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Hand Sanitizer with Sustained Antibacterial and Virucidal Activities Mitigates Upper Respiratory Symptoms and Work Restrictions: Double-blind Household Cluster- randomized Controlled Trial

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Abstract

Repeated hand sanitizer use provides immediate but short-lived bactericidal and virucidal effects, necessitating frequent use to reduce contact transmission. This double-blind, parallel-group, cluster-randomized controlled trial evaluated the health impact of repeated use of a novel hand sanitizer with both immediate and prolonged antimicrobial activities. Healthy employees and their cohabiting family members (clusters) were assigned to use either the novel sanitizer (active) or a 79.7% ethanol-based sanitizer (control) 5–10 times daily for 72 days (December 2023–February 2024). The primary outcome was cumulative incidence of upper respiratory symptoms, defined as fever ≥ 37.8°C with cough, sore throat, and/or nasal discharge. Among 568 (active: 285; control: 283) participants, across 417 clusters, upper respiratory symptoms occurred in 58 in the control group and 35 in the active group. The active group showed significantly lower risk (hazard ratio [HR]: 0.58; 95% confidence interval [CI]: 0.37–0.89, *P* = 0.013; approximately 40% relative-risk reduction), with fewer illness-related work restrictions. Adverse events were infrequent (control: 1; active: 2) and unrelated to the study interventions. Repeated use of the novel sanitizer over 72 days was well tolerated and potentially reduced upper respiratory symptoms and work restrictions during winter compared with conventional alcohol-based sanitizers.

Introduction

Since its emergence in Wuhan, People's Republic of China, in December 2019, the coronavirus disease 2019 (COVID-19) has resulted in over seven million deaths worldwide and conferred substantial economic and societal impacts [1]. The post-pandemic period has been characterized by the continued circulation of respiratory infections, such as influenza and common cold, that are transmitted via droplets, aerosols, and contact [2–4]. Preventive measures include vaccination and non-pharmaceutical interventions, such as physical distancing, handwashing, hand hygiene, gargling, and mask use. Hand hygiene plays a central role in preventing contact transmission.

Conventional hand sanitizers, typically based on ethanol or quaternary ammonium compounds, provide rapid bactericidal and virucidal effects upon application but lack sustained activity. Thus, recontamination of hands following contact with environmental surfaces after the implementation of hand-hygiene measures has been reported [5, 6], and international guidelines recommend frequent hand-hygiene measures to mitigate the risk of transmission. However, frequent use may cause skin dryness and irritation, which can reduce adherence to hand-hygiene practices. Therefore, there is a need for novel hand sanitizers that provide sustained antimicrobial activity while maintaining usability.

Human hands possess intrinsic antimicrobial activity against a range of pathogens [7]. We term this the "hand barrier" and have previously shown that individuals with lower susceptibility to common colds and influenza exhibit higher hand-barrier activity [8]. Based on mechanistic insights, including the antimicrobial role of lactic acid under weakly acidic conditions [9], we developed a formulation that mimics the hand barrier and provides sustained antimicrobial activity on the skin for approximately 2 hours [10]. By incorporating benzalkonium chloride, we further developed a novel hand sanitizer that

combines immediate and prolonged antimicrobial and virucidal activities and confirmed its efficacy against multiple pathogens as well as its persistence on the skin [11]. However, its effectiveness in reducing infection-related outcomes with repeated use under real-world conditions has not yet been established.

We hypothesized that a hand sanitizer with sustained antimicrobial and virucidal activity would reduce the risk of contact transmission and the incidence of respiratory symptoms during winter compared with conventional ethanol-based sanitizers. We conducted a double-blind, cluster-randomized controlled trial using households as clusters to evaluate the effects of repeated use of a novel hand sanitizer with sustained antimicrobial activity on upper respiratory symptoms and illness-related work restrictions, with a commercially available 79.7% ethanol-based sanitizer as the control.

Results

Participant flow and baseline characteristics

A total of 623 individuals responded to the recruitment survey, of whom 578 received study information, and 572 provided written informed consent. Participants were randomly assigned (Fig. 1) to the active group (novel hand sanitizer, n = 287) or the control group (control sanitizer, n = 285).

Baseline characteristics were compared between the groups using all randomized participants (intention-to-treat population), and no significant imbalances were observed (Table 1). During the study period, 7 participants (active group, n = 5, control group, n = 2) discontinued due to insufficient diary records or difficulty adhering to the intervention, and 4 participants (2 per group) were excluded for missing data. A total of 568 participants (active: 285 and control: 283) were included in the full analysis set (FAS), comprising 417 household clusters (active: 208 and control: 209), with a mean cluster size of 1.36 (range, 1–4). Participants who discontinued treatment were censored at their last recorded date.

Table 1
Baseline characteristics of the study participants (intention-to-treat population).

Characteristic	Control group (n = 285)	Active group (n = 287)	P value
Age, years	41.5 ± 11.5	41.6 ± 11.9	0.922
Sex			0.808
Male	157 (55.1%)	162 (56.4%)	
Female	128 (44.9%)	125 (43.6%)	
Influenza vaccination			0.383
Not planned	121 (42.5%)	106 (36.9%)	
Planned	50 (17.5%)	58 (20.2%)	
Vaccinated	114 (40.0%)	123 (42.9%)	
COVID-19 vaccination			0.529
Not planned	196 (68.8%)	201 (70.0%)	
Planned	25 (8.8%)	31 (10.8%)	
Vaccinated	64 (22.5%)	55 (19.2%)	
Number of children under 18 years in the household			0.764
0	155 (54.4%)	147 (51.2%)	
1	54 (18.9%)	52 (18.1%)	
2	62 (21.8%)	76 (26.5%)	
3	12 (4.2%)	10 (3.5%)	
> 4	2 (0.7%)	2 (0.7%)	
Work location			0.931
Tokyo	142 (49.8%)	139 (48.4%)	
Wakayama	103 (36.1%)	108 (37.6%)	
Tochigi	40 (14.0%)	40 (13.9%)	

Data are presented as mean ± standard deviation (SD) or number of participants. *P*-values were calculated using the Student's *t*-test for age and the chi-square test for categorical variables.

Primary outcome

The primary outcome, defined as upper respiratory symptoms (fever ≥ 37.8°C accompanied by at least one of cough, sore throat, or nasal discharge), occurred in 58 participants in the control group and 35 in the active group.

Cox proportional hazards analysis with adjustment for intra-cluster correlation showed a significantly lower risk of upper respiratory symptoms in the active group than in the control group (hazard ratio [HR] = 0.58; 95% confidence interval [CI] 0.37–0.89, *P* = 0.013).

At the end of the study period, the cumulative incidence was 20.5% in the control group and 12.3% in the active group, with incidence curves shown in Fig. 2.

Secondary outcomes

The results of secondary outcomes are summarized in Table 2. Compared with the control group, the active group showed significantly lower incidences of feverishness (HR = 0.60, 95% CI: 0.40–0.88, *P* = 0.009), sneezing (HR = 0.38, 95% CI: 0.20–0.72, *P* = 0.003), joint pain (HR = 0.47, 95% CI: 0.25–0.89, *P* = 0.020), and fatigue (HR = 0.46, 95% CI: 0.31–0.70, *P* < 0.001). No significant between-group differences were observed for sputum (*P* = 0.145), headache (*P* = 0.104), abdominal pain (*P* = 0.423), or diarrhea (*P* = 0.229) or for vomiting (*P* = 0.054). After Bonferroni correction for multiple comparisons, only sneezing and fatigue remained significant.

Table 2
Cumulative incidence of illness-related symptoms.

Symptoms	Cases (Control)	Cases (Active)	HR	95% CI	P value	Adjusted P value
Respiratory symptoms						
Sneezing	36	14	0.37	0.20–0.72	0.003	0.027
Sputum	35	24	0.68	0.40–1.14	0.145	1.000
Systemic symptoms						
Feverish feeling	70	44	0.60	0.40–0.88	0.009	0.081
Fatigue	65	32	0.46	0.31–0.70	< 0.001	< 0.001
Headache	38	25	0.65	0.38–1.09	0.104	0.936
Joint pain	29	14	0.47	0.25–0.89	0.020	0.180
Gastrointestinal symptoms						
Abdominal pain	15	11	0.73	0.33–1.58	0.423	1.000
Diarrhea	15	9	0.59	0.25–1.39	0.229	1.000
Vomiting	12	4	0.33	0.11–1.02	0.054	0.486

Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated using the Cox proportional hazards model with cluster-robust standard errors. Adjusted *P*-values were calculated using the Bonferroni correction for multiple comparisons.

The proportion of participants with work restrictions due to illness (absence or remote work for at least 1 day during the intervention period) was 23.7% (67/283) and 14.7% (42/285) in the control and active groups, respectively. In a generalized linear mixed model accounting for household clustering, the odds of work restriction were significantly lower in the active group than in the control group (odds ratio [OR] = 0.49; 95% CI: 0.28–0.83, $P = 0.009$).

Frequency of product use

The mean (± standard deviation [SD]) number of daily uses was 5.7 ± 1.3 and 5.7 ± 1.2 in the control and active groups, respectively, without significant between-group difference.

Safety

Three adverse events were reported: one in the control group (gout) and two in the active treatment group (one fall-induced fracture and one case of dacryoadenitis). None of the adverse events were considered related to the study interventions, and no significant between-group difference in incidence was observed (P = 0.623).

Subgroup analysis

Exploratory subgroup analyses were conducted to examine whether hygiene behaviors during the intervention period (mask use, handwashing frequency, and gargling frequency) modified the effect of the intervention on the primary outcome. No significant interactions were observed (Supplementary Figure S1).

Discussion

In this study, we evaluated the effects of repeated use of a novel hand sanitizer with sustained bactericidal and virucidal activity over 72 days during winter, compared with a conventional alcohol-based sanitizer. The cumulative incidence of upper respiratory tract symptoms at day 72 was significantly lower in the intervention group, 12.3%, compared with 20.5% in the control group, representing a relative reduction of approximately 40%, and the adjusted hazard ratio was 0.58. Illness-related work restrictions were similarly reduced in the active group. These findings suggest that repeated use of a hand sanitizer with sustained antimicrobial activity may help reduce respiratory symptoms and mitigate work disruption.

This study was conducted between December 2023 and February 2024, a period during which COVID-19 and influenza outbreaks were prevalent in Japan [12, 13], along with other infectious diseases [14]. Conducting the study during a season with elevated risk of respiratory infections was appropriate for evaluating the effectiveness of hand hygiene interventions.

Hand hygiene is a key measure for preventing contact transmission, and the use of alcohol-based hand sanitizers is recommended by international guidelines [15, 16]. Previous intervention studies have demonstrated reductions in respiratory infections and absenteeism associated with hand hygiene interventions [17–19]. However, conventional alcohol-based sanitizers provide only transient antimicrobial effects and do not prevent recontamination after application.

The novel sanitizer used in this study was designed to mimic the intrinsic “hand barrier” and provides both immediate and sustained antimicrobial activity [11]. In the present study, participants used the assigned products at similar frequencies in both groups, yet the active group showed a significantly lower incidence of symptoms. This finding suggests that the observed effect is unlikely to be explained by differences in adherence, but rather by qualitative differences in the intervention.

The mechanisms underlying this effect may be partially explained by the suppression of hand recontamination. Hands are known to become recontaminated through contact with environmental surfaces even after hand hygiene, and face-touching behavior may contribute to self-inoculation of pathogens [20, 21]. Contact transmission via hands is therefore considered one of the possible routes of respiratory infection [22]. Sustained antimicrobial activity on the skin may reduce recontamination and interrupt this transmission pathway.

This interpretation is further supported by the subgroup analyses, which showed no significant interaction between baseline hygiene behaviors (mask use, handwashing frequency, and gargling) and the intervention effect. Together with the comparable usage frequency between groups, these findings suggest that the reduction in symptoms may be attributable to the intrinsic properties of the sanitizer rather than differences in hygiene practices.

In the secondary outcomes, reductions were observed in symptoms commonly associated with upper respiratory infections, whereas no significant differences were found for symptoms less directly related to infectious diseases, such as abdominal pain and diarrhea. This pattern supports the specificity of the observed effect and suggests that the intervention influenced infection-related outcomes rather than general symptom reporting.

Although contact transmission has been suggested to contribute less to respiratory infections than airborne transmission, its relative contribution remains uncertain and is not negligible [22, 23]. The present findings suggest that improving the control of contact-mediated transmission, even modestly, may contribute to a measurable reduction in symptom incidence.

This study has several limitations. First, outcomes were based on self-reported symptoms without laboratory confirmation, limiting inference on specific infections. Second, participants were employees and their families, which may reflect higher baseline hygiene awareness. Third, although cluster randomization was used, interactions in shared environments may have affected independence between clusters. Further studies in more diverse populations and with objective outcome measures are warranted.

In conclusion, repeated use of a hand sanitizer with sustained antimicrobial activity significantly reduced upper respiratory symptoms and illness-related work restrictions during winter, despite similar usage frequency to conventional alcohol-based sanitizers. These findings highlight the potential role of sustained antimicrobial activity in enhancing infection control in community settings.

Methods

Study design

This was a double-blind, parallel-group, cluster-randomized controlled trial, with households defined as clusters. A cluster was defined as a household comprising an employee and cohabiting family members,

and all participants within the same household were assigned to the same intervention group to avoid contamination.

Participants were recruited via email and web-based announcements between November and early December 2023. The intervention period lasted 72 days, from December 20, 2023, to February 29, 2024. According to the allocation, participants used either the novel hand sanitizer or a control sanitizer (79.7% ethanol; Softy Hand Clean Hand Sanitizing Gel, Kao Corporation) 5–10 times a day. Participants recorded daily usage frequency and health conditions, and these data were used to evaluate symptom incidence.

Ethics statement

This study was conducted in accordance with the Declaration of Helsinki and the Ethical Guidelines for Medical and Health Research Involving Human Subjects and was approved by the Kao Corporation Human Research Ethics Committee (Approval No. K0276-2310; approved on November 9, 2023). The trial was registered with the UMIN Clinical Trials Registry (UMIN000054408) on May 16, 2024.

Participants

Participants were employees of Kao Corporation and Kao Professional Services Co., Ltd. (Tokyo, Japan) and their cohabiting family members. Employees were recruited via email and web-based announcements, and their family members were enrolled through participating employees. All candidates received an explanation of the study through either an in-person briefing session or explanatory video. Participation was voluntary and candidates were informed that declining to participate or withdrawing from the study would not result in any disadvantage. Recruitment, study explanation, and informed consent were conducted by study investigators, with no involvement of supervisors or managers. Written informed consent was obtained from all eligible participants.

Inclusion criteria were adults aged 20–65 years and their cohabiting family members. Exclusion criteria were as follows: (1) serious illness or injury requiring medical treatment or surgery within 2 months prior to the study (excluding transient conditions such as common cold or hay fever); (2) current steroid use; (3) existing hand eczema, dermatitis, or itching; (4) inability to use alcohol-based sanitizers; (5) inability to comply with restrictions on the use of non-study hand sanitizers or non-designated hand creams; (6) non-daytime workers; and (7) participation in other studies related to health conditions.

Sample size

Sample size was estimated based on previous unpublished data. Assuming a hazard ratio (HR) of 0.7 for the cumulative incidence between groups, with a two-sided significance level of 5% and 80% power, the required sample size was calculated using the powerSurvEpi package (function ssizeCT) in R. The required sample size was estimated as 285 participants per group (total n = 570).

As cluster randomization was used, the design effect (DE) was considered (DE = 1 + (m − 1) × ICC), where m is the average cluster size and ICC is the intra-cluster correlation coefficient. Assuming an average cluster size of 1.4 and an ICC of 0.1, the design effect was estimated to be 1.04. After adjusting for clustering, the required sample size increased to 593 participants. Assuming a dropout rate of 5%, the final target sample size was set to approximately 624 participants.

Randomization and blinding

Randomization was performed at the household (cluster) level with a 1:1 allocation using a computer-generated random sequence by personnel not involved in the study. Block randomization with a block size of 4 was used, with stratification by sex, number of children under 18 years of age in the household, COVID-19 vaccination status, and workplace.

Allocation codes were generated and maintained by independent staff members. To ensure blinding, the study interventions were identical in appearance, scent (unscented), and container design. Both participants and investigators were blinded to the group allocation. Allocation was unblinded only after completion of all analyses.

Study interventions

The control sanitizer contained 79.7 vol% ethanol, N-(tetradecyloxyhydroxypropyl)-N-hydroxyethyldecanamide, glycerin, talc, carbomer, and triethanolamine. The novel sanitizer contained benzalkonium chloride (0.05 vol%), ethanol (62 vol%), medium-chain triglycerides, hydroxypropyl cellulose, glycyrrhetinic acid, 1,3-butylene glycol, dipropylene glycol, sodium lactate, lactic acid, polyoxyethylene lauryl ether, polyethylene glycol, and purified water.

Participants applied one pump (approximately 0.5 mL) per use and spread it evenly over both hands. They were instructed to use the product 5–10 times daily, including mandatory use when going out, leaving work, and before lunch. Additional use was recommended after handwashing or before entering crowded environments.

To avoid interference with sustained antimicrobial effects, only a designated hand cream (Biore u Moisturizing Milk; Kao Corporation) was used during the intervention period.

Data collection

Participants recorded their daily usage frequency, symptoms, and work status in a diary (Excel-based or paper). Symptoms were self-reported using a predefined checklist and body temperature was measured when fever was suspected. Absence of symptoms was recorded.

Work status included an absence from work or remote work due to illness. Study investigators reviewed the records weekly. Questionnaires were administered before and after the intervention to collect demographic information, hygiene practices, skin condition, and product usability.

Outcomes

The primary outcome was the cumulative incidence of upper respiratory symptoms, defined as fever ≥ 37.8 °C accompanied by at least one of cough, sore throat, or nasal discharge.

Secondary outcomes included the cumulative incidence of additional symptoms (feverishness, sputum, sneezing, fatigue, joint pain, headache, diarrhea, and vomiting) and work restrictions due to the illness.

An episode of upper respiratory symptoms was defined based on the Wisconsin Upper Respiratory Symptom Survey (WURSS-11) as symptoms lasting ≥ 2 days with at least one fever episode ≥ 37.8 °C during the episode [24]. Only the first episode in the intervention period was counted [25]. The WURSS-11 was used to define symptoms but not for severity scoring.

Symptoms unrelated to infection (e.g., allergies, menstrual symptoms, and vaccine reactions) and those occurring within 3 days after intervention initiation were excluded.

Adverse events were assessed for causality by the investigators and physicians. Infectious diseases such as COVID-19 or influenza were not classified as adverse events.

Statistical analysis

Descriptive statistics were expressed as mean, standard deviation, and 95% confidence intervals. The primary outcome was analyzed using the Cox proportional hazards model in the full analysis set. Cluster-robust standard errors were used to account for within-household correlations. Secondary symptom outcomes were analyzed similarly, with Bonferroni correction for multiple comparisons. Work restriction was analyzed using a generalized linear mixed model (GLMM) with group as a fixed effect and household as a random effect, and results were expressed as odds ratios with 95% confidence intervals. Exploratory subgroup analyses were conducted using Cox models to examine associations between the primary outcome and hygiene behaviors. All analyses were performed using R (version 4.3.1; R Foundation for Statistical Computing, Vienna, Austria) with a two-sided significance level of 5%.

Declarations

Data availability

The datasets generated and/or analyzed during the current study are not publicly available due to confidentiality restrictions but are available from the corresponding author on reasonable request.

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Author contributions

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Visualization: YN;

Writing – original draft: YN;

Writing – review & editing: MK, AK, MT, NY, and HA.

Competing interests

This study was funded by the Kao Corporation. All authors are employees of the Kao Corporation.

Code availability

No custom code was used in this study.

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Figures

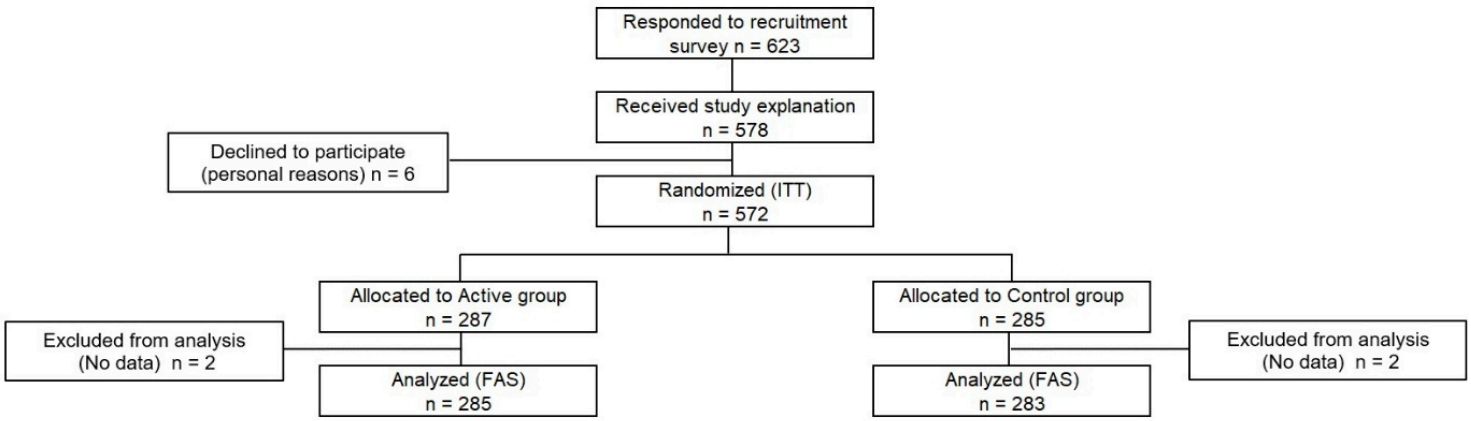
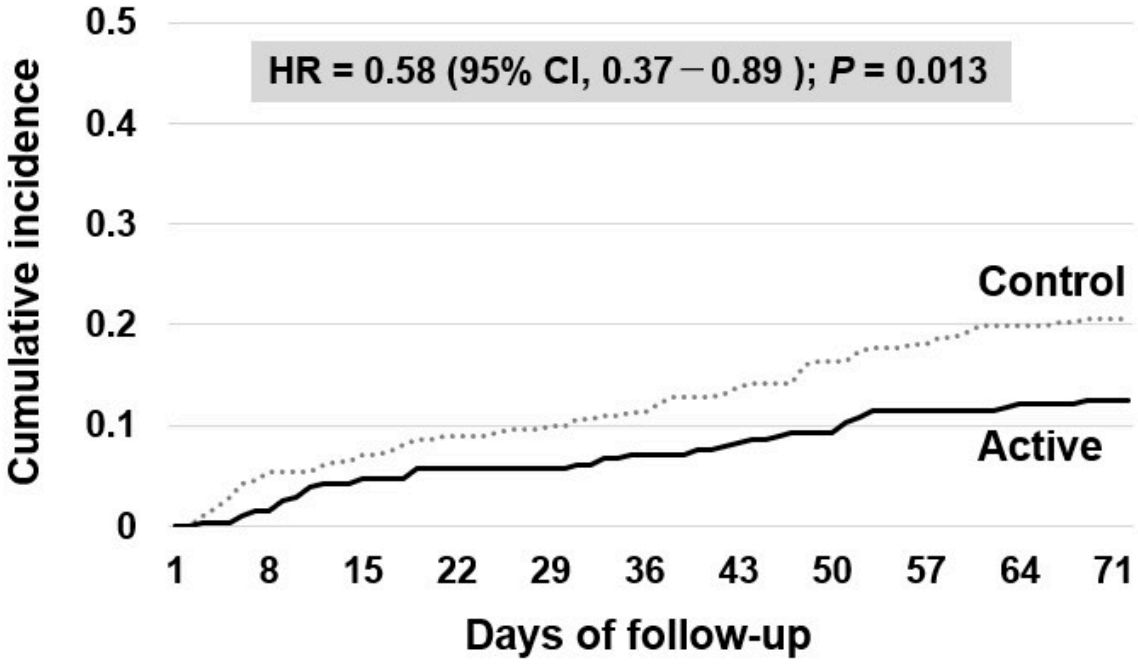


Figure 1

CONSORT flow diagram of the household cluster-randomized trial.

The diagram shows the number of participants who responded to the recruitment survey, received an explanation of the study, were randomized, and included in the full analysis set (FAS). Participants who discontinued the intervention (active group, n = 5; control group, n = 2) were censored at their last recorded date and included in the FAS.



Number at risk

Days	0	14	28	42	56	70
Control	283	265	256	246	232	225
Active	285	273	269	263	253	250

Figure 2

Effect of the intervention on upper respiratory symptoms.

Kaplan–Meier curves for time to first upper respiratory symptoms in the active and control groups. Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated using the Cox proportional hazards model with cluster-robust standard errors to account for household clustering. There were 58 and 35 events in the control and active groups, respectively.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SupplementaryInformation.pdf