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# Carrageenan Nasal Spray and Probiotic Lozenges to Prevent Flu-Like Illness in Healthcare Workers: A Pragmatic Field Study at the Arbaeen Mass Gathering

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## Abstract

**Introduction:** The Arbaeen pilgrimage is among the world's largest mass gatherings and is associated with a high burden of respiratory and gastrointestinal infections. Practical, low-cost prophylactic measures suitable for crowded, resource-constrained settings are needed. Oral probiotics and nasal barrier agents may offer a feasible approach.

**Methods:** We conducted a pragmatic, open-label field intervention study across 10 health centers (Mawkibs) in Najaf, along the Najaf–Karbala walking route, and in Karbala during Arbaeen 2023. Healthcare workers aged 16–70 years received carrageenan nasal spray, Streptococcus salivarius lozenges (K12/M18), the combination, or no intervention (control), according to operational feasibility at each site. Self-reported gastro-respiratory symptoms (GIRS: fever, cough, sore throat, runny nose, diarrhea, vomiting) were collected by telephone on day 25 to capture symptoms within the Arbaeen target period. Analyses used Chi-square/Fisher's exact tests, Kruskal–Wallis, and age- and sex-adjusted logistic regression (two-sided $p \leq 0.05$).

**Results:** A total of 222 participants were included and analyzed (control n=106; intervention n=116: lozenge n=19, spray n=60, combination n=37). Mean reported product use was 5.36 days. Compared with control, the combination arm showed lower odds of fever (OR 0.114; 95% CI 0.045–0.291), cough (OR 0.183; 95% CI 0.075–0.446), and sore throat (OR 0.174; 95% CI 0.074–0.406). Diarrhea and vomiting were not significantly different. No serious adverse events were reported.

**Conclusion:** In this real-world setting, combined carrageenan spray and S. salivarius lozenges were associated with lower odds of flu-like symptoms among healthcare workers. Findings are exploratory and should be confirmed in larger placebo-controlled studies.

**Keywords:** Mass gathering; Arbaeen; Infection prevention; Field intervention; Respiratory infection; Travel medicine.

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## Introduction

Mass gatherings create unique challenges for infectious disease control because they bring large numbers of people into crowded environments with close contact and shared facilities.[1,9] The Arbaeen pilgrimage attracts an estimated 17–20 million pilgrims to Karbala, Iraq, many undertaking multi-day journeys on foot and staying in temporary accommodations (Mawkibs).[2-6] Inadequate ventilation, crowded sleeping spaces, and shared utensils and towels can facilitate respiratory virus transmission.[6] Conventional prevention (vaccination, masks, hand hygiene, distancing) is often difficult to implement consistently during Arbaeen, given the sheer scale and infrastructure constraints.[7-9] Therefore, complementary, practical strategies are needed for frontline personnel and volunteers operating within Mawkibs and medical posts.

Prebiotics such as carrageenan—sulfated polysaccharides from red algae—can form topical barriers and may inhibit viral attachment and replication in the nasal cavity.[11-14,19] Probiotics, particularly oral *Streptococcus salivarius* strains that colonize the upper

aerodigestive tract, can modulate mucosal immunity and may reduce respiratory symptom burden.[10,15,20] Prior trials suggest carrageenan nasal sprays can shorten cold duration, and certain probiotics may reduce cold incidence or fever days.[16-18]

The combined use of a carrageenan-based nasal spray with an S. salivarius lozenge has not been evaluated in a real-world mass-gathering context such as Arbaeen. We therefore conducted an exploratory, non-randomized, open-label field study during Arbaeen 2023 to assess whether either agent alone—or the combination—was associated with a lower incidence of self-reported gastro-respiratory symptoms (GIRS) among healthcare workers serving in health centers (Mawkibs).[3,4]

## Methods

### Study design and setting

We conducted a non-randomized, open-label, exploratory field trial across 10 health centers (Mawkibs) operating in Najaf, along the Najaf–Karbala walking route (Mashaya), and in Karbala during Arbaeen 2023.[3,4] The study was implemented under real-world mass-gathering constraints, where standard preventive measures are difficult to apply consistently.

### Participants

Eligible participants were Iranian healthcare workers aged 16–70 years with ≥7 days of experience in patient-facing roles during the event. Key exclusions were immunodeficiency; severe cardiovascular, endocrine, respiratory, or gastrointestinal disease; pregnancy or lactation; irritable bowel syndrome, active ulcerative colitis, or short bowel syndrome; hypersensitivity to study products; severe nasal septum deviation or polyps; and recent treatment for common cold that might confound symptoms. All participants provided written informed consent.

