Efficacy of a multi-faceted intervention to deprescribe PPI in primary care:
protocol for a population-based, pragmatic, cluster-randomized controlled trial

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CONTEXT

- Inappropriate use of proton pump inhibitors (PPI) = severe adverse drug reactions + major economic impact
- Deprescribe when inappropriate prescription of PPI is identified
- Deprescribing interventions solely on prescribers = limited efficacy

➡ Deprescribing interventions should be also targeted to patients

OBJECTIVES

To assess the :

I) Efficacy of a multi-faceted intervention on patients and general practitioners (GPs) to deprescribe PPI.

II) Effectiveness of the intervention – Acid rebound – Patients' attitudes towards deprescribing

METHODS

Design: Pragmatic, cluster-randomized controlled trial. **Setting:** Population-based study conducted in two departments of Western France.

Criteria

Inclusion: - GPs with ≥ 100 patients
- Patients ≥ 18 years old, dispensed with ≥ 300 defined daily dose (DDD) in the year before baseline

Exclusion: Patients with nonsteroidal anti-inflammatory drugs combined with corticosteroids/anticoagulants/antiplatelet aggregants or combined with an age > 65 years

Intervention materials

- *Patient education material* on PPI deprescribing (designed after a focused review and tested with patients) inviting patients to consult their GPs
- *"Dear doctor" letter* sent to GPs containing the Bruyere Research Institute's PPI deprescribing algorithm (Farrell *Can Fam Physician*. 2017) modified for the French population

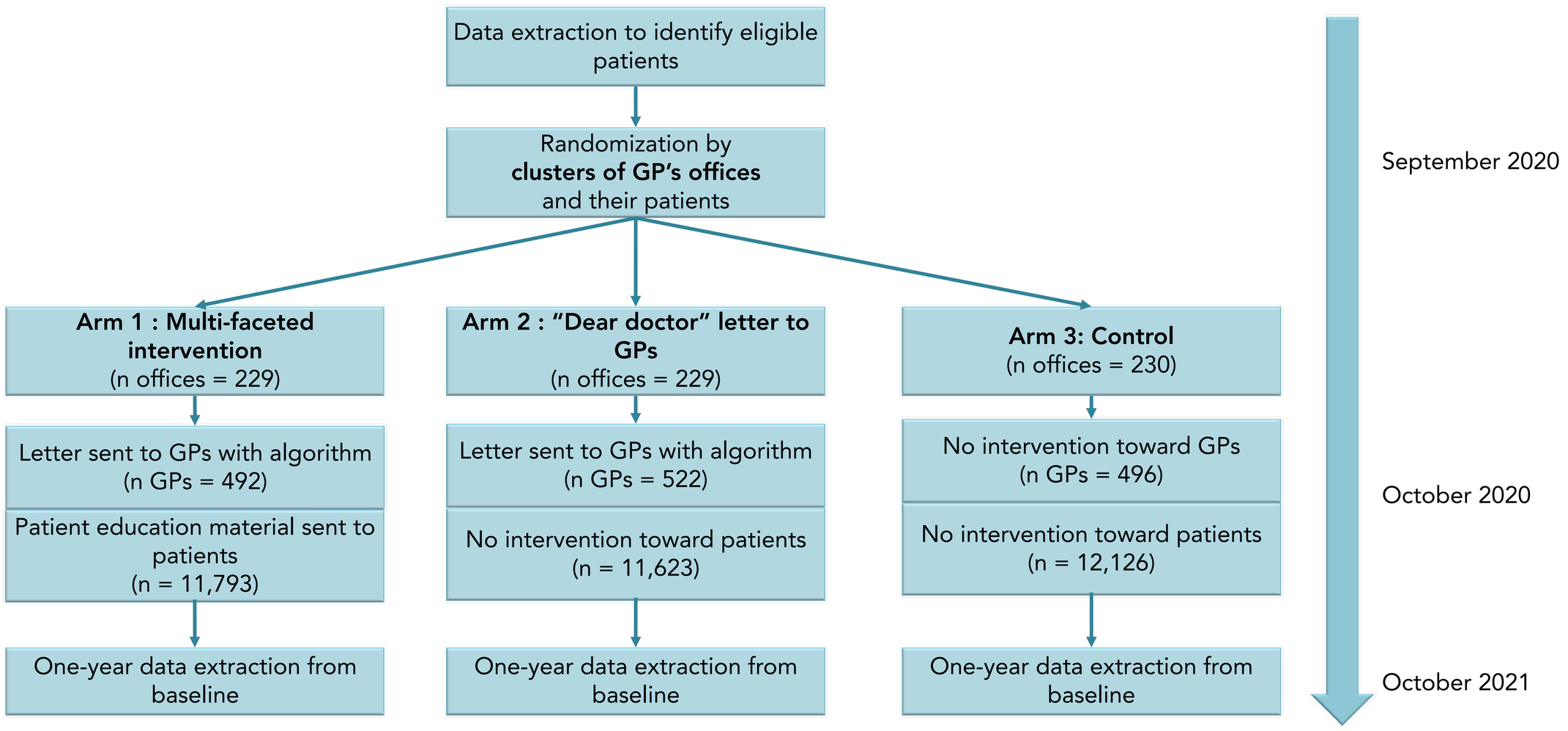
Outcome Measures

I) Primary outcome:

PPI deprescribing → proportion of patients achieving at least a 50% decrease in their PPI dispensing (DDD/year) at 12 months compared to baseline (using Health Insurance's reimbursement database).

II) Secondary outcomes: 3 questionnaires sent twice to a 10% sample of patients one month before baseline and one month before the end of the study

- *incremental cost-utility ratio* using EQ5D-5L (to calculate Quality-adjusted life year) and Health Insurance's reimbursement database
- *acid rebound* using the GERD Impact Scale
- *patients' attitudes towards deprescribing* using the French rPATD (Reeve *Drugs Aging*. 2016)



FIRST FIGURES

Eligibility
- **35 542 patients** identified
- **1510 GPs** identified
- **688 GPs' offices** randomized by clusters

Three arms:
Arm 1: 11 793 patients – 492 GPs
Arm 2: 11 623 patients – 522 GPs
Arm 3: 12 126 patients – 496 GPs

Among the 10% patient sample (n=3554) receiving the questionnaires one month before baseline:
Response rate > 44%.

PERSPECTIVE

Based on previous trials, we anticipate more than 10% "successful PPI deprescribing" in the multi-faceted intervention compared to the single intervention on GPs and the control arm (Wilsdon *Drugs Aging*. 2017). This study has been funded through a national grant and started in October 2020, for preliminary results by early 2022.

ClinicalTrials.gov Identifier: NCT04255823. IRB 00010804 approval No. 08062011. contact : jerome.nguyen-soenen@univ-nantes.fr; jean-pascal.fournier@univ-nantes.fr