CONCLUSION:

Daily nasal isotonic saline irrigation reduces frequent seasonal upper respiratory symptoms and indicators of illness without any serious side effects and alleviates the demand of medical resources with minimal daily costs. Thus, this simple and pleasant method of daily hygiene qualifies - comparable to teethbrushing - as a public health measure for the maintenance of respiratory health in everyone.

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JALA NETI SET

REDUCTION OF UPPER RESPIRATORY INFECTION AND ALLERGY SYMPTOMS THROUGH DAILY NASAL ISOTONIC SALINE IRRIGATION COMPARED TO SEASONAL EFFECTS – RESULTS FROM A RANDOMIZED CONTROLLED CROSSOVER TRIAL

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Ninth International Congress of Behavioral Medicine, November 29 - December 2, 2006, Bangkok, Thailand

Abstract: International Journal of Behavioral Medicine, ISSN 1070-5503, Volume 13, Supplement, 2006, p. 243

Cleansing the nasal mucous membrane through saline irrigation has been practised for centuries in folk medicine and yoga, where it is known as JALA NETI. Meanwhile it is also recognized by official medical health authorities as a simple, effective, inexpensive and safe intervention and adjunctive therapy for acute and chronic sinusitis as well as allergic respiratory symptoms in children and adults. In cystic fibrosis patients, practising daily nasal irrigation is vital for reducing the viscous mucus and recurrent respiratory infection. However, additionally to this, daily nasal irrigation could also be an effective hygienic measure for all to reduce the burden of respiratory symptoms and disease in the general population. This aspect was investigated in the present study.

The effect of daily nasal irrigation was tested in a Randomized Controlled Crossover Trial over two twelve week periods against the daily intake of a multivitamine effervescent (Xotic) in a healthy working population. Participants were randomized to two groups: In group A they rinsed their noses daily in phase 1 for twelve weeks and took in phase 2 the vitamin effervescent once a day during the following twelve weeks. In group B the order of interventions was reversed. Accordingly participants served as their own controls.

Participants prepared their own isotonic saline solution with normal iodized table salt and lukewarm tap water using a newly developed JALA NETI SET consisting of a neti pot for nasal irrigation with a large rinsing volume (>400 ml) together with a salt measuring spoon, both manufactured from recyclable, food-grade synthetic material.

297 adult male (182) and female (115) volunteers aged 41.1 ± 11.1 years from a healthy working population in four service enterprises in Hanover, Germany, participated in the study. They daily recorded 21 symptoms or indicators of illness with regard to upper respiratory infection and allergy symptoms in symptom diaries. Documentation was available for 6.95 out of 7 days on average during the two twelve week study periods.

The 21 symptom scores documented daily could be attributed by factor analysis to six groups of symptoms indicating different illness entities with their corresponding portions of the total variance explained (55.5%) (figure 3):