Among the 10 participating Mawkibs, the largest health center (Imam-Hassan) was designated as the control site to minimize cross-contamination and operational disruption. The remaining nine Mawkibs implemented one of three intervention regimens based on field feasibility and onsite operational decisions.

### Interventions

Participants received one of the following: (i) Coldanese Plus® nasal spray (carrageenan), one spray per nostril three times daily; (ii) Lactogum® lozenges (Streptococcus salivarius K12 and M18), one lozenge nightly before sleep; (iii) the combination of both agents; or (iv) no study product (control). Products were shipped from Tehran to Najaf under temperature-controlled conditions (~25°C) and distributed via Mawkib coordinators after briefings on use and potential side effects.[12-14,16-21]

### Outcomes

The primary outcome was the incidence of ≥1 self-reported gastro–respiratory symptom (GIRS) during the Arbaeen target period (≤15 days), defined as fever, cough, sore throat, runny nose, diarrhea, or vomiting. Secondary outcomes were the incidence of each symptom individually and the adjusted odds ratios for each intervention regimen compared with control. Outcomes were assessed via standardized telephone follow-up on day 25, in which participants were asked to report symptom presence and self-rated severity experienced during the target period.

### Data Collection

Baseline data (age, sex, and service role) were recorded at enrollment. Intervention delivery and field implementation were documented by Mawkib coordinators using structured operational logs (e.g., product receipt/distribution and brief adherence notes) to support feasibility assessment under mass-gathering conditions. For outcome ascertainment, during the standardized day-25 telephone follow-up we collected self-reported GIRS outcomes for the Arbaeen target period, including symptom presence and self-rated severity. During the same call, we assessed adherence by recording the consumption period (days used) and reasons for non-adherence/cessation (e.g., too busy, not received product, lost medication), and asked about any adverse effects potentially related to the products.

### Statistical analysis

Baseline characteristics are reported as mean (SD) for continuous variables and frequency (%) for categorical variables. We compared age across groups using the Kruskal–Wallis test and compared categorical variables using the chi-square or Fisher's exact test, as appropriate. For outcome comparisons, we fitted logistic regression models adjusted for age and sex and reported odds ratios (ORs) with 95% confidence intervals (CIs). Statistical significance was defined as a two-sided p value ≤0.05. Analyses were performed using SPSS version 26.

## Results

### Participant flow

A total of 222 healthcare workers were included and analyzed across 10 health centers (Mawkibs) during Arbaeen 2023: 106 in the control group and 116 in the intervention group (Lactogum® n=19, Coldanese Plus® n=60, and combination n=37) (Figure 1).

