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A pilot study of information about sleep mailed directly to patients

Submission date
01/05/2020

Recruitment status
No longer recruiting

Registration date
05/05/2020

Overall study status
Completed

Last Edited
12/10/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Sleeping pills called benzodiazepines or benzodiazepine receptor agonists ("z-drugs") are often prescribed for insomnia. Some, but not all, studies suggest that sleeping pills are associated with increased risk of falls, hip fracture, cognitive impairment, and death in older adults. The purpose of this study is to investigate whether a program designed to promote discontinuation of sleeping pills improves health outcomes in older patients compared to a "control" program that provides information about general sleep information only.

Who can participate?
Individuals aged 65 years or older who obtain care from VA medical centers in VISN 19 (Colorado, Oklahoma, Utah, Montana, Wyoming, Idaho) and have been prescribed a benzodiazepine or z-drug from a VA pharmacy within the past 18 months.

What does the study involve?
We will randomly select patients 65 years or older who received sleeping pills within the past 18 months from VA facilities in VISN 19 to receive the active program alone, active program plus telephone call, or control program. The active program includes a mailed brochure on the risks of taking sleeping pills and information about a free, anonymous online cognitive behavioral therapy for insomnia program. The active program plus telephone call group receives the same brochure and also a call from research staff to promote the use of the online insomnia program. The control group includes a mailed brochure about the importance of sleep and information about a website about the importance of sleep. A mailed survey on insomnia severity is administered before and after the program. Usability of the mailed materials is assessed in the mailed survey after the program. Up to 50 participants will also receive a call from research staff at the end of the study to discuss their experience with the intervention materials. At six and twelve months after randomization, VA patient data will be extracted from the medical record and analyzed to assess sleeping pill, falls, hip fractures, and mortality rates.

What are the possible benefits and risks of participating?
There are no immediate direct benefits but participants may find the sleep material useful and

may find it satisfying to know that participants may be helping to improve care for veterans with sleep problems in the future. There is little risk other than the possible unintended loss of privacy or breach of confidentiality resulting from human error.

Where is the study run from?
Department of Veterans Affairs Greater Los Angeles Healthcare (USA)

When is the study starting and how long is it expected to run for?
November 2019 to June 2021

Who is funding the study?
Kripke Trust (USA)

Who is the main contact?
Dr Constance Fung, constance.fung@va.gov

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
4.4.19

Study information

Scientific Title
Sleep EducatioN information sent Directly to patients: pilot study

Acronym
SEND-pilot

Study objectives
Primary: A direct-to-patient mailing (that contains information about sleeping pill risks and how to access a free, anonymous online non-drug treatment for insomnia [cognitive behavioral therapy for insomnia program]) reduces benzodiazepines/benzodiazepine receptor agonist ("z-drug") prescriptions in older adults compared to a control condition.
Secondary: A direct-to-patient mailing (that contains information about sleeping pill risks and how to access a free, anonymous online cognitive behavioral therapy for insomnia program) improves health outcomes (e.g., insomnia severity, hip fractures, mortality) in older adults compared to a control condition.
Exploratory: Participants in the direct-to-patient mailing with a booster call will have reduced benzodiazepine/z-drug prescriptions compared to participants who do not receive a booster call.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/05/2019, Department of Veterans Affairs Greater Los Angeles Healthcare System Institutional Review Board (VA Greater Los Angeles Healthcare System, 11301 Wilshire Boulevard (Mailcode 151), Los Angeles, CA 90073, USA; +1 310-268-4437; Elizabeth.Corey@va.gov), ref: PCC 2019-020113

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
insomnia

Interventions
After the initial opt-out period, eligible participants are randomized to one of three groups:
1) Active program: mailed information about sleeping pill risks and a free, anonymous online cognitive behavioral therapy for insomnia website,
2) Active program plus booster telephone call: mailed information about sleeping pill risks and a free, anonymous online cognitive behavioral therapy for insomnia website plus a booster telephone call asking about content of brochure and encouraging the participant to visit the online cognitive behavioral therapy for insomnia program described in the mailed information, or
3) Control program: mailed information about the importance of sleep (non-directed information) and information about a free, anonymous website about the importance of sleep (non-directed information).

Stratified block randomization is used for group allocation (Stata uniform() function). Stratification variables: whether or not the medication is approved by the US Food and Drug Administration (FDA) for insomnia and chronicity of the prescription (>= 3 months vs < 3 months).

Intervention Type
Behavioural

Primary outcome(s)
Active benzodiazepine and/or z-drug prescription listed in the electronic health record 6 months after randomization

Key secondary outcome(s))
1. Insomnia severity (measured using the Insomnia Severity Index) 6 months and 12 months after randomization
2. Active benzodiazepines and/or z-drug prescriptions listed in the electronic health record 12 months after randomization
3. Hip fracture rate at 6 and 12 months after randomization measured using the electronic health record
4. Mortality rate 6 and 12 months after randomization measured using the electronic health record
5. Usability of mailed program materials and websites measured using a mailed survey at the end of the program
6. Acceptability of mailed program materials and websites measured using a mailed survey at the end of the program

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Aged 65 years or older
2. Obtain care from VA medical centers in VISN 19 (Colorado, Oklahoma, Utah, Montana, Wyoming, Idaho)
3. Have been prescribed a benzodiazepine or z-drug from a VA pharmacy within the past 18 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
2009

Key exclusion criteria
1. History of seizures based on problem list in VA electronic health record
2. History of bipolar disorder based on problem list in VA electronic health record
3. Deceased

Date of first enrolment
27/11/2019

Date of final enrolment
06/03/2020

Locations

Countries of recruitment
United States of America

Study participating centre
Department of Veterans Affairs Greater Los Angeles Healthcare
16111 Plummer Street (11E)
North Hills
United States of America
91343

Sponsor information

Organisation
Department of Veterans Affairs Greater Los Angeles Healthcare

ROR
https://ror.org/05xcarb80

Funder(s)

Funder type
Not defined

Funder Name
Kripke Trust

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Constance Fung, MD, MSHS (constance.fung@va.gov). Data will become available on 31/12/2023 for 7 years. Limited deidentified datasets will be shared upon request for scientific analyses that have received approval from the requestor's institutional review board and compliance/privacy officers after review and approval by the local VA IRB and Compliance/Privacy Officer. Written informed consent was not obtained from participants.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/10/2022	12/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes