

Real-World Effectiveness in Hypertension and Hyperlipidemia Collaborative Management between Pharmacies and Primary Care in Portugal: A Multicenter Quasi-Experimental Pragmatic Controlled Trial (USFarmácia®)

Suzete COSTA^{1,2}, José Luís BISCAIA³, Maria Rute HORTA⁴, Sónia ROMANO⁵, José GUERREIRO⁵, Peter HEUDTLASS⁵, Maria CARY⁵, Mariana ROMÃO⁵, António TEIXEIRA RODRIGUES⁵, Ana MIRANDA⁶, Ana Paula MARTINS^{2,7}, Ana Sofia BENTO³, João PEREIRA^{1,8}, Céu MATEUS⁹, Dennis K HELLING^{2,10}

¹ Escola Nacional de Saúde Pública (ENSP), Universidade NOVA de Lisboa, Lisboa, PORTUGAL
² Institute for Evidence-Based Health (ISBE), Lisboa, PORTUGAL
³ USF S. Julião da Figueira, Agrupamento dos Centros de Saúde (ACeS) do Baixo Mondego, Figueira da Foz, PORTUGAL
⁴ Center for Medicines Information & Health Interventions (CEDIME), Infosaúde, Associação Nacional das Farmácias (ANF), Lisboa, PORTUGAL
⁵ Center for Health Evaluation & Research (CEFAR), Infosaúde, Associação Nacional das Farmácias (ANF), Lisboa, PORTUGAL
⁶ Registo Oncológico Nacional, Instituto Português de Oncologia (IPO) Lisboa Francisco Gentil, Lisboa, PORTUGAL
⁷ Pharmacy, Pharmacology & Health Technologies Department, Faculty of Pharmacy, Universidade de Lisboa, Lisboa, PORTUGAL
⁸ Centro de Investigação em Saúde Pública (CISP) and Comprehensive Health Research Centre (CHRC), Lisboa, PORTUGAL
⁹ Health Economics at Lancaster, Division of Health Research, Lancaster University, Lancaster, UK
¹⁰ Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Denver, Colorado, USA



1. INTRODUCTION

There is evidence of the efficacy of certain public health services provided by pharmacists in appropriate collaborative environments with physicians, but little is known about the effectiveness of such interventions in real-world trials.

2. AIMS

To assess the effectiveness and discuss the design and challenges of hypertension and hyperlipidemia management between pharmacies and a National Health Service (NHS) primary care family health unit (USF) in Portugal using decision algorithms; data exchange between providers, refill SMS reminders to patients, and experimental bundled payment.

3. METHODS

Multicenter, pragmatic, quasi-experimental controlled trial.

The collaborative intervention package is detailed in (Fig. 1). We developed two choice options for the patient to consent to the exchange of relevant health data from/to pharmacists to/from physicians/nurses which were added to the Consent Form of the NHS Patient Electronic Health Record RSE® for the first time in Portugal (Fig. 2).

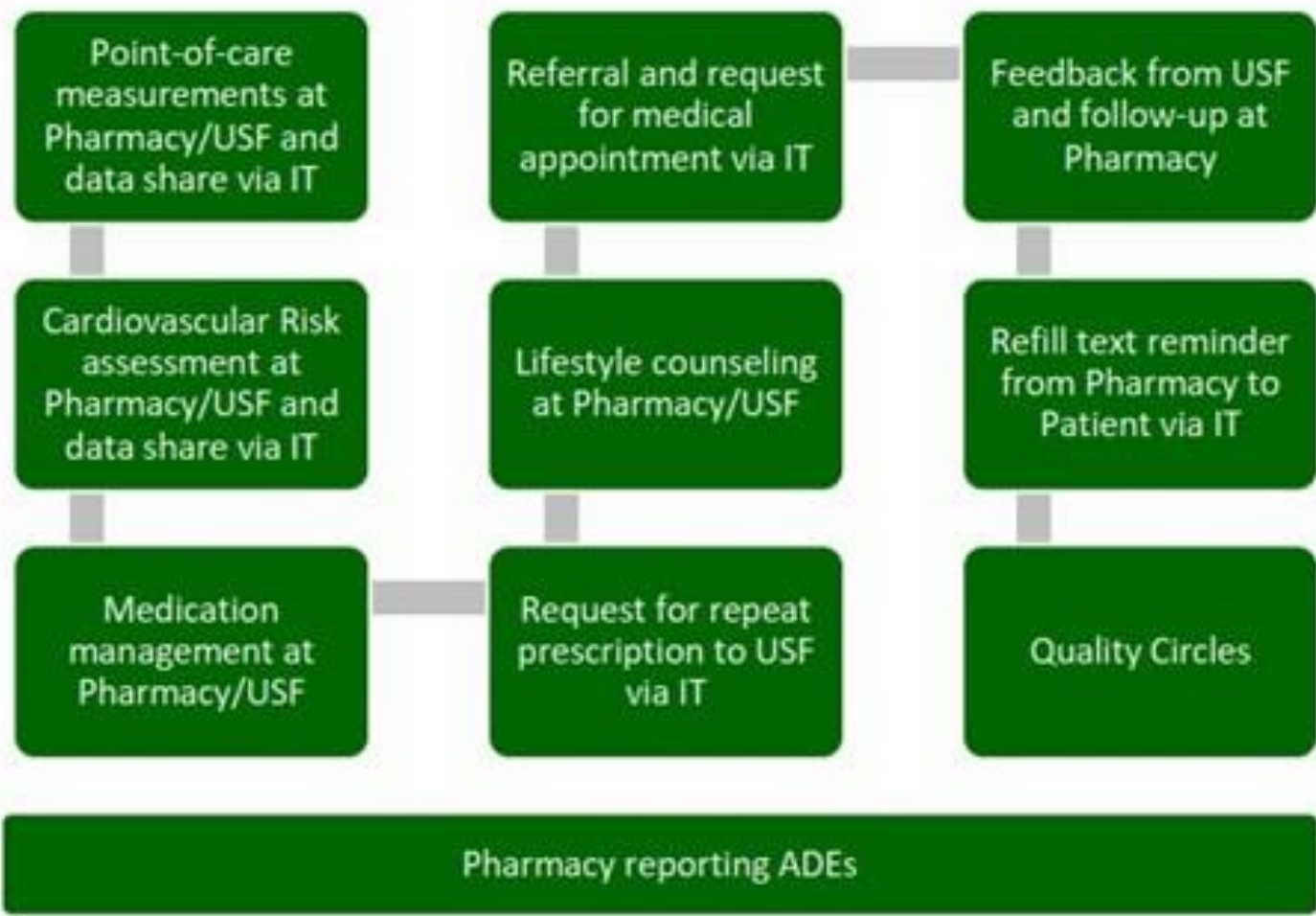


Fig 1. Intervention package

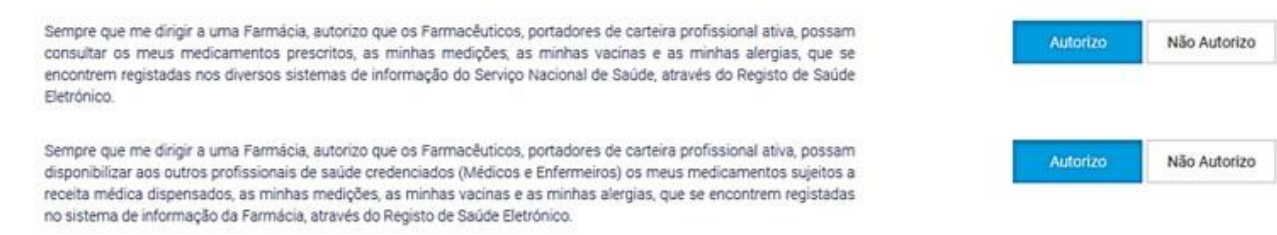


Fig 2. Choice options added to the Consent Form of the NHS RSE®

We collected patient-level data from primary care prescription claims BDNP® and Electronic Medical Record SCLínico® databases, pharmacy claims Sifarma® database, and patient telephone surveys at several time points. Primary outcomes: changes in blood pressure (BP) and total cholesterol. We used matched controls with 1) Difference-in-difference estimators in a GLM at 6 months; 2) Controlled interrupted time series (CITS) 6 months before/after the intervention. We collected additional data for economic and qualitative studies.

Trial registration: Current Controlled Trials: ISRCTN13410498, retrospectively registered on 12-12-2018: <https://www.isrctn.com/ISRCTN13410498>.

DISCLOSURE

This poster reports work that is part of the first author's Ph.D. in Public Health, specialization in Health Economics. Promoters: NHS ACeS Baixo Mondego and the National Association of Pharmacies (ANF), in collaboration with Glintt and SPMS, EPE. Funding: ANF. Saúde® (ANF's Pharmacy Customer Loyalty Program) covered the costs of point-of-care supplies and remunerated intervention pharmacies for a maximum number of interventions per patient (risk-share bundled payment). Hartmann provided blood pressure monitors in intervention pharmacies. The promoters and funder had no role in the: study design; project management; data collection; analysis and interpretation, writing, review; or approval of this abstract and poster.

