Effects of sumac powder capsule (Rhus coriaria L.) with restricted calorie diet on anthropometric indices, body composition, level of inflammatory biomarkers, oxidative stress, appetite hormones, glycemic indices, lipid profile and depression in obese or overweight women with depression

Protocol summary

Study aim
Determine the effects of sumac powder with calorie-restricted diet on anthropometric indices, body composition, inflammatory factors, oxidative stress, appetite hormones, glycemic indexes, lipids profile and depression symptoms in overweight or obese women with depression.

Design
This study is a randomized double-blind controlled clinical trial with two parallel groups. Sixty-six patients are randomly divided into two groups: sumac and control.

Settings and conduct
Invite overweight or obese individuals referring to nutrition clinic of Shahid Beheshti. After examining the criteria for entering the study, 10cc blood samples are taken. food recall questionnaire, depression, appetite and physical activity questionnaire are completed. Supplements are given to individuals for 6 weeks. For double-blind execution of this research, at the start of the study, the collection of Supplement cans are coded by third person as A and B.

Participants/Inclusion and exclusion criteria
Inclusion: overweight and obesity; moderate and mild depression
Exclusion: Use of anti-inflammatory drugs; antidepressants; Diabetes; inflammatory diseases; Infectious diseases; Acute psychiatric disorders; Sensitivity to sumac

Intervention groups
The intervention group receive a weight loss diet and 3 capsules each contains 1000 mg of sumac and control group receive, weight loss diet and 3 placebo capsules (starch) for 12 weeks.

Main outcome variables
Weight; body mass index; waist circumference; hip circumference; waist to hip; body fat percentage; visceral fat; fat free mass; serum level of hs-CRP; TNF-α; IL-6; malondialdehyde; leptin; neuropeptideY; triglyceride; total cholesterol; low density lipoprotein-C; high density lipoprotein-C; glucose; insulin; Insulin resistance.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20131228015968N6
Registration date: 2019-05-10, 1398/02/20
Registration timing: registered_while_recruiting

Last update: 2019-05-10, 1398/02/20
Update count: 0

Registration date
2019-05-10, 1398/02/20

Registrant information
Name
Atoosa Saidpour

Name of organization / entity
Shahid Beheshti University of Medical Sciences, School of nutrition

Country
Iran (Islamic Republic of)

Phone
-

Email address
a.saidpour@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source
Scientific title

Effects of sumac powder capsule (Rhus coriaria L.) with restricted calorie diet on anthropometric indices, body composition, level of inflammatory biomarkers, oxidative stress, appetite hormones, glycemic indices, lipid profile and depression in obese or overweight women with depression

Public title

Effects of sumac powder capsule (Rhus coriaria L.) with restricted calorie diet on obesity and depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female gender Willingness to cooperate Age 20-65 years Body mass index above 24/9 kg/m2 Mild to moderate depression

Exclusion criteria:
Use of anti-inflammation drugs (Steroids and non steroids) Continuous use (more than once a week) of vitamin and mineral supplements with anti-inflammatory and antioxidant properties such as omega-3, vitamin E in the past month Use of weight loss and appetite suppressants Use of antidepressants Diabetes Cases of various autoimmune inflammatory diseases such as multiple sclerosis, rheumatoid arthritis and ... Acute gastrointestinal disease (gastric ulcer, bowel disease, etc.) Chronic kidney or liver disease, with the exception of non-alcoholic fatty liver Infectious diseases up to 1 month before the start of the study Acute mental disorders, Bipolar Disorders, Schizophrenia Weight loss diet in one months ago Surgery in a recent month Sensitivity to sumac Pregnancy Lactation

Age

From 20 years old to 65 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are classified into overweight and obese groups based on body mass index and are randomly assigned to one of the sumac group or placebo group. The random grouping of the two groups is done using Stratified Blocked Randomization. Separate randomization is done within each group. The size of the blocks is 4, with two allocations to the intervention group (A) and two allocations to the placebo group (B). With 6 different permutations, AABB, ABAB, BBAA, BABA, ABBA, BAAB will be created.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind clinical trial (patients and researchers). In order to implement this study, at the start of the study, a set of cans contains sumac or placebo are coded by a third party (someone other than the researchers) as A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Institute of Nutrition Research and Food Industry of the country

Street address

No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1397.020

2

Ethics committee

Name of ethics committee

Ethics committee of Institute of Nutrition Research and Food Industry of the country

Street address

No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code
Health conditions studied

1
Description of health condition studied
Overweight and obesity
ICD-10 code
E66
ICD-10 code description
Overweight and obesity

2
Description of health condition studied
depression
ICD-10 code
F32.0
ICD-10 code description
Major depressive disorder, single episode, mild

Primary outcomes

1
Description
Body weight
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
seca scale

2
Description
Body Mass Index

3
Description
Waist Circumference
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Meter strip

4
Description
Hip circumference
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Meter strip

5
Description
Waist circumference to hip ratio
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Calculation

6
Description
Body fat percentage
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Body Analyzer

7
Description
Visceral fat
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Body Analyzer

8
Description
Body fat free mass
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Body Analyzer

Secondary outcomes

1
Description
Malondialdehyde
Timepoint
Before intervention and after 12 weeks of intervention
Method of measurement
ELISA

2
Description
Serum concentration of Leptin
Timepoint
Before intervention and after 12 weeks of intervention
Method of measurement
ELISA

3
Description
Serum concentration of Neuropeptide Y
Timepoint
Before intervention and after 12 weeks of intervention
Method of measurement
ELISA

4
Description
Serum concentration of hs-CRP
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
ELISA

5
Description
Serum concentration of TNF-alpha
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
ELISA

6
Description
Serum concentration of IL-6
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
ELISA

7
Description
Serum concentration of glucose

8
Description
Serum concentration of insulin
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
ELISA

9
Description
Serum concentration of triglyceride
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
Enzymatic method

10
Description
Serum concentration of total cholesterol
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
Enzymatic method

11
Description
Serum concentration of High Density Lipoprotein
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
Enzymatic method

12
Description
Serum concentration of low density lipoprotein
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
Enzymatic method

13
Description
HOMA-IR
Timepoint
calculation ([Glucose (mg/dl)]*[Insulin]/405)
Method of measurement
Before intervention, twelve weeks after intervention

14
Description
Appetite
Timepoint
Before intervention, twelve weeks after intervention

**Method of measurement**

simple appetite questionnaire

---

15

**Description**

Depression

**Timepoint**

Before intervention, twelve weeks after intervention

**Method of measurement**

Beck Depression Inventory

---

**Intervention groups**

1

**Description**

Intervention group: daily intake of 3 g sumac powder as 3 capsules of 1000 mg before each meals with weight reduction diet for 12 weeks

**Category**

Treatment - Drugs

2

**Description**

Control group: daily intake of 3 g starch as 3 capsules of 1000 mg before each meals with weight reduction diet for 12 weeks

**Category**

Placebo

---

**Recruitment centers**

1

**Recruitment center**

In English:

**Name of recruitment center**

In Persian:

کلینیک تغذیه و رژیم درمانی دانشگاه علوم پزشکی شهید بهشتی

**Full name of responsible person**

Nastaran Hariri

**Street address**

Baran St., Hafezi (Arghavan) Ave., Farahzadi Blvd., Qods (Gharb) twon, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2235 7483

**Email**

nastaranhariri@gmail.com

---

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical sciences- School of Nutrition

**Full name of responsible person**

Esmat Nasseri

**Street address**

No. 7, Hafezi (Arghavan) st., Farahzadi Blvd., Qods (Gharb) twon, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2235 7483

**Email**

Nasseri_esm@hotmail.com

---

**Person responsible for general inquiries**

Contact

**Name of organization / entity**

Shahid Beheshti University of Medical sciences- School of Nutrition

**Full name of responsible person**

Nastaran Hariri

**Position**

PhD. student of nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

NO. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd, Qods (Gharb) twon, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**
Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical sciences-
School of Nutrition
Full name of responsible person
Atoosa Saidpour
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
No. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd., Qods
(Gharb) twon, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7384
Email
atoosa.saidpour@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical sciences-
School of Nutrition
Full name of responsible person
Nastaran Hariri
Position
PhD. student of nutrition
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
NO. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd, Qods
(Gharb) twon, Tehran
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
nastaranhariri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to
make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to
make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to
make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to
make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable