Conflits d'intérêts: J Bourbeau

① Consultation fees   aucun

② Stock ownership/profit   aucun

③ Patent fees   aucun

④ Remuneration for lecture/advisory board   Privé: AZ, COVIS, GSK, Pfizer
                                                 Publique: UDM, RQESR, Chest, SCT, Respiplus

⑤ Manuscript fees   aucun

⑥ Trust research/joint research funds   Privé: Aerocrine, AZ, BI, COVIS, Grifols, GSK,
                                                 Moderna, Novartis, Pfizer
                                                 Publique: CIHR, CRRN, FRQS, RI MUHC

⑦ Affiliation with Endowed Department   aucun

⑧ Other remuneration   aucun

J. Bourbeau est membre du comité scientifique de GOLD, auteur principal des guides de la SCT de pharmacothérapie (2017, 2019 and 2023) et member du comité de Pulmonary Rehabilitation Assembly de l'ATS and SCT.
Il est aussi le président et fondateur de la société à but non lucrative RESPIPLUS ce qui a permis de mettre en œuvre les programmes Mieux vivre avec une MPOC (…avec fibrose pulmonaire, avec asthme sévère).

Chronic obstructive pulmonary disease (COPD) disproportionately affects low- and middle-income countries.
Health systems are ill prepared to manage the increase in COPD cases.

Pilot effectiveness-implementation randomized field trial of a community health worker (CHW)- supported,

- 1-year self-management intervention in individuals with COPD grades B–D
- low-resource settings of Nepal, Peru, and Uganda.

Standardization and Assessment of Fidelity to the Intervention Protocol

Intervention group

- four components surrounding prevention and self-management of COPD and monthly CHW visits over 1 yr.
- using a context-adapted action plan, which included training and support on recognition of symptoms; rescue packs delivered or refilled by a CHW consisting of antibiotics and steroids for use during exacerbations

Control group

- received basic COPD education from a CHW and were offered access to the same medications for AECOPD

Primary outcome: St. George's Respiratory Questionnaire (SGRQ) score at 1 year.

Secondary outcomes: moderate to severe AECOPD, all-cause hospitalizations, and EuroQol score

Also assessment of patient engagement and CHW fidelity
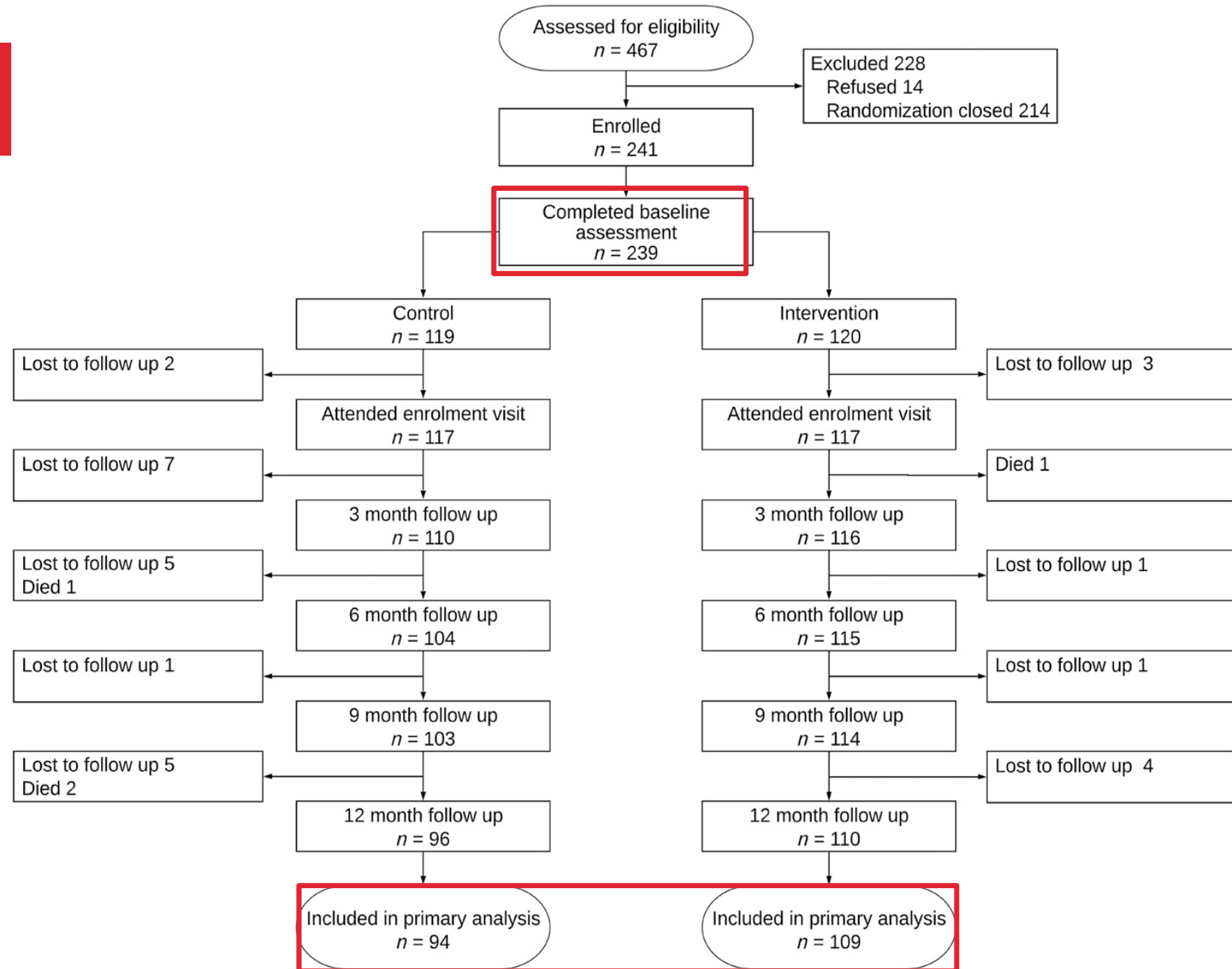
Diagramme de l'ECR