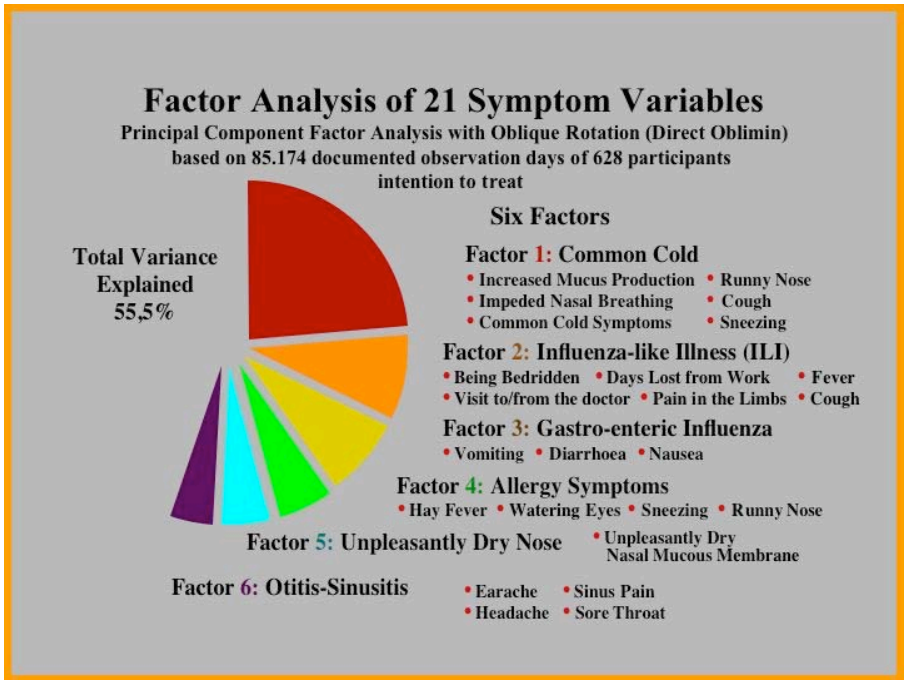

Figure 3

Factor 1: Common cold (23.7%), factor 2: influenza-like illness (ILI) (8.5%), factor 3: gastro-enteric influenza (8.0%), factor 4: allergy symptoms (5.7%), factor 5: unpleasantly dry nasal mucous membrane (4.9%), factor 6: otitis-sinusitis (4.6%) (figure 3).

The factor scores (FS) of five of these factors were significantly reduced by nasal irrigation (NI) when compared to the vitamin period (VIT) (figure 4):

Common cold ($\{|FS^{VIT}| + |FS^{NI}|\} \times 10^2 = 11{,}38$), influenza-like illness (ILI) (6.56), allergic respiratory symptoms (11.81), unpleasantly dry nasal mucous membrane (17.82) as well as otitis-sinusitis (8.23) with pain in the tympanum, sinuses, pharynx and throat (figure 4).

Seasonal effects are found for the factor scores of following factors: common cold (22.12), influenza-like illness (ILI) (16.89), unpleasantly dry nasal mucous membrane (9.96) and otitis-sinusitis (12.80) with a higher incidence in the winter and a lower incidence in the summer (figure 5). Allergy symptoms (10.49) are more common during the spring-summer season.

Seasonal effects of gastro-enteric influenza (2.21) are not significant (figure 5).