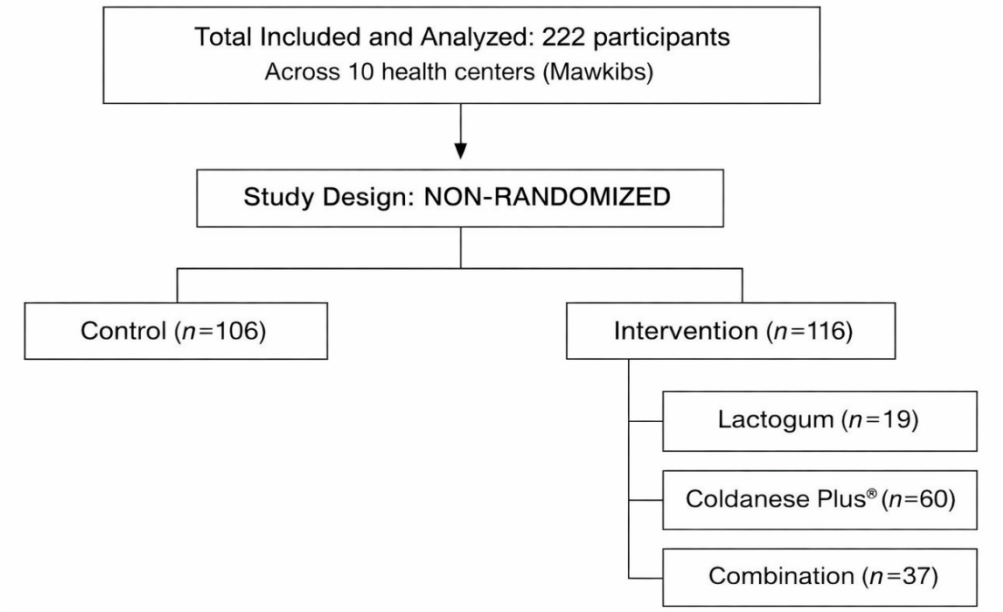


**Figure 1.** CONSORT 2010 flow diagram (non-randomized trial). Flow of participants included in the analysis. A total of 222 healthcare workers were included and analyzed across 10 health centers (Mawkibs): control (n=106) and intervention (n=116), comprising Lactogum® (n=19), Coldanese Plus® (n=60), and combination (n=37).

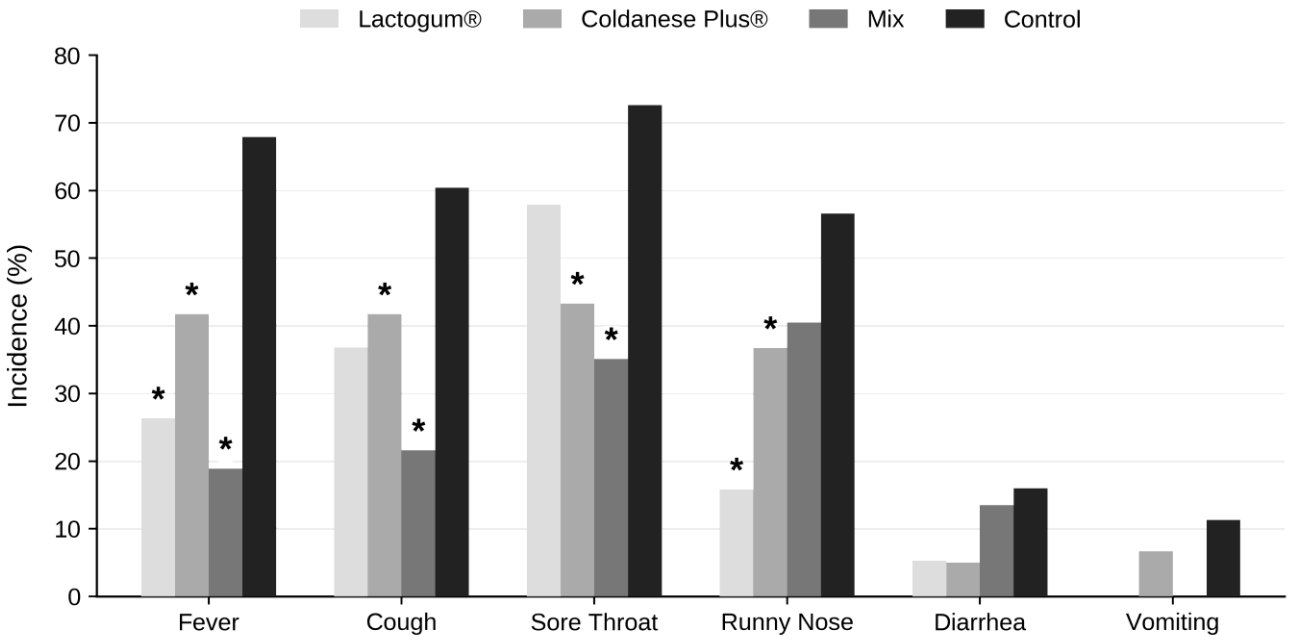


**Figure 2.** Incidence of GIRS symptoms by group. Percentage of participants with each symptom (fever, cough, sore throat, runny nose, diarrhea, and vomiting) in the Lactogum®, Coldanese Plus®, Mix, and Control groups. Asterisks above intervention bars indicate $p<0.05$ versus the control group in age- and sex-adjusted logistic regression models; the control group was the reference category (see Table 2 for adjusted ORs and 95% CIs). Group sizes: Lactogum® n=19; Coldanese Plus® n=60; Mix n=37; Control n=106. Abbreviation: GIRS, gastro-respiratory symptoms.

**Baseline characteristics**

Baseline demographics and service roles by study arm are summarized in Table 1. Overall, participants' age was similar across groups (p=0.146). However, sex distribution differed between arms (p<0.001), with a higher proportion of males in the Lactogum® and combination groups. Because this was a non-randomized field study conducted under mass-gathering constraints, residual baseline differences and unmeasured confounding may remain; therefore, outcome comparisons were additionally evaluated using age- and sex-adjusted logistic regression models (Table 2).