Figure 1. Consolidated Standards of Reporting Trials diagram of participant flow through the GECo2 study.

Caractéristiques de base

| Characteristic	Intervention	Control
Age, yr, mean (SD)	68.0 (10.9)	65.1 (10.8)
Number of females (%)	52 (43.3)	45 (37.8)
Income in USD/mo, mean (SD)	116.8 (156.8)	133.8 (184.6)
Number of current smokers (%)	29 (24.2)	25 (21.0)
Previous diagnosis of pulmonary tuberculosis (%)	13 (10.8)	16 (13.4)
Uses biomass daily to cook, n (%)	51 (42.5)	52 (43.7)
Body mass index, kg/m^2, mean (SD)	22.5 (4.3)	22.9 (5.0)
Lung function		
Post-bronchodilator FEV_1 z-score, L, mean (SD)	−2.08 (1.23)	−2.19 (1.16)
Post-bronchodilator FEV_1 percentage predicted, mean (SD)	64.5% (21.5%)	63.5% (20.2%)
Post-bronchodilator FEV_1/FVC z-score, mean (SD)	−2.87 (0.95)	−2.94 (1.04)
Post-bronchodilator FEV_1/FVC, mean (SD)	0.56 (0.10)	0.56 (0.11)
COPD category, n (%)		
B	79 (66.4)	97 (80.8)
C	3 (2.5)	3 (2.5)
D	31 (26.1)	17 (14.2)
Site, n (%)		
Nepal	49 (41.2)	51 (42.5)
Peru	20 (16.8)	20 (16.7)
Uganda	50 (42.0)	49 (40.8)
Prior chronic respiratory disease diagnosis, n (%)		
COPD	10 (8.3)	10 (8.4)
Chronic bronchitis	40 (33.3)	39 (32.8)
Emphysema	1 (0.8)	1 (0.8)
Comorbidities, n (%)		
Hypertension	32 (26.7)	23 (19.3)
Heart disease	6 (5.0)	4 (3.4)
Angina	4 (3.3)	1 (0.8)
Diabetes	8 (6.7)	7 (5.9)
Lung cancer	0 (0)	0 (0)
Tuberculosis	13 (10.8)	16 (13.4)
Regular medication use, n (%)		
Inhaled corticosteroids	1 (0.8)	2 (1.7)
Short-acting β-agonists	9 (7.5)	8 (6.7)
Short-acting antimuscarinic	3 (2.5)	6 (5.0)
Long-acting β-agonists	5 (4.2)	4 (3.4)
Long-acting antimuscarinic	4 (3.3)	4 (3.4)
Xanthines	0 (0.0)	1 (0.8)
Noninhaled steroids	1 (0.8)	2 (1.7)
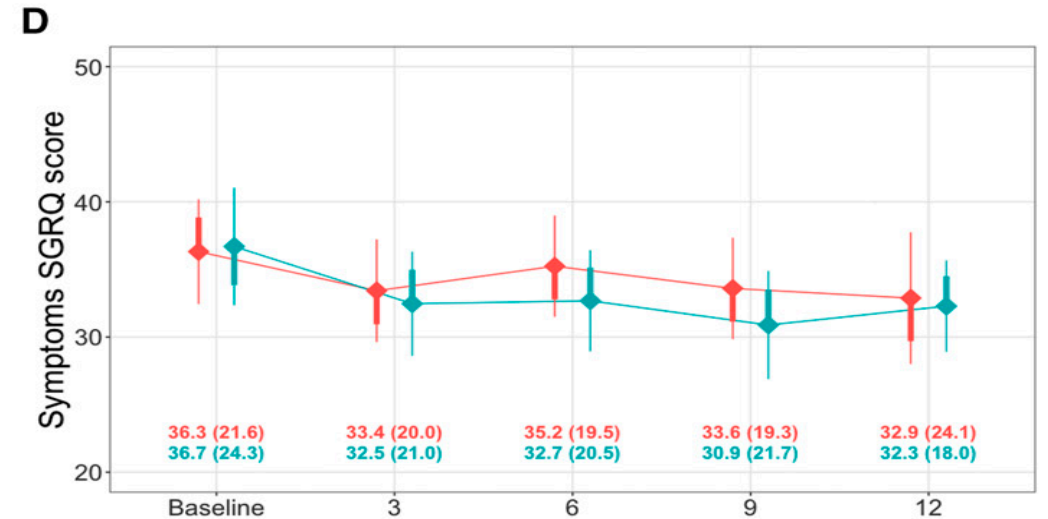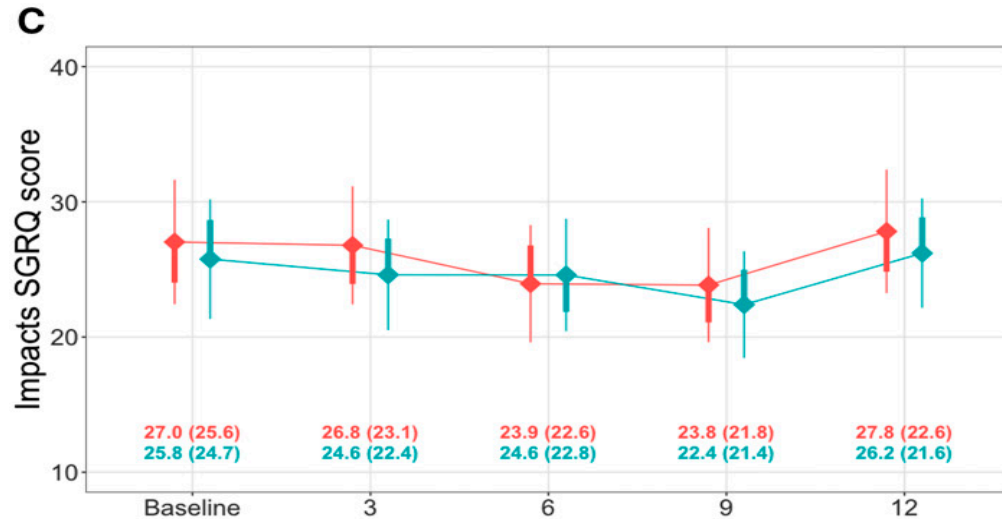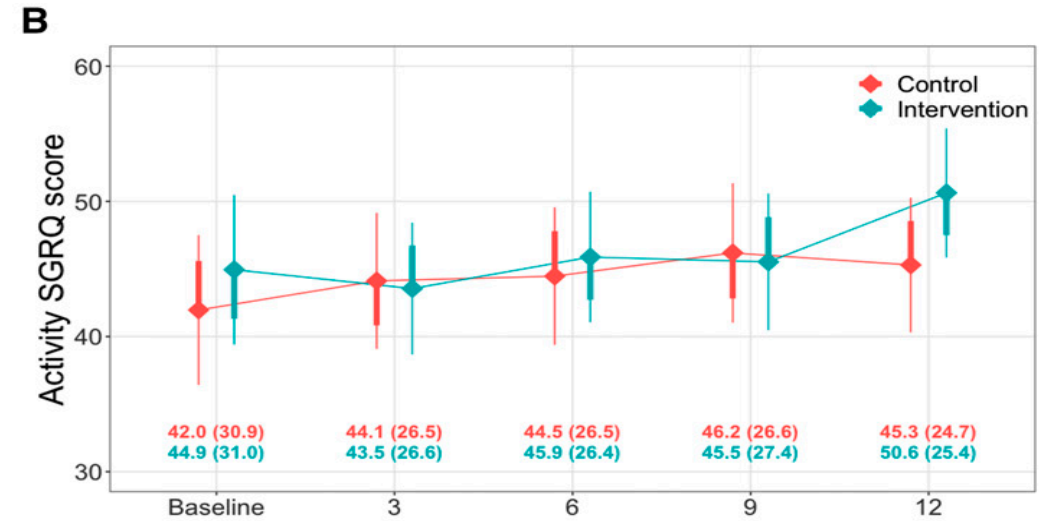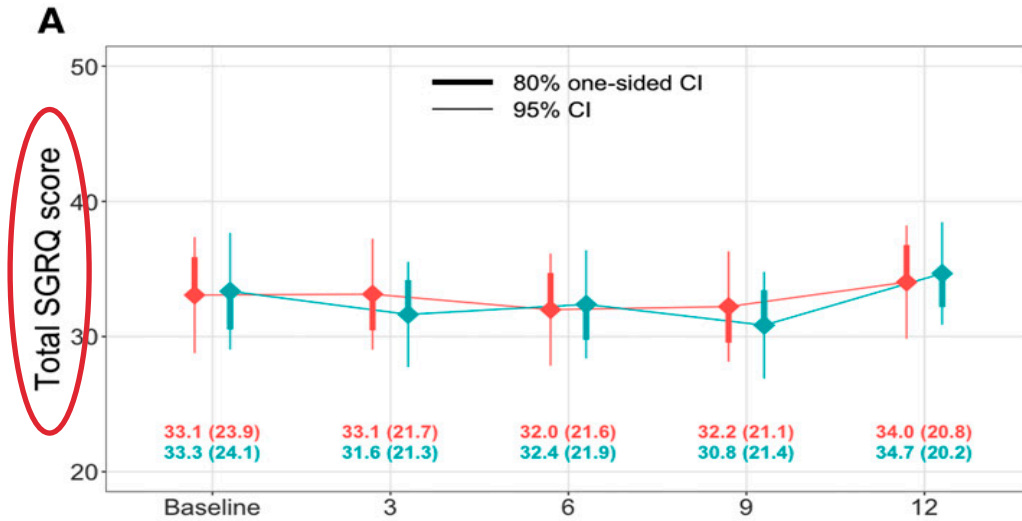
Mesures primaire et secondaires

Table 3. Unadjusted and Adjusted Differences in Primary and Secondary Outcomes, by Study Arm at 12-Month Follow-Up

| Outcome	Intervention (*n* = 110)	Control (*n* = 96)	Mean Unadjusted Difference (95% CI) or RR (95% CI)	Mean Adjusted Difference (95% CI) or RR (95% CI)
Total SGRQ score, mean (SD)*	34.7 (20.2)	34.0 (20.8)	0.6 (−5.1 to 6.3)	1.0 (−4.2 to 6.1)
SGRQ subscores*				
Impact, mean (SD)	26.2 (21.6)	27.8 (22.6)	−1.6 (−7.8 to 4.5)	−1.0 (−6.5 to 4.5)
Activity, mean (SD)	50.6 (25.4)	45.3 (24.7)	5.3 (−1.6 to 12.3)	5.2 (−1.1 to 11.4)
Symptoms, mean (SD)	32.3 (18.0)	32.9 (24.1)	−0.6 (−6.6 to 5.4)	−0.2 (−5.7 to 5.3)
Participants experiencing at least one hospitalization, *n* (%)	11 (10.0)	5 (5.2)	1.9 (0.7 to 5.2)	2.2 (0.8 to 7.5)
Participants receiving treatment for at least one moderate-to-severe exacerbation, *n* (%)	78 (70.9)	26 (27.1)	1.4 (0.8 to 1.9)	3.0 (0.7 to 2.1)
EQ-5D-3 L score, mean (SD)	7.5 (1.8)	7.8 (2.2)	−0.03 (−0.9 to 0.3)	−0.02 (−0.7 to 0.3)
EQ-5D visual analog scale score, mean (SD)	69.1 (14.8)	71.3 (15.1)	−2.1 (−6.2 to 2.1)	−1.7 (−5.4 to 2.1)