Table 1 EFFECTS OF NASAL IRRIGATION **Symptom Variables**	**Days with Symptoms/1000 Observation Days Vitamin Period** M ± S.D.	**Days with Symptoms/1000 Observation Days Irrigation Period** M ± S.D.	**F-Value** df 1 / 295	**p-Value**	**Absolute Risk Reduction** Symptom Days / 1000 **Vitamin** minus **Irrigation Period**	**NNT** Number Needed to Treat	**Relative Risk** Symptoms Days / 1000 Observation Days **Irrigation Period / Vitamin Period** (±95% CI)	**Relative Risk Reduction** Percent (1-Relative Risk) x 100	**Effect Size** Percent
00. Total Symptom Score	**516.1 ± 445.5**	**424.7 ± 432.6**	**22.70**	**0.000**	**91.4**	**10.9**	**0.823 (0.794-0.852)**	**17.7**	**20.5**
01. Unpleasantly Dry Nose	**191.2 ± 370.0**	**138.4 ± 324.4**	**11.01**	**0.001**	**52.7**	**19.0**	**0.724 (0.690-0.760)**	**27.6**	**14.2**
02. Impeded Nasal Breathing	**178.0 ± 344.7**	**130.4 ± 294.3**	**13.91**	**0.000**	**47.6**	**21.0**	**0.733 (0.697-0.770)**	**26.7**	**13.8**
03. Increased Mucus Production	**161.4 ± 327.8**	**120.5 ± 289.1**	**9.79**	**0.002**	**40.9**	**24.4**	**0.747 (0.710-0.786)**	**25.3**	**12.5**
04. Common Cold Symptoms	**176.9 ± 348.6**	**141.5 ± 306.7**	**6.80**	**0.010**	**35.4**	**28.2**	**0.800 (0.762-0.840)**	**20.0**	**10.2**
05. Sneezing	**113.8 ± 267.4**	**89.8 ± 227.9**	**4.95**	**0.027**	**24.0**	**41.6**	**0.789 (0.744-0.837)**	**21.1**	**9.0**
06. Sore Throat	**64.4 ± 199.4**	**43.8 ± 161.7**	**9.05**	**0.003**	**20.6**	**48.5**	**0.680 (0.629-0.736)**	**32.0**	**10.3**
07. Hay Fever	**64.6 ± 216.3**	**44.4 ± 185.2**	**3.17**	**0.076**	**20.3**	**49.4**	**0.687 (0.635-0.743)**	**31.3**	**9.4**
08. Headache	**72.3 ± 190.1**	**52.4 ± 143.7**	**11.21**	**0.001**	**20.0**	**50.1**	**0.724 (0.673-0.780)**	**27.6**	**10.5**
09. Runny Nose	137.4 ± 301.4	121.2 ± 279.8	1.51	ns	16.2	61.9	0.883 (0.837-0.930)	11.8	5.4
10. Pain in the Limbs	**31.4 ± 139.0**	**17.8 ± 92.5**	**4.91**	**0.027**	**13.6**	**73.7**	**0.567 (0.504-0.639)**	**43.3**	**9.8**
11. Watering Eyes	39.5 ± 167.3	29.5 ± 141.3	2.08	ns	10.0	100.3	0.748 (0.678-0.824)	25.3	6.0
12. Earache	27.3 ± 134.2	18.1 ± 91.5	2.31	ns	9.2	108.7	0.663 (0.588-0.748)	33.7	6.9
13. Nausea	**12.0 ± 80.4**	**4.4 ± 35.2**	**3.99**	**0.047**	**7.6**	**131.8**	**0.365 (0.293-0.456)**	**63.5**	**9.4**
14. Fever	**14.5 ± 89.3**	**7.0 ± 48.8**	**3.71**	**0.055**	**7.5**	**133.2**	**0.481 (0.401-0.578)**	**51.9**	**8.4**
15. Cough	63.0 ± 195.9	57.2 ± 189.5	0.57	ns	5.8	172.7	0.908 (0.843-0.978)	9.2	3.0
16. Sinus Pain	29.0 ± 138.9	23.3 ± 123.9	0.75	ns	5.6	177.3	0.806 (0.721-0.900)	19.5	4.1
17. Diarrhoea	12.2 ± 77.2	7.2 ± 47.8	1.80	ns	5.0	199.2	0.590 (0.490-0.710)	41.0	6.5
18. Vomiting	4.9 ± 46.7	1.0 ± 11.1	1.22	ns	3.8	259.7	0.214 (0.140-0.328)	78.6	8.3
19. Being Bedridden (ARI)	**11.8 ± 70.1**	**8.3 ± 52.3**	**3.10**	**0.079**	**3.6**	**280.9**	**0.699 (0.584-0.837)**	**30.1**	**5.1**
20. Visit to / from the doctor	**10.0 ± 47.8**	**7.2 ± 37.5**	**3.32**	**0.070**	**2.8**	**352.1**	**0.717 (0.591-0.870)**	**28.3**	**5.9**
Visit to / from the doctor	**3.9 ± 24.8**	**2.3 ± 15.9**	**4.08**	**0.044**	**1.6**	**628.9**	**0.595 (0.429-0.824)**	**40.6**	**6.4**
21. Days lost from Work (ARI)	13.7 ± 77.3	11.2 ± 73.0	0.77	ns	2.5	396.8	0.817 (0.696-0.958)	18.3	3.3

