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
**Expected recruitment start date**  
2019-01-06, 1397/10/16

**Expected recruitment end date**  
2019-09-21, 1398/06/30

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**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**  
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**Province**  
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**Postal code**  
1981619573

**Approval date**  
2019-01-01, 1397/10/11

**Ethics committee reference number**  
IR.SBMU.NNFTRI.REC.1397.020

**2**

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**Name of ethics committee**  
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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
   - Timepoint: before intervention, after 6 weeks of intervention and after 12 weeks of intervention
   - Method of measurement: calculation (kg/m²)

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

**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**

**Name of recruitment center**
کلینیک تغذیه و رژیم درمانی دانشگاه علوم پزشکی شهید بهشتی

**Full name of responsible person**
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### 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**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Vice chancellor for research, Shahid Beheshti University of Medical sciences- School of Nutrition

**Proportion provided by this source**
100%

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
empty

**Country of origin**

**Type of organization providing the funding**
Academic

### 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

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Person responsible for scientific inquiries

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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