Total Product: 10oz Diet composition: ND	Menstrual cycle length Sex Hormone Binding Globulin Estradiol Estrone Progesterone Prolactin DHEA/DHEAS Ratio Progesterone Ratio 2-OH	AE:ND Drop out: 3 OC users reported alterations in their menstrual cycle with the addition of soy (breakthrough bleeding or slightly delayed menses)highly irregular periods; soy allergy Comment: duration= 2 menstrual cycles
Maskarinec 2002	Age (yr):43 Male%:0 Country: US Sites:1	Design:RCT Randomized: Yes Blinding: double	Premenopausal women 35-46 yr, regular dietary consumption of soy foods <7 serving/wk, normal mammogram during the last 6 mo, intact uterus and ovaries, regular menstrual	Soy_isoflavone_mixture as 100 mg tablets Diet composition: E 1795kcal/d, Fat 60.9g/d	Placebo tablet Protein Product:100 mg/d Diet composition: E 1705kcal/d, Fat 63.5g/d	Menstrual cycle length Sex Hormone Binding Globulin LH FSH Estradiol	AE:no Drop out:ND Comment: same as paper w/ REF ID 2111

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI:ND Weight:145lbs Soy1 N:17 Control N:17	Duration:12 mo	periods Excluded: previous h/o cancer, oral contraceptive or any hormonal replacement, pregnancy, serious medical conditions			Estrone Estrone Sulfate Progesterone	
Maskarinec 2003	Age (yr):41.1 (SD 3.1) Male%:0 Country: US Sites:1 BMI:23.6 Soy1 N:15 Control N:15	Design:RCT Randomized: Yes Blinding: double Duration:12 mo	Women who had received a normal screening mammogram Excluded:ND	Soy Isoflavone daily regimen of 100 mg of Soy Isoflavone mixture equivalent to 76 mg glycosidess Diet composition:E 1735kcal/d; fat 66g	placebo Protein Product Diet composition: E 1736kcal/d; fat 61g	Mammographic density	AE:ND Drop out: 2 women decided not to have another mammogram at the end of the study, one follow-up mammogram not located, one woman left the study after 8 mo Comment: randomization, blinding, and allocation concealment not explicitly described
Maskarinec 2004	Age (yr):43.2 (SD 2.7) Male%:0 Country: US Sites:1 BMI:25.9 Soy1 N:109 Control N:111	Design:RCT Randomized: Yes Blinding: double Duration:24 mo	Women who had received a normal screening mammogram Excluded:Women on oral contraceptives or other sex hormones, diagnosed with cancer, no uterus, one ovary, regular menses, ≥6 wk serving of soy	Soy diet Tofu, soy milk, soy nuts, soy protein bar and soy protein powder Diet composition: 641kcal from soy	Regular diet Protein:ND Product:ND Diet composition: ND	E1 E2 Free E2 SHBG Progesterone Adione	AE:ND Drop out: 17 (15.6%) in the soy and 14 (12.6%)in the control Comment: randomization: blocked randomization, blinding, and allocation concealment not explicitly described
McMichael Phillips 1998	Age (yr):33.5 (SD 8.09) Male%:0 Country: UK Sites:1	Design:RCT Randomized: Yes Duration:14 days	women with benign and malignant breast conditions who were attending clinics fo women with symptomatic breast problems at the University Hospital of South Manchester Excluded:menstrual	Soy bread rolls 4 bread rolls daily that contained a total of 60 g soy (in the form of ground textured vegetable pro Textured1 Diet composition:	normal unsupplemented (without soy) diet Protein ND Product ND Diet composition:	number of epithelial cells in the S phase of the cell cycle progesterone receptor expression	AE:no Drop out:no

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI:ND Soy1 N:19 Control N:29		irregularities; medication likely to alter pituary function from baseline; consumption of lucagons or soy-rich diets				
Meinertz 1988	Age (yr):41 (SD 14) Male%:50 Country: Denmark Sites:1 BMI:62 Soy1 N:10 Control N:10	Design:Xover Randomized: Unclear Blinding:No Duration:1 mo	healthy normolipidemic men and women of normal body weight, Excluded: smoking, meds	ISP soy protein formula diet Supro ISP with Isoflavone Diet composition:ISP 140 g, 54 g safflower oil, energy 1430 kcal, protein 287 g/l, fat 45 g/l, carb 184 g/l, chol 8 mg/l	casein formula diet Protein119 = 2263/1500*315/4 Product:ND Diet composition:casein 139 g, energy 1500 kcal, protein 315 g/l, fat 43 g/l, carb 198 g/l, chol 46 mg/l. Mean 2263 Kcal/day	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100	AE:no AE Report: Drop out:no Comment: None
Meinertz 1989	Age (yr):33 Male%:45 Country: Denmark Sites:1 BMI:64.1 Soy1 N:11 Control N:11	Design:Xover Randomized: Unclear Blinding:No Duration:31 days	healthy normolipidemic men and women of normal body weight Excluded:ND	Soy protein diet ISP without isoflavone Soy protein diet (soy-protein isolate) (Purina 660) Supro Diet composition:energy 2477 kcal, 112 g/d protein, fat 75 g/d, carb 338 g/d, chol 486 mg/d	Calcium caseinate Protein121 ProductNd Diet composition:139 g casein, 54 g safflower oil energy 2494 kcal, 121 g/d protein, fat 69 g/d, carb 296 g/d, chol 549 mg/d	Total Cholesterol LDL HDL Triglyceride	AE:no Drop out:no Comment: See Meinertz 1988 RefID #4197 Unclear what was extracted from the soy protein
Meinertz 2002	Age (yr):30 (SD 13) Male%:50 Country: Denmark Sites:1 BMI:22.5	Design:Xover Randomized: Unclear Blinding:No Duration:32 days	normolipidemic subjects, mostly medical students. All had normal liver, kidney, thyroid function—none used meds regularly, none used HRT. Excluded:as above	1 extracted protein soy diet Liquid-formula diet containing ethanol-extracted soy protein. Supro 670IF=8.2 mg lipid, 0.11 mg iso Supro ISP without isoflavone Diet composition: 1 intact protein	liquid-formula casein diet Protein Product Diet composition:energy 2494 kcal, 121 g/d protein, fat 69 g/d, carb 296 g/d, chol 549 mg/d	Total Cholesterol LDL HDL Triglyceride Lpa	AE:no AE Report:"excellent compliance" Drop out:no Comment: Unclear what was extracted;Change in extracted soy protein significantly greater than

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy1 N:12 Soy2 N:12 Control N:12			diet Liquid-formula diet containing soy protein. Supro 670HG=63 mg lipid, 2.39 mg isoflavone (glycosides)/ Supro ISP with Isoflavone Diet composition:			change in soy protein. Data from Meinertz 1989
MerzDemlow 2000	Age (yr):26.3 (SD 4.8) Male%:0 Country: US Sites:1 BMI:64 Soy1 N:20 Soy2 N:20 Control N:20	Design:Xover Randomized: Yes Blinding: double Duration:3 menstrual cycles + 9d	Healthy premenopausal women 18-35 yr, normal menstrual cycles, not taking antibiotics or oral contraceptives within 6 mo, not taking regular meds, relatively sedentary, 90-120% ideal body lucag, BMI 18-25 kg/m2, not vegetarian, consumed diets low in fiber Excluded:h/o of food allergies, smokers, pregnant or lactating	1 SPI as beverage powder ISP with Isoflavone (high) Diet composition: energy 2216 kcal, protein 117.7 g, carb 291.3 g, total fat 67.4, SFA 21.2, PUFA 11, MUFA 15.8, cholesterol 181.8 1 SPI as beverage powder ISP with Isoflavone (low) Diet composition: energy 2275 kcal, protein 114 g, carb 296.9 g, total fat 73.7, SFA 23.7, PUFA 13, MUFA 17.4, cholesterol 238.5	soy protein isolates as beverage powder 10mg isoflavone Total Protein: ND Total Product: ND Diet composition:0.15 with- 0.01 mg isoflavones, or 10 mg isoflavones/d energy 2277 kcal, protein 115 g, carb 294.2 g, total fat 75.8, SFA 23.7, PUFA 12.4, MUFA 20, cholesterol 194.3	Total Cholesterol LDL HDL Triglyceride Lpa	AE:no Drop out: 6/20 lack of compliance difficulties. 1/14 was hypercholesetrolemic and was excluded. Comment: In the article 10mg isoflavone was the control; but report no control arm for soy
Meyer 2004	Age (yr):54.0 (SD 1.8) Male%:57 Country: Australia Sites:1 BMI:75.9 Soy1 N:26 Control N:26	Design:Xover Randomized: Yes Blinding:No Duration:5 wks	Men or post-menopausal women, total plasma cholesterol > 5.5 mmol/l, mildly elevated BP > 140/90 mm Hg Excluded:taking meds for either HTN or lipids, low habitual consumption of soy or n-3 foods	soy 4 serving/day (250 ml per serving) consisting of: So Natural Milk: fat 2.9g/100, carb 7.5 g/100, 3.1 g protein SoyMilk and yoghurt Diet composition: Energy 2100 Kcal, protein 21%E, carb 45%E, fat 29%E, SFA 44%E, MUFA 42%E, PUFA 25%E	4 serving/day (250 ml per serving) of low fat dairy milk or yoghurt into their normal diet nonfat milk ProteinND Product Diet composition: Energy 1900 Kcal, protein 20%E, carb 43%E, fat 33%E, SFA 36%E, MUFA 36%E, PUFA 30%E	Total Cholesterol LDL HDL Triglyceride Lpa SBP DBP Systemic arterial compliance	AE:no AE Report: Drop out: ND Comment: Self-reporting of dairy & soy consumption; significant differences in fat composition between soy and control arm
Mitchell	Age (yr): ND	Design:NRNCT	Healthy, 18 – 35 y males, no significant reproductive	soy_extract subjects received 500 mg	No control	LH FSH	AE:no Drop out: 1 WD midway

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
2001	Male%:100 Country: UK Sites:1 BMI:ND Soy1 N:15 Control N:0	Randomized: No CohortSing Blinding:No Duration:2 mo	medical h/o, normal semen quality, normal serum levels of oestradiol, testosterone, FSH, LH Excluded:Vegetarian, significant reproductive medical h/o	tablets consisting of standardized soy extract containing 40 mg, in total, Soy Isoflavones without protein Diet composition:ND		Estradiol Testosterone	in supplement period, 3 at final post-supplement assessment Comment: limited data; assessments twice before intervention, twice during and 3 times post-intervention
Morabito 2002	Age (yr):52 3 Male%:0 Country: Italy Sites:1 BMI:24 Soy1 N:30 Control N:30	Design:RCT Randomized: Yes Blinding: double Duration:1 years	Healthy, ambulatory women aged 47-57 who had not undergone surgically-induced menopause, had not had a period in the preceding year, and who had a FSH level >50 UI/L and an E2 level of <=100 pmol/L Excluded:Cardiovascular, lucago, or renal disorders, coagulopathy, use of oral or transdermal estrogen, progestin, androgen, or other steroids in the preceding year, smoking habit of more than 2 cigarettes per day, previous treatment with any drug that could affect the skeleton; family h/o estrogen dependent cancer; BMD at femoral neck >0.795 g/cm2	Genistein 54 mg/day. Soy Isoflavones without protein Genistein tablets obtained for Lab. Plants (Messina, Italy). The purity of the genistein Diet composition: Isocaloric fat-restricted diet 30%E from fat, <10% E from sat fat, Cholesterol intake <300mg/d	Placebo tablets Protein Product Diet composition: Isocaloric fat-restricted diet 30%E from fat, <10% E from sat fat, Cholesterol intake <300mg/d	PTH:1 Bone mineral density Serum bone specific alkaline phosphatase Urine deoxypyridinoline Urine pyridinoline Bone Gla p FSH Estradiol	AE:yes AE Report: endometrial thickness >5 mm (3/30 genistein, 3/30 placebo); vaginal bleeding (1/30 genistein, 1/30 placebo); also reported “ Drop out:no Comment: There is also a 3rd arm, HRT; Do not report allocation concealment, do not address drop-outs/withdrawals
Murkies 1995	Age (yr):53.8 (SD 1.07) Male%:0 Country: Australia	Design:RCT Randomized: Yes Blinding: double Duration:12	postmenopausal women (from interested patients and newspaper ads) with at least 12 mo amenorrhea, an FSH >15 mIU/mL, hot flushes>14/wk; non-smokers; not on antibiotics or HRT for the previous 3	Soy flour 45 g/d soy flour: the flour was to be taken preferably raw (eg added to a drink or mixed w/ cereal). Soy diet Soy flour Diet composition:ND	45 g/d wheat flour: the flour was to be taken preferably raw (eg added to a drink or mixed w/ cereal Other control: wheat flou Protein Product45 g Diet composition:ND	Total Cholesterol HDL Triglyceride Urinary calcium urine hydroxyproline Vaginal cell maturation index FSH	AE:ND Drop out: 11 (5 soy and 6 wheat) Comment: no data on baseline diet, co-morbidities or medcation;exclusion

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Sites:1 BMI:26.5 Soy1 N:28 Control N:30	wks	mo Excluded:ND			Equol Menopausal symptom score flushes, score urine enterolactone	criteria not explicitly reported;amount of protein not specified
Murray 2003	Age (yr):56.3 7.4 Male%:0 Country: US Sites:1 BMI:24.6 Soy1 N:8 Soy2 N:8 Control1 N: Control2 N:	Design:RCT Randomized: Yes Blinding: double Duration:6 mo	Healthy postmenopausal women over 45 years old with an FSH level > 40 mIU/mL and an intact uterus Excluded:Use of HRT within 3 mo of initiating study, obesity (BMI > 30), endometrial hyperplasia or cancer, breast cancer, cerebrovascular accident, myocardial infarction, CVD, gallbladder disease, h/o of thrombosis, active liver disease, undiagnosed ge	1.ISP with Isoflavone SPI plus 0.5 mg Estradiol Protein powder plus oral micronized estradiol tablets Diet composition:ND 1 ISP with Isoflavone SPI plus 1.0 mg Estradiol Protein powder plus oral micronized estradiol tablets: 38 g SPI as lucagons packets containing 2 Diet composition:ND	1.placebo plus 0.5mg Estradiol Protein:ND Product38 g Diet composition:ND 2.placebo plus 1.0 mg Estradiol Protein:ND Product38 g Diet composition:ND	Total Cholesterol LDL HDL Triglyceride Type 1 Collagen cross-linked N-teleopeptide Endometrial thickness	AE:yes AE Report:GI intolerance 1 in SPI group, 1 in TMP placebo; 2 cervical stenosis; 1 unrelated surgery in SPI+1mgE group, 1 abnormal uterine bleeding in SPI+1mgE group Drop out:same as AE Comment:This paper in table 5 compares 9 other isoflavone RCTs on the effect on postmenopausal endometrium
Nagata 1998	Age (yr):26.1 7.9 Male%:0 Country: Japan Sites:1 BMI:20.6 Soy1 N:31 Control N:29	Design:RCT Randomized: Yes CohortMult Blinding:No Duration:2 menstrual periods	Female students and teachers who were premenopausal and not lucagon in a nursing school course. Excluded:Endocrine disease (DM or adrenal). Taking hormonal medication	Soy.milk Instructed to consume about 400 mL of soymilk daily. Diet composition:1570 Kcal; Protein 60.0 g; Fat 54.2 g; Cholesterol 231 mg; carb 199 g; Fiber 2.7 g; EtOH 3.6 mL 45.4 g soy products; Isoflavones from soy products 19.4with-15.0 mg	Continue with their usual diet. Other control: Regular di Protein51.4 g Product Diet composition:Results imply that controls were told to not drink any soy milk. 1486 Kcal; Protein 51.4 g; Fat 48.8 g; Cholesterol 221 mg; carb 202 g; Fiber 2.6 g; EtOH 2.7 mL 0 g soymilk. 43.9 g soy products; Isoflavones from soy products 18.4with-13.4 mg	Menstrual cycle length Sex Hormone Binding Globulin Estradiol Estrone	AE:no Drop out: No Comment: Subanalysis of women who had blood drawn on days 9-12 in both cycles 1 and 3. The remaining women are included in the main analysis.
Nagata 2001	Age (yr):32 (SD 8.4)	Design:RCT Randomized: Yes	Teachers and students in a nurse school Excluded:Current use of	soymilk The soymilk-supplemented group was required to consume 400 ml (408 g) of	habitual diet Protein0 g from soymilk ProductND Diet composition:2030 kcal/day: 72.7	Sex Hormone Binding Globulin Estradiol Estrone	AE:ND Drop out:One in the soymilk-group dropped

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
11303585	Male%:100 Country: Japan Sites:1 BMI:23.3 Soy1 N:17 Control N:17	Blinding:No Duration:8 wks	hormonal medication, diagnosis of prostatic disease, DM, chronic liver disease, or any endocrine disease	soymilk daily for 8 weeks. Diet composition: E 2244Kcal, protein 73.6g/d, fat 77.3g/d, carb 287g/d	g/d protein, 63.5 g/day fat; 290 g/day carb	Testosterone	out-sick on the first day Comment: randomized method not clear, no blinding
Nestel 1997	Age (yr):54.0 (SD 6.0) Male%:0 Country: Australia Sites:1 BMI:27.0 Soy1 N:21 Control N:21	Design:Xover Randomized: Yes Blinding:other Duration:5 wks	postmenopausal, perimenopausal women Excluded:age > 69 y and HRT, other supplements such as vitamin E and primrose oil, meds that might affect lipids or CV function, smoking, >14 standard alc drinks/wk	soy isoflavone tablet isoflavone tablet 40g for 5 wks ISP with Isoflavone Diet composition: <30%E fat	Placebo tablet Protein Product Diet composition: <30%E fat	Total Cholesterol LDL HDL Triglyceride MAP Peripheral endothelial function Systemic arterial compliance Oxidized LDL FBS	AE:no Drop out: 2 drop out; reasons ND Comment: Oxidation stress outcomes were carried out only in 1st 15 subjects; Trial began 40 mg/d X 5 wks. When results did not lucago, dosage was raised to 80 mg and the trial was extended 5 more wks.
Nikander 2003 12798527	Age (yr):54 (SD 6) Male%:0 Country: Finland Sites:1 BMI:26.3 Soy1 N:60 Control N: 60	Design:Xover Randomized: Yes Blinding: double Duration:3 mo	postmenopausal women who had been treated for breast CA; no residual malignant disease; incapacitating climacteric complaints; FSH>30 U/L Excluded:use of sex steroids including tamoxifen; use of natural products with possible estrogenic activity; use of drugs possibly affecting climacteric symptoms, or metabolism or absorption of phytoestrogens (eg, abx during the previous 3 mo); h/o of any throm	phyto 6 phytoestrogens tablets (total of 114 mg of phytoestrogens, an extract of soy isoflavones) per day SSP1 Diet composition:ND	similar-looking placebo tablets Protein:0 Product:6 tab/d Diet composition:ND	Menopausal symptom Kupperman index Work ability depression Sr creatinine Sex Hormone Binding Globulin LH FSH Estradiol Equol Other outcomes: Anxiety and Self-confidence aspartate transaminase; alanine transaminase	AE:ND Drop out: 2 stomache ache, 1 recurrent breast CA, 1 personal reason, 1 vaginal bleeding, 1 lack of effect Comment: Same as Nikander 14602747, 15001611, 15240647

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
Nikander 2003 14602747	Age (yr):54 (SD 6) Male%:0 Country: Finland Sites: BMI:26.3 Soy1 N:60 Control N:60	Design:Xover Randomized: Yes Blinding: double Duration:3 mo	Post menopausal women who were treated for breast cancer previously and devoid of metastasis at recruitment. Patients who had chemotherapy had been discontinued 5 mo to 4 yr before recruitment. All women had incapacitating hot flashes and other climacteric symptoms and menopause confirmed by FSH >30U/L Excluded:FSH <30U/L and taken a course of antibiotics within previous 3 mo	phytoestrogen tablet Three phytoestrogen tablets were to be taken every 12 hr with a glass of water (6 tablets/day). Diet composition: ND	Placebo tablets Protein:ND Product: 6 tab/day Diet composition:ND	C-reactive protein E-selectin Nitrous oxide	AE:no Drop out: 6 women discontinued the trial during the first treatment regimen: 4 in the phytoestrogen group (1-stomach ache; 1-personal reason; 1-recurrent breast cancer) and 2 in the placebo group (1-lack of effect and 1-vaginal bleeding) Comments: See Nikander 2003, and 2004; 15001611, 15240647
Nikander 2004	Age (yr):54 (SD 6) Male%:0 Country: Finland Sites:1 BMI:25.8 Soy1 N:60 Control N:60	Design:Xover Randomized: Yes Blinding: double Duration:3 mo	postmenopausal women treated for breast cancer 8 mo to 22 yr before. 1) lack of residual malignant disease 2) incapacitating climacteric complaints such as hot flashes, night sweats, sleeplessness 3) FSH >30 U/L Excluded:1) use of sex steroids such as tamoxifen 2) use of natural products withpossible estrogenic activity 3) use of drugs affectring climacteric symptoms, metabolism, or absorption of phytoesterogens incl antibiotics within 3 mo 4) h/o of thromboembolic or hepatic	Isoflavonoid tablets (Bonette, Novomed, Helsinki) 19 mg of isoflavoids each. 3 tablets every 12 hour Soy Isoflavones without protein Diet composition: ND	Similar looking placebo Protein:0 Product: ND Diet composition: ND	Serum bone specific alkaline phosphatase Urine deoxypyridinoline Urine pyridinoline Type 1 Collagen cross-linked N-teleopeptide PINP; PICP	AE:yes AE Report:4 in PE group= 2 for stomach ache, 1 personal, 1 recurrence of lucag cancer, 2 in placebo group= 1 for lack of effect, 1 for vaginal bleeding Drop out:Same as AE Comment: See Nikander 12798527, 14612747, 15240647
Nikander 2004	Age (yr):54 (SD 6)	Design:Xover Randomized:	Post-menopausal women treated for breast cancer more than 6 mo earlier,	Isoflavonoid tablets (Bonette, Novomed, Helsinki) 19 mg of	Similar looking placebo Protein:0 Product: ND	Total Cholesterol LDL HDL	AE:yes AE Report:2 stopped

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
15240647	Male%:0 Country: Finland Sites:1 BMI:26.3 Soy1 N:62 Control N:62	Yes Blinding: double Duration:3 mo	without metastatis, Incapacitating hot flashes and other climacteric symptoms. At least 6 mo post-menopausal. FSH > 30 U/L. Excluded:HRT, Tamoxifen, statins, natural products with presumed estrogenic activity, drugs possibly affecting lucagons c symptoms, antibiotics and other substances affecting the metabolism or absorption of phytoestrogens. History of thromboembolic or hepatic event	isoflavoids each. 3 tablets every 12 hour Soy Isoflavones without protein Diet composition: ND	Diet composition: ND	Triglyceride Lpa Apo A1 Apo B/100 SBP DBP FBS Oral glucose tolerance test Insulin	during phytoestrogen treatment because of stomach ache. Drop out: 6 (4 isoflavonoid: 2 stomach ache, 1 personal, 1 breast ca recurrence; 2 placebo: 1 “lack of effect”, 1 vaginal bleeding) Comment: See Nikander 12798527, 14612747, 15001611
Nilausen 1999	Age (yr): 37 (SD 16.8) Male%:100 Country: Denmark Sites:1 BMI:22.9 Soy1 N:9 Control N:9	Design:Xover Randomized: Unclear Blinding:No Duration: 4.2 wks	active healthy normolipidemic men Excluded:ND	1 liquid formula soy diet Supro ISP with Isoflavone Diet composition: daily intake 154 g, protein constituted ~20E intake carb ~55E, fat ~25E, chol 55 mg/MJ	casein Total Protein: ND Total Product: ND Diet composition:carb ~55E, fat ~25E, chol 55 mg/MJ	Total Cholesterol LDL HDL Triglyceride Lpa	Adverse event: No Dropouts:0 Comment: None
Onning 1998	Age (yr):31.5 Male%:50 Country: Sweden Sites:1 BMI:20-25	Design:Xover Randomized: Yes Blinding:No Duration:4 wks	healthy nonsmoking volunteers Excluded:ND	soya milk Tofu-line sweetened . Women 750 mL/day; Men 1L/day SoyMilk Diet composition:energy 1900 kJ, 30 g protein, 20 g fat, 40 g carb, 5.6 dietary fiber	Oat milk medium fat Protein:15g Product Women 750 mL/day; Men 1L/day Diet composition:energy 1990 kJ, 34 g protein, 17 g fat, 49 g carb	Total Cholesterol LDL HDL Triglyceride Antioxidant status FBS	AE:no Drop out: 1 dropout due to pregnancy Comment: insufficient data; group A received oat milk 4 w and soya milk 4 w; group B received oat milk 4 w and

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy1 N:24 Control N:24						cow's milk 4 w.
Pap 1983	Age (yr):43.9 Male%:56 Country: Hungary Sites:1 BMI:ND Soy1 N:34 Control N:0	Design:NRNCT Randomized: No CohortSing Blinding:No Duration:1 mo	chronic pancreatitis based on typical h/o, starch tolerance test or limiodol test or both;pancreatic insufficiency for 6 mo based on screening tests Excluded:ND	soy flour Natural (raw) soy flour (Rakosvolgye Co., Budapest) three times a day, 30 gm in 250 ml water 15 min Diet composition:ND	No control	Lundh Test measurement of Trypsin, Lipase and Amylase Secretin-Pancreozymin Test of Trypsin, Lipase	AE:ND Drop out:yes Comment: %change from pretreatment value (100%) and pretreatment value not reported
Pap 1984	Age (yr):42.6 (SD 2.78) Male%:70 Country: Hungary Sites:1 BMI:ND Soy1 N:10 Control N:10	Design:Xover Randomized: Yes CohortMult Blinding:No Duration:1 mo	chronic pancreatitis Excluded:ND	soy flour Natural (raw) soy flour (Rakosvolgye Co., Budapest) three times a day, 30 gm in 250 ml water 15 min Diet composition:ND	Cholecystokinin octapeptide as intranasal drops Protein:0 Product:2 dropsx3 times daily Diet composition:ND	Lundh test result Trypsin, Lipase, Amylase results	AE:ND Drop out:ND Comment:wide interval between two treatments; incomplete data; estimated from graph; lacking complete data on the actual study design
Penotti 2003	Age (yr):52.5 Male%:0 Country: Italy Sites:1 BMI:23.2 Soy1 N:28 Control N:34	Design:RCT Randomized: Yes Blinding: double Duration:6 mo	45-60 yr women; postmenopausal for at least 6 mo; FSH , and 17-Beta E2 levels within the postmenopausal range within the authors' laboratory; LDL cholesterol <160 mg/dl; no major disease, no HTN, DM, heart disease, renal or peripheral vascular diseases Excluded:	isoflavone One gram tablet before lunch and before dinner. Contains 36 mg of soy-derived isoflavones Soy Isoflavones without protein Diet composition:ND	one gram tablet twice a day; contains 0.5 g of talc and 0.5 g of microcrystalline cellulose Protein:ND Product1g Diet composition:ND	Menopausal symptom hot flushes Endometrial thickness pulsatility	AE:ND Drop out: one patient in the isoflavone group: onset of diarrhea; the other dropouts in both groups: persistence of hot flushes. Comment:None

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
Persky 2002	Age (yr):59.3 (ISP56) Male%:0 Country: US Sites:multiple BMI:28.0 Soy1 N:24 Soy2 N:23 Control N:25	Design:RCT Randomized: Yes Blinding: double Duration:24 wks	completion of menopause, >= 1 y since the last menstrual period, and a total plasma cholesterol concentration of 6.2 – 7.8 mmol/L. Excluded: On hormone replacement therapy, other medication to lower cholesterol, h/o of lucagon mellitus or thyroid lucago, chronic illness that affect lipid measurements or limit participation in the study	1 ISP56 Group patients continue their basal diets to which 40 g test protein/d was incorporated as ISP conta Supro ISP with Isoflavone Diet composition: 1 ISP90 Group patients continue their basal diets to which 40 g test protein/d was incorporated as ISP conta Supro ISP with Isoflavone Diet composition:ND	Casein+usual diet Group patients continue their basal diets to which 40 g test protein/d was incorporated as casein Protein40 Product:ND Diet composition:ND	T3 T4 TSH Cortisol Other ENDO:1 free thyro Sex Hormone Binding Globulin FSH Estradiol Estrone Estrone Sulfate DHEA/DHEAS Sex Hormone Binding Globulin-bound Urinary 2OHE Urinary 16aOHE Equol Insulin: lucagons Insulin Glucagon	AE:no Drop out:yes 1 moved to another state, 3 withdrew:medical problems unrelated to soy-product consumption, and 3 withdrew :Lack of compliance with the study protocol. One woman who was taking levothyroxine was excluded from the analysis. Comment: patients and laboratory personnels blinded
Petrakis 1995	Age (yr): 29-58 Male%:0 Country: US Sites:1 BMI:ND Soy1 N:24 Control N:24	Design:NRCT Randomized: No Blinding: No Duration: Intervention:6 mo Follow-up:12 mo	Pre and postmenopausal women volunteered to a prior study on nipple aspirate fluid. Also included were nonpregnant women who had yielded breast fluid by nipple aspiration Excluded:ND	Soy supplement as beverage Two pkts of ISP 37.4 g of protein 37.4 g of genistein Diet composition: ND	Daily diet Historical control Protein:ND Product: ND Diet composition: ND	Nipple fluid aspirate Volume Color Cytology GCDFP15 Estradiol Progesterone SHBG Prolactin Composite menstrual cycle Total Cholesterol HDL Triglyceride	AE:No Drop out:37% for 12 mos Comment: Included were 24 women from an original cohort of 37
Petri 2004	Age (yr):53.7 (SD 5.45) Male%:0	Design:RCT Randomized: Yes Blinding:	last menses 12 mo before study, FSH > 40 mIU/L, symptoms of estrogenic privation (hot flushes) and contraindications or	soy supplement 4 cap X 500 mg soy germ/d ***These capsules contained soy germ in a glycosilated natural form	lactose caps milk1 lactose Protein:ND Product:4cap/day	Total Cholesterol LDL HDL Triglyceride LH	AE:yes AE Report:2 isoflavones, 1 placebo=discreet vaginal bleeding (2

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Country: Brazil Sites:1 BMI:27.97 Soy1 N:25 Control N:25	double Duration:6 mo	intolerance to conventional HRT Excluded:veg or macrobiotic diets, Asians, smokers, alcoholics, h/o of chronic GI diseases, use of HRT, tamoxifen or antibiotics within 6 mo, thyroid dysfunctions	isoflavone soy capsule Diet composition:ND	Diet composition: ND	FSH Estradiol Kupperman menopausal index	atrophic endometrium, 1 polyp), 3 isoflavones reported constipation, 2 flatulence, 2 nausea. 2 placebos reported constipation , and flatulence. Drop out: no dropouts Comment: pts randomized at baseline exhibited elevated baseline values of cholesterol and LDL compared to placebo group (P< 0.05); from graph
Potter 1993	Age (yr):61 Male%:100 Country: US Sites:1 BMI:93.3 Soy1 N:25 Soy2 N:25 Soy3 N:25 Control N:25	Design:Xover Randomized: Yes Blinding:other Duration:4 wks	Male outpatients at VAMC, Danville Illinois. Excluded:chol <5.17 mmol/L, hyperlipidemia secondary to renal disease, med use known to alter lipoid metabolism, BB use for HTN, documented abnormality of thyroid	1. soy flour partially defatted extruded soy flour 6.5% fat Diet composition: E ND, protein 20%E, carb 55%E, Fat 25%E 2. soy protein isolate 50 g daily Supro 610 ISP without isoflavone Diet composition: E ND, protein 20%E, carb 55%E, Fat 25%E 3.ISP with cellulose 20 g dietary fiber (cellulose) Diet composition: E ND, protein 20%E, carb 55%E, Fat 25%E	2. nonfat dry milk Diet composition: E ND, protein 20%E, carb 55%E, Fat 25%E	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100	AE:yes AE Report:dropouts not related to soy consumption Drop out: 6 dropouts in 1st wk, 6 dropouts who did not complete the project, 1 who required ophthalmol surgery Comment: 2 subjects were eliminated because TG were >5.65 mmol/L; same study as Ham 1993
Potter 1998	Age (yr):59.8 (SD 9.1) Male%:0 Country: US	Design:RCT Randomized: Yes Blinding: double	Completion of menopause with >= 1 yr since the last menstrual period, plasma cholesterol concentration between 6.2 and 7.8 mmol/L.	1.ISP56 ISP with Isoflavone Basal diet + 40 g of soy protein and 56 mg total glycosides isoflavones/day, Supro 675, Protein Techno 2. ISP90	Casein and non fat dry milk (CNFDM, containing 0 mg total glycosides isoflavones/d; New Zealand Milk Product) Protein40 g Product:ND	Bone mineral density Bone mineral content LDL receptor mRNA Total cholesterol HDL	AE: Drop out: Comment: same as Baum 1998

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Sites:ND BMI:28.2 Soy1 N:23 Soy2 N:21 Control N:22	Duration:24 wks	Excluded:Hormone Replacement Therapy, Any medications known to lower lipids, h/o of DM mellitus or thyroid disease, or chronic illness, allergies to soybean protein.	ISP with Isoflavone Basal diet + 40 g of soy protein and 90 mg total glycosides isoflavones/day, Diet composition:ND	Diet composition:ND	Non-HDL Total:HDL	
Puska 2002	Age (yr):52 Male%:75 Country: Finland Sites:1 BMI:84 Soy1 N:24 Control N:28	Design:RCT Randomized: Yes Blinding: double Duration:6 wks	chol 6.9-9.9 mmol/L, Triglyceride <4.5 mmol/L, age 17-75 for men, 45-70 for postmenopausal women (at elast 6 mo witho vaginal bleeding). Excluded:any signs of CV, renal, hepatic, endocrine, GI disease; familial hypercholesterolemia, type 1 or 2 DM treated withinsulin, any past or concomitant use of statins, n-3 or other lipid-lowering drugs (incl foods) during past 8 wk. HRT within past 6 mo, no drug or alcohol dependency, no eating disorder and no plan for loss of weight	soya ISP supplement Abacor ISP with Isoflavone Diet composition:ND	Milk powder, calcium caseiate, and cellulose Protein Product Diet composition:ND	Total Cholesterol LDL HDL Triglyceride Lpa Apo B/100 Homocysteine	AE:yes AE Report:"no seriius adverse effects"--slight increase in serum uric acid values. Drop out:6/30 from Abacor tx , and 2/30 placebo dropped out because of GI symptoms Comment: The difference between the study groups for drop outs was sig from the soy
Puska 2004	Age (yr):58 Male%:48 Country: Finland Sites:ND BMI:82.2 Soy1 N:69 Control N:74	Design:RCT Randomized: Yes Blinding: double Duration:8 wks	chol 6.9-9.9 mmol/L, Triglyceride <4.5 mmol/L, age 17-75 for men, 45-70 for postmenopausal women (at elast 6 mo witho vaginal bleeding). Excluded:any signs of CV, renal, hepatic, endocrine, GI disease; familial hypercholesterolemia, type 1 or 2 DM treated withinsulin, any past or	Soy yogurt 1 cup bid soya protein Diet composition: ND	placebo yoghurt Protein:12.2 Product:ND Diet composition: ND	Total Cholesterol LDL HDL Triglyceride SBP DBP Homocysteine	AE:yes AE Report:intolerability of product: nausea, vomiting, stomach pain, feeling of stomach swelling--symptoms all mild and transient Drop out: 14 from the soy arm and 3 from the placebo group. Statistically sig drop out from the soy arm

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
			concomitant use of statins, n-3 or other lipid-lowering drugs (incl foods) during past 8 wk. HRT within past 6 mo, no drug or alcohol dependency, no eating disorder and no plan for loss of weight				compared to control Comments: None
Quella 2000	Age (yr): 34, 66 Male%:0 Country: US Sites:1 BMI: Soy1 N:175 Control N:175	Design:Xover Randomized: Yes Blinding: double Duration: 8 wks	women >18 yr, h/o of breast CA; currently no residual malignant disease;hot flashes (requiring interventions) ≥14 times/week for at least 1 month;life expectancy ≥6 mo AND Eastern Coop Onc Group score of 0 or 1; tamoxifen or raloxifene Rx is allowed if the pt had started such drug at least 4 weeks before registration and was planning to continue throughtout the term of the trial Excluded:current or planned Rx with antineoplastic chemo, androgens, estrogens, progestational agents or steroids; agents for hot flashes, like megestrol acetate, clonidine, vit E, belladonna, phenobarb, ergotamine tartrate or other SOY products	soy tablet 600 mg tablet one tablet three times a day for 4 weeks Diet composition: ND	identical appearing placebo tablet Total Protein: ND Total Product: ND Diet composition: ND	hot flash score hot flash as mild, moderate, severe or or very severe	AE:no AE Report:no difference between the two study arms with regard to diarrhea, vomiting, nausea or bloating/gas Drop out: 12%stopped medication early;did not complete diary forms appropriately Comment: May be some biases because some patients are on tamoxifen and/or raloxifene
Rivas 2002	Age (yr):47.5 (SD 10.4) Male%:14/20	Design:RCT Randomized: Yes	Both Men and women with essential HTN as diagnosed after no cause of HTN was detected after a complete investigation were	Soy milk Diet composition:Supplied by Calcimel, Santivery s.a., Barcelona, Spain Isoflavanoid concentration	Cow's milk Protein15.5 grams Product1 Liter Diet composition:Leche Pasual desnatada (Spain)	SBP DBP Mean blood pressure Equol	AE:no Drop out:ND Comment: Men aged 18-70 yr and women aged

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Country: Spain Sites:1 BMI:ND Soy1 N:20 Control N:20	Blinding:ND Duration:3 mo	included in the study. Patients had HTN of degree 1 or 2 according to the JNC on Detection, Evaluation, and Treatment of High Blood P Excluded:Urinary genistein >100 mu mol/L	and chemical characteristics in soy milk: Genistein 80 (SD 8); Daidzein 63 (SD 9); Equol ND; protein 18 g/L; carb 13.5 g/L; Lipids 10.5 g/L; Calcium 600 mg/L; Energy 2	Isoflavanoid concentration and chemical characteristics in cows milk: Genistein ND; Daidzein ND; Equol ND; protein 15.5 g/L; carb 25 g/L; Lipids 1.5 g/L; Calcium 600 mg/L; Energy 175 kJ/L		50-70 yr were included. NO definite description of pre or post menopause Method of randomization, blinding, allocation concealment not stated
Ross 1995	Age (yr):ND Male%:47 Country: US Sites:1 BMI:ND Soy1 N:23 Control N:23	Design:Xover Randomized: Yes Blinding:ND Duration:9 days	healthy adults consuming a typical american diet (low in fruit and vegetables) Excluded:medical H/o of gastrointestinal symptoms; food allergies; weight loss and gain >4.5kg within the past year; major changes in eating habits within the last year or significant short-term dietary changes (such as seen with high intensity exercise regimens, alcohol intake >2 drinks/d, OCD by women, smoking and unwillingness to consume all foods provided	Soy diet Tofu control diet plus daily servings of firmed tofu and 45g FriChick, a textured vegetable protein product Diet composition:ND	commonly consumed foods and no fruits and vegetables and was essntially phytochemical free Protein:ND Product:ND Diet composition:ND	Platelet derived growth factor PDGF-AA; PDGF-BB mitogenic activity	AE:ND Drop out:4;unexpected prgnancy; logistical problems; non-compliance Comment:no specific baseline characteristics are given;quantity of tofu not reported
Russo 2003	Age (yr):53.3 (SD 3.3) Male%:0 Country: Italy Sites:1 BMI:26.3 Soy1 N:50 Control N:50	Design:Xover Randomized: Yes Blinding: double Duration:3 mo	Recent menopause, 48 - 54 y, Caucasian, Neg PAP test, normal pelvic US, symptoms of Climacteric syndrome Excluded:Surgical h/o for genital or mammary neoplasia, HRT within 6 mo, arterial hypertension and/or cardiovascular pathologies, endocrinological pathologies, nicotinism, obesity, alcohol or narcotic	isoflavones Comercially available preparation based on phyto-oestrogens against a placebo Soy oil, 5 mcg vitamin D, Diet composition:ND	Comercially available preparation based on phyto-oestrogens against a placebo Protein:ND Product:ND Diet composition:ND	Menopausal symptom hot flushes	AE:No Drop out:Non-hormone-dependent neoplastic pathology (1), intense vegetative syndrome (1), spotting after 15 days (1) Comment:None

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
			abuse				
Sagara 2004	Age (yr):52.2 (SD 3.9) Male%:100 Country: UK Sites:12 BMI:27.6 Total enroll:61 Soy1 N:25 Control N:25	Design:RCT Randomized: Yes Blinding: double Duration:5 wks	Systolic blood pressure 130 mmHg or higher and/or Total Cholesterol 220 mg/dL or higher. Excluded:Presence of DM mellitus and any other chronic illnesses that could affect BP or blood lipid concentration or limit individual's ability to participate in the study, and use of anti-hypertensive drugs, cholesterol lowering drugs and any medication kn	Soy powder Soy powder mixed in cereals, biscuits and bread rolls were consumed in addition to the usual diet. Diet composition:ND	placebo group Other control: cereals, b Protein26.7 g Product Diet composition:ND	Total Cholesterol HDL SBP DBP non HDL-C non HDL-C/HDL-C ratio	AE:ND Drop out:8 (13%) subjects withdrew during the 5 wk intervention; 2 because of missing the blood sampling; One excluded prior to data analysis for noncompliance with the diet Comment: There is a difference in soy protein and isoflavones between the text and the table. Entered below are from the text.
Saxena 1999	Age (yr): Male%: Country: India Sites:1 BMI:ND Soy1 N:45 Control N:0	Design:NRNCT Randomized: No CohortSing Duration:3mo	Patient with platelet functional defect and with lab test available for PCI, PF3 availability and platelet aggregation studies Excluded:ND	Soya Bean, consumed in the form of boiled beans, soya flour or soya milk. Soy bean SoyMilk Soy diet soya flour Diet composition:ND	No control	Miscellaneous outcomes; Bleeding Platelet studies	AE: AE Report: Drop out: Reason:
Scambia 2000	Age (yr):54 (SD 7.1) Male%:0 Country: Italy Sites:1 BMI:26.2 Soy1 N: 20	Design:RCT Randomized: Yes Blinding: double Duration:10 wks	Postmenopausal women: spontaneous amenorrhea at least 12 mo, surgical or early menopause; and Ecarb endomerial thickness <4.5 mm; negative X-ray mammograpphy; metabolic and biochemical index within normal range Excluded: involved in any clinical trial 6 mo before	1. Soy tablet 12% isoflavones and 35% saponins. 200 mg SOYSELECT, lactose, cellulose microcrystalline, sillica colloidal, and sodium Mg stearic Soy Isoflavones without protein Diet composition: ND	Placebo tb contained lactose, cellulose microcrystalline, sillica colloidal, and sodium Mg stearic Total Protein: ND Total Product: ND Diet composition: ND	PTH Total Cholesterol LDL HDL Triglyceride Endothelin -1 Serum Osteocalcin Vaginal cell maturation index Menopausal symptom vasomotor	AE:No side effects Drop out: refusal of patients to undertake certain tests Comment: diet and medication not reported; not explicitly reported whether women on HRT were excluded; power calculations not reported;

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Control N:19		entering this study			symptoms and the Greene climacteric scale Endometrial thickness Pulsatility index of uterine artery LH FSH Prolactin	race not reported; No follow up values or differences were reported
Scheiber 2001	Age (yr):55.5 (SD 5.2) Male%:0 US:1 Country: US Sites:1 BMI:27.1 Soy1 N:42 Control N:0	Design:NRNCT Randomized: No Blinding:No Duration:12 wks	Menopausal (either natural or surgical) women with amenorrhea for > 6 mo and an FSH level > 23 IU/L at enrollment. Excluded:Women on estrogens, progestins, androgens, corticosteroids, or antioxidant drugs within the 4 mo before enrollmen, or on a full course of antiobiotics within 3 mo of enrollment, or h/o of estrogen-dependent	Soy Nuts Whole soy nuts (10 gm/serving) or commercially available soy milk drinks (SoGood, 250 mL/serving). SoyMilk SSP1 Diet composition:	No control	Total Cholesterol LDL HDL Triglyceride Oxidized LDL Serum bone specific alkaline phosphatase Serum Osteocalcin Type 1 Collagen cross-linked N-teleopeptide FSH Estradiol	AE:yes AE Report:2 subjects dropped out due to intestinal bloating Drop out:no Comment: Did not define "post-menopausal;Do not report total grams of soy protein in intervention, or bread down the different levesl of isoflavones.
Secreto 2004	Age (yr):53 Male%:0 Country: Italy Sites:3 BMI:Median 23.8 Soy1 N:65 Soy2 N:64 Control N:67	Design:Factorial Randomized: Yes Blinding: double Duration:3 mo	Postmenopausal women aged >= 35 years; last menstrual flow > 6 mo before recruitment; any condition for which classic HRT is not recommended Excluded:Breast cancer therapy or HRT during the previous 3 mo; overt endocrinopathy (DM, hyperthyroidism etc.); intolerance to soy	1. Soy isoflavones Each soy capsule contained 300 mg of soy extract, equivalent to 40 mg of isoflavones. Soy extract Diet composition:ND 2. Isoflavone+melatonin Each soy capsule contained 300 mg of soy extract, equivalent to 40 mg of isoflavones. Soy extract Diet composition:ND	Placebo sorbitol Protein0 Product2 identical capsules per day Diet composition:ND	Greene Climacteric Scale Psychological subscale Somatic subscale Vasomotor subscale	AE:yes AE Report:Gastric intolerance, tachycardia, increased body weight, insomnia, excessive drowsiness, headache and constipation. Drop out: 9%; lost to follow-up, did not received allocated treatment, discontinued treatment for adverse events or other causes. Comment: NOTE: Some subjects also received

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
							melatonin only; AE breakdown incomplete report
Shorey 1981	Age (yr):26 (SD 4) Male%:100 Country: US Sites:1 BMI:79.1 Soy1 N:14 Control N:13	Design:RCT? Randomized: Unclear Blinding:ND Duration:6 wks	Mildly hypercholesterolemic males from the student and Faculty population at the University of Texas at Austin and those who gave informed consent for the study Excluded:ND	Soy protein diet Soy analogs and soy milk Soy diet SoyMilk Diet composition: Energy 2469 with-137 kcal; Protein 87with-7g; carb 333with-26g; Fiber 7with-2 g; Fat 93with-7 g; Sat fat 33g cholesterol 183	Animal protein diet Other control: Restructur Protein58.5 g Product Diet composition: 2400 kcal with 13 to 15% of energy from protein, 30 to 35% from fat and remainder from carb.	Total Cholesterol HDL Triglyceride HDL-C/Total cholesterol	AE:yes AE Report:Increased fecal bulk and flatulence unclear if reported by soy arm or both arms Drop out:One withdrew for job related reasons, one was in a car accident, and one exhibited wide fluctuations in triglyceride from lipid analysis. Comment: None
Simons 2000	Age (yr):59 Male%:0 Country: Australia Sites:1 BMI:26.8 Soy1 N:23 Control N:23	Design:Xover Randomized: Yes Blinding: double Duration:8 wks	Healthy postmenopausal volunteers 50-70 yr (LMP >12 mo), significant endothelial dysfunction, nonsmoking, cholesterol <8.0 mmol/L and Triglyceride <3.0 Excluded: Cardiac renal, hepatic disease or DM. Vitamins, and minerals supplementation, lipid-regulating drugs, warfarin, antihypertensive medications, sex hormones	Phytoestrogen (PE) tablets bid Soy bean Diet composition: isocaloric fat restricted diet, 30%E fat, <10% E sat fat, cholesterol <300	placebo Total Protein: ND Total Product: ND Diet composition: isocaloric fat restricted diet, 30%E fat, <10% E sat fat, cholesterol <300	Total Cholesterol LDL HDL Triglyceride Lpa BP Peripheral endothelial function Glyceryl trinitrate induced dilation Flow mediated dilation	AE:yes AE Report:on placebo, 1 parasthesiae in arm and leg, 1 head noises, 1 laparocholecystectomy.On PE, 1 parasthesiae and 1 brief menstrual period 5 wk into tx. Drop out: 3 dropout--one PE- vaginal spotting and bleeding; One on placebo severe menopausal symptoms and 1 moved out Comment:None
Sirtori 1999	Age (yr):51.9 (SD 13.5) Male%:38 Country: Italy	Design:Xover Randomized: Yes Blinding:	Severe hypercholesterolemia (13 genetic, 8 sporadic) with cholesterol >7.8 mmol/L and LDL >5.8 mmol/L in absence of drug tx,	Soya milk supplemented diet Diet composition:500 ml fluid milk to achieve 7% protein content energy	Cows' milk supplemented diet Total Protein: 70g/d Total Product: 500ml Diet composition: 2 dietary schedules 1400 kcal (carb 56.7, fat 25.1, protein 18.2) and 2000kcal	Total Cholesterol LDL HDL Triglyceride SBP DBP	AE:no no dropouts--side effects vague (side effects occurred during cows' milk period probably as

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Sites:1 BMI:24.4 Soy1 N:21 Control N:21	double Duration:4 wks	Triglyceride <2 mmol/L Excluded:type I or II DM, alcoholism or alcohol liver disease, severe ailments: cancer, degenerative mental disease, heart or kidney failure	1124 kJ/d, protein 70 g/l, fat 22 g/l 2 dietary schedules 1400 kcal and 2000kcal	(carb 59.9, fat 24.3, protein 15.8)	FBS	result of lactose intolerance" Comment: Data below derives from later study: Sirtori 2002 RefID#354;Control baseline and final values from graph
Sirtori 2002	Age (yr):59.5 8.35 Male%:20 Country: Italy Sites:1 BMI:24.2 Soy1 N:20 Control N:20	Design:Xover Randomized: Yes Blinding: double Duration:4 wks	type II hypercholesterolemics withcholesterol >7 mmol/L, LDL >5.5. Excluded:alc intake >4 standard drinks/d or >40 g alcohol/d, diabetics on meds or insulin, SBP >160 mm Hg or DBP >95. Meds for dyslipidemia or agents that affect lipids, vegetarians or those consuming >1 soy-containing milk serving/d	Soya milk supplemented diet Diet composition:500 ml fluid milk to achieve 7% protein content energy 1124 kJ/d, protein 70 g/l, fat 22 g/l 2 dietary schedules 1400 kcal and 2000kcal	Cows' milk supplemented diet Total Protein: 70g/d Total Product: 500ml Diet composition: 2 dietary schedules 1400 kcal (carb 56.7, fat 25.1, protein 18.2) and 2000kcal (carb 59.9, fat 24.3, protein 15.8)	Total Cholesterol LDL	AE:no no dropouts--side effects vague (side effects occurred during cows' milk period probably as result of lactose intolerance" Comment: same as Sirtori 1999 RefID#783
Soroka 1998	Age (yr): 30-85 Male%:56 Country: Israel Sites:1 BMI:ND Soy1 N:15 Control N:15	Design:Xover Randomized: Yes Blinding:ND Duration:6 mo	CRF patients, CrCl between 15 and 50 ml/min/1.73 m2 and the 24-hour urinary protein excretion < 3 g/day/1.73 m2 (i.e. no patient had nephrotic syndrome) Excluded:DM or other systemic diseases	Vegetable protein diet (VPD): (1) soya-based schnitzels, hamburger, and sausage (2) Soy drink Diet composition: E 2,049kcal/d, protein 48.9g/d, carb 54.5%E, fat 35.8%E, proteins 9.45%E	Animal-protein diet (APD) 50% protein from eggs, chicken, meat, turkey, fish, and milk; 50% protein from bread. Protein:0.75 g/kg/day Product:ND Diet composition: E 1,838 kcal/d, protein 52.5 g/d, carb 55.5%E, fat 33.3%E, proteins 11.13%E	Total Cholesterol LDL HDL Triglyceride GFR Sr creatinine BUN serum albumin Urinary calcium	AE:ND Drop out:6 2 cerebrovascular accidents, 1 refusal to have GFR test performed a second time, 1 rapid worsening of the renal function after receiving an ACE inhibitor, and 2 non-compliant Comment: VPD had a highercaloric intake, a lower proteinintake, and a lower protein intake per kilogram body. Small sample size and high

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
							dropout rate (40%)
Squadrito 2002	Age (yr):54 (SD 7) Male%:0 Country: Italy Sites:1 BMI: ND Soy1 N:30 Control N:30	Design:RCT Randomized: Yes Blinding: double Duration:6 mo	healthy ambulatory women aged 52-60 who had not undergone surgical menopause, had no menstrual cycle in preceding yr, FSH > 50 IU/L, estradiol <100 pmol/L. Excluded:any clinical or lab abnormailities that suggested cardiovasc, hepatic, or renal disorders; coagulopathy; used oral or transdermal estrogen, progestin, androgen or other steroids in preceding yr; smoked >10 cigs/d; had taken cholesterol-lowering or CV meds	genistein genistein 54 mg/d Diet composition:isocaloric fat restricted diet 30%E fat, 10%E from sat fat, chol <300 mg/d	placebo Protein:ND Product:ND Diet composition:isocaloric fat restricted diet 30%E fat, 10%E from sat fat, chol <300 mg/d	Total Cholesterol LDL HDL Triglyceride SBP DBP Endothelin -1 Peripheral endothelial function Estradiol	AE:yes AE Report:In genistein, 2 women had brief menstrual period after 5 wk tx, 1 woman had vertigo. In placebo, 2 pts had paresthesiae and 1 had vertigo. Drop out: genistein, 2 brief menstrual period after 5 wk tx, 1 vertigo. In placebo, 2 paresthesiae and 1 vertigo. Comment:Similar cohor as Squadrito 2003
Squadrito 2003	Age (yr):56 (SD 7) Male%:0 Country: Italy Sites:1 BMI: Soy1 N:27 Control N:26	Design:RCT Randomized: Yes Blinding: double Duration:12 mo	healthy ambulatory women aged 52-60 who had not undergone surgical menopause, had no menstrual cycle in preceding yr, FSH > 50 IU/L, estradiol <100 pmol/L. Excluded:clinical or lab abnormailities that suggested cardiovasc, hepatic, or renal disorders; coagulopathy; used oral or transdermal estrogen, progestin, androgen or other steroids in preceding yr; smoked >10 cigs/d; had taken cholesterol-lowering or CV meds.	genistein genistein 54 mg/d Soy diet genistein Diet composition:ND	placebo ProteinND Product ND Diet composition:ND	Peripheral endothelial function Endothelin -1 vascular resistance Estradiol	AE:yes AE Report:Breast tenderness in 3 on genistein, 5 on HRT, 1 on placebo. Vaginal bleeding in 1 on genistein, 5 on HRT, 1 on placebo. Hot flushes on 5 in genistein, 1 on HRT, 11 during placebo Drop out:Same as AE and Endometrial thickness >5 mm occurred to 3 Comment: a 3rd arm is EPT: 17B-estradiol 1 mg/d withnorethisterone acetate n=26. Similar cohort as Squadrito 2003

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
St Germain 2001	Age (yr):50 Male%:0 Country: US Sites:1 BMI: ND Soy1 N:24 Soy2 N:24 Control N:21	Design:RCT Randomized: Yes Blinding: double Duration:12 wks	nonsmoking perimenopausal women, experiencing at least nd hot flushes and/or night sweats/week, within 12 minths of their last menstrual cycle, free from chronic disease or chronic medication use, not taking HRT or ERT during the time of the study or 12 m Excluded:FSH < 30 IU/mL	1. SPI+ Soy protein isolate with isoflavones (Supro) Diet composition: 2. SPI- Soy protein isolate without isoflavones (Supro) Diet composition:ND	Whey protein control Total Protein: 40 Total Product: ND Diet composition: ND	Menopausal symptom hot flush Other symp Menopausal Index (to measure hot flush and night sweat frequency, duration and severity)	AE:no Drop outs:Inability to tolerate treatment (n=6), death (n=1), death of a fmily member (n=1), medical conditions preventing their continual (n=2), or noncompliance (n=1) Comment: No breakdown demographic data for each group.
Steinberg 2003	Age (yr):54.9 (SD 1.0) Male%:0 Country: US Sites: BMI:24.6 Total enroll:42 Soy1 N:28 Soy2 N:28 Control N:28	Design:Xover Randomized: Yes Blinding: double Duration:6 wks	healthy postmenopausal women; Excluded:HRT use within 6 mo, hyperlipidemia (chol >5.17 mmol/L or 200 mg/dL), meds to treat high BP or hypercholesterolemia, GI abnormalities affecting dietary intake, prev heart attack or dx heart disease, hepatic or renal disease, DM, h/o of thrombosis or blood	ISP w/ isoflavones ISP w/ naturally occurring isoflavones ISP with Isoflavone Diet composition:25 g protein, 1g fat energy 7.6 MJ, carb 247.9 g/d, protein 89.6 g/d, total fat 52.4 g/d, saturated fat 15.5 g/d, chol 164.4 mg/d, fiber 21.6 mg/d ISP w/o isoflavones ethanol-washed ISP w/ trace amounts of isoflavones ISP without isoflavone Diet composition:24 g protein, 1 g fat energy 7.2 MJ, carb 225.7 g/d, protein 84.3 g/d, total fat 52.1 g/d, saturated fat 16.3 g/d, chol 175.9 mg/d, fiber 19.4 mg/d	total milk protein Protein25 g Product Diet composition:energy 8.0 MJ, carb 263.7 g/d, protein 91.1 g/d, total fat 55.3 g/d, saturated fat 17.1 g/d, chol 178.1 mg/d, fiber 21.2 mg/d	Total Cholesterol LDL HDL Triglyceride Peripheral endothelial function Oxidized LDL E-selectin Endothelin -1 Nitrous oxide VCAM-1 ICAM	AE:yes AE Report:no withdrawals due to adverse events once the trial began Drop out: 42 enrolled/28 completed. Of 14 dropouts, 3 could not tolerate the tx, 2 GI disturbances, 1 because of taste intolerance. Comment: no baseline values
Stroescu 2001	Age (yr):14.9 (SD 1.3) Male%:0	Design:RCT Randomized: Yes Blinding:	Elite female gymnasts, members of the Romanian Olympic Team with primary amenorrhea (13/14	ISP Daily supplementation of 1 g of soy protein per kg body weight in the form of cocoa-flavoured bevera	placebo beverage: 10 g sugar, 3 g cocoa, 250 ml water. The total protein ratio per day and kg was 2. Protein without fat none repor	Total Cholesterol T3 T4 serum: proteins, total fat, FFA,	AE: ND Drop out: ND Comment: Small sample size; withdrawals are not

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Country: Romania Sites:1 BMI:33.1 Soy1 N:7 Control N:7	double Duration:4 mo	gymnasts) Excluded: ND	Supro Isolated Soy Protein, unclear re: Isoflavones Diet composition: ND	Total Protein: 2.8/Kg BW Total Product: ND Diet composition: protein amount is higher in controls than in Tx subjects; type of protein in controls not specified	SGOT, SGPT, total Ca, Mg, IgA, IgM, IgG; urine mucoproteins Sr creatinine BUN Estradiol Progesterone Prolactin Testosterone 17-ketosteroids metabolites of androgenic steroids	reported; no statistical comparison between Tx and conrols at baseline is reported
Swain 2002	Age (yr):50.2 (SD 3.6) Male%:0 Country: US Sites:1 BMI:24.1 Soy1 N:24 Soy2 N:24 Control N:21	Design:RCT Randomized: Yes Blinding: double Duration:24 wks	perimenopausal women throughout Iowa and bordering states; >/= 10 flushes/wk; irregular menses or menstrual period cessation; FSH./=30 IU/L; BMI=20-31; no chronic disease; no excessively exercising; one or both ovaries remaining; able and willing to participate Excluded:chronic disease; routine use of medications; smoking; alcohol abuse; estrogen or HRT during the prior 12 mo; H/o of eating disorders	1. Isoflavone poor SPI 40g/day w/ 50% of this protein incorporated into a muffin and the 50% as a powder that subject 2. ISP without isoflavone Isoflavone rich SPI 40g/day w/ 50% of this protein incorporated into a muffin and the 50% as a powder that subject ISP without isoflavone Diet composition:ND	whey protein: 40g/day w/ 50% of this protein incorporated into a muffin and the 50% as a powde Protein40 g ProductND Diet composition:ND	Total Cholesterol LDL HDL Lpa FSH Estrone 17b-estradiol serum ferritin, serum iron, transferrin saturation Hb concentration anthropometric measurements	AE:no Drop out:ND Comment: seperate description for each arm is not shown; isoflavone amount not specified
Takatsuka 2000	Age (yr):26.1 (SD 7.6) Male%:100 Country: Japan Sites:1 BMI:20.4 Total enroll:60	Design:RCT Randomized: Yes Blinding: double Duration:2 mo	all premenopausal female students and teachers at Gifu Nursing SChool. Excluded:h/o of endocrine diseases and HRT, chronic hepatitis or CVD. Total Chol >220 mg/dl or Triglyceride >160.	soy supplements 400 ml (408 g) commercial regular soymilk/d. Diet composition: E 1569 kcal/d, protein 59.9g, fat 54.5g, carb 197.5g	usual diet Total Protein: ND Total Product: ND Diet composition: E 1491 kcal/d, protein 50.7g, fat 50.2g, carb 200g	Total Cholesterol LDL HDL Triglyceride	AE:No Drop out: 8 excluded after randomization Comment:None

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy1 N:27 Control N:25						
Teede 2001	Age (yr):61 (SD 1) Male%:53.6 Country: Australia Sites:1 BMI:25 Soy1 N:105 Control N:108	Design:RCT Randomized: Yes Blinding: double Duration:3 mo	Healthy participants men and women 50-75 yr Excluded:no antibiotics or soy products or suppls for 3 mo, no estrogen therapy for 3 mo;moderate to severe menopausal symptoms, smoking over past 10 yr, alcohol consumption >30 g/d, hypertension, abnormal uterine bleeding, cervical cytology, or mammogram and coexistent major illness	soy ISP w/isoflavones, 2 sachets/d 28 g powdered ISP ISP with Isoflavone Diet composition: ND	casein Total Protein: ND Total Product: ND Diet composition: ND	Total Cholesterol LDL HDL Triglyceride Lpa SBP DBP Peripheral endothelial function Systemic arterial compliance pulse wave LH FSH Testosterone	AE:yes AE Report:34/213 withdrew soy: 3 GI including constipation, placebo: 2; soy: 1 diarrhea, placebo 2; soy: 1 hot flashes; soy: 2 exclusions due to high FSH Drop out: 34/213 withdrew Comment: None
Teede 2004	Age (yr):61 (SD 1) Male%:0 Country: Australia Sites:1 BMI:26 Soy1 N:30 Control N:20	Design:RCT Randomized: Yes Blinding: double Duration:3 mo	postmenopausal women 50-75 yr with 12 mo amenorrhea and FSH >20IU/L Excluded:no antibiotics or soy products or suppls for 3 mo, no estrogen therapy for 3 mo; moderate to severe menopausal symptoms, smoking over past 10 yr, alcohol consumption >30 g/d, HTN, abnormal uterine bleeding, cervical cytology, or mammogram result and coexistent major illness.	soy ISP with Isoflavone Diet composition: ND	Casein placebo Protein:ND Product:ND Diet composition:ND	TBG C-reactive protein Sex Hormone Binding Globulin LH FSH DHEA/DHEAS	AE:No Drop out:no Comments: nested trial from a larger study of 210 healthy participants (Teede 2001 11443167)
Teixeira 2000	Age (yr):43.3 (SD 11.4) Male%:100 Country: US Sites:1	Design:RCT Randomized: Yes Blinding: double Duration:6	Free living men age >23, Total Cholesterol 5.69-7.76 mmol/L, BMI 20-33 Excluded:DM, thyroid disease, chronic disease that affect lipids, any medication that affect lipds.	1. 20 g Supro Plus 675HG plus 30 g casein ISP with Isoflavone 2. 30 g Supro 675HG plus 20 g casein ISP with Isoflavone 3. 40 g Supro 675HG plus 10 g casein	50 g casein Total Protein: 50 g Total Product: ND Diet composition:NCEPstepI diet 30%E fat, <10%E sat fat, <300mg cholesterol/d	Total Cholesterol LDL HDL Triglyceride Lpa Apo A1 Apo B/100	AE:yes AE Report:2 possible allergic reactions such as skin rash and itching Drop out: 8 dropouts due to AE

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI:27.1 Soy1 N:15 Soy2 N:18 Soy3 N:17 Soy4 N:15 Control N:16	wks	Weight variation >3 kg during the study.	ISP with Isoflavone50 g ISP 4. 50 g Supro 675HG Supro ISP with Isoflavone Diet composition:NCEPstepI diet 30%E fat, <10%E sat fat, <300mg cholesterol/d			Comment:None
Tonstad 2002	Age (yr):51.4 (SD 9.8) Male%:83 Country: Norway Sites:2 BMI:24-25 Total enrol: 159 Soy1 N:34 Soy2 N:31 Control N1:29 Control N2:36	Design:RCT Randomized: Yes Blinding: double Duration:16 wks	Men aged 30-70 yr and post menopausal women aged 45-70 yr with total cholesterol 5.8-7.9 mmol/L and triacylglycerol conc <4.5 mmol/L were eligible Excluded:Significant CVD, renal , GI, endocrine disease, including DM type 1 and 2 treated with drugs; familial hypercholesterolemia; obesity (BMI >=30) and uncontrolled HTN (BP >160/100 mmHg), plan to lose weight during the study, alcohol consumption 28units/wk, intake of statins, n-3 supplements, other lipid lowering drugs and women on HRT within 6 mo of study	1. ISP 30g Isolated soy protein 30 gram available as ready to mix beverage ISP with Isoflavone Diet composition: 2. ISP 50g Isolated soy protein 50g available as ready to mix beverage ISP with Isoflavone Diet composition:<30% E fat, <10%E sat fat, <300 mg cholesterol/d	Casein 30g and 50g Protein30g and 50g Product Diet composition:<30% E fat, <10%E sat fat, <300 mg cholesterol/d	Total Cholesterol LDL HDL Triglyceride Lpa Apo B/100 SBP DBP Homocysteine Fibrinogen Alpha Tocopheral in mu mol/L, vit B12, folate	AE:no Drop out:Total 29: 19 withdrawals: 2 were lost to follow-up; 9 withdrew consent or were unable to comply with the study protocol; 1 developed angina pectoris; 1 complained dizziness; 6 complained GI problems. An additional 10 subjects were excluded from the statistical analysis Comment: Quantity of ISP and soy protein clearly stated
Uesugi 2002	Age (yr):51.8 (SD 1.9) Male%:0 Country: Japan Sites:1 BMI:22.9	Design:RCT Randomized: Yes Blinding: double Duration:4	healthy perimenopausal employees of a food processing factory age 40-62 Excluded:ND	soybean isoflavone extract Isoflavone only Diet composition:ND	placebo capsules Protein:ND Product:ND Diet composition:ND	Total Cholesterol LDL HDL Triglyceride Serum Osteocalcin Urine deoxypyridinoline Urine pyridinoline Bone stiffness	AE:No AE Report:"no side effects were detected" Drop out:no Comment:None

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy1 N:12 Control N:11	wks				HgbA1c	
Uesugi 2003	Age (yr):53.7 (SD 6.9) Male%:0 Country: Japan Sites:1 BMI:52.0 Soy1 N:11 Control N:10	Design:RCT Randomized: Yes Blinding: double Duration:3 mo	age 45-65, 5-10 yr after natural menopause, weight 35-70 kg, no evidence of disease associated with osteoporosis or other med problems, no h/o of drug use, including estrogen, known to affect bone metabolism Excluded:as above	isoflavone extract Soy Isoflavones without protein Diet composition:ND	dextrin Protein:ND Product:2 times daily Diet composition:	Total Cholesterol HDL Triglyceride Urine pyridinoline Urinary calcium vaginal parabasal cytology FSH	AE: AE Report: Drop out:no Comment:None
Unfer 2004	Age (yr):49 (SD 4.3) Male%:0 Country: Italy Sites:1 BMI:67 Soy1 N:179 Control N:197	Design:RCT Randomized: Yes Blinding: double Duration:5 years	intact uterus, absense of menses for 12 mo, FSH >30 IU/L, body weight range within 20% normal weight Excluded:any meds containing estrogens, progestins, androgens within 8 wks of trial, presence of endometrial hyperplasia	phytoestrogens 3 tablets/d soy=150 mg isoflavones Soy Isoflavones without protein Diet composition:ND	Placebo tablets ProteinND Product:3/day Diet composition:ND	Endometrial thickness	AE:no Drop out: 25 in the soy and 32 in the control Comment:Limited data
Upmalis 2000	Age (yr):54.8 (SD 4.9) Male%:0 Country: US Sites:15 BMI:152.2 Soy1 N:89 Control N:86	Design:RCT Randomized: Yes Blinding: double Duration:12 wks	Healthy postmenopausal women age 50 years or older and in good overall health, with a BW within =-35% range for BMI, FSH levels of 40 mIU/mL or more, E2 levels of 25 pg/mL or less, and an average of 3 or more vasomotor symptoms per day. Subjects have discontinued Excluded:H/o of breast	Soy isoflavone extract tablet (with little protein) Diet composition: ND	Placebo Total Protein: ND Total Product: ND Diet composition: ND	Total Cholesterol LDL HDL Triglyceride Serum Osteocalcin Type 1 Collagen cross-linked N-teleopeptide Endometrial thickness FSH Hot flushes Night sweats	AE:yes AE Report:30 (33.7%) of 89 subjects in the soy group reported a total of 70 adverse experiences, and 39 (45.3%) in the placebo group reported a total of 79 adverse experiences. Adverse experiences including respirotory, GI, and genital/reproductive systems. 1 subject due to

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
			cancer, hyperplasia, endometrial carcinoma, or cervical neoplasia; a positive pregnancy test' undiagnosed abnormal vaginal bleeding, a bilateral oophorectomy or hysterectomy; thromboembolic disorders; h/o of CVDs; liver disease; h/o chronic alcoholism, medication hypersensitivity, or allergy to dietary supplement, uncontrolled addiction or severe depression, acute systemic infection or abnormal lab values				UTI Drop out:16 Medication and diet noncompliance, discontinued the study before week 12, discontinued because of a urinary infection, baseline transvaginal ultrsound was not performed within 10 days of the first dose of study medication; 5 invalidity of endometrial and lab analysis
Van Horn L 2001	Age (yr):66.6 Male%:0 Country: US: Sites:1 BMI:26.6 Soy1 N:32 Control N:32	Design:RCT Randomized: Yes Duration:6 wks	Age > 50 yr and/or confirmed post menopausal status, Total Cholesterol concentrations above 5.17mmol/L on average with two screenings, and BMI <35. Additional eligibility criteria: not being on a weight loss diet; not taking fiber, soy or other dietary suppleme Excluded:Subjects allergic to soy, milk, or oats were excluded.	1. Oats/soy 2. Wheat/soy Soy protein powder ISP without isoflavone Diet composition: E ~1400, total fat 24%E, protein 18-19%E	1. Oats and milk arm Protein without fat Total Protein: ND Total Product: 29 gram Diet composition:The oat group incorporated 2 servings (56 g dry weight) of cooked oatmeal or (2oz) ready to eat oat bran cereal per day. Non fat milk protein powder served as the control product for soy 2. Wheat+milk Cream of wheat or a non-oat ready to eat cereal and non fat milk protein powder Total Protein: ND Total Product: ND Diet composition: Diet composition: E ~1400, total fat 23%E, protein 18-19%E	Total Cholesterol LDL HDL	AE:No Drop out:1/127 was unable to provide a final blood sample or food record Comment: Non fat milk protein powder served as the control product for soy. Cream of wheat or a non oat ready to cereal served as the control for oats. Well described study characteristics
Van Patten CL 2002	Age (yr):55.5 (SD 8.9)	Design:RCT Randomized: Yes	Breast cancer pts > 4 mo since cancer tx, menopausal, moderate hot	soy milk Soybean beverage, 250 mL twice per day, was vanilla flavored, with similar calorie	Rice beverage as placebo, 250 mL of study beverage twice a day, vanilla flavored with similar calori milk1	Menopausal symptom	AE:yes AE Report:Bloating 15, flatulence 6, constipation

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Male%: Country: Canada Sites:Multiple BMI:26.8 Total:157 Soy1 N:59 Control N:64	CohortMult Blinding: double Duration:	flashes (score => 10 wk) Excluded:Amenorrhea < 12 mo, HRT preceding 4 mo, smokers, antibiotic use, IBD, liver impairment, recurrent breast cancer. allergies, consumed soy foods	& fat content SoyMilk Diet composition:Donated by Soya World Inc in BC, Canada	rice milk ProteinND Product250 mL 2 @ day Diet composition:	hot flashes	4, gastritis 3, diarrhea 9, nausea 2, vomiting 1, heartburn 2, wt gain 9, vaginal spotting 5, other 5 Drop out:Of 157 randomized, 9 became ineligible after randomization, 25 WD for time commitment (9), intolerance to soy (10: soy 7, placebo 3), other reasons (6) Comment: 3 subjects didn't complete last 4 weeks, their previous 4 week data was carried forward
Verrillo 1985	Age (yr):Male 48;Female 54 Male%:44% Country: Italy Sites:1 BMI:28.0 Soy1 N:44 Soy2 N:22 Control N:0 (66 on 8 wk low fat diet)	Design:RCT Randomized: Yes CohortMult Blinding:No Duration:16 wks	Stable hypercholesterolemia.Total Cholesterol > 7.8 mmol/L and LDL > 4. Excluded:Clinical or biochemical evidence of cardiac, renal, hepatic or endocrine disease.	1.Soy.Addition Cholsoy granules (60 g/day) as a supplement to the low fat diet. Diet composition:Actual: 2353 Kcal, Protein 19.7% (animal 8.5%, soy 5.3%), Fat 31.0%, Sat fat 6.5%, MUFA 11.5%, PUFA 13.0%, carb 49.3%, Cholesterol 205 mg 2.Soy.Substitution Animal proteins replaced with Cholsoy (Gipharmex, Milan), a soybean preparation (26.5% carb, 5% sucro Diet composition:Actual: 2150 Kcal, Protein 15% (animal 2.3%, Soy 5.8%), Fat 33.5%, Sat fat 7.4%, MUFA 11.4%, PUFA 14.7%, carb 51.5%,	No non soy control	Total Cholesterol LDL HDL Triglyceride	AE:yes AE Report:1/66 did not finish because of gastric discomfort Drop out: 3 soy substitution (1 died of MI, 1 did not return after 1 month, 1 non-compliance),6 soy addition (1 gastric discomfort, 2 dental prosthesis, 3 non-compliance) Comment: No non-soy control (except baseline diet)

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
				Cholesterol 188 mg			
Vigna 2000	Age (yr):53.8 (SD 3.1) Male%:0 Country: Italy Sites:2 BMI:25.9 Soy1 N:51(46+5 post initial randomization) Control N:53 (46+7 post initial randomization)	Design:RCT Randomized: Yes Duration:12 wks	Post menopausal women with hot flushes. Amenorrhea for at least 6 mo or bilateral oopherectomy at least 6 wks earlier. Severe hot flushes (>7/24 hr); baseline FSH > 50 IU/L, Serum estradiol < 130 pmol/L; TSH and thyroxine normal. Excluded:ND	Soy.powder Replace breakfast with beverage containing 60 g soy powder (ISP, Supro brand) and to increase liquid intake Supro ISP with Isoflavone Diet composition:ND	Replace breakfast with beverage containing 60 g caseinate powder and to increase liquid intake. TotalProtein: 40 g TotalProduct: 60 g Diet composition: ND.	LDL:HDL Total Cholesterol LDL HDL Triglyceride Lpa Apo A1 Apo B/100 SBP DBP	AE:yes AE Report:See dropouts. Drop out: Constipation: 3 soy, 4 control; Nausea/vomiting: 4 soy, 3 control;Lack of compliance: 1 soy, 1 control; switch to HRT because of climacteric symptoms: 1 soy, 3 control;excluded from lipid analysis because of Triglyceride > 11.3 mmol/L Comment: Dropouts because of symptoms. Exclusions because of Tg. After initial randomization, 12 additional women enrolled to make up for drop outs. Note smaller N's in final than baseline. Same study as Albertazzi 1998 9464712 (JL)
Wangen 2000 2 parallel studies (1 post- and 1 pre-menopausal women)	Age (yr):14 pts (peri) 26.5;17 pts (post) 57.1 Male%:0 Country: US Sites:1 BMI:14 pts (peri) 63.4; 17 pts (post) 65.5 Soy1 N: 14	Design:Xover Randomized: Yes Blinding: double Duration:3 mo	premenopausal or postmenopausal women Excluded:strict vegetarian, high fiber, high soy, or low fat diets; regular vitamin and mineral supplementation >Recommended Dietary Allowances; athleticism; cigarette smoking; antibiotic or hormone use within six mo; bleeding within 12 mo; hysterectomy or	1. Isolated soy protein powder ISP with Isoflavone (high) Diet composition: energy 1.21 MJ or 290 kcal, protein 53g, carb 15 g, fat 1.9 g in premenopausal study; energy 1.46 MJ or 349 kcal, protein 63g, carb 21 g, fat 1.9 g in postmenopausal study. 2. Isolated soy protein powder	ISP powder containing 10 + 1.1 isoflavones/d (14 premenopausal) ISP powder containing 7 + 1.1 isoflavones/d (17 postmenopausal subjects) Total Protein: ND Total Product: ND Diet composition: E 1799kcal, protein 111g, carb 242g, fat 46g, fiber 13g	Bone specific alkaline phosphatase Osteocalcin Deoxypyridinoline cross-links IGF-I IGFBP3 Carboxy terminal telopeptide I collagen	AE:ND Drop out: 10/31 had compliance issues; 1 postmenopausal woman was not postmenopausal; 1 postmenopausal used alendronate sodium. Comment: No baseline data given. Same patients as in Duncan 1999 10522983

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	(peri); 17 (post) Soy2 N: 15 (peri); 17 (post) Control N: 14 (peri); 17 (post)		oopherectomy; FSH concentration of less than 25 IU/L; history of chronic disorders, endocrine or gynecological diseases; benign breast disease; regular use of medication known to interfere with study endpoints (including aspirin); less than 90% or more than 120% ideal body weight; weight change >10 lb within the previous year, and inability to abstain from alcololic beverages duing the study.	ISP with Isoflavone (low) Diet composition: E 1755kcal, protein 114g, carb 232g, fat 45g, fiber 13g:			
Wangen 2001	Age (yr):56.9 (SD) 5.8 Male%:0 Country: US Sites:mutiple BMI:25.2 Soy1 N:23 Soy2 N:23 Control N:23	Design:Xover Randomized: Yes Blinding: single Duration: 13wks	Postmenopausal women Excluded:strict vegetarian, high fiber, high soy, or low fat diets; regular vitamin and mineral supplementation >RDA; athleticism; cigarette smoking; antibiotic or hormone use within six mo; bleeding within 12 mo; hysterectomy or oopherectomy; FSH concentration of less than 25 IU/L; history of chronic disorders including endocrine or gynecological diseases; benign breast disease; regular use of medication known to interfere with study endpoints (including aspirin); less than 90% or more than 120% ideal body weight; weight change of more than 10 lb within the	1. Soy protein powders ISP with Isoflavone (high) Diet composition: E:1783Kcal; Protein 114g, carb 233g, total fat 47.7g, SFA 15.1g, PUFA 8.1 g, MUFA 13.9g, Cholesterol 149mg 2. Soy protein powders with ISP with Isoflavone (low) Diet composition: E:1755Kcal; Protein 114g, carb 232g, total fat 45.3g, SFA 14.4g, PUFA 7.7 g, MUFA 13.3g, Cholesterol 155mg	Soy protein powders with very low isoflavones Total Protein: ND Total Product: ND Diet composition: E:1799Kcal; Protein 112g, carb 243g, total fat 45.9g, SFA 14.3g, PUFA 8.1 g, MUFA 13.2g, Cholesterol 154mg	Total Cholesterol:HDL LDL:HDL Total Cholesterol LDL HDL Triglyceride Lpa Apo A1 Apo B/100 T3 T4 TBG TSH Cortisol Sex Hormone Binding Globulin LH FSH Estradiol Estrone Estrone Sulfate Prolactin Testosterone Androstenedione	AE:ND Drop out:4 subjects due to inability to comply with the study protocol, and one for not postmenopausal. Comment: Secondary analysis of Duncan 1999 (9920082, Adam).

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
			previous year, and inability to abstain from alcololic beverages duing the study.			DHEA/DHEAS Insulin	
Washburn 1999	Age (yr):51 (SD 4.8) Male%:0 Country: US Sites:1 BMI: 74.3 Soy1 N:51 Soy2 N:51 Control N:51	Design:Xover Randomized: Yes Blinding: double Duration:6 wks	Perimenopausal women aged 45-55 yr. Menopausal symptoms (at least one hot flush or night sweat daily), not on HRT (or in the past 6 mo) and currently perimenopausal (missing at least 3 menstrual periods in the last 12 mo and having last menstrual period not > 12 mo prior). Excluded: ND	1. Soy.Supplement Daily ISP with Isoflavone 2. Soy.SupplementTwice.Daily ISP with Isoflavone Diet composition:68% Protein, 17% carb, 3% Fat, 0% Sat Fat, 108.3 Kcal.Niacin 0 mg, Folate 59.0 mcg.Calcium 708 mg, Potassium 203.6 mg, Sodium 203.6 mg	20 g complex carb supplement no phytoestrogens. Total Protein: <0.02 g Total Product: 20g Diet composition:94% carb, <1.0 % Protein, <1.0% Fat, 0% Sat Fat, 83.6 Kcal. Vitamin supplement	Total Cholesterol LDL HDL Triglyceride SBP DBP BUN FBS Menopausal symptoms: Hot flash frequency, score Night sweat frequency, score Estrogenic symptom score	Adverse event: 1 dropout for acne rosacea. 9 drop out (5 personal reasons, 1 unrelated illness, 1 concern about aspartame, 1 remembered allergic to soy, 1 recurrence of acne rosacea) Comment:unclear N possibly equal 51 (? if includes dropouts)
Watanabe 2000	Age (yr): Male%:0 Country: Japan Sites:1 BMI: Soy1 N:20 Soy2 N:20 Control N:0(?20)	Design:Unclear Xover Randomized: Unclear Blinding:ND Duration:1 mo	Female students in the nutritional course (pre-menopausal) who provided data for at least 2 menstruation cycles before the experiment Excluded:ND	Soy Isoflavones (without protein) 40mg from Soya hypocotyl tea Diet composition: ND. Soy Isoflavones (without protein) 20mg from Soya hypocotyl tea Diet composition: ND.	No non isoflavone control arm	Total Cholesterol LDL HDL Triglyceride BP (not specified if SBP or DBP), leucine aminopeptidase, total bilirubin Menstrual cycle length 17-b estradiol Progesterone	AE:no Drop out:yes Comment: exclusion criteria not explicitly described;no data on soy protein per day;cross-over design not explicitly described;not explicit description of the design (randomization cannot be excluded). Unclear control arm
Wong 1998 9848504_Hyper	Age (yr):41.4 (SD 7.8) Male%:100 Country: US Sites:1	Design:Xover Randomized: Yes Blinding:No Duration:5wks	Hypercholesterolemic (Total Cholesterol>6.21, Triglyceride<5.65, LDL>4.53) men. HDL>0.91 mmol/L. Age 20-50 y Excluded:Hypertensive or cholesterol-lowering medication, on special diet,	Soy protein diet NCEP Step I. Supro isolated soy protein (Protein Technologies International, St Louis). Usual energy Supro Diet composition:20%	Animal protein diet Protein≥75% of each diet Product:ND Diet composition: 20% protein, 30% fat, 50% carb	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 LDL:HDL	AE:no Drop out: No dropouts Comment: HDL normal Two parallel studies of normo and hyper cholesterolemics. Hyper here; did not quantify

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	BMI:87.1 Soy1 N:13 Control N:13		chromic condition including GI problems and DM.	protein, 30% fat, 50% carb			isoflavone
Wong 1998 9848504_ Normo	Age (yr):35.5 (SD 7.2) Male%:100 Country: US Sites:1 BMI:87.6 Soy1 N:13 Control N:13	Design:Xover Randomized: Yes Blinding:No Duration:5 wks	Normocholesterolemic (Total Cholesterol 3.10-4.91 mmol/L, Triglyceride <1.69, LDL<3.49). HDL>0.91 mmol/L. Age 20-50 y Excluded:Hypertensive or cholesterol-lowering medication, on special diet, chromic condition including GI problems and DM.	Soy protein diet NCEP Step I. Supro isolated soy protein (Protein Technologies International, St Louis). Usual energy Supro Diet composition:20% protein, 30% fat, 50% carb	Animal protein diet Protein≥75% of each diet Product:ND Diet composition: 20% protein, 30% fat, 50% carb	Total Cholesterol LDL HDL Triglyceride Apo A1 Apo B/100 LDL:HDL	AE:no Drop out:No dropouts Comment: 20-50 y. Normal HDL;High fiber in both treatment and control;Two parallel studies of normo and hyper cholesterolemics. Normo here; did not quantify isoflavone
Wu 2000	Age (yr):34.1 (SD 7.4) Male%:0 Country: US Sites:1 BMI:23.1 Soy1 N:20 Control N:0	Design:NRNCT2 Randomized: No CohortMult Blinding:No Duration:3 mo	Premenopausal Excluded:Current or recent pregnancy or lactation, irregular menstrual cycles, oral or hormonal contraceptives or hormones, h/o chronic illness or cancer, smoker, special diets	Soy diet Tofu SoyMilk soybean peas 3 cycle intervention of usual diets supplemented with 3 traditional Asian soy foods (tofu, soymilk, Diet composition: 16.7% protein, 33.0% fat, 51% carb, 236 mg cholesterol	No control arm	Menstrual cycle length Sex Hormone Binding Globulin Estradiol Progesterone	AE:no Drop out:No Comment: 3 different soy sources & no data on consumption levels of 3 soy sources. Ten Asians & ten non-Asians in soy intervention study
Xu 2000	Age (yr):56.9 (SD 5.8) Male%:0 Country: US Sites:1 BMI:25.2 Total enrol:23	Design:Xover Randomized: Yes Blinding: single Duration:93 days	Postmenopausal women Excluded:Athleticism, strict vegetarian, high fiber or high soy or low fat diet, cigarette smoking, regular vitamin/mineral supplementation > RDA, meds incl aspirin, hormones or antibiotics preceding 6 mo, menses preceding 12 mo,	1. Habitual diets supplemented with soy protein powders ISP with Isoflavone (high) 2. Habitual diets supplemented with soy protein powders ISP with Isoflavone (Low) Diet composition: 1779kcal, 113g protein, 236 g carb, 46 g fat, 13g dietary fiber	Habitual diets supplemented with soy protein powders ISP with Isoflavone (Lowest) Diet composition: Total Protein: 63g Total Product:ND Diet composition: 1779kcal, 113g protein, 236 g carb, 46 g fat, 13g dietary fiber	Urinary 2OHE Urinary 16aOHE Equol	AE:no Drop out: 4 WD in 1st diet period for noncompliance, one subject excluded from analyses - not postmenopausal Comment: Data referrred to Duncan 1999; 3 diet periods of 93-days, each separated by 26-day washout periods; subjects

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Soy1 N:18 Soy2 N:18 Control N:18		hysterectomy, and oophorectomy				blinded to intervention
Yamaguchi 2001	Age (yr):17-58 yr Male%:50 Country: Japan Sites:1 BMI:ND Soy1 N:12 Control N:0	Design:NRNCT Randomized: No CohortSing Blinding:No Duration:60 days	adult volunteers with no abnormal liver or kidney function Excluded:intake of foods abundant in Vitamin K	nijiru nijiru powder (byproduct of natto which is fermented soybeans) Diet composition:ND	No control	Total Cholesterol HDL Triglyceride Serum Osteocalcin Urinary calcium BUN Albumin	AE:no Drop out:no Comment:None
Yamashita 1998	Age (yr):40 (SD 9) Male%:0 Country: Australia Sites:1 BMI:32.4 Soy1 N:17 Control N:19	Design:NRNCT Randomized: No Blinding:No Duration:16 wks	premenopausal obese women; BMI >25 kg/m2, age 30-61, absence of DM ane endocrine, hepatic, or renal disease or pharmacotherapy that might affect arterial function or glucose metabolism. Excluded:ND	plant diet plant-white meat diet--soybean was substituted for lean meat with 130g dried soybean. Soybeans offer Soy bean Diet composition:energy 1500 kcal, protein 25E, soy protein 31% total protein, fat 22% total energy, SFA 19% fat, carb 51% total energy, 54 mg cholesterol	lean red meat diet (5d/wk, 2 d fish or non-soy legumes) red meat Protein Product: 150 g Diet composition:energy 1500 kcal, protein 25E, fat 23% total energy, SFA 28% fat, carb 50% total energy, 79 mg cholesterol	Total Cholesterol LDL HDL Triglyceride Lpa MAP Systemic arterial compliance FBS	AE:yes AE:. 1 subject has lengthy infection, Drop out: 6 were unwilling to keep appts and were excluded. Comment:Basically this is a weight-reduction trial designed to find whether SAC improves with weight loss.
Yamori 2002	Age (yr):52.7 3.3 Male%:0 Country: Brazil Sites:1 BMI:59.7 Soy1 N:20	Design:RCT Randomized: Yes Blinding: double Duration:10 wks	healthy postmenopausal Japanese immigrants from Okinawa living in Brazil, aged 45-59 Excluded:none mentioned	isoflavone diet mixture of roasted soybean and sesame Soy bean Diet composition:total protein 1800 mg, lipids 2400 mg, carb 1600 mg	roasted sesame mixture Protein:ND Product:ND Diet composition:ND	Urine deoxypyridinoline Urine pyridinoline Bone stiffness	AE:no Drop out:no Comment: Limited data available on the control

Appendix C. Evidence Tables

Author, Year	Characteristics	Studydesign	Eligibility criteria of the study population	Soy Intervention	Control/Placebo	Outcomes	Adverse event, Dropout, Comments
	Control N:20						
Yildirir 2001	Age (yr):50.1 11.8 Male%:100 Country: Turkey Sites:1 BMI:25.3 Soy1 N:20 Control N:0	Design:NRNCT Randomized: No CohortSing Blinding:No Duration:6 wks	Hypercholesterolemic, non-smoking men with normal BMI. Total Cholesterol > 230 mg/dL, LDL > 160 despite the use of NCEP/AHA Step 1 diet for at least 6 mo. Excluded:Taking cholesterol-lowering medications. Consuming EtOH or special diets. Chronic illnesses including GI problems or DM.	Soy.Protein.Diet 60% of animal Diet composition: proteins of the diet were replaced by soy protein Soy flour, bean, bean sprouts Diet composition:1846 Kcal; Protein 68.5 g; Animal protein 16.4 g, Plant excluding soy protein 32.2 g, Fat 52.3 g, Sat fat 11.5 g, MUFA 21.7 g, PUFA 19.4 g, carb 280 g, Cholesterol 95 mg, Fiber 5.8 g.	Compared to before diet Protein68.2with-12.2 Product Diet composition:1844 Kcal, Protein 68.2 g, Animal protein 30.2 g, Plant protein excluding soy 36.4 g, Fat 51.6 g, Sat fat 20.8 g, MUFA 21.3 g, PUFA 9.4 g, carb 278 g, Cholesterol 160 mg, Fiber 5.6 g	Lpa Apo A1 Apo B/100 Peripheral endothelial function Also Total Cholesterol, HDL, LDL, Triglyceride, Total Cholesterol:HDL, but no control arm	AE:no Drop out: No dropouts Comment: Not controlled

Appendix C. Evidence Table (Part 2)

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Adams 2003	Insulin like growth factor (IGF-I) IGFBP-3 IGF-I/IGFBP-3	1º	ISP with Isoflavone . ISP without isoflavone	74 76	Outcomes tabulated							
Adams 2004	PSA	1º	ISP with Isoflavone ISP without isoflavone	61 51	Outcomes tabulated							
Albert A 2002	Vasomotor Symptoms: Score	1º	Isoflavone	146	82.73±17.14	Other	SD	f/up	36.33±27.71			
Albertazzi 1998	Vasomotor Symptoms: Score and Frequency	1º	Soy	40*	Kupperman Index: 11.4 (Range: 10.7 - 12.7)			ΔΔ	-1.59			
			Control/Pl	39*	Kupperman Index: 10.9 (Range: 10.2 - 11.8)							
					Significantly improved weekly hot flash frequency in both groups (44% reduction with soy, 31% with placebo) at 12 weeks, p<0.01							
Albertazzi 1999 (Same as Albertazzi 1998)	Vaginal cell maturation index Equol	1º	ISP with Isoflavone casein	51 53	Outcomes tabulated							
Alekel 2000	bAP	1º	ISP w/ Isofl ISP w/o Isofl Casein	24 24 21	Data expressed in a scatterplot. Baseline values for bAP were significantly different (p=0.036) among the groups; ISP+ had higher values than control. Treatment per se had no significant effect on bAP (p=0.32).							
	NTx	1º	ISP w/ Isofl ISP w/o Isofl Casein	24 24 21	Data expressed in a scatterplot. Treatment per se had no significant effect on N-Tx (p=0.12).							
Anderson 1998	GFR	1º	Soy diet	8	49±7		SE	ΔΔ	0			NS
			Control/Pl	8	49±6							
Anderson 2002	BMC: Lumbar	1º	Isoflavone	15	58.32±9.17	g	SD	f/up	59.23±9.38	0.11		0.61
			Control/Pl	13	57.73±10.68				58.41±10.83	0.19		
	BMD: Femoral Neck	1º	Isoflavone	15	0.93±0.10	g/cm2	SD	f/up	0.90±0.11	0.01	0.39	
			Control/Pl	13	0.89±0.14				0.88±0.15	0.40		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Arjmandi 2003	bAP	1°	Soy protein	20	0.438±0.032		SE	f/up	0.412±0.032	0.1394		0.7601
			milk-based	22	0.381±0.031				0.348±0.031	0.0493		
	E2	1°	Soy protein	20	51.5±22.4		SE	f/up	66.6±23.1	0.3428	0.8292	
			milk based	22	84.8±21.5				95.0±22.2	0.5135		
	E2 (HRT)	1°	Soy protein	20	93.4±16.8		SE	f/up	116.9±28.1	0.3335		0.3990
			milk based	22	122.84±28.7				158.3±48.38	0.6299		
	E2 (no HRT)	1°	Soy protein	20	35.6±6.4		SE	f/up	61.7±16.9	0.7793		0.9610
			milk based	22	45.9±13.9				93.2±44.4	0.6596		
Ashton E 2000	HDL	1°	Tofu	42	1.25±0.35	mmol/L	SD	ΔF	-0.08 (95% CI: -0.14, -0.02)		0.01	
			Control/Pl	42	x-over							
	LDL	1°	Tofu	42	3.68±0.86	mmol/L	SD	ΔF	0.09 (95% CI: -0.10, 0.27)	<0.05	<0.05	
			Control/Pl	42	3.68±0.86							
	LDL oxidation	1°	Tofu	42	nd		SD	ΔF	+6.77 (95% CI: +2.39, +11.15)		0.01	
			Control/Pl	42	nd							
	Lp(a)	1°	Tofu	42	nd	mg/L	SD	ΔF	-7.78 (95% CI: -35.59, +20.04)		0.30	
			Control/Pl	42	nd							
	TC	1°	Tofu	42	5.79±0.97	mmol/L	SD	ΔF	-0.23 (95% CI: -0.43, -0.02)		0.03	
			Control/Pl	42	x-over							
	Tg	1°	Tofu	42	1.96±1.33	mmol/L	SD	ΔF	-0.15 (95% CI: -0.31, +0.02)		0.02	
			Control/Pl	42	x-over							
Azadbakht 2003	HDL	1°	Soy protein	14	46.5±12.8	mg/dL	SD	ΔΔ	2±8.5			NS
			Control/Pl	14	45.8±12.2							
	LDL	1°	Soy protein	14	145±6.3	mg/dL	SD	Δ	-6.3±9.3			
			Control/Pl	14	144.2±6.7				2.07±5.8			
	TC	1°	Soy protein	14	201.4±45.2	mg/dL	SD	ΔΔ	-16.2±20.1			<0.01
			Control/Pl	14	197.0±47.2							
	Tg	1°	Soy protein	14	242.5±60.0	mg/dL	SD	ΔΔ	-13.1±12.9			<0.002
			Control/Pl	14	240.5±61.6							
Baird DD 1995	FSH	1°	Soy	66	61.1±22.1	Other	SD	f/up	58.4±21.2			
			Control/Pl	25	63.4±24.5				61.6±25.8			
Bakhit R 1994	HDL	1°	Soy Protein	21	1.33±0.19	mmol/L	SD	f/up	1.30±0.11	NS		NS

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Soy Protein	21					1.30±0.18	NS		
			Casein + S	21					1.28±0.16	NS		
			Control/Pl	21					1.31±0.20	NS		
	HDL: TC > 220 mg/dL		ISP + cell	11	1.38±0.26	mmol/L	SD	f/up	1.30±0.13	NS		NS
			ISP + SCF	11					1.30±0.22	NS		
			Casein + S	11					1.31±0.20	NS		
			Control/Pl	11					1.38±0.23	NS		
	LDL	1º	Soy Protein	21	4.08±0.62	mmol/L	SD	f/up	4.01±0.54	NS		NS
			Soy Protein	21					4.07±0.46	NS		
			Casein + S	21					4.03±0.55	NS		
			Control/Pl	21					4.21±0.70	NS		
	LDL: TC > 220 mg/dL		ISP + cell	11	4.37±0.66	mmol/L	SD	f/up	4.14±0.63	NS		0.07
			ISP +SCF	11					4.09±0.56	NS		
			Casein + S	11					4.11±0.64	NS		
			Control/Pl	11					4.35±0.76	NS		
	TC	1º	Soy Protein	21	5.74±0.64	mmol/L	SD	f/up	5.63±0.48	NS		NS
			Soy Protein	21					5.73±0.46	NS		
			Casein + S	21					5.70±0.48	NS		
			Control/Pl	21					5.84±0.65	NS		
	TC: TC(base) > 220 mg/dL		ISP + cell	11	6.20±0.45	mmol/L	SD	f/up	5.79±0.53	<0.05		0.04
			ISP + SCF	11					5.72±0.54	<0.05		
			Casein + S	11					5.83±0.60	NS		
			Control/Pl	11					6.03±0.71	NS		
	Tg	1º	Soy Protein	21	1.72±0.99	mmol/L	SD	f/up	1.48±0.51	NS		NS
			Soy Protein	21					1.68±0.76	NS		
			Casein + S	21					1.57±0.82	NS		
			Control/Pl	21					1.57±0.66	NS		
	Tg: TC >220 mg/dL		ISP + cell	11	1.98±1.27	mmol/L	SD	f/up	1.43±0.51	<0.05		NS
			ISP + SCF	11					1.80±0.93	NS		
			Casein + S	11					1.74±0.89	NS		
			Control/Pl	11					1.65±0.74	NS		
Balk JL 2002	Vasomotor Symptoms: per wk	1º	Soy	7	1.31			f/up	.857	.059		
			Control/Pl	12	1.28				.50	.014		
Baum JA; 1998	HDL	1º	ISP56	23	1.34±0.27	mmol/L	SD	ΔΔ	0.12			0.01
			ISP90	21	1.38±0.32				0.1			0.03
			Control/Pl	22	1.38±0.31							
	TC	1º	ISP56	23	6.57±0.85	mmol/L	SD	f/up	6.18±0.91			NS

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			ISP90	21	6.47±0.88				6.13±0.91			NS
			Control/Pl	22	6.26±0.67				6.08±0.72			
	Tg	1º	ISP56	23	1.89±1.02	mmol/L	SD	f/up	1.73±0.99			NS
			ISP90	21	1.74±0.75				1.74±0.96			-
			Control/Pl	22	1.75±1.11				1.76±1.28			
Bazzoli 2002	plasma lipid peroxides	1º	ISP w/ Isofl	9	3.9±0.6	μM	SD	f/up	2.9 ±0.3			<0.05
			Whey	9	3.0±0.4	μM	SD	f/up	2.8±0.3			
	urinary 8-hydroxyl-2-deoxyguanosine and total antioxidant status	1º	ISP w/ Isofl	9	Outcome tabulated							
			Whey	9								
Blum A 2003	BA.endo.fxn_Flow .hyp	1º	ISP w/ Isofl	24			SD	f/up	76±40		0.65	
			Control/Pl	24					81±44			
	HDL	2º	ISP w/ Isofl	24	1.56±0.46	mmol/L	SD	f/up	1.53±0.33	0.53	NS	
			Control/Pl	24	x-over				1.60±0.39			
	LDL	2º	ISP w/ Isofl	24	4.62±0.74	mmol/L	SD	f/up	3.70±0.77	0.0001	0.72	
			Control/Pl	24	x-over				3.57±0.74			
	TC	2º	ISP w/ Isofl	24	7.00±0.82	mmol/L	SD	f/up	6.23±0.93	0.0001	0.97	
			Control/Pl	24	x-over				6.18±0.85			
	Tg	2º	ISP w/ Isofl	24	1.50±0.56	mmol/L	SD	f/up	2.18±0.86	0.04	P=0.70	
			Control/Pl	24	x-over				2.20±1.34			
Bricarello 2004	HDL	1º	Soy Milk	60	58±2	mg/dL	SE	f/up	62	<0.05		<0.05
			Control/Pl	60	x-over				57			
	LDL	1º	Soy Milk	60	157±4	mg/dL	SE	f/up	148	<0.05		<0.05
			Control/Pl	60	x-over				158			
	TBARs	2º	Soy Milk	60	1.82±0.12	?	SE	f/up	1.49±0.09			<0.05
			Control/Pl	60	x-over				1.91±0.11			
	TC	1º	Soy Milk	60	241±5	mg/dL	SE	f/up	237	NS		NS
			Control/Pl	60	x-over				241			
	Tg	1º	Soy Milk	60	136±9	mg/dL	SE	f/up	133	NS		NS
			Control/Pl	60	x-over				135			
Brooks J 2004	E2	1º	Soy	13	10.60±1.00	Other	SE	f/up	20.27±9.92			
			Control/Pl	15	20.11±3.55				15.14±2.11			
Brown BD 2002	Menstrual Cycle Length	1º	Soy diet	13		Other		f/up	31±0.7			
			Control/Pl	14					29.2±0.7			
Bruce B; 2003	TSH	1º	Soy	21	3.00±0.44	Other	SE	f/up	3.49±0.52			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Burke GL 2003	Vasomotor Symptoms: per wk	1º	Med Isofla	76	2.6±0.31	Other	SE	f/up	1.5±0.29	<0.0001		
			High Isofl	65	3.2±0.38				1.3±0.28	<0.0001		
			Control/Pl	70	3.5±0.38				0.8±0.20	<0.0001		
Burke V; 2001	DBP	1º	High (Soy)	9	74.1 (95% CI: 66.7, 81.4)	mm Hg		ΔΔ	-2.6 (95% CI: (-4.2, -1.0))			0.006
			High (Soy)	9	76.8 (95% CI: 69.3, 84.3)							
			Low protein	9	78.1 (95% CI: 69.4, 86.9)							
			Control/Pl	9	74.6 (95% CI: 67.8, 81.5)							
	SBP	1º	High (Soy)	9	135.0 (95% CI: 120.0, 150.0)	mm Hg		ΔΔ	-5.9 (95% CI: (-8.0, -3.8))			0.001
			High (Soy)	9	133.7 (95% CI: 123.7, 143.4)							
			Low protein	9	131.6 (95% CI: 121.0, 142.2)							
			Control/Pl	9	131.8 (95% CI: 122.6, 141.0)							
Carroll 1978	TC	1º	Cross 1	5	161(graph)	mg/dL	SE	f/up	161±4		<0.05	
			Cross 2	5	164 (graph)				161±3			
			Calculated	10	163 (mean of 1 and 2)				161 (mean of 1&2)			
			Control/Pl	(5,					(175, 166) 170±(5, 3)			
Cassidy 1994	E2	1º	Soy diet	6			SD	f/up	362.5±82.0			
			Control/Pl	6*	246.2±38.4							
	FSH	1º	Soy diet	6		Other	SD	f/up	7.8±4.6			
			Control/Pl	6*	14.6±5.6							
Cassidy 1995	FSH	1º	45 mg conj	6					7.2±0.9	not significant	not significant	
			Isoflavone	5					4.6±0.6		not significant	
			23 mg conj	6					4.2±0.1		not significant	
			Control/Pl	6					8.7±0.8	ns		
			Control/Pl	5					4.6±0.2			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Cassidy 1995	E2	1º	Isoflavone	6	81.7				*-11*	not significant		
			Isoflavone	5	114.4				*-30*	not significant		
Chen YM; 2003, 2004	BMD: Femoral Neck	1º	40 mg Isof	57		g/cm2	SD	Δ	-0.47±2.14			
			80mg Isofl	50					0.14±2.19			
			Control/Pl	53					0.04±2.86			
	BMD: Hip	1º	40 mg Isof	57		g/cm2	SD	Δ	-0.48±1.81			
			80mg Isofl	50					-0.21±1.62			
			Control/Pl	53					-0.51±1.82			
	BMD: Lumbar	1º	40 mg Isof	57		g/cm2	SD	Δ	-0.47±2.60			
			80mg Isofl	50					-0.89±1.88			
			Control/Pl	53					-0.63±2.56			
Chiechi 2002	DBP		Diet group	24	81.3±8.7	mm Hg	SD	Δ	0.2 (95% CI: -5.3/5.76)	ns		
			HRT	41	80.2±8.2				-1.07 (95% CI: -4.45/2.3)	ns		
			Control/Pl	43	81.4±9.0				2.8 (95% CI: -1.51/7.23)	ns		
	HDL		Diet group	24	52.01±11.6	mg/dL	SD	Δ	-1.8 (95% CI: -4.69/0.94)			
			HRT group	41	51.9±11.3				-5.5 (95% CI: -7.59/-3.45)	<0.05		
			Control/Pl	43	54.7±11.7				-3.6 (95% CI: -5.51/-1.83)			
	LDL		Diet group	24	159.3±34.5	mg/dL	SD	Δ	-6.1 (95% CI: -17.11/4.76)	ns		
			HRT group	41	156.8±31.7				-12.0 (95% CI: -21.67/-2.37)	<0.05		
			Control/Pl	43	145.02±26.9				0.3 (95% CI: -5.39/6.1)	ns		
	NTx	1º	Soy diet	24	29.5±31.3		SD	Δ	4.92 (95% CI: -20.1, 29.9)			
			HRT	41	40.6±64.4				-10.1 (95% CI: -23, 2.7)			
			Control/Pl	43	29.9±40.7				1.34 (95% CI: -17.6, 20.3)			
	SBP		Diet group	24	131.8±14.3	mm Hg	SD	Δ	-3.4 (95% CI: -11.9/5.11)	NS		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			HRT group	41	130±13.5				-9.7 (95% CI: -14.8/-4.71)	<0.05		
			Control/Pl	43	129.5±14.8				-3.1 (95% CI: -10.06/3.7)	NS		
	Serum Osteocalcin	1º	Soy diet	24	21.9±44.3		SD	Δ	5.45	<0.05		0.13
			HRT	41	14.5±11.3				-1.10	NS		
			Control/Pl	43	15.5±10.5				1.7	NS		
	TC		diet group	24	235.5±38.7	mg/dL	SD	Δ	-8.6 (95% CI: -20.98/3.65)	ns		
			HRT group	41	233.8±36.5				-15.1 (95% CI: -23.37/-6.94)	<0.05		
			Control/Pl	43	220.08±31.5				-2.6 (95% CI: -8.65/3.35)	ns		
	Tg		Diet group	24	119.7±65.4	mg/dL	SD	Δ	-3.3 (95% CI: -22.7/15.4)	ns		
			HRT group	41	124.6±56.1				-7.02 (95% CI: -20.64/6.59)	ns		
			Control/Pl	43	99.5±49.8				3.6 (95% CI: -3.31/10.6)	ns		
Chiechi 2002 12191852												
Chiechi 2003	E2	1º	Soy diet	22	10.1±18.8	Other	SD	f/up	6.2±18.8			
			Control/Pl	41	13.6±16.3				15.7±22.6			
	FSH	1º	Soy diet	22	60.9±21.6	Other	SD	f/up	61.8±18.8			
			Control/Pl	41	59.1±27.6				58.4±26.1			
Crisafulli 2004	Vasomotor Symptoms: Score	1º	Genistein	30*	4.6±0.58	no unit	SE	error				
			Control/Pl	30*	4.7±0.58							
Crouse J 1999	HDL: LDL 140-166 mg/dL	1º	3mg Isofla	16	1.24±0.31	mmol/L	SD	f/up	1.24±0.31	NS		
			27mg Isofl	12	1.14±0.34				1.14±0.28	NS		
			37mg Isofl	18	1.09±0.18				1.19±0.18	NS		
			62mg Isofl	15	1.22±0.26				1.27±0.28	<0.04 FOR TRE		
			Control/Pl	15	1.06±0.21				1.06±0.21			
	HDL: LDL 140-200 mg/dL	1o	3 mg Isofl	28	1.19±0.28	mmol/L	SD	f/up	1.19±0.28	NS		
			27 mg Isof	27	1.16±0.26				1.16±0.23	NS		
			37 mg Isof	30	1.16±0.23				1.19±0.21	NS		
			62 mg Isof	30	1.19±0.23				1.22±0.28	NS		
			Control/Pl	31	1.16±0.23				1.14±0.23			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	HDL: LDL 166-200 mg/dL	1º	3mg Isofla	12	1.16±0.23	mmol/L	SD	f/up	1.11±0.18	NS		
			27mg Isofl	15	1.16±0.18				1.22±0.21	NS		
			37mg Isofl	12	1.24±0.18				1.19±0.28	NS		
			62mg Isofl	15	1.19±0.21				1.16±0.26	NS		
			Control/Pl	16	1.24±0.23				1.19±0.23			
	LDL: : LDL 140-166 mg/dL	1º	3mg Isofla	16	3.83±0.23	mmol/L	SD	f/up	3.85±0.52	NS		
			27mg Isofl	12	3.88±0.23				3.98±0.57	NS		
			37mg Isofl	18	3.77±0.23				3.88±0.36	NS		
			62mg Isofl	15	3.80±0.23				3.83±0.31	NS		
			Control/Pl	15	3.77±0.21				3.85±0.41			
	LDL: LDL 140-200 mg/dL		3 mg Isofl	28	4.24±0.59	mmol/L	SD	f/up	4.14±0.57	NS		
			27 mg Isof	27	4.40±0.62				4.27±0.65	NS		
			37 mg Isof	30	4.16±0.59				4.03±0.49	NS		
			62 mg Isof	30	4.29±0.65				4.03±0.44	<0.05 VS CASEIN		
			Control/Pl	31	4.27±0.54				4.27±0.59			
	LDL: LDL 166-200 mg/dL	1º	3 mg Isofl	12	4.78±0.47	mmol/L	SD	f/up	4.53±0.44	NS		
			27 mg Isof	15	4.81±0.52				4.50±0.62	NS		
			37 mg Isof	12	4.71±0.49				4.27±0.57	<0.03 VS CONTROL		
			62 mg Isof	15	4.78±0.54				4.22±0.47	<0.03 VS CONTROL		
			Control/Pl	16	4.71±0.31				4.65±0.47			
	TC: LDL 140-166 mg/dL	1º	3mg Isofla	16	5.77±0.44	mmol/L	SD	f/up	5.79±0.52			NS
			27mg Isofl	12	5.92±0.49				5.87±0.67			NS
			37mg Isofl	18	5.66±0.49				5.82±0.44			NS
			62mg Isofl	15	5.84±0.39				5.95±0.47			NS
			Control/Pl	15	5.72±0.31				5.74±0.52			
	TC: LDL 140-200 mg/dL	1º	3 mg Isofl	28	6.18±0.70	mmol/L	SD	f/up	6.10±0.65			NS
			27 mg Isof	27	6.41±0.75				6.21±0.78			NS
			37 mg Isof	30	6.08±0.70				5.97±0.57			NS
			62 mg Isof	30	6.28±0.67				6.03±0.52			<0.05 vs con

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Control/Pl	31	6.21±0.62				6.23±0.70			
	TC: LDL 166-200 mg/dL	1º	3 mg Isofl	12	6.75±0.57	mmol/L	SD	f/up	6.52±0.54			NS
			27mg Isofl	15	6.83±0.70				6.47±0.80			NS
			37 mg Isof	12	6.72±0.41				6.21±0.65			<0.03 VS CON
			62 mg Isof	15	6.75±0.59				6.13±0.54			<0.03 VS CON
			Control/Pl	16	6.67±0.41				6.67±0.54			
	Tg: LDL 140-166 mg/dL	1º	3mg Isofla	16	1.54±0.72	g/L = mg/mL	SD	f/up	1.56±0.64	NS		
			27mg Isofl	12	1.93±0.56				1.85±0.80	NS		
			37mg Isofl	18	1.70±0.68				1.63±0.63	NS		
			62mg Isofl	15	1.82±0.59				1.87±0.81	NS		
			Control/Pl	16	1.87±0.78				1.84±0.76			
	Tg: LDL 140-200 mg/dL	1º	3 mg Isofl	28	1.63±0.68	g/L = mg/mL	SD	f/up	1.72±0.65	NS		
			27 mg Isof	27	1.87±0.71				1.74±0.79	NS		
			37 mg Isof	30	1.69±0.62				1.64±0.63	NS		
			62 mg Isof	30	1.73±0.67				1.72±0.75	NS		
			Control/Pl	31	1.73±0.70				1.89±0.84			
	Tg: LDL 166-200 mg/dL	1º	3 mg Isofl	12	1.76±0.63	g/L = mg/mL	SD	f/up	1.93±0.64	NS		
			27 mg Isof	15	1.83±0.81				1.65±0.80	<0.03 VS CONTROL		
			37mg Isofl	12	1.66±0.54				1.64±0.67	NS		
			62mg Isofl	15	1.65±0.75				1.57±0.65	<0.03 VS CONTROL		
			Control/Pl	16	1.59±0.60				1.93±0.91			
Cuevas A 2003	DBP		Soy protein	ND	73±2	mm Hg	SE	f/up	70±3	NS	NS	
			Control/Pl	ND	73±2				69±3	NS		
	FMD (RH)		Soy protein	18	5.3±1.2	%	SE	f/up	9.4±1.8	<0.03	<0.05	
			Control/Pl	18	5.3±1.2				4.9±1.5	NS		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	FSH		Soy protein	18	56.5±5.8	Other	SE	f/up	58.6±6.6	NS	NS	
			Control/Pl	18	56.5±5.8				60.4±6.3	NS		
	HDL		Soy protein	ND	53.8±2.5	mg/dL	SE	f/up	53±1.9	NS	NS	
			Control/Pl	ND	53.8±2.5				50.8±1.9	<0.05		
	LDL	1º	Soy protein	ND	194.8±6.0	mg/dL	SE	f/up	160±6.8	<0.05	NS	
			Control/Pl	ND	194.8±6.0				160.8±8.0	<0.05		
	SBP		Soy protein	ND	132±4	mm Hg	SE	f/up	127±5	NS	NS	
			Control/Pl	ND	132±4				127±5	NS		
	TC		Soy protein	18	285.9±6.8	mg/dL	SE	f/up	240.5±7.5	<0.05	NS	
			Control/Pl	18	285.9±6.8				243.7±9.6	<0.05		
	Tg		Soy protein	ND	190.3±18.7	mg/dL	SE	Δ	-54.7	<0.05	NS	
			Control/Pl	ND	190.3±18.7				-30.1	NS		
D'Amico 1992	DBP	2º	Soy diet	20	87±8	mm Hg	SD	f/up	87±10	NS		
	SBP	2º	Soy diet	20	143±20	mm Hg	SD	f/up	141±21	NS		
Dalais 1998	Vasomotor symptoms	1º	Soy bread Wheat bread	44	No statistically significant decrease in hot flush rate was detected during soy ingestion. Women consuming soy showed a statistically significant increase of 103% in vaginal cytology maturation index pattern compared to baseline (p=0.03)							
Dalais 2003	D-pyr	1º	ISP w/ Isofla	37	15.29	nmol/umol		Δ	-0.8		NS	
			Wheat protein	40	14.47	creatinine			-0.3			
	Pyr	1º	ISP w/ Isofla	37	7.07	nmol/umol		Δ	-0.38		NS	
			Wheat protein	40	7.35	creatinine			-0.08			
Davis 2001	NF-kB 5-OhmdU	1º	Soy isoflavone No control	Outcomes tabulated								
Dent SB 2001	HDL		SPI+	24	1.51	mmol/L		f/up	1.39			
			SPI-	24	1.45				1.42			
			Control/Pl	21	1.48				1.42			
	LDL		SPI+	24	3.28	mmol/L	SE	f/up	3.43			
			SPI-	24	3.49				3.51			
			Control/Pl	21	3.47				3.51			
	Lp(a)		SPI+	24	18.75	nmol/L		f/up	18.75			
			SPI-	24	18.75				18.75			
			Control/Pl	21	26.25				48.75			
	TC		SPI+	24	5.42	mmol/L	SE	f/up	5.42			
			SPI-	24	5.63				5.48			
			Control/Pl	21	5.49				5.48			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	Tg		SPI+	24	1.062	mmol/L	Unclear SD/SE	f/up	1.186			
			SPI-	24	1.124				1.062			
			Control/Pl	21	0.812				1.31			
Dewell A 2002	HDL	1°	Isoflavone	20	1.2±0.1	mmol/L	SE	f/up	1.0±0.1			NS
			Control/Pl	16	1.2±0.1				1.0±0.1			
	TC	1°	Isoflavone	18	6.8±0.2	mmol/L	SE	f/up	6.4±0.2			NS
			Control/Pl	16	6.3±0.5				6.0±0.2			
	Tg	1°	Isoflavone	17	0.8±0.1	mmol/L	SE	f/up	0.9±0.1			NS
			Control/Pl	16	1.3±0.2				1.4±0.2			
Djuric 2001	5-OHmdU levels	1°	SPI+	12	Outcomes tabulated							
Duncan A 1999	E2	1°	low Isofla	18	35.6±3.1		SE	f/up	34.7±2.4	ns		
			high Isofl	18	35.6±3.1				29.7±2.3	P=0.04		
	FSH	1°	low Isofla	18	56.2±1.13		SE	f/up	52.6±0.70	0.01	<0.05	
			low-Isofla	14					4.24±0.8		not significant	
			high Isofl	18	56.2±1.13				54.2±0.67	ns	ns	
			high-Isofl	14					4.15±0.8		not significant	
			Control/Pl	18	56.2±1.13				52.6±0.67	ns		
	Testosterone	1°	low Isofla	18	0.94±0.04	nmol/L	SE	f/up	0.90±0.02	ns		
			high-Isofl	18	0.94±0.04				0.83±0.02	ns		
	TSH	1°	low Isofla	18	3.48±0.15		SE	f/up	3.33±0.14	ns	ns	
			low Isofla	14					1.52±0.3		not significant	
			high Isofl	18	3.48±0.15				3.49±0.13	ns	ns	
			high Isofl	14					1.41±0.3		not significant	
			Control/Pl	18	3.48±0.15				3.25±0.13	ns		
			Control/Pl	14					1.44±0.3			
Duffy 2003	Cognitive function	1°	Isoflavones	18	Soy isoflavones group showed significantly greater improvement in delay recall of pictures, in immediate story recall							

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	tests		Lactose	15	tests, and in PASAT. Groups did not differ in any other cognitive function tests.							
Faure ED 2002	Vasomotor Symptoms: per wk	1º	Isoflavone	38	10.1±6.4		SE	Δ	-6.4±1.0			
			Control/Pl	35	9.4±3.4				-2.2±1.2			
File 2001	Memory Tests	1º	High soya Low soya	27	High soy diet showed significant improvements in short-term (immediate recall of prose and 4 sec delayed matching to sample of patterns) and long-term memory (picture recall after 20 min) and in mental flexibility (rule shifting and reversal). In a letter fluency test and in a test of planning (Stockings of Cambridge), the high soy diet improved performance only in females. There was no effect of diet on tests of attention or in a category generation task.							
Foth D;N 2003	E2	1º	Soy	16	32.30±11.69	Other	SD	f/up	27.40±13.23			
	FSH	1º	Soy	16	70.94±39.23	Other	SD	f/up	72.47±30.38			
Gallagher 2004	HDL	2º	SPI 96	17	55.0±3.1	mg/L	SE	f/up	52.9±3.5	<0.05		
			SPI 52	19	56.9±3.0				51.7±2.6	<0.05		
			SPI 4	14	55.8±2.8				51.9±2.2	<0.05		
	LDL	2º	SPI 96	17	137.9±7.6	mg/dL	SE	f/up	140.9±7.1	NS		
			SPI 52	19	135.5±7.4				138.2±6.7	NS		
			SPI 4	14	134.5±13.5				133.8±13.8	NS		
	TC	2º	SPI 96	17	220.6±8.3	mg/dL	SE	f/up	223.3±7.5	NS		
			SPI 52	19	219.5±7.7 (per author by email)				218.3±6.9	NS		
			SPI 4	14	212.5±13.6				212.4±14.5	NS		
	Tg	2º	SPI 96	17	137.7±19.5	mg/dL	SE	f/up	147.3±14.7	NS		
			SPI 52	19	135.3±16.4				141.7±14.6	NS		
			SPI 4	14	109.9±11				133.4±15.6	NS		
Gardner 2001	HDL	1º	Soy-Isofla	33	1.4±0.3	mmol/L	SD	f/up	1.5±0.2			NS
			Soy+Isofla	31	1.5±0.3				1.6±0.3			NS
			Control/Pl	30	1.5±0.4				1.5±0.4			
	LDL	1º	Soy-Isofla	33	3.9±0.6	mmol/L	SD	Δ	-0.09			NS
			Soy+Isofla	31	3.9±0.6				-0.38			NS
			Control/Pl	30	4.0±0.5				ND			
	TC	1º	Soy-Isofla	33	5.9±0.7	mmol/L	SD	Δ	-0.02			NS
			Soy+Isofla	31	5.9±0.6				-0.27			NS
			Control/Pl	30	6.1±0.6				ND			
	Tg	1º	Soy-Isofla	33	1.3±0.5	mmol/L	SD	f/up	1.3±0.6			NS
			Soy+Isofla	31	1.3±0.8				1.3±0.7			NS
			Control/Pl	30	1.3±0.7				1.4±1.0			
Gardner-Thorpe 2003	E2	1º	Soya flour	19	102.80 (95% CI: 93.07-113.55)		SD	ΔF	0.05 (95% CI: -1.07, 1.16)	0.47		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	HDL	1º	Soya flour	19	1.00 (IQR: 0.90-1.18)	mmol/L	SD	ΔF	0.00 (IQR: -0.10,0.00)		0.25	
			Control/Pl	ND*								
	LDL	1º	Soya flour	19	3.60 (IQR: 3.30-4.70)	mmol/L	SD	ΔF	0.15 (IQR: -0.15,0.40)		0.39	
			Control/Pl	ND*								
	TC	1º	Soya flour	19	5.5 (IQR: 4.70-6.83)	mmol/L	SD	ΔF	0.00 (IQR: -0.15,0.35)		0.37	
			Control/Pl	ND								
	Testosterone	1º	Soya flour	19	19.30 (95% CI: 16.98-21.93)	nmol/L	SD	ΔF	1.06 (95% CI: 1.01, 1.12)		0.03	
	Tg	1º	Soya flour	19	1.20 (IQR: 1.00-2.90)	mmol/L	SD	ΔF	0.00 (IQR: -0.30,0.45)		0.82	
			Control/Pl	ND*								
	Hydroperoxides	1º	Soya flour	19	2.69	µmol /L		ΔF%	*-13%*			0.009
			Control/Pl	ND*					*-4%*			
	Lag time	1º	Soya flour	19	59	min		ΔF%	*+2%*			NS
			Control/Pl	ND*					*+2%*			
Gentile 1993	DBP	2º	Soy diet	20	89.2±1.9	mm Hg	SE	f/up	87.4±2.2	NS		
	SBP	2º	Soy diet	20	141.1±4.8	mm Hg	SE	f/up	142.4±4.6	NS		
Goldberg 1982	HDL	1º	Soy diet	12	45±10	mg/dL	SD	f/up	44±11	NS	NS	
			Control/Pl	12	same				45±10	NS		
	LDL	1º	Soy diet	12	191±19	mg/dL	SD	f/up	158±27	<0.0001	<0.05	
			Control/Pl	12	same				168±21	<0.001		
	TC	1º	Soy diet	12	260±23	mg/dL	SD	f/up	220±21	<0.0001	<0.05	
			Control/Pl	12	same				228±21	<0.0001		
	Tg	1º	Soy diet	12	116±45	mg/dL	SD	f/up	104±34	NS	NS	
			Control/Pl	12	Same				103±39	<0.025		
Habito 2000	Estradiol	1º	Soy diet	42				ΔF	0.1 (-0.6, 0.8)			NS
			Lean meat diet	42								
	Testosterone	1º	Soy diet	42				ΔF	4.6 (-3.0,12.2)			NS
			Lean meat diet	42								
Ham 1993	TSH	1º	Soy flour	17	1.8	mIU/L		f/up	*-0.6*	NS		nd
			ISP w/Isoflavones + cotyledon		1.8	mIU/L		f/up	*-0.6*	NS		nd
			ISP w/Isoflavones + cellulose		1.8	mIU/L		f/up	*-0.7*	NS		nd
			Casein+cellulose		1.8	mIU/L		f/up	*-0.3*	NS		
Han KK 2002	DBP	1º	Isoflavone	40	84±1		SE	f/up	85±1	NS		NS
			Placebo	40	84±2				84±1	NS		
	E2	1º	Isoflavone	40	9±1.2		SE	f/up	19±2.2	<0.001		<0.001

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Placebo	40	9.6±0.5				10.9±0.6	NS		
	Fasting Blood Glucose	1°	Isoflavone	40	95.6±1.5		SE	f/up	97.4±1.4	NS		NS
			Placebo	40	96.8±1.7				93.9±1.4	NS		
	FSH	1°	Isoflavone	40	90.3±3.3		SE	f/up	67±3.2	<0.01		NS
			Placebo	40	84.3±0.5				65.4±3.7	<0.01		
	HDL	1°	Isoflavone	40	40.2±1.4	mg/dL	SE	f/up	44.3±1.6	<0.005		NS
			Placebo	40	40±1.3				43.9±1.6	<0.005		
	LDL	1°	Isoflavone	40	133.6±5.3	mg/dL	SE	f/up	120.3±4.3	<0.001		<0.001
			Placebo	40	133.5±6.4				139±5.2	NS		
	SBP	1°	Isoflavone	40	131±2			f/up	131±1	NS		NS
			Placebo	40	133±3				133±2	NS		
	TC	1°	Isoflavone	40	225.6±6.2	mg/dL	SE	f/up	199±5	<0.001		<0.001
			Placebo	40	226.6±7.7				226.8±8.1	NS		
	Tg	1°	Isoflavone	40	204.3±23.3	mg/dL	SE	f/up	210.8±15.8	<0.05		NS
			Placebo	40	175.8±23.3				186.1±6.2	<0.05		
Hargreaves 2005	Breast cell epithelial proliferation	1°	ISP w/Isoflav	28	Outcomes tablulated							
			Control	56								
Hermansen 2001	DBP	1°	Soy	20	78±5	mm Hg	SD	f/up	77±7			NS
			Control/Pl	20	78±6				77±6			
	HDL	1°	Soy	20	1.31±0.22	mmol/L	SD	ΔΔ	0%		p=0.20	NS
			Control/Pl	20	1.28±0.29							
	Homocysteine	1°	Soy	20	11.2±3.9	mmol/L	SD	ΔΔ	-14%		0.004	0.006
			Control/Pl	20	10.6±2.6							
	LDL	1°	Soy	20	3.63±0.78	mmol/L	SD	ΔΔ	-10%		0.0044	0.048
			Control/Pl	20	3.64±0.80							
	Lp(a)	1°	Soy	20	29.5±29.9		SD	ΔΔ	+8%		NS	NS
			Control/Pl	20	32.3±37.5							
	SBP	1°	Soy	20	130±9		SD	f/up	130±10	NS		NS
			Control/Pl	20	130±9				129±10	NS		
	TC	1°	Soy	20	5.68±0.84	mmol/L	SD	f/up	5.11±0.78		p=0.0041	
			Control/Pl	20	5.59±0.81				5.45±0.88			
	Tg	1°	Soy	20	1.70±1.17	mmol/L	SD	ΔΔ	-22%		NS	0.04
			Control/Pl	20	1.70±1.49							
Hill S 2004	Lipid Peroxides	1°	ISP	9*	~5.2		SE	error				
			Control/Pl	9*	~4.8							

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Hsu CS;S 2001	E2	1º	Isoflavone	37	9.6±7.7		SD	f/up	21.4±22.6	sig		
Huff MW; 1984	Fasting Blood Glucose	2º	Soy	5*	ND	mg/dL	SE	f/up	76±8		NS	
			Control/Pl	5*	ND			f/up	86±10			
Jayagopal 2002	DBP	1º	Soy	29	81.5±8.78	mm Hg	SD	Δ	-0.41%±10.4%		0.991	
			Control/Pl	29	82.6±7.8				-0.23%±8.83%			
	FSH	2º	Soy	32	48.7±18.7		SD	Δ	-5.23%±16.8%		0.443	
			Control/Pl	32	49.2±18.6				-2.29%±13.1%			
	HDL	1º	Soy	31	1.32±0.33	mmol/L	SD	Δ	+0.69%±10.1%		0.787	
			Control/Pl	31	1.30±0.30				+1.29%±8.78%			
	LDL	1º	Soy	31	3.63±0.91	mmol/L	SD	Δ	-7.09%±12.7%		0.001	
			Control/Pl	31	3.47±1.06				+5.35%±15.2%			
	SBP	1º	Soy	29	146.9±18.8		SD	Δ	-0.76%±9.63%		0.325	
			Control/Pl	29	147.2±15.2				+1.65%±7.46%			
	TC	1º	Soy	31	5.78±1.02	mmol/L	SD	Δ	-4.07%±8.13%		0.004	
			Control/Pl	31	5.62±1.05				+2.82%±8.70%			
	TSH	2º	Soy	32	2.15±1.08		SD	Δ	+9.23%±36.4%		0.739	
			Control/Pl	32	2.18±1.08				+9.48%±46.1%			
Jenkins 1999	DBP	1º	Soy	31	79±2	mm Hg	SE	ΔΔ	2.1%±1.9%			0.277
			Control/Pl	31	80±2							
	HDL	1º	Soy	31	1.26±0.06	mmol/L	SE	ΔΔ	-0.2%±1.6%			0.915
			Control/Pl	31	1.24±0.06							
	LDL	1º	Soy	31	4.40±0.15	mmol/L	SE	ΔΔ	-6.7%±1.7%			<0.001
			Control/Pl	31	4.37±0.15							
	Lp(a)	1º	Soy	31	31.8±4.7	mg/L	SE	ΔΔ	7.2%±5.2%			0.179
			Control/Pl	31	28.8±4.2							
	SBP	1º	Soy	31	120±3	mm Hg	SE	ΔΔ	1.3%±2.2%			0.548
			Control/Pl	31	120±3							
	TBARS	1º	Soy	31	6.08±0.21	?	SE	ΔΔ	-2.6%±3.3%			0.442
			Control/Pl	31	6.35±0.17							
	TC	1º	Soy	31	6.48±0.16	mmol/L	SE	ΔΔ	-6.2%±1.2%			<0.001
			Control/Pl	31	6.42±0.17							
	Tg	1º	Soy	31	1.79±0.13	mmol/L	SE	ΔΔ	-8.3%±4.4%			0.068
			Control/Pl	31	1.78±0.14							
Jenkins 1999 Jenkins 2000 (2 publications that include patients	Conjugated dienes	1º	Soy	31	67	pmol/L		ΔΔ%	-16%			<0.001
			Control/Pl	31	62				+2%			
	Conjugated	1º	Soy	31	15.7	µmol/mmol		ΔΔ%	-4%			0.03

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
from Jenkins 1999 paper)	dienes:LDL		Control/Pl	31	14.6				+8%			
	Conjugated dienes:LDL	1º	Soy	20		µmol/mmol		ΔΔ%	12.9			0.02
			Control/Pl	20					14			
Jenkins 2002	DBP	1º	low Isoflav	41	78±1	mm Hg	SE	f/up	76±1			
			high Isoflav	41	78±2				77±1			
			Control/Pl	41	78±2				78±1			
	HDL	1º	low Isoflav	41	1.32±0.05	mmol/L	SE	f/up	1.27±0.05			
			high Isoflav	41	1.32±0.06				1.25±0.05			
			Control/Pl	41	1.33±0.05				1.23±0.05			
	Homocysteine	1º	low Isoflav	41	8.2±0.3	mcmol/L	SE	f/up	7.4±0.3			
			high Isoflav	41	8.2±0.4				7.6±0.4			
			Control/Pl	41	7.6±0.3				8.0±0.4			
	LDL	1º	low Isoflav	41	4.52±0.12	mmol/L	SE	f/up	4.18±0.11			
			high Isoflav	41	4.55±0.11				4.14±0.11			
			Control/Pl	41	4.62±0.10				4.47±0.11			
	Lp(a)	1º	low Isoflav	41	20.2±3.1	mg/dL	SE	f/up	21.7±3.4			
			high Isoflav	41	19.2±2.5				20.1±3.2			
			Control/Pl	41	19.6±3.1				21.6±3.4			
	SBP	1º	low Isoflav	41	124±3	mm Hg	SE	f/up	120±2			
			high Isoflav	41	123±3				122±2			
			Control/Pl	41	125±3				123±3			
	TC	1º	low Isoflav	41	6.68±0.13	mmol/L	SE	f/up	6.22±0.12			
			high Isoflav	41	6.76±0.12				6.32±0.12			
			Control/Pl	41	6.84±0.10				6.64±0.12			
	Tg	1º	low Isoflav	41	1.84±0.18	mmol/L	SE	f/up	1.70±0.17			
			high Isoflav	41	1.96±0.17				2.04±0.23			
			Control/Pl	41	1.96±0.17				2.07±0.22			
Jenkins 2002	Conjugated dienes	1º	low Isoflav	37		pmol/L		f/up	-16%		NS	NS
			high Isoflav	37					-16%			<0.05
			Control/Pl	37					*+1%*			
Jenkins 2003	PSA	1º	Soy based diet	46	Outcomes tabulated							
			Control/Pl									
Jones G, 2003	bAP	1º	Isoflavone	69	46.3±21.2	no unit	SD	Δ	9.69±9.04	<0.05	NS	
			Control/Pl	59	49.0±24.9				8.37±10.1	<0.05		
Kanazawa 1995	Oxidized LDL	1º	Soycreme	15	Outcomes tabulated							
			Control/Pl	10								

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Katsuyama 2004	bAP	1º	1/mo	21	54.3±16.6		Unclear SD/ SE	Δ	+1.9±24.4			NS
			1/wk	16	51.9±19.0				-7.1±17.5			NS
			3/wk	18	63.8±19.8				+6.7±20.8			NS
			Control/Pl	18	60.8±21.5				-0.6±20.9			
	NTx	1º	1/mo	21	45.8±23.2		Unclear SD/ SE	Δ	-12.0±16.7			NS
			1/wk	16	36.0±15.3				-11.7±19.1			NS
			3/wk	18	46.7±13.8				-2.2±30.4			NS
			Control/Pl	18	35.7±14.0				-2.7±24.4			
	Serum Osteocalcin	1º	1/mo	21	1.42±0.99		Unclear SD/ SE	Δ	-0.29±0.73			NS
			1/wk	16	1.95±1.55				+0.22±1.68			NS
			3/wk	18	1.68±1.46				+1.18±2.88			NS
			Control/Pl	18	1.91±1.03				-0.01±1.43			
Khalil 2002	Bone biomarkers	1º	ISP w/ Isofl	24	Outcomes tabulated							
			Casein	22								
Knight D 2001	FSH	1º	Isoflavone	9	74.7±30.9	Other	SD	f/up	67.4±40.7			
			Control/Pl	11	74.3±24.3				63.9±26.7			
	Vasomotor Symptoms: per wk	1º	Isoflavone	9	50.2±13.6		SD	f/up	29.1±42.5			
			Control/Pl	11	56.2±26.5				45.5±31.3			
Kotsopoulos 2000	Vasomotor Symptoms: Score	1º	Soy	34	0.82±0.17		SE	f/up	0.77±0.17			
			Control/Pl	41	0.85±0.12				0.83±0.12			
Kreijkamp-Kaspers 2004	BMD: Hip	2º	Soy	88	0.861±0.112	g/cm2	SE	ΔΔ	0.005 (95% CI: -0.004, 0.013)			0.27
			Control/Pl	87	0.831±0.119							
	BMD: Lumbar	1º	Soy	88	0.917±0.15	g/cm2	SE	ΔΔ	-0.001 (95% CI: -0.010, 0.008)			0.79
			Control/Pl	87	0.895±0.166							
	bAP	2º	Soy	88	12.7±3.9		SE	ΔΔ	-0.229 (95% CI: -0.983, 0.525)			0.55
			Control/Pl	87	12.9±4.0							

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	HDL	2º	Soy	88	59.08±15.8	mg/dL	SE	ΔΔ	+1.93 (95% CI: -0.39, 3.86)			0.09
			Control/Pl	87	59.0±13.14							
	LDL	2º	Soy	88	161±38.2	mg/dL	SE	ΔΔ	+5.40 (95% CI: -1.54, 12.74)			0.12
			Control/Pl	87	159.4±33.9							
	Lp(a)	2º	Soy	88	0.27±0.37	g/L = mg/mL	SE	ΔΔ	0.03 (95% CI: -0.01, 0.06)			0.14
			Control/Pl	87	0.24±0.27							
	TC	1º	Soy	88	240.15±45.1	mg/dL	SD	ΔΔ	+5.79 (95% CI: -2.3, 13.9)			0.15
			Control/Pl	87	236.2±36.6							
	Tg	1º	Soy	88	120.3±63.7	mg/dL	SE	ΔΔ	-7.96 (95% CI: -19.5, 2.65)			0.14
			Control/Pl	87	110.6±52.2							
KreijkampKaspers 2005	FMD (RH)	1º	Soy	75	4.8	%		f/up	*+0.3*			NS
			Control/Pl	78	4.4				*0*			
	SBP	1º	ISP w/isoflav	88	138.4±16.7	mm Hg	SD	ΔΔ	139.2±18.2			NS
			Milk protein	87	143.4±18.2	mm Hg			139.9±18.1			
	DBP	1º	ISP w/isoflav	88	74.1±10.7	mm Hg		ΔΔ	74.4±14.1			
			Milk protein	87	76.2±12.9	mm Hg			74.5±12.4			
Kritz-Silverstein, 2003	Cognitive function	1º	Isoflavones	27	Performance in category fluency in the soy isoflavones group improved by 23% between baseline and follow-up, whereas the performance in the placebo group improved only by 3% (P=0.02)							
			Placebo	26	No significant differences in any other cognitive function tests between the groups.							
Kumar NB 2002	E2	1º	Soy protein	33	1.31±0.21		SE	f/up	1.28±0.19	0.19		0.48
			Control/Pl	33	1.54±0.18				1.59±0.25	0.19		
Kurowska 1997	DBP	1º	milk	34	77±10	mm Hg	SD	f/up	73±10	p=0.02		
			Soybean	34	77±10				77±8	p=0.02		
	HDL	1º	milk	34	1.31±0.32	mmol/L	SD	f/up	1.30±0.41	p=0.04		
			milk/Soy o	34	1.31±0.32				1.37±0.38			
			Soybean	34	1.31±0.32				1.40±0.28	p=0.04		
	LDL	1º	milk	34	4.45±0.95	mmol/L	SD	f/up	4.36±1.07			
			milk/Soy o	34	4.45±0.95				4.29±1.15			
			Soybean	34	4.45±0.95				4.26±1.04			
	SBP	1º	milk	34	131±17	mm Hg	SD	f/up	123±15	p=0.04		
			Soybean	34	131±17				128±15	p=0.04		
	TBARs	1º	milk	34	1.35±0.43	?	SD	f/up	1.26±0.43	0.01		
			Soybean	34	1.35±0.43				1.41±0.55	0.01		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	TC	1º	milk	34	6.86±0.99	mmol/L	SD	ΔF	-1%			
			milk/Soy	34	6.86±0.99				4%			
			Soybean	34	6.86±0.99				9%			
	Tg	1º	milk	34	1.75±0.64	mmol/L	SD	f/up	1.85±0.72			
			milk/Soybean	34	1.75±0.64				1.90±0.85			
			Soybean	34	1.75±0.64				1.94±0.83			
Laskowski 2003	Adaptation process	1º	soy protein supplement	6	Outcomes tabulated							
			no soy protein supplement	6								
Lenn 2002	Cortisol	1º	ISP+	8	Outcomes tabulated							
			Control/Pl	7								
Lichtenstein 2002	HDL		Soy w/o Isoflav	42	1.32±0.28	mmol/L	SD	f/up	1.36±0.34			
			Soy w/ Isoflav	42	1.32±0.28				1.36±0.33			
			animal die	42	1.32±0.28				1.33±0.32			
			animal die	42	1.32±0.28				1.31±0.34			
	LDL	1º	Soy w/o Isoflav	42	4.14±0.65	mmol/L	SD	f/up	4.34±0.92			
			Soy w/ Isoflav	42	4.14±0.65				4.29±0.96			
			animal wit	42	4.14±0.65				4.42±0.97			
			animal WIT	42	4.14±0.65				4.44±1.01			
	TC	1º	Soy w/o Isoflav	42	6.17±0.78	mmol/L	SD	f/up	6.37±1.12			
			Soy w/ Isoflav	42	6.17±0.78				6.24±1.11			
			animal wit	42	6.17±0.78				6.47±1.17			
			animal WIT	42	6.17±0.78				6.42±1.17			
	Tg	1º	Soy w/o Isoflav	42	1.54±0.66	mmol/L	SD	f/up	1.27±0.50			
			Soy w/ Isoflav	42	1.54±0.66				1.27±0.46			
			animal die	42	1.54±0.66				1.44±0.57			
			animal die	42	1.54±0.66				1.46±0.52			
Lissin L 2004	LDL	1º	Isoflavones	20*	163±29	mg/dL	SE	Δ	-0.56%±2.5%			0.16
			Control/Pl	20*	165±22				-5.6%±2.5%			
	TC	1º	Isoflavones	20*	243±26	mg/dL	SE	Δ	-2.2%±1.7%			0.27
			Control/Pl	20*	236±22				-5.2%±2.0%			
	FMD (RH)	1º	Isoflavones	20*	1.3	%		Δ	+3.4	NS		NS
			Control/Pl	20*	3.8				-0.6	NS		
Lu 1996	Menstrual Cycle Length	1º	Soy milk	6	28.3	days		Δ	+3.5	NS		
Lu LJ;An 2000	Menstrual Cycle Length	1º	Soy milk	10	26.6±1.6	days	SD	f/up	26.0±2.0	NS		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Lu LJ 2001	FSH	1º	Soymilk w/	9	2.7	IU/L		Δ	-0.2	NS		
			Soymilk w/									
	estradiol	1º	Soymilk w/	9	107	pg/mL		Δ	0	NS		
			Soymilk w/									
Luz LJW; 2000	Menstrual Cycle Length	2º	Soymilk w/	8		Other	SD	f/up	26.6±2.9			
			Soymilk no	8					25.8±1.9			
Lydeking-Olsen 2004	BMD: Femoral Neck	1º	Soymilk w/	23	ND	g/cm2	SD	Δ	-0.9	NS		NS
			Soymilk w/	22	ND				+0.2	NS		
	BMD: Lumbar	1º	Soymilk w/	23	0.925±0.260	g/cm2	SD	Δ	+1.1%	NS		0.009
			Soymilk w/	22	0.865±0.190				-4.2%	0.006		
Mackey R 2000	HDL	1º	ISP+	25	1.52±0.39	mmol/L	SD	f/up	1.52±0.31			
			ISP-	24	1.66±0.45				1.70±0.45			
			?	tot	1.59±0.42				1.60±0.39			
	LDL	1º	ISP+	25	5.07±0.73	mmol/L	SD	f/up	4.71±0.73			
			ISP-	24	5.11±1.02				4.78±0.96			
			?	tot	5.09±0.88				4.74±0.84			
	SHBG_outcomes	1º	ISP+	22	43.73±22.89		SD	f/up	38.85±20.19			
			ISP-	24	45.03±17.79				43.07±19.18			
			?	tot	44.41±20.17				41.05±19.57			
	TC	1º	ISP+	25	7.29±0.90	mmol/L	SD	f/up	6.94±0.84			
			ISP-	24	7.47±1.04				7.15±1.02			
			?	Tot	7.38±0.96				7.04±0.93	0.0003		
	Tg	1º	ISP+	25	1.53±0.82	mmol/L	SD	f/up	1.54±0.74			
			ISP-	24	1.54±0.72				1.46±0.82			
			?	tot	1.53±0.77				1.50±0.77			
Mackey 2000 11216493_study 2	Testosterone FSH TSH	1º	ISP+	27	Outcomes tabulated							
Martini 1999	E2	1º	ISP+	36	Outcomes tabulated							
Maskarinec 2002	E2	1º	Soy Isofla	13	3.7±1	Other	SD	ΔΔ	-0.51 (95% CI: -1.62, +0.61)			0.36
			Control/Pl	13	3.2±1.4							
	FSH	1º	Soy Isofla	12	3.2±1.2		SD	ΔΔ	-0.82 (95% CI: -2.53, +0.897)			0.34
			Control/Pl	16	4.1±1.8							
Maskarinec 2004	E2	1º	ISP+	91	150	pg/mL		Δ	+2	NS		NS

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
				96	136	pg/mL		Δ	-14	NS		
Maskarinec 2003	Mammographic density	1º	Soy Isofla Control/Pl	15	Outcomes tabulated							
Mc Michael Philips 1998	epithelial cells in the S phase progesterone receptor expression	1º	Soy bread	19	Outcomes tabulated							
			normal unsupplemented (without soy) diet	29								
Meinertz 1988	HDL	1º	ISP	10	47±13	mg/dL	SD	f/up	47±11	NS		
			casein	10	47±13				46±10			
	LDL	1º	ISP	10	110±25	mg/dL	SD	f/up	68±21	NS		
			casein	10	110±25				67±19			
	TC	1º	ISP	10	171±32	mg/dL	SD	f/up	127±24	NS		
			casein	10	171±32				125±24			
	Tg	1º	ISP	10	68±32	mg/dL	SD	f/up	63±25	NS		
			casein	10	68±32				56±14			
Meinertz 1989	HDL	1º	ISP	11	1.49±0.32	mmol/L	SD	ΔF	+16%	<0.01		
			casein	11	same							
	LDL	1º	ISP	11	2.64±0.97	mmol/L	SD	ΔF	-16%	<0.02		
			casein	11								
	TC	1º	ISP	11	4.43±0.98	mmol/L	SD	ΔF	-4%	NS		
			casein	11	same							
	Tg	1º	ISP	11	0.65±0.23	mmol/L	SD	ΔF	+2%	NS		
			casein	11	same							
Meinertz 2002	HDL	1º	casein	12		mmol/L	SD	f/up	1.27±0.23	<0.05		--
			extracted	12					1.34±0.22	NS		NS
			intact Soy	12					1.40±0.19	NS		<0.05
	LDL	1º	casein	12	2.05±0.60	mmol/L	SD	f/up	1.65±0.35	<0.01		--
			extracted	12	2.17±0.52				1.71±0.41	<0.01		NS
			intact Soy	12	2.16±0.50				1.61±0.36	<0.001		NS
	TC	1º	casein	12	4.02±0.87	mmol/L	SD	f/up	3.15±0.43	<0.001		--
			extracted	12	4.16±0.64				3.25±0.37	<0.001		NS
			intact Soy	12	4.15±0.86				3.39±0.34	<0.001		NS
	Tg	1º	casein	12	0.87±0.30	mmol/L	SD	f/up	0.74±0.20	NS		--
			extracted	12	0.92±0.34				0.66±0.14	<0.01		NS

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			intact Soy	12	1.00±0.43				0.83±0.22	NS		NS
Merz- Demlow 2000	HDL	1º	high Isofl	13	47.8±0.5	mg/dL	SE	f/up	48.8±1.1			
			low Isofla	13					48.6±1.1			
			no Isoflav	13					47.3±1.0			
	LDL	1º	high Isofl	13	84.4±1.0	mg/dL	SE	f/up	79.8±2.0			
			low Isofla	13					86.8±2.0			
			no Isoflav	13					88.7±1.9			
	TC	1º	high Isofl	13	143.8±1.1	mg/dL	SE	f/up	139.1±2.9			
			low Isofla	13					146.3±2.9			
			no Isoflav	13					148.7±2.7			
	Tg	1º	high Isofl	13	56.3±1.6	mg/dL	SE	f/up	52.4±3.8			
			low Isofla	13					54.3±3.8			
			no Isoflav	13					62.9±3.5			
	Lp(a)	1º	high Isofl	13	nd	mg/dL	SE		14.59±0.63	NS		
			low Isofla	13					15.16±0.63			
			no Isoflav	13					14.64±0.58			
Meyer BJ 2004	DBP	1º	Soy	23	77±1.9		SE	ΔF	-2.00±1.7		NS	
			dairy	23	77±1.9							
	HDL	1º	Soy	23	1.28±0.09	mmol/L	SE	ΔF	0.06±0.03		NS	
			dairy	23	1.28±0.09							
	LDL	1º	Soy	23	4.13±0.24	mmol/L	SE	ΔF	-0.05±0.10		NS	
			dairy	23	4.13±0.24							
	Lp(a)	1º	Soy	23	15.4±26.0	mg/dL	SE	ΔF	-0.30±-0.87		NS	
			dairy	23	15.4±26.0							
	SAC (Large Arteries)	1º	Soy	23	13.0±0.07	mL/mmHg	SE	ΔF	-0.03±0.04		ns	
			dairy	23	13.0±0.07							
	SAC (Small Arteries)	1º	Soy	23	5.8±0.6	mL/mmHg	SE	ΔF	-0.05±0.36		NS	
			dairy	23	5.8±0.6							
	SBP	1º	Soy	23	132±2.9		SE	ΔF	-0.60±1.7		NS	
			diary	23	132±2.9							
	TC	1º	Soy	23	6.00±0.25	mmol/L	SE	ΔF	0.00±0.13		NS	
			control	23	6.00±0.25							
	Tg	1º	Soy	23	1.30±0.14	mmol/L		ΔF	-0.02±0.10		NS	
			dairy	23	1.30±0.14							
Mitchell 2001	E2	1º	Soy	14	4.44	Other	SE	f/up	4.40			
	FSH	1º	Soy	14	35.21	Other	SE	f/up	33.38			
Morabito 2002	BMD: Femoral	1º	Placebo	30*	0.689±0.06	Other	SE	Δ	-0.65±0.1			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	Neck		Genistein	30*	0.687±0.05				3.6±3			
	BMD: Lumbar	1°	Placebo	30*	0.934±0.07	g/cm2	SE	Δ	-1.6%±0.3			
			Genistein	30*	0.915±0.07				3%±2	<0.04		
	bAP	1°	Placebo	30	10±4		SD	f/up	9.6±3			
			Genistein	30	9.7±1.2				12±4			
	E2	1°	Placebo	30	77±14	Other	SD	f/up	73±7.3			
			Genistein	30	73±2.9				77±2.9			
Murkies 1995	FSH	1°	Soy Flour	23	84.52±4.63	Other	SE	f/up	83.17±4.62	<0.05		0.32
			Control/Pl	24	82.93±3.85				74.84±4.64			
	HDL	1°	Soy flour	23	1.73±0.09	mmol/L	SE	f/up	1.68±0.10	NS		0.35
			Control/Pl	24	1.64±0.06				1.60±0.06			
	TC	1°	Soy flour	23	6.09±0.21	mmol/L	SE	f/up	5.82±0.20	NS		0.38
			Control/Pl	24	5.93±0.17				5.69±0.21	NS		
	Tg	1°	Soy flour	23	1.07±0.13	mmol/L	SE	f/up	1.05±0.15	NS		0.62
			Control/Pl	24	1.08±0.10				1.12±0.15			
	Vasomotor Symptoms: Flush Score	1°	Soy flour	28	6±0.5	no unit	SE	f/up	3.5±0.6	<0.001		0.82
			Control/Pl	30	5.3±0.5				4±0.6			
Murray M 2003	HDL	2°	placebo+0	7	67±9	mg/dL	SD	f/up	71±10	0.21		0.43
			placebo+1m	7	62±21				60±19	0.87		
			SPI+0.5mgE	8	64±15				68±15	0.40		
			SPI+1mgE	8	69±16				64±17	0.24		
	LDL	2°	placebo+0	7	125±17	mg/dL	SD	f/up	118±15	0.35		0.45
			placebo+1m	7	164±43				168±105	0.35		
			SPI+0.5mgE	8	120±28				120±24	0.74		
			SPI+1mgE	8	129±35				107±37	0.12		
	TC	2°	placebo+0	7	211±12	mg/dL	SD	f/up	209±18	0.60		p=0.46
			placebo+1m	7	261±15				244±19	0.13*		
			SPI+0.5mgE	8	212±29				213±22	0.73		
			SPI+1mgE	8	216±25				203±44	0.26		
	Tg	2°	placebo+0	7	99±55	mg/dL	SD	f/up	87±24	0.69		0.04
			placebo+1m	7	191±89				256*±150	0.46		
			SPI+0.5mgE	8	116±60				119±58	0.78		
			SPI+1mgE	8	97±38				150±58	0.02		
Nagata C 1998	E2	1°	Soymilk	21	98.0±85.0		SD	f/up	65.4±51.7	0.10	0.13	
			Control/Pl	23	84.8±74.8				93.6±90.1	0.60		
Nagata 2001	testosterone	1°	Soymilk	17	16.3			f/up	*-2.2*	NS		NS

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Control/Pl	17	15.6				*-0.4*	NS		
Nestel P 1997	Diene Oxidation Rate	1°	Isoflavone	15	ND		SD	f/up	14.1±1.9		NS	
			placebo	15	ND				14.4±2.3			
	HDL	1°	Isoflavone	21	1.30±0.43	mmol/L	SD	f/up	1.23±0.31			
			placebo	21	1.30±0.43				1.30±0.39			
	Lagtime: Copper	1°	Isoflavone	15	ND	min	SD	f/up	53.2±5.2		NS	
			placebo	15	ND				53.5±5.7			
	LDL	1°	Isoflavone	21	3.57±0.84	mmol/L	SD	f/up	3.43±0.85			
			placebo	21	3.57±0.84				3.35±0.14			
	MAP	1°	Isoflavone	21	86±10		SD	f/up	80±10	<0.05		NS
			placebo	21	86±10				80±12	<0.05		
	Max. Diene Concentration	1°	Isoflavone	15	nd	nmol/mg	SD	f/up	406.0±41		NS	
			placebo	15	nd				409.0±45			
	SAC	1°	Isoflavone	21	0.67±0.33		SD	f/up	0.99±0.54	<0.05	0.011	
			placebo	21	0.67±0.33				0.81±0.4	<0.05		
	TBARS (after oxidation)	1°	Isoflavone	15	nd		SD	f/up	72.0±14		NS	
			placebo	15	nd				70.0±16			
	TC	1°	Isoflavone	21	5.54±0.94	mmol/L	SD	f/up	5.37±0.93			
			placebo	21	5.54±0.94				5.25±1.28			
	Tg	1°	Isoflavone	21	1.45±0.71	mmol/L	SD	f/up	1.53±0.99			
			placebo	21	1.45±0.71				1.30±0.67			
Nikander 2003	CRP		Isoflavones 1st	56	1.16±1.03	mg/L	SD	f/up	1.10±0.91	0.779		
			Placebo 1st	56	1.10±0.79				1.10±0.84	0.322		
	E2	2°	Isoflavones 1st	28	0.140±0.085	Other	SD	f/up	0.138±0.144	0.579		
			Placebo 1st	28	0.127±0.085				0.141±0.156	0.542		
	FSH	2°	Isoflavones 1st	28	79.9±34.5	Other	SD	f/up	79.5±32	0.851		
			Placebo 1st	28	78.8±31.3				77.8±30.7	0.552		
	Vasomotor Symptoms: Score	1°	Isoflavones 1st	28	2±0.9	no unit	SD	f/up	1.8±1.0	0.235		
			Placebo 1st	28	2.1±0.8				1.8±0.9	0.006		
Nikander 2004	2-hr OGTT	2°	Isoflavones 1st	56	5.9±2.0	mmol/L	SD	f/up	5.5±1.4			NS
			Control/Pl	56	6.0±1.8				6.3±2.2			
	bAP	1°	Isoflavones 1st	28	14.6±5.8	mg/L	SD	Δ	0.00±2.5	0.896		
			placebo	28	14.7±6.2				0.5±2.3	0.024		
	Fasting Blood Glucose	2°	Isoflavones 1st	56	5.1±1.1	mmol/L	SD	f/up	5.6±2.2			NS
			Control/Pl	56	5.1±0.9				5.1±0.9			
	HDL	2°	Isoflavones 1st	56	1.78±0.45	mmol/L	SD	Δ	-0.028±0.26	NS		
			Control/Pl	56	1.76±0.38				-0.008±0.27	NS		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	LDL	2º	Isoflavones 1st	56	3.87±0.93	mmol/L	SD	Δ	+0.28±0.63	NS		
			Control/Pl	56	3.80±1.17				-0.06±0.68	NS		
	LDL: Baseline > 162 mg/dL	2º	Isoflavones 1st	26	nd	mmol/L	SD	Δ	+0.65±0.60			0.009
			Control/Pl	26	nd				-0.45±0.67			
	Lp(a)	2º	Isoflavones 1st	56	171.2±204.8	mg/L	SD	Δ	+8.7±66.9	NS		
			Control/Pl	56	175.8±221.7				-8.6±79.1	NS		
	NTx	1º	Isoflavones 1st	28	71.9±48.1		SD	Δ	-2.4±22.7	0.388		
			Control/Pl	28	73.7±49.1				+3.1±37.8	0.185		
	TC	2º	Isoflavones 1st	56	5.88±0.97	mmol/L	SD	Δ	+0.14±0.95	NS		
			Control/Pl	56	5.83±1.04				+0.06±0.67	NS		
	Tg	2º	Isoflavones 1st	56	1.22±0.57	mmol/L	SD	Δ	+0.015±0.48	NS		
			Control/Pl	56	1.25±0.53				+0.005±0.39	NS		
Nilausen 1999	Lp(a)	1º	Soy diet liquid	9	12.7	mg/L	SEM	Δ	-2.7	NS		<0.002
			Casein, liquid	9	12.0	mg/L			-7.2	<0.0002		
Onning G 1998	Fasting Blood Glucose	1º	Soya milk	12*	5.3±0.1	mmol/L	SE	Δ	+0.1±0.1	NS		
			oat milk									
	HDL	1º	Soya milk	12*	1.1±0.1	mmol/L	SE	Δ	0.0±0.0	NS		
			oat milk									
	LDL	1º	Soya milk	12*	2.9±0.3	mmol/L	SE	Δ	-0.2±0.1	<0.05		
			oat milk									
	TC	1º	Soya milk	12*	4.4±0.3	mmol/L	SE	Δ	-0.1±0.1	NS		
			oat milk									
	Tg	1º	Soya milk	12*	0.9±0.1	mmol/L	SE	Δ	+0.1±0.1	NS		
			oat milk									
Pap A 1983	Secretin-pancreozymin	1º	Soy flour	34	Outcomes tabulated							
Pap A 1984	Pancreatic enzyme secretory capacity	1º	Soy flour	10	Outcomes tabulated							
			cholecystokinin -octapeptide	10								
Penotti 2003	Vasomotor Symptoms: per wk	1º	Isoflavone	22	9.9±4.5	no unit	SD	f/up	4.6±3.8			
			Control/Pl	27	8.6±2.9				4.0±3.9	not significant diff		
Persky V 2002	E2	1º	ISP56	24	17.5 (95% CI: 8.1-37.9)			f/up	24.5 (95% CI: 11.7-51.5)	ns		ns
			ISP90	23	9.7 (95% CI: 3.0-31.4)				10.8 (95% CI: 3.9-30.1)	ns		ns

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	FSH	1°	ISP56	24	39.7 (95% CI: 34.6-44.8)			f/up	36.8 (95% CI: 30.7-42.9)	ns		ns
			ISP90	23	43.7 (95% CI: 34.9-52.4)				44.0 (95% CI: 37.0-51.0)	ns		ns
	TSH	1°	ISP56	24	2.22 (95% CI: 1.94-2.54)			f/up	2.05 (95% CI: 1.83-2.29)	ns		ns
			ISP90	22	2.04 (95% CI: 1.68-2.49)				2.22 (95% CI: 1.79-2.75)	ns		0.01
			Control/Pl	24	2.25 (95% CI: 1.82-2.79)				2.00 (95% CI: 1.65-2.43)	ns		
Petrakis 1996	E2 pre	1°	ISP+	14	81.2	pg/mL		Δ	+8.6	NS		
	E2 post	1°	ISP+	10	53.3	pg/mL		Δ	-0.5	NS		
Petri NE 2004	E2	1°	Soy	25	15.8±7.3		SD	f/up	17.7±6.7	< 0.05		
			Control/Pl	25	14.6±6.0				12.3±3.8			
	FSH	1°	Soy	25	76.8±13.4		SD	f/up	77.7±19.6			
			Control/Pl	25	75.2±28.7				82.5±30.7			
	HDL	1°	Soy	25	43.95±11.31	mg/dL	SD	f/up	57	<0.05		
			Control/Pl	25	48.10±12.96				48	NS		
	LDL	1°	Soy	25	151.50±39.22	mg/dL	SD	f/up	132	<0.05		
			Control/Pl	25	130.50±23.57				143	NS		
	TC	1°	Soy	25	229.65±31.58	mg/dL	SD	f/up	217	NS		
			Control/Pl	25	203.75±25.08				204	NS		
	Tg	1°	Soy	25	150.35±94.38	mg/dL	SD	f/up	150	NS		
			Control/Pl	25	139.00±68.93				143	NS		
Potter S 1993	HDL	1°	Soy flour	24	0.96±0.18	mmol/L	SD	f/up	0.95±0.16			
			ISP w/fiber	24	0.96±0.18				0.91±0.15			
			ISP w/fiber	24	0.96±0.18				0.91±0.15			
			control	24	0.96±0.18				0.92±0.14			
	LDL	1°	Soy flour	24	4.53±0.61	mmol/L	SD	f/up	4.30±0.78			
			ISP w/fiber	24	4.53±0.61				4.15±0.75	<0.01		
			ISP w/cell	24	4.53±0.61				4.17±0.65	<0.01		
			control	24	4.53±0.61				4.64±0.87			
	TC	1°	Soy flour	25	5.90±0.70	mmol/L	SD	f/up	5.61±0.88		<0.05	
			ISP w/fiber	25	5.90±0.70				5.45±0.81	<0.05	<0.01	
			ISP w/cell	25	5.90±0.70				5.44±0.69	<0.05	<0.01	
			control	25	5.90±0.70				6.10±1.04			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	Tg	1°	Soy flour	23	1.95±0.82	mmol/L	SD	f/up	2.12±0.86			
			ISP w/fiber	23	1.95±0.82				2.00±0.70			
			ISP w/cell	23	1.95±0.82				2.00±0.75			
			control	23	1.95±0.82				2.29±0.96			
Potter 1998	BMD	1°	ISP56	23	Lumbar spine BMD increased significantly in the high-dose group (soy protein with 90 mg/day of total isoflavones) compared to control.							
			ISP90	21								
			Nonfat milk	22								
Puska P; 2002	HDL	1°	Soya	24*	1.58±0.44	mmol/L	SD	ΔΔ	+0.01 (95% CI: +0.10, -0.09)			0.904
			placebo	28*	1.56±0.43							
	Homocysteine	1°	Soya	24*	10.52±3.68	mmol/L	SD	ΔΔ	-1.74 (95% CI: -0.87, -2.60)			<0.001
			placebo	28*	9.65±2.27							
	LDL	1°	Soya	24*	5.13±0.48	mmol/L	SD	ΔΔ	-0.27 (95% CI: -0.06, -0.49)			0.014
			placebo	28*	5.15±0.74							
	Lp(a)	1°	Soya	24	272±341	g/L = mg/mL	SD	ΔΔ	+43.6 (95% CI: +111.0, -23.9)			0.212
			placebo	24	341±495							
	TC	1°	Soya	24*	7.50±0.57	mmol/L	SD	ΔΔ	-0.25 (95% CI: -0.01, -0.50)			0.049
			placebo	28*	7.68±0.54							
	Tg	1°	Soya	24*	1.76±0.78	mmol/L	SD	ΔΔ	+0.06 (95% CI: +0.35, -0.22)			0.663
			placebo	28*	1.81±1.30							
Puska P; 2004	DBP	1°	Soya	69	80.5±8.7	mm Hg	SD	f/up	80.6±8.2			
			placebo	74	81.1±9.4				81.3±9.7			
	HDL	1°	Soya	69*	1.67±0.53	mmol/L	SD	ΔΔ	+0.01 (: -0.05, 0.03)			0.60
			placebo	74*	1.72±0.45							
	Homocysteine	1°	Soya	69*	10.41±2.74	mmol/L	SD	ΔΔ	+0.58 (95% CI: -1.48, 0.32)			0.20
			placebo	74*	11.16±5.50							
	LDL	1°	Soya	69*	5.11±0.69	mmol/L	SD	ΔΔ	-0.40 (95% CI: 0.25, 0.55)			<0.001
			placebo	74*	5.13±0.75							
	SBP	1°	Soya	69	130.0±15.8	mm Hg	SD	f/up	129.6±15.8			
			placebo	74	132.4±17.1				131.3±15.7			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	TC	1°	Soya	69*	7.53±0.79	mmol/L	SD	ΔΔ	-0.40 (95% CI: -0.26, -0.55)			<0.001
			placebo	74*	7.59±0.77							
	Tg	1°	Soya	69*	1.68±0.80	mmol/L	SD	ΔΔ	0 (95% CI: -0.15, 0.15)			1.00
			placebo	74*	1.67±0.58							
Quella 2000	Hot flash score	1°	Isoflavones	177	12	1 score		ΔΔ	-30%			NS
			Placebo	/149	13	unit			-32%			
Ross 1995	PDGF	1°	tofu	23	Outcomes tabulated							
Rivas M; 2002	DBP		Soy milk	20*	100.3±8.8	mm Hg	SD	Δ	-15.9±9.8	<0.0001		
			Control/Pl	20*	99.2±5.4				-3.7±5.0			
	SBP		Soy milk	20*	155±12.5	mm Hg	SD	Δ	-18.4±10.7	<0.0001		
			Control/Pl	20*	151.7±13.8				-1.4±7.2			
Russo 2003	Menopausal symptoms	1°	Isoflavones Placebo	47	Although a crossover trial, the data were analyzed descriptively in the study. The percent change for both treatment arms was calculated as follows: (# subjects reported no improvement after soy treatment – # reporting no improvement after placebo treatment) / (# reported no improvement after soy treatment). Dropouts excluded from analyses. This analysis does not consider time effect (i.e.. the order of getting treatments). No significant difference in the overall improvement rate of menopausal symptoms between the groups.							
Sagara M 2004	DBP		Soy	25	87.1±1.8	mm Hg	SE	Δ	-5.1	<0.01		0.138
			Control/Pl	25	80.8±10.2				-1.7	ns		
	HDL		Soy	25	53.7±2.0	mg/dL	SE	Δ	3.7	<0.01		0.057
			Control/Pl	25	55.0±2.5				4.7	<0.01		
	SBP		Soy	25	142.0±3.0	mm Hg	SE	Δ	-10.8	<0.01		0.05
			Control/Pl	25	134.0±3.2					ns		
	TC		Soy	25	239.5±7.9	mg/dL	SE	Δ	-14.8	<0.05		0.357
			Control/Pl	25	231.5±7.2				-5.0	ns		
Saxena 1999	Misc. outcomes		Soy diet	45	Outcome tabulated							
Scambia 2000	Vasomotor Symptoms: per wk	1°	Soy extract	20*	27±5.2		SD	error		<0.01		
			Control/Pl	19*	33±5.1							
Scheiber 2001	bAP	1°	Soy	42	19.4±9.3		SD	f/up	20.5±12.5			
	E2	2°	Soy	42	17.4±7.0		SD	f/up	18.9±12.4			
	FSH	2°	Soy	42	54.1±23.4		SD	f/up	52.5±20.8			
	LDL oxidation lag time	1°	Soy	42	34.9±6.8		SD	f/up	38.2±7.6	<0.05		
	NTx	1°	Soy	42	52.4±26.3		SD	f/up	45.1±21.1	<0.02		
	Serum Osteocalcin	1°	Soy	42	5.8±2.1		SD	f/up	6.4±2.1	<0.03		
Secreto 2004	Vasomotor Symptoms: Score	1°	Isoflavone	61	Median=24 (IQR: 20-30)		SD	Δ	9.8±11.4			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Isoflavone	59	Median=25 (IQR: 19-30)				8.9±8.4			
			Melatonin	54	Median=25.5 (IQR: 16-31)				7.3±8.1			
			Control/Pl	58	Median=23 (IQR: 17-32)				9.2±9.9			
Shorey R 1981	HDL		Soy protein	13	52±14	mg/dL	SD	Δ	-8±6	0.001		
			Control/Pl	11	46±12				-4±8	NS		
	TC		Soy protein	13	241±38	mg/dL	SD	Δ	-16±22	0.027		
			Control/Pl	11	221±21				-22±18	0.002		
	Tg		Soy protein	13	97±48	mg/dL	SD	Δ	+40±66	0.046		
			Control/Pl	11	130±56				+12±50	ns		
Simons L 2000	BP	1º	Soy	20	135/82±4/2	mm Hg	SE	f/up	125/80±4/1		NS	
			placebo	20	135/82±4/2				126/80±4/2			
	HDL	1º	Soy	20	1.42±0.07	mmol/L	SE	f/up	1.33±0.06		NS	
			placebo	20	1.42±0.07				1.34±0.06			
	LDL	1º	Soy	20	3.94±0.26	mmol/L	SE	f/up	3.61±0.25		NS	
			placebo	20	3.94±0.26				3.69±0.22			
	Lp(a)	1º	Soy	20	nd	mg/L	SE	f/up	166 (IQR: 53-855)		NS	
			placebo	20	nd				179 (IQR: 43-720)			
	TC	1º	Soy	20	5.86±0.29	mmol/L	SE	f/up	5.45±0.29		NS	
			placebo	20	5.86±0.29				5.52±0.27			
	Tg	1º	Soy	20	1.12±0.13	mmol/L	SE	f/up	1.12±0.15		NS	
			placebo	20	1.12±0.13				1.07±0.09			
	FMD (RH)	1º	Soy	20	2.1	%		f/up	+2	NS		NS
			placebo	20					+1.2	NS		
Sirtori 1999	LDL	1º	Soya	21	6.39±0.95	mmol/L	SD	Δ	-7.8%	<0.05		
			Control/Pl	21	6.41					NS		
	TC	1º	Soya	21*	8.74±0.74	mmol/L	SD	Δ	-6.2%			
			Control/Pl	21*	Same				-3.9%	NS		
Sirtori 2002	LDL	1º	Soya	20	226	mmol/L		f/up	233	NS		NS
			Control/Pl	20	225				235	NS		
	TC	1º	Soya milk	20	314	mmol/L	SD	f/up	308	NS		NS
			Control/Pl	20	318				321	NS		
Squadrito 2002	DBP	1º	genistein	30	80±7	mm Hg	SD	f/up	79±12	NS		NS
			Control/Pl	30	77±10				78±7	NS		
	HDL	1º	genistein	30	1.2±0.5	mmol/L	SD	f/up	1.2±0.6	NS		NS
			Control/Pl	30	1.2±0.3				1.3±0.4	NS		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	LDL	1º	genistein	30	3.6±0.4	mmol/L	SD	f/up	3.6±0.4	NS		NS
			Control/Pl	30	3.8±0.9				3.7±0.2	NS		
	SBP	1º	genistein	30	113±11	mm Hg	SD	f/up	110±13	NS		NS
			Control/Pl	30	112±13				113±15	NS		
	TC	1º	genistein	30	5.3±1.1	mmol/L	SD	f/up	5.5±0.9	NS		NS
			Control/Pl	30	5.4±0.8				5.5±0.7	NS		
	Tg	1º	genistein	30	1.5±1.8	mmol/L	SD	f/up	1.8±1.5	NS		NS
			Control/Pl	30	1.7±1.5				1.6±1.2	NS		
Squadrito 2003	DBA FMD (RH)	1º	genistein	27	24±4	mL/dL/min		f/up	35±9			<0.001
			Control/Pl	26	24±6				25±8			
	DBA FMD (RH) (size)	1º	genistein	27	3.5±0.7	Diam mm		f/up	4.0±0.5			p=0.02
			Control/Pl	26	3.5±0.9				3.5±0.9			
	E2	1º	genistein	27	19.6	pg/mL		f/up	+0.6			NS
			Control/Pl	26	19.1				+0.2			
Steinberg 2003	Brachial Artery Reactivity	1º	ISP w/Isof	24		%		f/up (graph)	+13	0.03	NS	
			ISP w/o is	24		%			+15	NS		
			Control/Pl	24		%			+20			
	HDL	1º	ISP w/Isof	24	1.55±0.1	mmol/L	SE	f/up	1.49±0.1			
			ISP w/o is	24	1.55±0.1				1.55±0.1			
			Control/Pl	24	1.55±0.1				1.61±0.1			
	LDL	1º	ISP w/Isof	24	2.89±0.1	mmol/L	SE	f/up	2.86±0.1			
			ISP w/o is	24	2.89±0.1				2.87±0.1			
			Control/Pl	24	2.89±0.1				2.94±0.1			
	TC	1º	ISP w/Isof	24	4.91±0.1	mmol/L	SE	f/up	4.82±0.1			
			ISP w/o is	24	4.91±0.1				4.92±0.2			
			Control/Pl	24	4.91±0.1				5.00±0.1			
	Tg	1º	ISP w/Isof	24	1.03±0.1	mmol/L	SE	f/up	1.04±0.1			
			ISP w/o is	24	1.03±0.1				1.08±0.1			
			Control/Pl	24	1.03±0.1				0.98±0.1			
St Germain 2001	Hot flash	1º	ISP w/Isof	24	36	Weekly		Δ	-50%			NS
			ISP w/Isof	24	36.5	frequency			0			NS
			Wheat protein	21	32				-47%			
Stroescu 2001	estradiol	1º	ISP	7	nd	pg/mL		f/up	*-18.3*	<0.01		NS
			Control/Pl	7	nd				*-17.4*	<0.01		
Swain 2002	FSH	1º	ISP w/Iso	24	Outcomes tabulated							
			ISP w/o Iso	24								

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Control/Pl	21								
	estradiol	1º	ISP w/Iso ISP w/o Iso Control/Pl	24 24 21	Outcomes tabulated							
Takatsuka 2000	HDL	1º	Soy	27	65.7±12,5	mg/dL	SD	f/up	63.4±10.2	0.276		0.184
			Control/Pl	25	63.3±8.9				65.0±9.8	0.431		
	LDL	1º	Soy	27	91.3±22.9	mg/dL	SD	f/up	86.0±32.0	0.109		0.142
			Control/Pl	25	94.2±20.2				96.7±19.4	0.428		
	TC	1º	Soy	27	176.6±24.2	mg/dL	SD	Δ	-10.9	0.004		0.022
			Control/Pl	25	176.7±23.8					0.931		
	Tg	1º	Soy	27	98.2±51.4	mg/dL	SD	f/up	81.6±32.0	0.154		0.962
			Control/Pl	25	95.9±45.6				80.0±29.6	0.152		
Teede HJ 2001	DBP	1º	Soy	105	76±1	mm Hg	SE	Δ	-4.3±0.8			<0.05
			Control/Pl	108	76±2				-1.9±0.7			
	FSH: Men	1º	Soy	55	11.1±1.4	mmol/L	SE	Δ	2.7±1.5			
			Control/Pl	53	9.2±0.8				4.7±2.7			
	FSH: women	1º	Soy	50	97.4±6	mmol/L	SE	Δ	1.1±3.4			
			Control/Pl	55	112.7±6				-2.6±3.2			
	HDL	1º	Soy	105	1.44±0.1	mmol/L	SE	Δ	-0.04±0.03			
			Control/Pl	108	1.51±0.1				-0.11±0.04			
	LDL	1º	Soy	105	3.9±0.1	mmol/L	SE	Δ	-0.42±0.07			
			Control/Pl	108	3.8±0.1				-0.28±0.07			
	Lp(a)	1º	Soy	105	286 (95% CI: 207-365)	mg/L	SE	Δ	42 (95% CI: 17-67)			<0.05
			Control/Pl	108	341 (95% CI: 251-433)				4 (95% CI: -22 –30)			
	SAC: combined	1º	Soy	105	0.53 (95% CI: 0.49-0.58)		SE	Δ	0.04 (95% CI: -0.003-0.08)			
			Control/Pl	108	0.56 (95% CI: 0.49-0.63)				0.01 (95% CI: -0.06-0.08)			
	SAC: men	1º	Soy	55	0.54 (95% CI: 0.47-0.61)		SE	f/up	0.60 (95% CI: 0.53-0.68)			
			Control/Pl	53	0.62 (95% CI: 0.51-0.73)				0.62 (95% CI: 0.55-0.68)			
	SAC: women	1º	Soy	50	0.52 (95% CI: 0.46-0.58)		SE	f/up	0.54 (95% CI: 0.47-0.61)			
			Control/Pl	55	0.50 (95% CI: 0.43-0.56)				0.52 (95% CI: 0.49-0.63)			
	SBP	1º	Soy	105	130±2	mm Hg	SE	Δ	-7.5±1.2			<0.05
			Control/Pl	108	128±2				-3.6±1.1			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	TC	1º	Soy	105	5.9±0.1	mmol/L	SE	Δ	-0.55±0.09			
			Control/Pl	108	5.9±0.1				-0.4±0.09			
	Testosterone	1º	Soy	55	16.8±0.9	nmol/L	SE	Δ	-1.5±0.9			
			Control/Pl	53	15.8±0.8				-1.0±0.6			
	Tg	1º	Soy	105	1.2±0.1	mmol/L	SE	Δ	-0.19±0.05			<0.05
			Control/Pl	108	1.2±0.1				-0.01±0.05			
	FMD (RH) in ♂	1º	Soy	96		%		Δ	-3.5			0.02
			Control/Pl						0			
	FMD (RH) in post ♀	1º	Soy	83		%		Δ	+0.5			NS
			Control/Pl						-1.0			
Teede HJ 2004	CRP	1º	Soy	30	1.91±0.33		SE	Δ	0.42±0.2	<0.05		
			Control/Pl	22	1.39±0.22				0.48±0.2	<0.05		
Teixeira 2000	HDL	1º	20 g ISP	15	1.07±0.06	mmol/L	SE	Δ	-0.039	NS		
			30 g ISP	18	1.13±0.09				0	NS		
			40 g ISP	17	1.11±0.08				0	NS		
			50 g ISP	15	1.13±0.05				0.039	NS		
			Control/Pl	16	1.10±0.08				-0.026	NS		
	Lp(a)	1º	20 g ISP	15	55.3 (95% CI: 7.6-266.4)		SE	f/up	52.3 (95% CI: 6.5-326.2)			
			30 g ISP	18	64.2 (95% CI: 3.1-310.7)				75.7 (95% CI: 4.2-272.6)			
			40 g ISP	17	61.3 (95% CI: 8.4-672.7)				59.0 (95% CI: 7.3-578.7)			
			50 g ISP	15	74.1 (95% CI: 3.3-469.2)				68.0 (95% CI: 2.3-514.7)			
			Control/Pl	16	42.8 (95% CI: 1.0-340.4)				43.9 (95% CI: 0.0-410.1)			
	TC	1º	20 g ISP	15	5.98±0.22	mmol/L	SE	Δ	-0.126	0.04		
			30 g ISP	18	6.01±0.18				-0.115	0.04		
			40 g ISP	17	5.96±0.20				-0.053	NS		
			50 g ISP	15	6.28±0.18				-0.167	0.02		
			Control/Pl	16	6.08±0.22				0.222	NS		
	Tg	1º	20 g ISP	15	1.77±0.12	mmol/L	SE	Δ	0.632	NS		
			30 g ISP	18	2.52±0.31				0.782	NS		
			40 g ISP	17	2.05±0.22				0.443	NS		
			50 g ISP	15	2.18±0.28				0.872	NS		
			Control/Pl	16	2.14±0.28				0.664	NS		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
Tonstad 2002	HDL		30 g ISP	34	1.48±0.42	mmol/L	SD	ΔΔ	0.04 (95% CI: -0.02, 0.10)			ns
			50 g ISP	31	1.35±0.33							
			Control 30 g	36	1.26±0.39							
			Control/Pl	29	1.33±0.37							
	Homocysteine		30 g ISP	34	10.0±2.2	Other	SD	ΔΔ	-0.8 (95% CI: -1.4, -0.2)			0.005
			50 g ISP	31	10.6±2.9							
			Control 30 g	36	10.1±2.2							
			Control/Pl	29	10.6±2.5							
	LDL		30 g ISP	34	4.81±0.54	mmol/L	SD	ΔΔ	-0.26 (95% CI: -0.43, -0.09)			0.01
			50 g ISP	31	4.58±0.50							
			Control 30 g	36	4.88±0.66							
			Control/Pl	29	4.96±0.50							
	Lp(a)		30 g ISP	34	437±410	mg/L	SD	ΔΔ	25 (95% CI: -4, 54)			ns
			50 g ISP	31	417±498							
			Control 30 g	36	405±314							
			Control/Pl	29	367±409							
	TC		30 g ISP	34	6.86±0.67	mmol/L	SD	f/up	6.00±0.55			
			50 g ISP	31	6.52±0.63				5.61±0.71			
			Control 30 g	36	6.84±0.72				6.29±0.54			
			Control/Pl	29	6.90±0.54				6.13±0.53			
	Tg		30 g ISP	34	1.28±0.38	mmol/L	SD	ΔΔ	-0.04 (95% CI: -0.22, 0.14)			ns
			50 g ISP	31	1.33±0.70							
			Control 30 g	36	1.57±0.76							
			Control/Pl	29	1.46±0.67							
Uesugi T 2002	HDL	1º	Isoflavone	12	66.2±15.8		SE	f/up	65.1±16.8			NS
			Control/Pl	11	64.9±15.2				68.1±14.2			
	LDL	1º	Isoflavone	12	148.1±34.7		SE	f/up	138.4±36.1	<0.05		NS
			Control/Pl	11	162.3±24.5				163.9±21.6	NS		
	Serum Osteocalcin	1º	Isoflavone	12	8.5±1.2		SE	f/up	7.4±1.1	NS		
			Control/Pl	11	7.2±0.7				7.1±0.6	NS		
	TC	1º	Isoflavone	12	226.3±39.7		SE	f/up	215.4±44.4	<0.05		NS
			Control/Pl	11	237.6±31.2				240.9±25.4	NS		
	Tg	1º	Isoflavone	12	94.8±43.9		SE	f/up	106.1±51.0	NS		NS
			Control/Pl	11	105.2±40.0				97.5±27.5	NS		
Uesugi T 2003	FSH	1º	Isoflavone	11	56.5±13.2		SD	f/up	55.8±10.8			0.89

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Control/Pl	10	73.5±12.4				60.9±13.3			
	HDL	1°	Isoflavone	11	65.2±4.0	mg/dL	SD	f/up	64.0±4.1			0.28
			Control/Pl	10	70.6±67.1				67.1±5.5			
	TC	1°	Isoflavone	11	223.7±14.7	mg/dL	SD	f/up	218.7±11.5			0.69
			Control/Pl	10	221.1±6.3				219.9±7.0			
	Tg	1°	Isoflavone	11	126.5±17.4	mg/dL	SD	f/up	112.3±16.0			0.22
			Control/Pl	10	117.7±15.4				135.2±9.9			
Upmalis 2000	FSH	2°	Soy Isofla	59	76.2			f/up	85.3	NS		
			Control/Pl	63	79.3				86.3	NS		
	NTx	2°	Soy Isofla	59	52.6			f/up	53.3			
			Control/Pl	63	54.8				53.4			
	Serum Osteocalcin	2°	Soy Isofla	59	13.43			f/up	13.75			
			Control/Pl	63	13.75				14.89			
	Vasomotor: Night Sweats/day	1°	Soy Isofla	59	1.52			Δ	-62%			NS
			Control/Pl	63	1.89				-34%			
Van Horn 2001	HDL		Oats/Soy	32*	1.59	mmol/L		Δ	-0.01	NS		
			Wheat/Soy	31*	1.66				-0.01	NS		
			Oats/Milk	32*	1.74				-0.03	NS		
			Control/Pl	32*	1.64				-0.02	NS		
	LDL		Oats/Soy	32*	3.89	mmol/L		Δ	-0.27	<0.02		
			Wheat/Soy	31*	3.80				0.01	NS		
			Oats/milk	32*	4.01				-0.23	<0.02		
			Control/Pl	32*	3.91				-0.03	NS		
	TC		Oats/Soy	32*	6.17	mmol/L		Δ	-0.21	<0.02		
			Wheat/Soy	31*	6.06				0.01	NS		
			Oats/milk	32*	6.33				-0.24	<0.02		
			Control/Pl	32*	6.21				0.00	NS		
Van Patten 2002	Hot flash	1°	Soy beverage	59	4.7	Weekly		Δ	-26%	<0.05		NS
			Rice beverage	64	5.2	frequency			-35%	<0.05		
Verrillo 1985	HDL	1°	Substitution	19	1.3±0.1	mmol/L	SD	Δ	+7.7%	NS		
			Addition	38	1.4±0.1				-7.1%	NS		
			Control/Pl	0*								
	LDL	1°	Substitution	19	6.7±0.5	mmol/L	SD	Δ	-38.8%	<0.01		
			Addition	38	6.3±0.2				-36.5%	<0.01		
			Control/Pl	0								
	TC	1°	Substitution	19	8.8±0.4	mmol/L	SD	Δ	-29.5%	<0.01		
			Addition	38	8.7±0.2				-29.9%	<0.01		

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
			Control/Pl	0								
	Tg	1º	Substitution	19	1.7±0.2	mmol/L	SD	Δ	-11.8%			
			Addition	38	2.2±0.6				-18.2%			
			Control/Pl	0								
Vigna GB 2000	DBP	2º	ISP w/ Isofl.	40	81.9±8.1		SD	Δ	-0.1±10.2	NS		
			Control/Pl	37	82.5±10.4				-3.1±13.1	NS		
	HDL	2º	ISP w/ Isofl.	40	1.57±0.36	mmol/L	SD	f/up	1.58±0.35	NS		
			Control/Pl	37	1.61±0.38				1.58±0.37	NS		
	LDL	2º	ISP w/ Isofl.	40	4.13±0.87	mmol/L	SD	f/up	3.78±0.77	<0.01		
			Control/Pl	37	4.33±0.87				4.01±0.73	<0.01		
	Lp(a)	2º	ISP w/ Isofl.	40	160 (Range: 30-1140)	mg/L		f/up	170 (Range: 20-1030)	NS		
			Control/Pl	37	170 (Range: 50-1010)				200 (Range: 40-1190)	NS		
	SBP	2º	ISP w/ Isofl.	40	127.2±15.8	mm Hg	SD	Δ	-3.2±16.1	NS		
			Control/Pl	37	129.9±15.1				-8.6±20.9	NS		
	TC	2º	ISP w/ Isofl.	40	6.37±1.01	mmol/L	SD	f/up	5.96±0.95	<0.01		
			Control/Pl	37	6.55±0.93				6.14±0.82	<0.01		
	Tg	2º	ISP w/ Isofl.	40	1.47±0.90	mmol/L	SD	f/up	1.31±0.60	NS		
			Control/Pl	37	1.32±0.77				1.19±0.57	NS		
Wangen 2000 (post-menopausal women only)	bAP	1º	ISP w/ Isofl.	17	20.9±0.7	U/L	SE	f/up	22.3±0.5	<0.05	NS	
			ISP w/ Isofl.						22.3±0.6	<0.05	NS	
			ISP w/o Isofl.						24.6±0.6	<0.05	<0.05	
	OC	1º	ISP w/ Isofl.	17	2.5	nmol/L		Δ	+0.36	NS	NS	
			ISP w/ Isofl.						+0.6	NS	NS	
			ISP w/o Isofl.						+0.6	NS	NS	
	D-pyr	1º	ISP w/ Isofl.	17	6.84	nmol/mmol creatinine		Δ	-0.52	NS	NS	
			ISP w/ Isofl.						-0.07	NS	NS	
			ISP w/o Isofl.						-0.73	NS	NS	
Wangen K 2001	HDL	2º	Low Isofla	17	52±17 SD	mg/dL	Unclear SD/SE	f/up	53.3±0.9 SE	NS		
			High Isofl	18	same				52.7±0.9 SE	NS		
			No Isoflav	18	same				52.0±0.9 SE	NS		
			Control/Pl	0								

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	LDL	2º	Low Isofla	17	136±31 SD	mg/dL	Unclear SD/SE	ΔF	ND	0.0006	0.07	
			High Isofl	18	Same				-6.5%	0.0003	0.02	
			No Isoflav	18	Same					0.02		
			Control/Pl	0								
	Lp(a)	2º	Low Isofla	17	25±1 SE	mg/dL	SE	f/up	27.2±0.9 SE	NS		
			High Isofl	18	Same				27.4±0.8 SE	NS		
			No Isoflav	18	Same				26.8±0.8 SE	NS		
			Control/Pl	0								
	TC	2º	Low Isofla	17	215±26 SD	mg/dL	Unclear SD/SE	f/up	193±3 SE	0.0004		
			High Isofl	18	same				191±2 SE	0.0004	0.17	
			No Isoflav	18	same				197±2 SE	0.0006		
			Control/Pl	0								
	Tg	2º	Low Isofla	17	130±114 SD	mg/dL	Unclear SD/SE	f/up	108±7 SE	NS		
			High Isofl	18	Same				108±7 SE	NS		
			No Isoflav	18	Same				103±7 SE	NS		
			Control/Pl	0								
Washburn 1999	DBP	1º	Soy qD	42	82.2±11.4 SD		Unclear SD/SE	f/up	76.3±1.4 SE	NS		
			Soy BID	42	Same				73.7±1.4	<0.01		
			Control/Pl	42	Same				78.6±1.4			
	Fasting Blood Glucose	2º	Soy qD	42	91.7±20.6 SD	mg/dL	Unclear SD/SE	f/up	92.6±1.4 SE	NS		
			Soy BID	42	Same				92.3±1.5	NS		
			Control/Pl	42	Same				91.8±1.4			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	HDL	1°	Soy qD	42	54.9±15.6 SD	mg/dL	Unclear SD/SE	f/up	52.2±0.9 SE		NS	
			Soy BID	42	Same				52.2±0.9		NS	
			Control/Pl	42	Same				53.3±0.9			
	LDL	1°	Soy qD	42	126.9±38.5 SD	mg/dL	Unclear SD/SE	ΔF	-7.5%		<0.05	
			Soy BID	42	Same				-7.5%		<0.01	
			Control/Pl	42	Same							
	SBP	1°	Soy qD	42	132.0±19.6 SD		Unclear SD/SE	f/up	124.2±1.6 SE		NS	
			Soy BID	42	Same				125.3±1.6		NS	
			Control/Pl	42	Same				126.6±1.7			
	TC	1°	Soy qD	42	208.0±40.5 SD	mg/dL	Unclear SD/SE	ΔF	-6%		<0.01	
			Soy BID	42	Same				-6%		<0.01	
			Control/Pl	42	Same							
	Tg	1°	Soy qD	42	131.1±67.1 SD	mg/dL	Unclear SD/SE	ΔF	-28		NS	
			Soy BID	42	Same				-15		NS	
			Control/Pl	42	Same							
	Vasomotor Symptoms: per wk	1°	Soy qD	42			SE	f/up	23.1±4.9		NS	
			Soy BID	42					22.3±2.7		NS	
			Control/Pl	42					21.3±3.0			
Watatnabe 2000	E2	1°	Soy	19		pg/mL		f/up	~20	NS		
			Control/Pl						~25	NS		
Wong WW 1998	HDL: Baseline < 50/40 mg/DL (m/w)	1°	Soy Protein	13	1.01±0.29	mmol/L	SD	f/up	0.96±0.26			NS
			Control/Pl	13	1.06±0.36				0.93±0.29			

Study	Outcome	Primary / Secondary	Cohort	N (final)	Base			Follow-up / Change		P W/in	P Diff	P net Δ
	HDL: Baseline > 50/40 mg/DL (m/w)	1°	Soy Protein	13	1.06±0.26	mmol/L	SD	f/up	0.98±0.31			NS
			Control/Pl	13	1.06±0.31				0.98±0.28			
	LDL: Baseline < 130 mg/dL	1°	Soy Protein	13	2.87±0.49	mmol/L	SD	f/up	2.53±0.65			0.03
			Control/Pl	13	2.82±0.62				2.69±0.54			
	LDL: Baseline > 130 mg/dL	1°	Soy Protein	13	4.68±0.65	mmol/L	SD	f/up	4.09±1.09			0.03
			Control/Pl	13	4.71±0.67				4.34±0.96			
	TC: Baseline < 200 mg/dL	1°	Soy Protein	13	4.40±0.60	mmol/L	SD	f/up	4.01±0.96			NS
			Control/Pl	13	4.37±0.75				4.14±0.72			
	TC: Baseline > 200 mg/dL	1°	Soy Protein	13	6.78±0.70	mmol/L	SD	f/up	6.39±0.98			NS
			Control/Pl	13	6.85±0.72				6.57±0.93			
	Tg: LDL <130 mg/dL	1°	Soy Protein	13	1.01±0.36	mmol/L	SD	f/up	1.11±0.47			NS
			Control/Pl	13	1.04±0.55				0.96±0.31			
	Tg: LDL >130 mg/dL	1°	Soy Protein	13	2.37±1.34	mmol/L	SD	f/up	3.00±2.28			NS
			Control/Pl	13	2.94±2.64				2.83±1.83			
Wu 2000	E2	1°	Soy diet	20	Outcomes tabulated							
Xu X 2000	Urinary 2OHE;Urinary 16aOHE	1°	ISP+ Control/Pl	18	Outcomes tabulated							
Yamaguchi 2001	Serum Osteocalcin	1°	nijiru	12	graphically represented		SE	f/up	graphically represented	<0.01		
			?	6 m						<0.01		
			?	6 w						<0.01		
Yamashita 1998	Fasting Blood Glucose	1°	Soy	17	4.6±0.4	mmol/L	SD	f/up	4.7±0.4			
			Control/Pl	19	4.7±0.5				4.8±0.3			
Yamori 2002	Urinary Pyr	1°	Soybean and sesame	20	3.04	nmol/umol creatinine		Δ	-0.95	<0.05		NS
			Sesame	20	2.65				--0.48	NS		
	Urinary D-Pyr	1°	Soybean and sesame	20	7.6	nmol/umol creatinine		Δ	-2.8	NS		<0.05
			Sesame	20	5.2				+0.7	NS		
Yildirir 2001	FMD (RH)	1°	Soy Diet	20	8.2±0.6	%	SD	f/up	12.6±0.6	0.002		
			Control/Pl	0*								
	Lp(a)	1°	Soy Diet	20	23.4±28.6	mg/dL	SD	f/up	22.2±28.0	0.49		
			Control/Pl	0*								

Δ = within cohort difference
ΔΔ = net difference from the reference group
Outcomes tabulated: The results not summarized but the study cited for the outcome in the report

Peer Reviewers

We gratefully acknowledge the following individuals who reviewed the initial draft of this Report and provided us with constructive feedback. Acknowledgments are made with the explicit statement that this does not constitute endorsement of the report.

David Atkins, MD, MPH

Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
Rockville, Maryland

D. Lee Alekel, PhD

Department of Food Science and Human Nutrition
Iowa State University
Ames, Iowa

Elizabeth Jackson, MD

Department of Medicine
Division of Cardiovascular Medicine
University of Massachusetts Medical School
Worcester, Massachusetts

Penny Kris-Etherton, PhD, RD

Pennsylvania State University
University Park, Pennsylvania

Mindy S. Kurzer, PhD

Director of Graduate Studies, Nutrition
Department of Food Science and Nutrition
University of Minnesota
St. Paul, Minnesotta

Gertraud Maskarinec, MD, PhD

Cancer Research Center of Hawaii
Honolulu, Hawaii

Katherine M. Newton, PhD

Center for Health Studies
Group Health Cooperative
Seattle, Washington

Frank M. Sacks, MD

Nutrition Department
Harvard School of Public Health
Boston, Massachusetts

Anne Thurn, PhD

Evidence-Based Review Program
Office of Dietary Supplements
National Institutes of Health
Bethesda, Maryland

Yvonne T. Van der Schouw, PhD

Julius Center for Health Sciences and Primary Care
University Medical Center Utrecht
Utrecht, Netherlands

Linda V. Van Horn, PhD

Department of Preventive Medicine
Feinberg Cardiovascular Research Institute
Northwestern University
Chicago,Illinois

Connie M. Weaver, Ph.D.

Foods and Nutrition
Purdue University
West Lafayette, Indiana