ETHICS APPROVAL & DATA PROTECTION

The study was approved by the NHS Regional Health Administration "ARS Centro" on 09-02-2017 following the opinion of its Ethics Committee. The Ethics Committee Instituto de Bioética de Universidade Católica Portuguesa also approved the study on 20-03-2018. Patients provided written consent.

REFERENCES
1. Costa S, Cary M, Helling DK, Pereira J, Mateus C. An overview of systematic reviews of economic evaluations of pharmacy-based public health interventions: addressing methodological challenges. Syst. Rev. 2019;8:272. doi: 10.1186/s13643-019-1177-3.
2. Zuidgeest MGP, Goetz I, Groenwold RHH, Irving E, van Thiel GJM, Grobbee DE. GetReal Work Package 3. Series: Pragmatic trials and real-world evidence: Paper 1. Introduction. J. Clin. Epidemiol. 2017;88:7-13. doi: 10.1016/j.jclinepi.2016.12.023.
3. Bernal JL, Cummins S, Gasparrini A. The use of controls in interrupted time series studies of public health interventions. Int. J. Epidemiol. 2018;47(6):2082-2093. doi: 10.1093/ije/dyy135.

4. RESULTS

The project started in March 2016 with interprofessional meetings (Quality Circles). Patient recruitment and baseline data collection started in May 2018, the end of recruitment was in November 2018, end of follow-up in November 2019, and trial closure in December 2019. Seven Quality Circles took place with 27 pharmacists from 7 intervention pharmacies, 6 physicians, and 6 nurses from intervention USF (Fig. 3).



Fig 3. Quality Circles

A total of 5 best-match control USFs and 13 control pharmacies (control). A total of 203 patients entered the study and were included in the baseline analysis. We included 107/114 patients for the 6-month prior/after recruitment analysis.

We experienced challenges during the trial that required creative strategies in real-time, e.g., adjustments in Feedback Reports to each Pharmacy (Fig. 4).

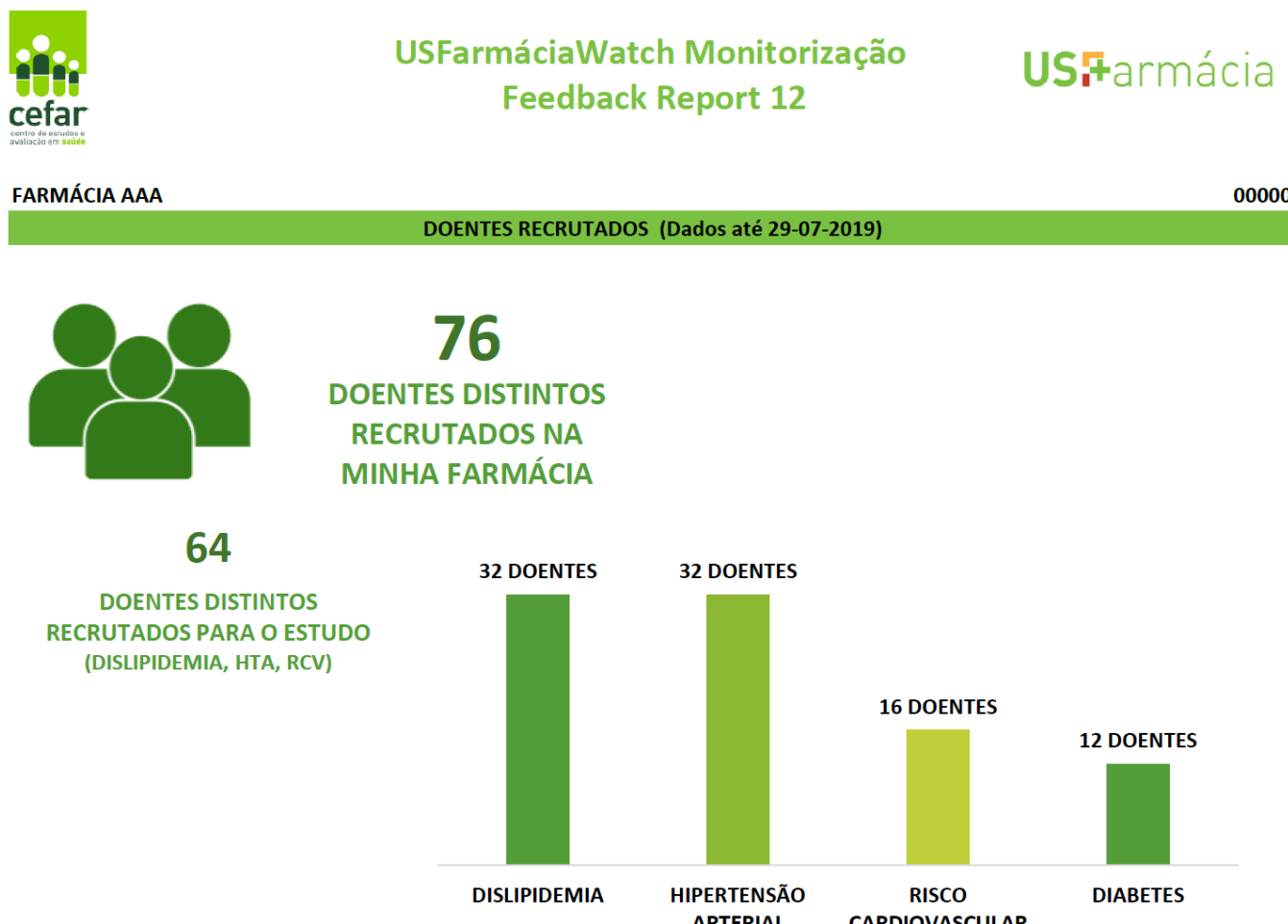


Fig 4. Feedback Report to Pharmacy AAA

After adjusting for covariates in GLM, we were not able to observe significant differences in the effect of the intervention vs control. When using CITS, the trend effect in systolic BP change, although negative, is not significant either (Fig. 5).

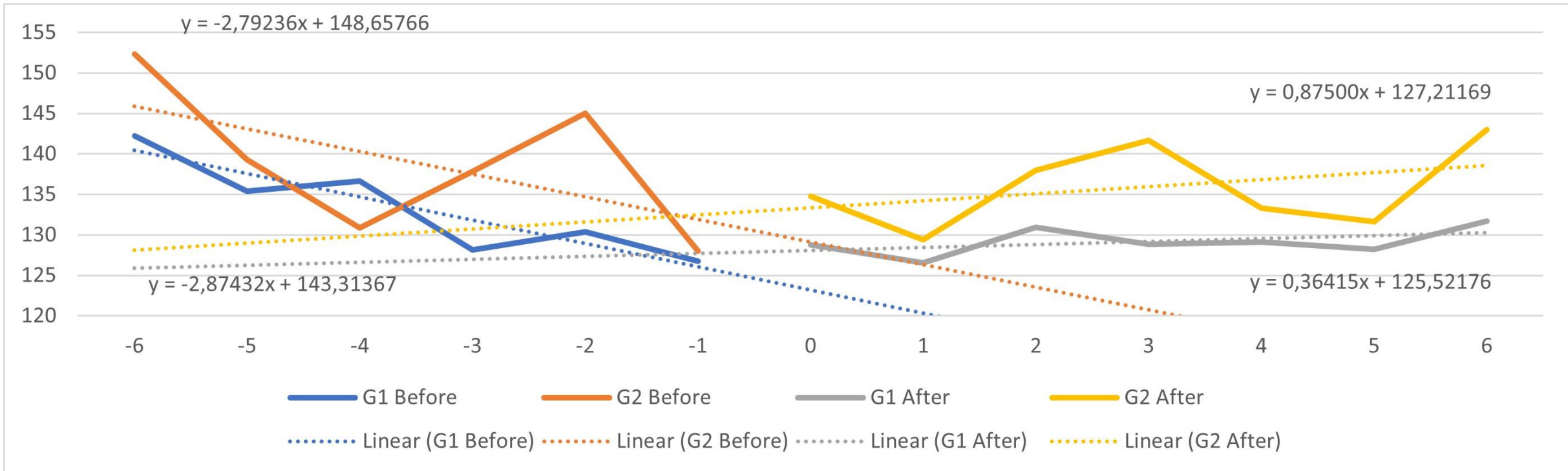


Fig. 5. CITS trend effect in systolic BP 6 months before / after; G1: Intervention; G2: Control

5. CONCLUSION

This trial was not able to show effectiveness likely due to the limitations of primary care technology. It offers valuable lessons on methods, strategies, and real-world evidence from various data sources. It paves the way for future real-world trials to mirror more realistic settings, advance integrated care between pharmacies and primary care, achieve appropriate use of medicines, and improve patient outcomes.

ACKNOWLEDGEMENTS
We gratefully acknowledge all patients, pharmacists, physicians, and nurses who accepted to participate in this trial, as well as supporting trial staff. We thank ANF, ACeS do Baixo Mondego, Farminveste, Glintt, Spirituc, and SPMS for the support provided in trial operations 2016-2019.

You are also welcome to check our POSTERS EE538 (cost-effectiveness and cost-utility) and PCR290 (preferences and cost-benefit of this trial).