**Table 1.** Baseline demographics and service roles by study arm.

| Characteristic | Lactogum® | Coldanese Plus® | Mix | Control | Total | p-value |
|---|---|---|---|---|---|---|
| Male, n (%) | 17 (89.5%) | 32 (53.3%) | 34 (91.9%) | 67 (63.2%) | 150 (67.6%) | <0.001 |
| Age, mean±SD | 36.94±10.52 | 42.68±11.37 | 42.67±9.98 | 43.55±12.60 | 42.60±11.76 | 0.146 |
| Ambulance driver, n (%) | 6 (31.6%) | 2 (3.3%) | 1 (2.7%) | 9 (8.5%) | 18 (8.10%) | — |
| Laboratory technician, n (%) | 1 (5.3%) | 2 (3.3%) | 0 (0.0%) | 0 (0.0%) | 3 (1.35%) | — |
| Pharmacy staff, n (%) | 3 (15.8%) | 11 (18.3%) | 3 (8.1%) | 9 (8.5%) | 26 (11.71%) | — |
| Logistics team, n (%) | 6 (31.6%) | 12 (20.0%) | 19 (51.4%) | 47 (44.3%) | 84 (37.83%) | — |
| Secretary, n (%) | 2 (10.5%) | 5 (8.3%) | 6 (16.2%) | 11 (10.4%) | 24 (10.8%) | — |
| Doctor, n (%) | 1 (5.3%) | 9 (15.0%) | 6 (16.2%) | 11 (10.4%) | 27 (12.16%) | — |
| Nurse, n (%) | 0 (0.0%) | 18 (30.0%) | 6 (16.2%) | 30 (28.3%) | 54 (24.32%) | — |
| Radiologist, n (%) | 0 (0.0%) | 1 (1.7%) | 0 (0.0%) | 0 (0.0%) | 1 (0.45%) | — |

*(Values are mean ± SD or n (%). p-values are reported only for age and sex.)*

**Table 2.** Adjusted odds ratios (age- and sex-adjusted) for GIRS outcomes by intervention vs control.

| Outcome | Group vs Control | OR (95% CI) | p-value |
|---|---|---|---|
| Fever | Lactogum® | 0.164 (0.053–0.507) | 0.02 |
| | Coldanese Plus® | 0.327 (0.168–0.634) | 0.01 |
| | Mix | 0.114 (0.045–0.291) | p<0.001 |
| Cough | Lactogum® | 0.385 (0.136–1.089) | 0.071 |
| | Coldanese Plus® | 0.467 (0.244–0.892) | 0.021 |
| | Mix | 0.183 (0.075–0.446) | <0.001 |
| Sore throat | Lactogum® | 0.368 (0.127–1.070) | 0.066 |
| | Coldanese Plus® | 0.266 (0.134–0.531) | <0.001 |
| | Mix | 0.174 (0.074–0.406) | <0.001 |
| Runny nose | Lactogum® | 0.126 (0.033–0.472) | 0.002 |
| | Coldanese Plus® | 0.417 (0.215–0.811) | 0.010 |
| | Mix | 0.539 (0.246–1.184) | 0.124 |
| Diarrhea | Lactogum® | 0.237 (0.029–1.938) | 0.179 |
| | Coldanese Plus® | 0.286 (0.080–1.025) | 0.055 |
| | Mix | 0.712 (0.236–2.149) | 0.547 |
| Vomiting | Lactogum® | NE (zero events) | — |
| | Coldanese Plus® | 0.535 (0.163–1.757) | 0.302 |
| | Mix | NE (zero events) | — |

*(ORs were obtained from age- and sex-adjusted logistic regression models. **CI**= confidence interval; **OR**= odds ratio; **NE**= not estimable due to zero events.)*

### Adherence and harms

Group sizes and reported consumption duration are presented in Table 3. The mean reported consumption duration across intervention arms was 5.36 days (range 1–20). Practical constraints typical of Arbaeen (e.g., high workload, loss of products, and interruptions in routine) limited adherence in the field. Reasons for non-adherence or cessation are summarized in Table 4, with environmental causes accounting for the majority. One participant reported a mild adverse effect (gastrointestinal discomfort) as the reason for stopping the product; no serious adverse events were reported.

**Table 3.** Group size and consumption duration among analyzed participants

| Group | Frequency | Percent (%) | Consumption period (mean [min–max]) |
|---|---|---|---|
| Lactogum® | 19 | 8.6 | 4.7368 [1–10] |
| Coldanese Plus® | 60 | 27.0 | 5.5667 [1–20] |
| Mix | 37 | 16.7 | 5.3514 [1–10] |
| Control | 106 | 47.7 | — |
| **Total** | **222** | **100.0** | **5.3621 [1–20]** |

*(Values are mean [min–max].)*

**Table 4.** Self-reported reasons for non-adherence among included participants.

| Cause of cessation | Frequency | Percent | Category total |
|---|---|---|---|
| Lack of knowledge | 23 | 39.6 | Non-environmental (48.2%) |
| Fear and distrust | 4 | 6.9 | |
| Side effects | 1 | 1.7 | |
| Not received product | 5 | 8.6 | Environmental (51.7%) |
| Too busy | 11 | 19.0 | |
| Lost medication | 6 | 10.3 | |
| Became ill | 8 | 13.8 | |
| **Total** | **58** | **100.0** | |

*(Environmental vs non-environmental categories as defined in Methods.)*

## Outcomes

The incidence of individual GIRS symptoms by study arm is shown in Table 5. Across groups, symptom frequencies differed significantly for fever, cough, sore throat, and runny nose, but not for diarrhea or vomiting. In adjusted analyses (Table 2), the combination regimen showed the largest and most consistent reductions compared with control, including lower odds of fever (OR 0.114; 95% CI 0.045–0.291; p<0.001), cough (OR 0.183; 95% CI 0.075–0.446; p<0.001), and sore throat (OR 0.174; 95% CI 0.074–0.406; p<0.001). Single-agent regimens showed intermediate effects. For runny nose, significant reductions were observed for Lactogum® (OR 0.126; p=0.002) and Coldanese Plus® (OR 0.417; p=0.010), while the combination arm did not reach statistical significance (p=0.124). For diarrhea and vomiting, differences were not statistically significant; models for vomiting in Lactogum® and combination arms were not estimable due to zero events.

**Table 5. Incidence of GIRS symptoms by study arm.**

| Symptom | Lactogum® n (%) | Coldanese Plus® n (%) | Mix n (%) | Control n (%) | Total n (%) | p-value |
|---|---|---|---|---|---|---|
| Fever | 5 (26.3%) | 25 (41.7%) | 7 (18.9%) | 72 (67.9%) | 109 (49.1%) | <0.001 |
| Cough | 7 (36.8%) | 25 (41.7%) | 8 (21.6%) | 64 (60.4%) | 104 (46.8%) | <0.001 |
| Sore throat | 11 (57.9%) | 26 (43.3%) | 13 (35.1%) | 77 (72.6%) | 127 (57.2%) | <0.001 |
| Runny nose | 3 (15.8%) | 22 (36.7%) | 15 (40.5%) | 60 (56.6%) | 100 (45.0%) | 0.003 |
| Diarrhea | 1 (5.3%) | 3 (5.0%) | 5 (13.5%) | 17 (16.0%) | 26 (11.7%) | 0.137 |
| Vomiting | 0 (0.0%) | 4 (6.7%) | 0 (0.0%) | 12 (11.3%) | 16 (7.2%) | 0.072 |

*(Values are n (%); p-values from Chi-square or Fisher's exact test.)*

## Discussion

In this non-randomized, open-label, exploratory field study conducted during Arbaeen 2023, we observed that the combination of a carrageenan-based nasal spray (Coldanese Plus®) and an S. salivarius lozenge (Lactogum®) was associated with lower odds of several self-reported gastro-respiratory symptoms compared with the control group, particularly fever, cough, and sore throat (Tables 5 and 2). These findings are biologically plausible: carrageenan-based nasal sprays may reduce viral attachment and replication at the nasal mucosa, while probiotic strains such as S. salivarius K12/M18 have been proposed to support upper-airway immune responses and microbiota-related defenses.[12–14,16–21] Importantly, our study contributes feasibility evidence from a uniquely challenging mass-gathering setting—Arbaeen—where implementation of preventive interventions and standardized follow-up is operationally difficult.[3,4]

Beyond symptom trends, the study provides practical insights into real-world implementation at Arbaeen health centers (Mawkibs). A total of 222 healthcare workers were included and analyzed across 10 Mawkibs (Figure 1; Table 6), with mean reported consumption duration of 5.36 days (Table 3). Field constraints typical of Arbaeen (e.g., high workload, loss of products, interruptions in routine) were prominent drivers of limited adherence (Table 4). Given the non-randomized design and baseline imbalances—particularly in sex distribution (Table 1)—we used age- and sex-adjusted models to reduce confounding (Table 2). Nevertheless, residual confounding and information bias remain possible, and the effect estimates should be interpreted cautiously. Future studies should prioritize more rigorous allocation methods, improved adherence-support strategies, and standardized (ideally blinded) outcome assessment to strengthen internal validity in mass-gathering research.[3,4]

### Limitations

This study has several important limitations. First, the design was non-randomized and open-label, and outcomes were self-reported; therefore, performance bias and measurement/recall bias are possible. Second, baseline imbalances—particularly in sex distribution (Table 1)—may have contributed to residual confounding despite age- and sex-adjusted analyses (Table 2). Third, adherence was limited by operational realities of Arbaeen, reflected in short consumption duration (Table 3) and reported reasons for non-adherence or cessation (Table 4). Fourth, because this was an exploratory field study implemented under real-world mass-gathering constraints, causal inference is limited and effect estimates may be overestimated; thus, findings should be interpreted as hypothesis-generating rather than confirmatory.[3,4] Finally, the uniquely challenging cross-border and mass-gathering conditions constrained data collection, standardization, and implementation fidelity; nevertheless, generating pragmatic feasibility evidence in this setting is valuable for designing future, more rigorous trials.

**Table 6.** Participating Mawkibs and analyzed healthcare staff.

| Mawkibs | Frequency | Percent |
|---|---|---|
| Malak Hotel | 18 | 8.1 |
| Aghile1 | 30 | 13.5 |
| Aghile2 | 2 | 0.9 |
| Tovarij | 1 | 0.5 |
| Amood 244 | 11 | 5.0 |
| Khodamol Hossein | 23 | 10.4 |
| Ansarol Hossein | 5 | 2.3 |
| Amood 1080 | 2 | 0.9 |
| Baqiyatallah | 24 | 10.8 |
| Imam-Hassan | 106 | 47.7 |
| **Total** | **222** | **100.0** |

*(Values are n unless otherwise specified.)*

## Conclusion

In an exploratory, non-randomized field study conducted during Arbaeen 2023, the combination of carrageenan-based nasal spray and an S. salivarius lozenge was associated with reduced odds of several self-reported gastro-respiratory symptoms compared with control, particularly fever, cough, and sore throat (Tables 5 and 2). Single-agent regimens showed intermediate effects. Given substantial methodological constraints—including non-randomized open-label implementation, self-reported outcomes, baseline imbalances (Table 1), and limited adherence in a mass-gathering environment (Tables 3 and 4)—these findings should be interpreted as hypothesis-generating. Larger, rigorously designed trials with improved outcome assessment and pre-specified sample-size planning are warranted to confirm effectiveness and define optimal implementation strategies for mass gatherings.[3,4]

## Highlights

**What Is Already Known?**

Respiratory symptoms are common during mass gatherings, while conventional preventive measures may be difficult to sustain. Carrageenan nasal sprays and oral S. salivarius probiotics have shown potential benefits when used separately.

**What Does This Study Add?**

In this pragmatic field study, combined use of a carrageenan nasal spray and S. salivarius lozenges was associated with lower odds of fever, cough, and sore throat among healthcare workers, providing exploratory feasibility evidence for a low-cost dual-route intervention.

## Conflicts of Interest Disclosures

The authors declare no conflicts of interest.

## Consent For Publication

Not applicable; no identifiable individual data are included.

## The extent of AI use

Generative AI tools were used to assist with language editing, manuscript organization, and preparation of draft responses to reviewers. No AI tool was used to generate primary data. All analyses, interpretations, citations, and final wording were reviewed and approved by the authors, who take full responsibility for the manuscript.

## Consent to participate

All participants provided written informed consent.

## Availability of data and materials

Data are stored in secure servers with restricted access; de-identified datasets are available upon reasonable request to the corresponding author.

## Competing interests

None declared.

## Funding/Support

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## Authors' contributions

All authors contributed to study design, data collection, analysis, and manuscript drafting; all approved the final manuscript.

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## Announcements

Trial registration IRCT (IRCT20231214060363N1).

## Ethics approval

Trial registration: IRCT (IRCT20231214060363N1).

## Abbreviations

GIRS: gastro-respiratory symptoms (composite)

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