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Effectiveness of a collaborative care intervention between pharmacies and primary care targeting hypertension and hyperlipidemia

Submission date
11/12/2018

Recruitment status
No longer recruiting

Registration date
12/12/2018

Overall study status
Completed

Last Edited
21/01/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Hypertension is a disease where the blood pressure in the vessels of a patient is too high, which requires the heart to work harder to circulate the blood in the body. Hyperlipidemia is a disease where the patient has too much cholesterol in his blood. This can damage the vessels and the heart. Both are chronic diseases and patients need to be treated for a long time, sometimes for life. In this study, primary care physicians and nurses and community pharmacists will work in close collaboration, following intervention protocols pre-agreed between providers making use of best available communication technology and regular interprofessional meetings. The study will look at whether patients improved compared with other patients using other pharmacies and other primary care units.

Who can participate?
Patients aged 18 and over on hypertension and/or hyperlipidemia medication

What does the study involve?
The intervention is provided by pharmacists, nurses and physicians and includes measuring blood pressure and blood lipids, managing medication for hypertension and/or hyperlipidemia, text message reminders from pharmacy to patients when end date of last package is approaching, direct referral to physician when required for appropriate assessment and communication between pharmacists and primary care team. This intervention is compared to usual care provided in other pharmacies and primary care units.

What are the possible benefits and risks of participating?
Patients under this intervention can benefit from a closer collaboration between providers. The intervention is not likely to cause risks for patients.

Where is the study run from?
The trial is run by the Centre for Health Evaluation & Research (CEFAR) under sponsorship of

Associação Nacional das Farmácias (ANF) and Agrupamento dos Centros de Saúde (ACeS) do Baixo Mondego. Intervention will take place in a primary care unit in Figueira da Foz, Portugal (USF S. Julião) and in seven pharmacies in the proximity.

When is the study starting and how long is it expected to run for?
March 2016 to July 2019

Who is funding the study?
ANF covered all costs for trial. ANF Pharmacy Loyalty Program Saúda® paid for a limited number of interventions per patient per pharmacy and for project promotion materials. Hartmann provided blood pressure monitors for pharmacies. Physicians, nurses and pharmacists provided their time for free on a voluntary basis.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
USFarmácia/001

Study information

Scientific Title
Effectiveness of a collaborative care intervention between pharmacies and primary care targeting hypertension and hyperlipidemia: a multi-centre quasi-experimental controlled trial (USFarmácia)

Acronym
USFarmácia

Study objectives
This research will use a naturalistic local collaborative experiment between the National Health Service (NHS) primary care (USF) and a local network of pharmacies which involves care protocols inserted into the pharmacy dispensing software, exchange of relevant information technology-driven (IT) between the two settings and interprofessional meetings (Quality Circles). The primary purpose is to understand whether a pharmacy-driven collaborative intervention with local primary care for the management of patients on hypertensive and/or hyperlipidemia medication can be effective compared with usual (fragmented) care. The secondary purpose is to assess changes in: risk factors, medication adherence and persistence. In addition, the aim is to explore changes in medication profile, use of healthcare resources, patient satisfaction, as well as to assess fidelity, applicability and transferability of this complex healthcare intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The NHS Regional Authority “Administração Regional de Saúde Centro” (ARS Centro)
2. The Ethics Committee “Comissão de Ética para a Saúde” of ARS Centro”, 09/02/2017
3. The Ethics Committee “Instituto de Bioética” of Universidade Católica Portuguesa, 20/03 /2018, Ethical Screening Report 02/2018

Study design
Multi-center pragmatic quasi-experimental controlled trial

Primary study design
Interventional

Secondary study design
Quasi-experimental controlled trial

Study setting(s)
Community

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

Hypertension and/or hyperlipidemia

Interventions

This is a 6 month multi-center, pragmatic, quasi-experimental controlled trial involving community pharmacies and primary care in Portugal. A primary care unit has expressed interest in this collaborative care model and has become the pilot site. Intervention pharmacies have been selected as per selection criteria. Control primary care units with similar patient populations have been identified and pharmacies in geographic proximity are invited to collect data on control patients. The trialists aim at recruiting patients with an allocation ratio of 1:1 in intervention and control arm. All patients are recruited in pharmacies. It will not be possible for intervention providers and patients to be blinded to which group due to the nature of the collaborative intervention.

1. Intervention: Hypertension and/or hyperlipidemia management in collaborative care by pharmacies and primary care according to pre-defined care protocols. Collaborative intervention package consists of the following components:
1.1. Point-of-care measurements at pharmacy/USF
1.2. Cardiovascular risk assessment at pharmacy/USF
1.3. Medication management at pharmacy/USF
1.4. Lifestyle counselling at pharmacy/USF
1.5. Referral and direct request for medical appointment from pharmacy to USF via IT, as per care protocol
1.6. Feedback from USF and follow-up at pharmacy, as per care protocol
1.7. Refill text reminder from pharmacy to patient (MED180®)
1.8. Quality Circles.
Intervention is not likely to cause an adverse event. Yet, the intervention package at the pharmacy includes 1.9. reporting a suspected adverse event to the study team and to the National Pharmacovigilance System.

2. Control: Usual care.

Intervention Type

Mixed

Primary outcome measure

1. Blood pressure at 6 months (patients with hypertension)
2. Total cholesterol at 6 months (patients with hyperlipidemia)
3. Proportion of controlled patients at 6 months
Collected using the following data sources: pharmacy dispensing software and/or primary care software (all available data points in pharmacy visits/primary care appointments) and patient telephone surveys (baseline, 3 and 6 months).

