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A GP training intervention to reduce benzodiazepine prescription in primary care

Submission date
02/02/2016

Recruitment status
No longer recruiting

Registration date
06/04/2016

Overall study status
Completed

Last Edited
10/05/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Clinicians mainly prescribe benzodiazepines (BZDs) to treat anxiety and insomnia, or as adjuvants (i.e. in addition to other therapy) in treatment of depression. International guidelines specifically recommend short-term use because long-term use can increase the risk of cognitive impairment (not being able to think clearly), falls, fractures, and mortality (death). Despite these potentially harmful consequences, many physicians prescribe BZDs for long periods. General practitioners (GPs) issue most of these prescriptions, so withdrawal should also be managed by GPs; however, doctors and patients often consider stopping BZD as very challenging. A primary care (GP-run) structured intervention (program) to reduce the use of BZD has led to a significant drop in the number of long-term benzodiazepine users. The aim of this study is to see whether GPs that have had workshop training in BZD prescription/discontinuation and have been provided with information on the BZDs they give to patients (prescribe) every month will prescribe less of them than GPs that are not given the training or information.

Who can participate?
GPs working in Balearic Island Primary Care, Tarragona-Reus Primary Care and Arnau de Vilanova-llíria Primary Care health care centers.

What does the study involve?
Health care centers enrolled in the study are randomly allocated to one of two groups, an intervention and a control group. GPs working in a health care center allocated to the intervention group attend a two hour workshop about BZD prescription and discontinuation. They then receive monthly information about the BZD prescriptions they provide over the next year. GPs working in a health center allocated to the control group do not receive any specific training, nor information about their prescriptions. All GPs are assessed after a year to see whether they have reduced the number of BZD prescriptions they provide.

What are the possible benefits and risks of participating?
GPs may benefit from a specific training in BZD prescription and discontinuation and their patients may benefit from reducing their use of these drugs. There are no known risks to participants taking part in this study.

Where is the study run from?
Son Serra- La Vileta Health care center, Palma (Spain)

When is the study starting and how long is it expected to run for?
January 2016 to December 2018

Who is funding the study?
Carlos III Health Institute of the Ministry of Economy and Competitiveness (Spain)

Who is the main contact?
Dr Caterina Vicens (scientific)
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Contact information

Type(s)
Scientific

Contact name
Mrs Catalina Vicens

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI15/01480

Study information

Scientific Title
Evaluation of a multifactorial intervention to reduce the consumption of benzodiazepines in primary care: a randomized cluster clinical trial

Acronym
BENZORED fase 4

Study objectives

A multifactorial intervention addressed to general practitioners including a two hours workshop training and followed by benzodiazepine prescription feed-back is effective in reducing benzodiazepine prescription.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Balearic Island Ethic Committee, 10/11/2015, ref: IB 3065/15

Study design
Cluster randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Benzodiazepine consumption

Interventions
Health centers enrolled in the study are randomly assigned to a intervention or a control group.
1. Intervention group: All GPs working in one of the intervention health centers attend a two hours workshop about the use of benzodiazepines and provided with monthly information about their benzodiazepine prescription indicators (DHD)
2. Control group: All GPs in this arm do not receive any specific training or information about their prescriptions

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Benzodiazepine

Primary outcome measure

Total GP Doses per 1000 Habitants per Day (DHD) of benzodiazepine at 12 months

Secondary outcome measures
1. Percentage of total long term benzodiazepine users at 12 months, measured via information about patient prescribed benzodiacepine for a period longer than six months registered in the prescription database of the electronic health records
2. Percentage of patient older than 65 long term benzodizepine users at 12 months, measured via information about patient older than 65 with a prescription of benzodiazepine registered in the prescription database of the electronic health records
3. Feasibility, adoption and fidelity of the intervention will be measured by an "ad hoc" questionnaire to measure GP opinion

Overall study start date
01/01/2016

Completion date
31/12/2018

Eligibility

Key inclusion criteria
All GPs from the health centers where the trials will be implemented

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
508 GPs

Total final enrolment
700

Key exclusion criteria
Unwillingness to participate

Date of first enrolment
01/06/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment

Spain

Study participating centre
IB-Salut (Balearic Island Primary Care)
Spain
07005

Study participating centre
Cat-Salut (Tarragona-Reus Primary Care)
Spain
43480

Study participating centre
Agencia Valenciana de Salut (Arnau de Vilanova-llíria Primary Care)
Spain
46980

Sponsor information

Organisation
Primary Care Management of Mallorca (Gerencia de Atención Primaria de Mallorca)

Sponsor details
C/ Reina Esclaramunda 9
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Sponsor type
Government

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
1. The effectiveness of the intervention will be published in a Primary Care/General Medicine journal
2. The factibility, adoption, feasibility and fidelity will be published in a Primary Care journal

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Caterina Vicens (caterinavicens@gmail.com). Data that will be shared: individual participant data that underlie the results reported in published articles. Data will be available: beginning 2 months following article publication. Data will be available for researchers who provide a methodologically sound proposal and individual participant data meta-analysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/01/2019	16/01/2020	Yes	No
Results article		06/05/2022	09/05/2022	Yes	No
Results article		28/07/2021	10/05/2024	Yes	No