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Reducing unnecessary prescriptions in healthcare of older adults through a behavioral intervention based on peer comparison

Submission date
02/03/2020

Recruitment status
No longer recruiting

Registration date
21/04/2020

Overall study status
Completed

Last Edited
14/12/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The prescription of drugs without evidence is a major health problem. In the case of people older than 65 years, polypharmacy (use of multiple medications) and adverse effects can have negative consequences for people's health and their quality of life. On the other hand, improper prescriptions cause expensive costs to the health system, without any benefit for the patient. Psychotropic drugs are among the inadequately prescribed drugs in the elderly population, including diverse medications for the treatment of patients with mild cognitive impairment and dementia. In Argentina, the most prescribed drug to treat cognitive impairment without a basis in evidence is nimodipine. The aim of this study is to reduce the unadvised prescription of nimodipine in the national healthcare system for older adults (INSSJP-PAMI). To achieve this, the researchers use a behavioral intervention based on the concept of social norm. According to this concept, the comparison with a social norm (or the perception of what most people do) has a major influence on people's behavior and has been shown to be successful in modifying specific behaviors in various areas of public policy, including physicians' prescriptive practice.

Who can participate?
Physicians working in ambulatory consultation at the INSSJP-PAMI in Argentina who prescribe nimodipine as a drug for the treatment of dementia o mild cognitive impairment.

What does the study involve?
The study involves a behavioral intervention delivered by email. Participants are randomly allocated to one of two groups. Those in the first group receive two emails with an interval of 3 months containing up-to-date evidence-based information about nimodipine correct use along with information on participants' prescription levels of nimodipine compared to that of their colleagues (social norm). Those in the second group, which serves as a control, receive two emails containing general information about the disadvantages of excessive medication in elderly.

What are the possible benefits and risks of participating?
Participants in the treatment group receive up-to-date information regarding the correct use of

nimodipine and evidence-based alternatives for treating dementia. Beyond this, patients who receive non-recommended prescriptions would benefit from its reduction and the healthcare system would diminish unnecessary expenditures. No harm or negative effects of the intervention are expected. The intervention implies no coercion over practitioners and always preserves their freedom to make medical decisions.

Where is the study run from?
INSSJP-PAMI (Argentina)

When is the study starting and how long is it expected to run for?
January 2019 to October 2020

Who is funding the study?
Interamerican Development Bank (IDB)

Who is the main contact?
Dr Fernando Torrente
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIMO2019

Study information

Scientific Title
Effect of social norm feedback e-mails on high-prescribers of Nimodipine in older adults: a randomized controlled trial

Study objectives
The experimental arm (behavioral "nudge") will show a significant reduction in nimodipine prescriptions during the 6 months intervention period in comparison with control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2019, Ethics Committee of INECO Foundation (Contact: Miss Paula Asorey, Pacheco de Melo 1854, CABA, Argentina; +54 (0)91163087722; pasorey@ineco.org.ar), no reference number

Study design
Pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Overprescription of nimodipine as a drug for treating or preventing cognitive deficit in older adults

Interventions
Participants are randomly allocated to control and experimental groups (1:1 ratio) controlling for number of nimodipine prescriptions over the last trimester of 2018 with R software with the package RandomizeR. Each arm receives two communications by email.

In the case of the experimental arm, the first communication includes two components: a) evidence-based information about the adequate use of nimodipine and b) the participant’s level of prescription of nimodipine compared to their peers (feedback with social norm). Three months later, a second message includes information on nimodipine prescriptions’ change observed by the participant during the previous quarter (“change” or “no change”). The email directed to those that reach a relative reduction of 10% of prescriptions compared to their baseline average includes an acknowledgement of their success (“acknowledgement version”).

The email directed to those who do not reach the target was intended to potentiate the social norm component and to encourage them to revise their prescriptive practice (“encouragement version”).

In the case of the control arm, the first message contains general information about the inconveniences of unnecessary drug prescription and polypharmacy in older adults and links to medical guidelines to improve the prescription. Three months later, the second email to the control group includes information about the risks and complications of the use of benzodiazepines in older adults.

Intervention Type
Behavioural

Primary outcome measure
Cumulative total number of nimodipine prescriptions per 1000 prescriptions of all drugs made by the targeted practitioner, registered in the electronic database of prescriptions of the INSSJP-PAMI, during the 6 months after the intervention started

Secondary outcome measures
1. Annual monetary savings attributable to the intervention at the national level. This number corresponds to the total estimated 1-year benefit minus the total estimated cost of the intervention. The total estimated 1-year benefit is projected as the product between the total number of physicians included in the study in both groups and the benefit per-physician/year (Treatment effect x Number of items prescribed by an average physician in the control group during 1 year x Direct average price of each item [in U$S], according to the registers of the INSSJP-PAMI). Total estimated cost corresponds to the salary of a public servant for two full-time weeks of work dedicated to intervention-related tasks according to national statistics (measured 6 months after the start of the intervention)
2. Qualitative perceptions of the participants regarding the intervention, assessed through a brief ad hoc survey to the intervention arm participants at the end of the study (6 months after the start of the intervention)

Overall study start date
01/01/2019

Completion date
31/10/2020

Eligibility

Key inclusion criteria
General practitioners who:
1. Prescribed nimodipine during the last quarter of 2018
2. Are within the top 25% prescribers of the drug

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1800

Total final enrolment
1811

Key exclusion criteria
1. Not in the top 25% of prescribers of nimodipine
2. Email address not available

Date of first enrolment
01/05/2019

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Argentina

Study participating centre
INSSJYP
Corrientes 665
Buenos Aires
Argentina
C1043AAG

Sponsor information

Organisation
INECO Foundation

Sponsor details
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Sponsor type
Research organisation

Website
http://www.fundacionineco.org

Funder(s)

Funder type
Other

Funder Name
Inter-American Development Bank

Alternative Name(s)
Banco Interamericano de Desarrollo, Banco Interamericano de Desenvolvimento, Banque Interaméricaine de Développement, IADB, BID, IDB

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United States of America

Results and Publications

Publication and dissemination plan
Future plans for publication and dissemination include:
1. Publication in a high-impact peer-reviewed journal
2. Reports of the IDB
3. Presentation in academic events

Intention to publish date
01/10/2020

Individual participant data (IPD) sharing plan
INSSJP-PAMI regulations and the agreement signed with the institution do not allow the researchers to share or make public the participant-level dataset of the study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			18/05/2020	No	No
Results article	results	01/12/2020	14/12/2020	Yes	No