Secondary outcome measures

1. Other cardiovascular risk factors in hyperlipidemia patients 40-65 years old, collected using the pharmacy dispensing software and/or primary care software (all available data points in pharmacy visits/primary care appointments) and patient telephone surveys (baseline, 3 and 6 months)
2. Adherence and persistence, collected using pharmacy dispensing software and/or primary care software (all available data points in refill/prescription data) and Measure Treatment Adherence (MAT) Scale validated for European Portuguese via patient telephone surveys (baseline, 3 and 6 months)

3. Proportion of adherent patients, collected using pharmacy dispensing software and/or primary care software (all available data points in refill/prescription data) and Measure Treatment Adherence (MAT) Scale validated for European Portuguese via patient telephone surveys (baseline, 3 and 6 months)

Exploratory outcomes:
1. Medication profile, measured using pharmacy dispensing software and/or primary care software (baseline and last available medication profile at 3 and 6 months) and patient telephone survey (baseline, 3 and 6 months)
2. Use of health care resources, collected using patient telephone survey at baseline and 6 months
3. Patient satisfaction with pharmacy, collected using patient telephone survey at baseline and 6 months
4. Risk factors and cardiovascular risk (SCORE) in individuals not on hypertension nor hyperlipidemia medication with at least one risk factor, using pharmacy dispensing software (following end of recruitment)
5. Fidelity assessed using pharmacy dispensing software (6 month data) and patient telephone survey (baseline, 3 and 6 months)
6. Applicability and transferability assessed using Wang's framework at the end of study

Quality of life, preferences and cost data collected for a separate economic evaluation study. These are not secondary nor exploratory outcomes but will be collected alongside this trial and treated as outcomes in a separate economic study.

Overall study start date
01/03/2016

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Patients of selected USF
2. Age 18 years or older
3. On medication for hypertension and/or hyperlipidemia

For technical reasons, intervention patients need to be holders of a NHS number, users of a mobile phone, registered in the NHS online portal Citizen Area, adherent to the National Association of Pharmacies (ANF) Pharmacy Loyalty Program Saúda®, with a Pharmacy Patient Medication Record.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Sample size estimate for primary outcome measures: 322 hypertension (161 in each arm) and 366 hyperlipidemia (183 in each arm) to detect that change with 80% power at 5% significance level (two-tailed) already accounting for a drop-out rate of 20%.

Total final enrolment
203

Key exclusion criteria
Diabetic patients

Date of first enrolment
27/04/2018

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
Portugal

Study participating centre
Centre for Health Evaluation & Research (CEFAR) of Associação Nacional das Farmácias (ANF)
Associação Nacional das Farmácias
R. Marechal Saldanha, 1
Lisbon
Portugal
1249-069

Sponsor information

Organisation
Associação Nacional das Farmácias

Sponsor details
R. Marechal Saldanha, 1
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1249-069

Sponsor type

Other

Website
http://www.anf.pt

Organisation
Agrupamento dos Centros de Saúde (ACeS) do Baixo Mondego

Sponsor details
Unidade de Saúde Familiar (USF) S. Julião da Figueira da Foz
R. de Moçambique, 10
Figueira da Foz
Portugal
3080-134

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Associação Nacional das Farmácias

Results and Publications

Publication and dissemination plan
The following references were used in the preparatory work of this trial:
1. Costa S. A Contribution for the Economic Evaluation of Pharmacy Services in a Collaborative Care Model in Portugal. PhD Thesis Protocol. Presented at: National School of Public Health (ENSP), Universidade NOVA de Lisboa, 2013 Dec 16; Lisbon.
2. Costa S, Pereira J, Helling D, Mateus C. An overview of systematic reviews of economic evaluations of pharmacy-based public health interventions: addressing methodological challenges. Review protocol. Registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 7 January 2016. Reference number PROSPERO 2016: CRD42016032768 (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016032768)

On completion of the study, a Final Report will be prepared and used for publication in peer-reviewed journals. A summary report of the study will be provided to sponsor and co-sponsor. The authors plan to hold stakeholder meetings to disseminate results, as well as present the

results at conferences. The study data, Preliminary Report and Final Report will be used for subsequent economic evaluation of this project, which is a PhD research project of the Principal Investigator.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Suzete Costa (Principal Investigator), Suzete.Costa@anf.pt.
Type of data: demographic and primary outcome variables collected from pharmacy dispensing software and/or patient telephone surveys (anonymized)
When the data will become available: after last paper published of PhD economic evaluation of PI (approx. tentative date: Dec 2020, to be confirmed at a later stage)
For how long: to be determined by main Sponsor (Associação Nacional das Farmácias)
Access criteria: to researchers, access to authorized file(s) in repository (anonymized non-identifiable patient-level and pharmacy-level data) complying to measures as per Privacy Impact Assessment of this project, access granted at the discretion of Sponsor
Consent: Yes – Patient Consent Forms were obtained both for intervention and control patients.
Ethical or legal restrictions: Identification of participating control pharmacies and control primary care units will not be disclosed for ethical reasons. Patient data from primary care software will be granted to research team for this project by Serviços Partilhados do Ministério da Saúde (SPMS, EPE). SPMS is the legal proprietor of primary care databases. Hence, future access to the anonymized patient data of this project deriving from primary care is subject to prior authorization of SPMS.
This project has a Privacy Impact Assessment (PIA) approved by Data Protection Officer and Chief Security Officer of Associação Nacional das Farmácias on 28-02-2018, conforming to EU General Data Protection Regulation (GDPR). The PIA is part of this project research submission process approved by the Ethics.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Cost-effectiveness and cost-utility	08/09/2022	27/09/2022	Yes	No
Other publications	Discrete choice experiment	05/10/2023	06/10/2023	Yes	No
Results article		01/08/2023	21/01/2025	Yes	No