The effect of Matricaria chamomilla extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

 Protocol summary

 Summary
 Sleep is one of the basic human needs. Research suggests that sleep quality is diminished with increasing age and the elderly are susceptible to damage caused by poor quality of sleep. Pharmacotherapy for the treatment of sleep disorders, which in many cases may cause adverse effects in the elderly. Research has shown that chamomile extract may be effective on sleep quality. Therefore, in this quasi-experimental clinical trial to determine the effect of MC extract on sleep quality in elderly people admitted to nursing homes takes place, aged 80, after informed consent, are divided into two groups. Intervention group twice daily after lunch and after dinner, chamomile extract 400 mg capsules and the control group received no intervention will be. Sleep quality in elderly people by participating in both pre- and post-intervention questionnaires Pittsburgh Sleep Quality Standard will be measured and will be compared.

 General information

 Acronym
 IRCT registration information
 IRCT registration number: IRCT2013102015080N1
 Registration date: 2014-05-23, 1393/03/02
 Registration timing: registered_while_recruiting

 Registration status
 Recruitment complete
 Funding source
 Khorasgan (Isfahan) Branch , Islamic Azad University

 Expected recruitment start date
 2014-05-14, 1393/02/24
 Expected recruitment end date
 2014-06-14, 1393/03/24
 Actual recruitment start date
 empty
 Actual recruitment end date
 empty
 Trial completion date
 empty

 Scientific title
 The effect of Matricaria chamomilla extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

 Public title
 The effect of chamomile on sleep in elderly

 Purpose
 Supportive

 Inclusion/Exclusion criteria
 Inclusion criteria: tend to participate in the study and give consent to do so; having more than 60 years of age; having mental health; the non- occurrence of whatever specific diseases of liver, kidney, asthma, cancer and mental disorders are diagnosed; stay in one of the nursing homes studied; ability to answer questions; lack of sensitivity to chamomile or any of its ingredients; lack of continuous consumption of tea or chamomile extract during the last six months; capability than chamomile capsules orally; lack of sleep-related illnesses, such as obstructive sleep apnea or restless legs syndrome; the lack of dependence on any drug, analgesics, anti-depressants, sleeping, alcohol and the lack of heparin, warfarin, and aspirin ( due to drug interactions with chamomile extract ). Exclusion criteria: stopping chamomile by subject, for whatever reason before the end of the intervention period; drug against the patient dose; catching whatever disease during the study period, which led to a ban by the oral administration of MC; indicate any allergic reaction to the MC during the research; lack of willingness to cooperate in the
investigation; withdrawal from the study for reasons such as death, illness, or transferred to other centers.

**Age**
From 60 years old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
No information

**Sample size**
Target sample size: 80

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

**1**

**Ethics committee**
Name of ethics committee
Isfahan University of Medical Sciences

**Street address**
Isfahan University of Medical Sciences

**City**
Isfahan

**Postal code**

**Approval date**
2014-05-14, 1393/02/24

**Ethics committee reference number**
23810403922004

**Health conditions studied**

**1**

**Description of health condition studied**
Insomnia

**ICD-10 code**
G47.0

**ICD-10 code description**
Disorders of initiating and maintaining sleep [insomnias]

**Primary outcomes**

**1**

**Description**

**Quality of sleep**

**Timepoint**
Pre-intervention and post-intervention

**Method of measurement**
Pittsburgh Sleep Quality Index

**Secondary outcomes**
empty

**Intervention groups**

**1**

**Description**
Chamomile extract of 400 mg twice daily

**Category**
Treatment - Drugs

**2**

**Description**
No action

**Category**
N/A

**Recruitment centers**

**1**

**Recruitment center**
Name of recruitment center
Nursing homes related to IsfahanWelfare

**Full name of responsible person**

**Street address**

**City**
Isfshsn

**Sponsors / Funding sources**

**1**

**Sponsor**
Name of organization / entity
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran

**Full name of responsible person**
Dr. payam najafi

**Street address**
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran

**City**
Isfahan

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran

**Proportion provided by this source**
Person responsible for general inquiries

Contact
Name of organization / entity
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran
Full name of responsible person
Mehrdad Abdullahzadeh
Position
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty