T he common cold, mainly caused by rhinoviruses or coronaviruses, is a frequent problem all over the world. Although the symptoms are generally benign, viral colds result in significant costs to the economy due to lost workdays and school attendance. Convincing treatment options without side effects are not known. Traditionally, the local application of heat is used to treat the symptoms of the common cold — for example, ingesting hot fluids such as tea or chicken soup, or inhaling hot vapour. Moreover, few clinical trials have been conducted to evaluate such treatment options. It has been suggested that local hyperthermia of the nasal mucosa can affect rhinovirus replication. A Cochrane review of six trials — one from Israel, two from the United Kingdom, and three from the United States — found that only the studies from Israel and UK showed that steam was beneficial for relief of common cold symptoms. Results on symptom indices were equivocal; therefore, it was concluded that steam inhalation cannot be recommended for the routine treatment of common cold symptoms and further blind randomised controlled trials needed to be conducted.

In the German city of Essen, a sauna with dry air heated to 90°C exists (www.unperfekthaus.de/projekte/angezogen-sauna) where people can visit dressed in street clothes for the relief of common cold symptoms. This type of sauna is widely available and offers enough dry air to heat the throat, and the wetness of the skin is only caused by sweating, not by high humidity. With the aim of heating the throat, people stay in this sauna for only a short period to avoid sweating. Use of this type of sauna has little in common with that of a regular sauna, where one usually stays longer than 10 minutes and sweating is desired. If proven to be effective, a dry air sauna would be an interesting option for treating common cold symptoms.

On the basis of experiences with the sauna in Essen, the aim of our study was to test the hypothesis that inhaling hot dry air reduces common cold symptoms. To do this, we compared the efficacy of applying hot dry air versus dry air at room temperature to the throat of patients with a newly acquired common cold, using a symptom severity score.

**ABSTRACT**

**Objective:** To compare the efficacy of applying hot dry air versus dry air at room temperature to the throat of patients with a newly acquired common cold using a symptom severity score.

**Design, setting and participants:** A randomised single-blind controlled trial with a treatment duration of 3 days and a follow-up period of 4 days was conducted at a sauna in Berlin, Germany. Between November 2007 and March 2008 and between September 2008 and April 2009, 157 patients with symptoms of the common cold were randomly assigned to an intervention group (n = 80) and a control group (n = 77).

**Interventions:** Participants in the intervention group inhaled hot dry air within a hot sauna, dressed in a winter coat, whereas participants in the control group inhaled dry air at room temperature within a hot sauna, also dressed in a winter coat.

**Main outcome measures:** Area under the curve (AUC) summarising symptom severity over time (Days 2, 3, 5 and 7), symptom severity scores for individual days, intake of medication for the common cold and general ill feeling.

**Results:** No significant difference between groups was observed for AUC representing symptom severity over time (intervention group mean, 31.2 [SEM, 1.8]; control group mean, 35.1 [SEM, 2.3]; group difference, –3.9 [95% CI, –9.7 to 1.9]; P = 0.19). However, significant differences between groups were found for medication use on Day 1 (P = 0.01), symptom severity score on Day 2 (P = 0.04), and participants’ ratings of the effectiveness of the therapy on Day 7 (P = 0.03).

**Conclusion:** Inhaling hot air while in a sauna has no significant impact on overall symptom severity of the common cold.

**Trial registration:** ClinicalTrials.gov identifier NCT00552981.

**METHODS**

**Design**

A randomised single-blind controlled trial was conducted, in which participants were randomly assigned to an intervention group (inhaling hot air within a hot sauna) or a control group (inhaling air at room temperature within a hot sauna). Unstratified and unrestricted randomisation was applied by one of us (RL) using SAS/BASE software v9.1 (SAS Inc, Cary, NC, USA) and data were transferred into a secure Microsoft Office Access 2003 (Microsoft Corporation, Redmond, Wash, USA) database that was not accessible to any staff members or study physicians.

This study adhered to the principles of the Declaration of Helsinki and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice (ICH GCP), and was approved by the local ethics committee (Charité University Medical Center).

**Participants**

Employees of the Charité University Medical Center, medical students and people working near the Charité campus were recruited between November 2007 and March 2008 and between September 2008 and April 2009. Participants received €10 for each visit to cover transportation costs.

We included patients between 18 and 60 years of age, with at least two out of 10 common cold symptoms — cough, headache, hoarseness, muscle ache, nasal discharge (nasal drip), nasal congestion, scratchy throat, sore throat, sneezing and fever (> 38.5°C) for 24 hours or less, and who were not planning to take medication for the cold. We excluded patients who had any of these cold symptoms for more than 24 hours, circulatory problems, severe

**To compare the efficacy of applying hot dry air versus dry air at room temperature to the throat of patients with a newly acquired common cold using a symptom severity score.**
CHRISTMAS OFFERINGS

1 Sauna set-up used for control and intervention groups

To have a comparable setting and enable maximum blinding in both groups, we used a face mask to cover the mouth and nose that was attached to a tube (80 cm long), similar to masks used for anaesthesia. The tube was lead through a screen, and the other end of the tube was either placed behind the screen (to allow inhalation of sauna air) or lead through the wall of the sauna (to allow inhalation of ambient air). After every application, the mask and tube were disinfected.

2 Recruitment, treatment and follow-up of patients with a newly acquired common cold, November 2007 – March 2008 and September 2008 – April 2009

287 people expressed interest in participating in the study

130 people were not eligible:
104 excluded based on inclusion or exclusion criteria;
2 refused to be randomly assigned; 2 refused to participate; 22 could not participate during business hours

157 eligible participants randomly assigned

80 participants assigned to intervention group
1 refused further participation on Day 2
Incomplete data for 2 participants:
1 did not participate after Day 1 because of the need for treatment of symptoms; 1 did not participate on Day 3
Follow-up data for 79 participants
80 included in intention-to-treat analysis (missing data replaced by maximum likelihood-based imputation)

77 participants assigned to control group
Incomplete data for 3 participants:
1 did not participate after Day 1 because of the need for treatment of symptoms; 2 did not participate after Day 2 because of the need for treatment of symptoms
Follow-up data for 76 participants
77 included in intention-to-treat analysis (missing data replaced by maximum likelihood-based imputation)
1 refused further participation on Day 5
Incomplete data for 3 participants:
1 did not participate after Day 1 because of the need for treatment of symptoms; 2 did not participate after Day 2 because of the need for treatment of symptoms

chronic illness, or systolic blood pressure below 100 mmHg or above 160 mmHg, or who were pregnant.

Intervention

Participants in both groups sat in a sauna (dry air [20% humidity], 90°C) in Berlin (at the Institute for Social Medicine, Epidemiology and Health Economics, Charité University Medical Center) dressed in a winter coat (63% acrylic, 37% polyester, 1.5 cm thick), for about 3 minutes on 3 consecutive days. The short stay and the insulation provided by the winter coat should avoid circulatory imbalance and sweating. The intervention group sat in the hot sauna and inhaled the hot dry sauna air through the mouth via a mask. The control group sat in the hot sauna and inhaled dry air from outside the sauna (24°C) through the mouth via a mask (Box 1). Fitness of participants was assessed before every treatment in the sauna by measuring blood pressure and heart rate and by asking about fever symptoms.

Outcome measures

The severity of each of the 10 symptoms used as inclusion criteria was rated by participants at baseline (on Day 1, before randomisation), after treatment episodes on Days 1, 2 and 3, and on Days 5 and 7, using a scale of 0 to 3 (0 = none, 1 = mild, 2 = moderate, 3 = severe). This scale has previously been used in a trial on the common cold.10 The primary outcome measure was the area under the curve (AUC) which summarised symptom severity over time (on Days 2, 3, 5 and 7), based on a sum score from the 10 symptoms that were rated.

Secondary outcomes measured were symptom severity scores on Days 1, 2, 3, 5 and 7, use of medication for the common cold on Days 1–7, general ill feeling on a rating scale of 0 (completely healthy) to 10 (very ill) on Days 1, 2, 3, 5 and 7, and safety according to incidence of adverse events on Days 1–7 (eg, symptoms or events other than the 10 symptoms that were rated). In addition, participants rated expected outcomes of therapy and expected effectiveness of therapy at baseline, guessed which group they had been assigned to on Day 3, and provided ratings of outcomes and effectiveness on Day 7.

Outcomes were assessed using standardised questionnaires. Apart from the questionnaires completed on Days 5 and 7, which the participants took home, all questionnaires were completed at the study site.
3 Baseline characteristics of study participants

|                           | Intervention (n = 80) | Control (n = 77) |
|---------------------------|-----------------------|------------------|
|                           | Mean (SD)             | Mean (SD)        |
|                           | or no. (%) Median     | Median           | P     |
| Women                     | 46 (58%) 47 (61%)     | 30.0             | 0.65  |
| Age (years)               | 33.7 (10.8) 30.2 (9.4) | 27.0             | 0.03  |
| Body mass index (kg/m²)   | 23.4 (4.0) 21.8 (2.9) | 21.3             | 0.003 |
| No. of common colds in past 6 months | 0.9 (1.1) 1.1 (1.5) | 1.0             | 0.63  |
| Duration of symptoms (h)  | 19.0 (6.1) 18.3 (5.9) | 19.0             | 0.44  |
| Symptom severity score    |                       |                  |       |
| Total                     | 9.4 (4.0) 9.1 (3.1)   | 9.0             | 0.92  |
| Cough                     | 0.9 (0.7) 0.8 (0.8)   | 1.0             | 0.24  |
| Headache                  | 1.1 (0.9) 1.2 (1.0)   | 1.0             | 0.47  |
| Hoarseness                | 0.8 (0.8) 0.7 (0.8)   | 0.0             | 0.20  |
| Muscle ache               | 0.6 (0.8) 0.7 (0.7)   | 1.0             | 0.33  |
| Nasal drainage            | 1.5 (0.9) 1.5 (0.9)   | 2.0             | 0.84  |
| Nasal congestion          | 1.1 (0.9) 1.2 (0.9)   | 1.0             | 0.65  |
| Scratchy throat           | 1.3 (0.9) 1.4 (0.7)   | 1.0             | 0.52  |
| Sore throat               | 1.1 (0.9) 1.0 (0.9)   | 1.0             | 0.30  |
| Sneezing                  | 0.9 (0.8) 0.8 (0.8)   | 1.0             | 0.69  |
| Fever                     | 0.2 (0.4) 0.1 (0.3)   | 0.0             | 0.01  |
| General ill feeling*      | 3.8 (1.7) 4.2 (1.6)   | 4.0             | 0.08  |
| Use of medications for other diseases | 15 (19%) 24 (31%) | 0.07  |
| Use of medications for common cold† | 15 (19%) 14 (18%) | 0.93  |
| Consultation because of common cold | 0 1 (1%) | 0.70  |
| Expected outcome          |                       |                  |       |
| Recovery                  | 2 (3%) 7 (9%)         |                 |       |
| Distinct improvement      | 37 (46%) 31 (40%)     |                 |       |
| Light improvement         | 41 (51%) 38 (49%)     |                 |       |
| No improvement            | 0 1 (1%)              |                 |       |
| Expected effectiveness    |                       |                  | 0.46  |
| Very effective            | 7 (9%) 12 (16%)       |                 |       |
| Effective                 | 55 (69%) 48 (62%)     |                 |       |
| Small effect              | 18 (23%) 17 (22%)     |                 |       |
| No effect                 | 0 0                   |                 |       |

* On a scale of 0 to 10 (0 = completely healthy; 10 = very ill). † Before the beginning of the study, during present common cold.

Statistics

Each randomly assigned participant was included in the analysis regardless of adherence to the assigned treatment or the provision of a full set of data (intention-to-treat analysis). To detect a medium effect size (Cohen’s d, 0.5) with 80% power and a two-sided significance level of 5%, we planned to recruit 160 patients (128 participants plus 25% extra to allow for patient drop out).

The symptom severity score and general ill feeling data were evaluated using generalised estimation equation (GEE) regression models which modelled treatment group, time, group–time interaction, baseline values and participants’ initial expectations from treatment as covariates. This resulted in adjusted symptom severity scores from which the adjusted AUC was calculated via the trapezoid rule (ie, linear interpolation of data points and summing up the resulting trapezoid areas). All reported treatment effects, 95% confidence intervals and P values are based on this GEE model.

Similar GEE models were fitted to the dichotomous data on participants’ use of medication for the common cold during the treatment period, assuming a logit link function and integrating over the study period (ie, trapezoid areas). All reported treatment effects, 95% confidence intervals and P values are based on this GEE model.

The symptom severity score and general ill feeling data were evaluated using generalised estimation equation (GEE) regression models which modelled treatment group, time, group–time interaction, baseline values and participants’ initial expectations from treatment as covariates. This resulted in adjusted symptom severity scores from which the adjusted AUC was calculated via the trapezoid rule (ie, linear interpolation of data points and summing up the resulting trapezoid areas). All reported treatment effects, 95% confidence intervals and P values are based on this GEE model.

RESULTS

Participants

Of 287 people who expressed interest in the study, 137 were randomly assigned to the intervention or control arms of the study (intervention group: n = 80, control group: n = 77; Box 2). The mean age of these participants was 32.0 years (SD, 10.2 years; median, 28 years), and 93 participants (59.2%) were women. Mean age and body mass index differed significantly between groups (P = 0.03 and P = 0.003, respectively) but other baseline characteristics were comparable (Box 3).

Outcome measures

For the AUC for symptom severity (Days 2, 3, 5 and 7), no significant differences between the groups were observed (adjusted group difference, −3.9 [95% CI, −9.7 to 1.9]); P = 0.19; Cohen’s d, 0.13; Box 4, Box 5). Moreover, for the symptom severity score on Day 2, there was a significant difference between groups (adjusted group difference, −1.0 [95% CI, −2.0 to −0.1]; P = 0.04; Box 4, Box 5). Additional adjustments for age and body mass index did not change the results.

The general ill feeling score was not significantly different between groups (P > 0.05 for all days observed; Box 5). During the course of the common cold, the proportion of participants who took medication for the cold only differed significantly between groups on Day 1 (ie, after the first treatment episode) (odds ratio, 0.2 [95% CI, 0.04 to 0.7]; Box 4).

The groups did not differ significantly in terms of incidence of adverse events (11 participants [13.8%] in intervention group vs nine participants [11.7%] in control group; P = 0.70). The most common adverse event was a cough directly stimulated by the intervention (intervention group, 2; control group, 1).

Expected outcomes according to participants had no significant impact on the AUC for symptom severity (P = 0.43).

DISCUSSION

Participants who had inhaled hot air in the sauna did not show significantly different common cold symptoms compared with
participants who had inhaled air at room temperature.

The main strengths of this trial are the rigorous study design, large sample size, high compliance and follow-up rates, and the clear research hypothesis. Moreover, the sauna set-up was very similar for the intervention and control groups, and the groups were comparable at baseline.

We might have underestimated the effect of sitting in the sauna. For example, some participants experienced pleasant warming of the face and relaxation while sitting in the sauna and less headache afterwards. However, initial worsening is often only observable in studies where participants suffered from an experimentally induced common cold.13 Taking this lack of initial

participants who had inhaled hot air, resulting in similar treatment outcomes in both groups. If so, we
worsening as an indication of longer disease duration (ie, greater than 24 hours at the start of the study), our intervention might have been too late to have had an impact on the course of the disease. However, the context effect\textsuperscript{14} or placebo effect\textsuperscript{15,16} may explain the initial improvement of symptoms. The placebo effect may also explain the significant group differences for the participants’ ratings of symptom severity on Day 2, medication intake on Day 1, and ratings of the effectiveness of the therapy on Day 7. As more participants in the control group guessed correctly that they were in the control group, the placebo effect might have been higher in the intervention group.

Inhaling hot dry air while in a sauna does not have a significant impact on the symptom severity of a common cold.

ACKNOWLEDGEMENTS
We thank Beatrice Eden and Iris Bartsch for their support with daily patient management, and Reinhard Wiesemann who developed the idea for this setting and provided the sauna cabin.

COMPETING INTERESTS
The study was funded by the Karl und Veronica Carstens Foundation.

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REFERENCES
1 Heikkinen T, Jarvinen A. The common cold. \textit{Lancet} 2003; 361: 51-59.
2 Papadopoulos NG, Sanderson G, Hunter J, Johnston SL. Rhinoviruses replicate effectively at lower airway temperatures. \textit{J Med Virol} 1999, 58: 100-104.
3 Roxas M, Jurenka J. Colds and influenza: a review of diagnosis and conventional, botanical, and nutritional considerations. \textit{Altern Med Rev} 2007; 12: 25-48.
4 Arroll B. Non-antibiotic treatments for upper-respiratory tract infections (common cold). \textit{Respir Med} 2005; 99: 1477-1484.
5 Saketkhoo K, Januszewicz A, Sackner MA. Effects of drinking hot water, cold water, and chicken soup on nasal mucus velocity and nasal airflow resistance. Chest 1978; 74: 408-410.
6 Singh M. Heated, humidified air for the common cold. \textit{Cochrane Database Syst Rev} 2006; (3): CD001728.
7 Tyrrell D, Barrow I, Arthur J. Local hyperthermia benefits natural and experimental common colds. \textit{BMJ} 1989, 298: 1280-1283.
8 Conti C, De MA, Mastromarino P, et al. Antiviral effect of hyperthermic treatment in rhinovirus infection. \textit{Antimicrob Agents Chemother} 1999; 43: 822-829.
9 Lwoff A. Death and transfiguration of a problem. \textit{Bacteriol Rev} 1969, 33: 390-403.
10 Prasad AS, Fitzgerald JT, Bao B, et al. Duration of symptoms and plasma cytokine levels in patients with the common cold treated with zinc acetate. A randomized, double-blind, placebo-controlled trial. \textit{Ann Intern Med} 2000, 133: 245-252.
11 Prasad AS, Beck FW, Bao B, et al. Duration and severity of symptoms and levels of plasma interleukin-1 receptor antagonist, soluble tumor necrosis factor receptor, and adhesion molecules in patients with common cold treated with zinc acetate. \textit{J Infect Dis} 2008, 197: 795-802.
12 Gwaltney JM Jr, Hendley JO, Simon G, Jordan WS Jr. Rhinovirus infections in an industrial population. II. Characteristics of illness and antibody response. \textit{JAMA} 1967; 202: 494-500.
13 Gwaltney JM Jr, Hendley JO, Patrie JT. Symptom severity patterns in experimental common colds and their usefulness in timing onset of illness in natural colds. \textit{Clin Infect Dis} 2003; 36: 714-723.
14 Di Blasi Z, Kleijnne J. Context effects. Powerful therapies or methodological bias? \textit{Eval Health Prof} 2003; 26: 166-179.
15 Kaptchuk TJ. Powerful placebo: the dark side of the randomised controlled trial. \textit{Lancet} 1998; 351: 1722-1725.
16 Brinkhaus B, Pach D, Lüdtke R, Willich SN. Who controls the placebo? Introducing a placebo quality checklist for pharmacological trials. \textit{Contemp Clin Trials} 2008; 29: 149-156.

(Received 17 Jun 2010, accepted 10 Nov 2010)