Indicateurs de l'engagement des patients

Overall percentages of individuals in the intervention arm who **reported using their action plans** at each follow-up time point
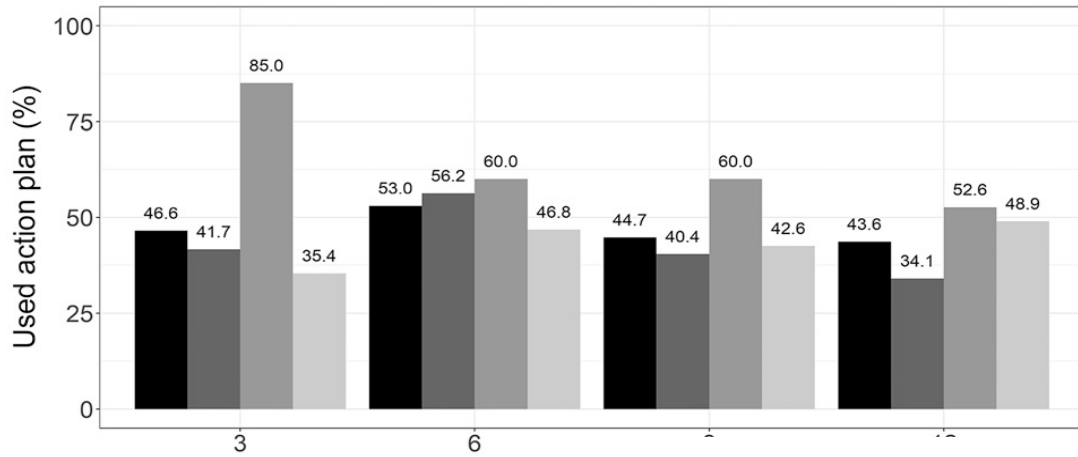
Intervention participants who **reported using rescue packs** during the previous 3 months
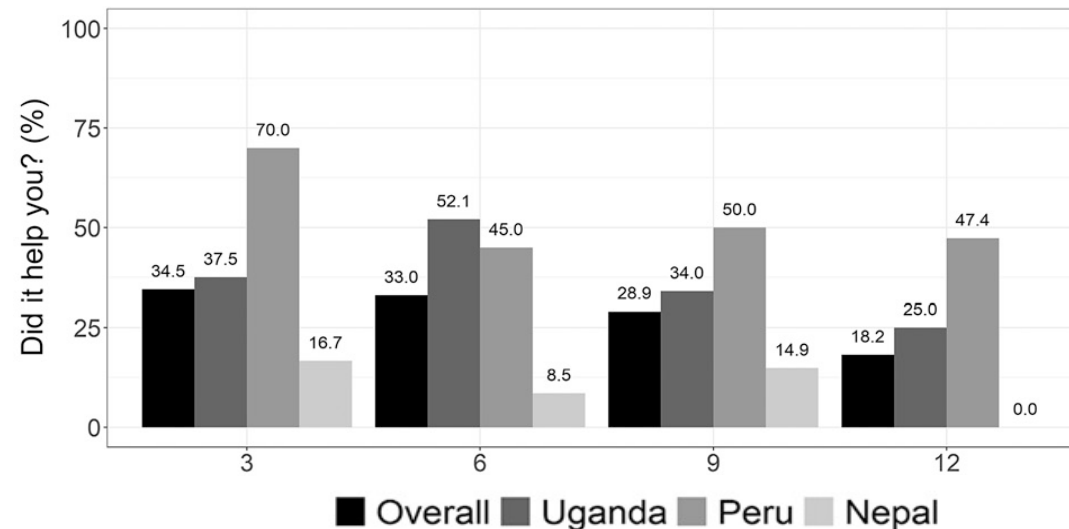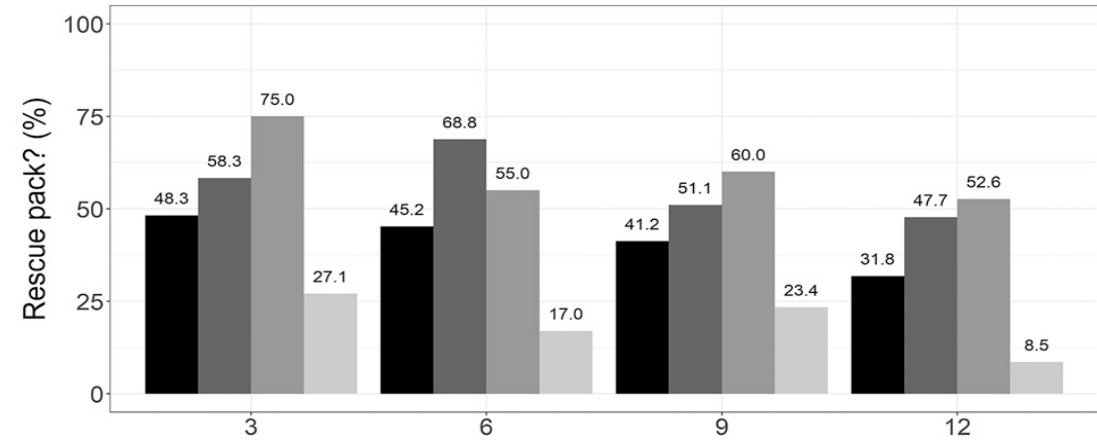
Indicateurs de l'engagement des patients: pauvre compréhension

There was **also evidence that understanding of the action plan zones did not always align with what the intervention was intended to communicate.**

When I'm in the yellow zone..., it's because I'm improving, right? ... So, if I don't improve, I'd be in the red zone, the red zone is danger, right? So now, I've been taking my pills and all, I'm improving, I'm in the amber [yellow] zone, and I want to get to the green zone. ... I hope I get there. (participant, Peru)

We observed that **some participants were taking the rescue packs preventatively or not completing the full course of medications.**

One [CHW] mentioned how one of the patients ... always takes the medicine as soon as he is given them and takes them irrespective of whether he has an exacerbation or not." (meeting notes, Uganda).
"[Participant] doesn't understand rescue pack usage and purpose. Wants to take steroids preventatively to help him when he leaves home.(field notes, Nepal)

Results from the fidelity checklists
- **CHWs had good adherence to protocol standards** during observation visits (online supplement)
- Field notes and interviews showed that **CHWs sometimes had challenges or forgot to emphasize the differences between the two yellow zones on the action plan**
- Some **correcting medication misuse**, others did not have the confidence to correct those behaviors. CHWs were comfortable

Overall, the CHWs exhibited excellent interpersonal skills and work ethics and excelled most at providing emotional and social support during the visits.

Limitations

Our study was **not powered to detect differences in clinical outcomes** at each of the study sites; rather, the **study was designed to inform the decision to proceed to a larger future trial.**

The **intervention did not include inhalers,** but rather **focused on training and support to identify COPD exacerbations** and make informed decisions on when to seek care.
The addition of inhaler education would be beneficial for any future iterations of this program, although **access to affordable medications at these sites is limited.**

One possible explanation for the higher number of hospitalizations and moderate exacerbations in the intervention arm in both studies is a heightened awareness of symptoms, as well as increased self-initiated antibio/prednisone and healthcare use.

There was a **larger proportion of participants who died or were lost to follow-up in the control arm**
Disparities in services offered to participants between the intervention and control arms may have contributed to **differential dropout.**

Limitations

Self-reported adoption of the COPD action plan across settings was moderate (generally less than 50%), highest in Peru, and lowest in Nepal.

Interviews, observations, and administrative records as part of the process evaluation (forthcoming) suggest that
- **the design and mode of delivery for the action plan** (e.g., didactic vs. interactive), as well as the user interface of our rescue packaging, **could have benefited from a more rigorous, iterative design process**

The **effectiveness of self-management interventions** such as the one tested in this study, whether delivered via task shifting or otherwise, **will be limited by the health system, economic, and geopolitical contexts in which they are implemented.**

Conclusion

A CHW-based intervention to support self-management of acute exacerbations of COPD in three resource-poor settings did not result in differences in SGRQ scores at 1 year.

Fidelity was high, and intervention engagement was moderate.

Although **these results**
- **cannot differentiate between a failed intervention or implementation**,
- **suggest that we need to revisit our strategy.**