Table 2 SEASONAL EFFECTS Phase 1: Winter Phase 2: Spring-Summer **Symptom Variables**	**Days with Symptoms**/1000 Observation Days during **Phase 1** M ± S.D.	**Days with Symptoms**/1000 Observation Days during **Phase 2** M ± S.D.	**F-Value** df 1 / 295	**p-Value**	**Absolute Risk Reduction** Symptom Days / 1000 **Phase 1** minus **Phase 2**	**NNT** Number Needed to Treat	**Relative Risk** Symptoms Days / 1000 Observation Days **Phase 2 / Phase 1** (±95% CI)	**Relative Risk Reduction** Percent (1-Relative Risk) x 100	**Effect Size** Percent
00. Total Symptom Score	**502.3 ± 434.9**	**438.5 ± 443.1**	**11.04**	**0.001**	**63.8**	**15.7**	**0.873 (0.843-0.904)**	**12.7**	**14.7**
01. Unpleasantly Dry Nose	174.5 ± 349.7	155.1 ± 344.7	1.49	ns	19.4	51.5	0.889 (0.848-0.932)	11.1	5.6
02. Impeded Nasal Breathing	**174.1 ± 333.2**	**134.3 ± 305.9**	**9.73**	**0.002**	**39.8**	**25.1**	**0.771 (0.734-0.810)**	**22.9**	**11.9**
03. Increased Mucus Production	**162.3 ± 325.7**	**119.6 ± 291.2**	**10.68**	**0.001**	**42.7**	**23.4**	**0.737 (0.700-0.775)**	**26.3**	**13.1**
04. Common Cold Symptoms	**198.6 ± 361.3**	**119.8 ± 293.9**	**33.63**	**0.000**	**78.8**	**12.7**	**0.603 (0.574-0.634)**	**39.7**	**21.8**
05. Sneezing	105.2 ± 246.8	98.5 ± 248.5	0.37	ns	6.6	152.3	0.938 (0.885-0.994)	6.2	2.7
06. Sore Throat	**64.8 ± 195.5**	**43.5 ± 165.7**	**9.65**	**0.002**	**21.3**	**47.0**	**0.672 (0.621-0.727)**	**32.8**	**10.9**
07. Hay Fever	**29.4 ± 150.5**	**79.6 ± 251.0**	**19.47**	**0.000**	**-50.2**	**-19.9**	**2.705 (2.480-2.949)**	**-170.5**	**-33.3**
08. Headache	**76.4 ± 184.1**	**48.3 ± 149.7**	**22.32**	**0.000**	**28.2**	**35.5**	**0.631 (0.586-0.680)**	**36.9**	**15.3**
09. Runny Nose	**151.2 ± 305.6**	**107.5 ± 275.6**	**11.09**	**0.001**	**43.7**	**22.9**	**0.711 (0.674-0.749)**	**28.9**	**14.3**
10. Pain in the Limbs	**33.1 ± 135.3**	**16.1 ± 96.1**	**7.69**	**0.006**	**17.0**	**58.9**	**0.486 (0.431-0.549)**	**51.4**	**12.5**
11. Watering Eyes	33.3 ± 147.9	35.7 ± 160.7	0.13	ns	-2.5	-404.9	1.074 (0.976-1.183)	-7.4	1.7
12. Earache	25.2 ± 122.5	20.3 ± 103.2	0.66	ns	4.9	203.0	0.804 (0.714-0.906)	19.6	4.0
13. Nausea	9.0 ± 58.8	7.4 ± 56.8	0.17	ns	1.6	632.9	0.824 (0.677-1.002)	17.6	2.7
14. Fever	12.9 ± 72.4	8.6 ± 65.8	1.21	ns	4.3	232.6	0.666 (0.560-0.792)	33.4	5.9
15. Cough	**80.0 ± 219.8**	**40.2 ± 165.6**	**27.17**	**0.000**	**39.8**	**25.1**	**0.502 (0.464-0.543)**	**49.8**	**18.1**
16. Sinus Pain	**32.3 ± 147.9**	**20.1 ± 114.9**	**3.51**	**0.062**	**12.2**	**81.9**	**0.621 (0.555-0.696)**	**37.9**	**8.3**
17. Diarrhoea	9.3 ± 53.0	10.1 ± 72.0	0.05	ns	-0.8	-1197.6	1.090 (0.911-1.3.3)	-9.0	-1.6
18. Vomiting	1.1 ± 11.8	4.8 ± 46.0	1.11	ns	-3.7	-272.5	4.219 (2.803-6.352)	-321.9	-31.0
19. Being Bedridden (ARI)	**14.9 ± 77.9**	**5.2 ± 44.5**	**23.34**	**0.000**	**9.8**	**102.4**	**0.346 (0.283-0.423)**	**65.4**	**12.5**
20. Visit to/from the doctor	**10.8 ± 49.7**	**6.4 ± 35.5**	**8.27**	**0.004**	**4.5**	**223.2**	**0.587 (0.482-0.714)**	**41.3**	**9.0**
Visit to/from the doctor (ARI)	**4.9 ± 29.2**	**1.4 ± 11.5**	**20.48**	**0.000**	**3.6**	**280.9**	**0.275 (0.188-0.403)**	**72.5**	**12.2**
21. Days lost from Work (ARI)	**18.8 ± 98.8**	**6.1 ± 51.5**	**19.57**	**0.000**	**12.7**	**78.9**	**0.326 (0.272-0.392)**	**67.4**	**12.8**

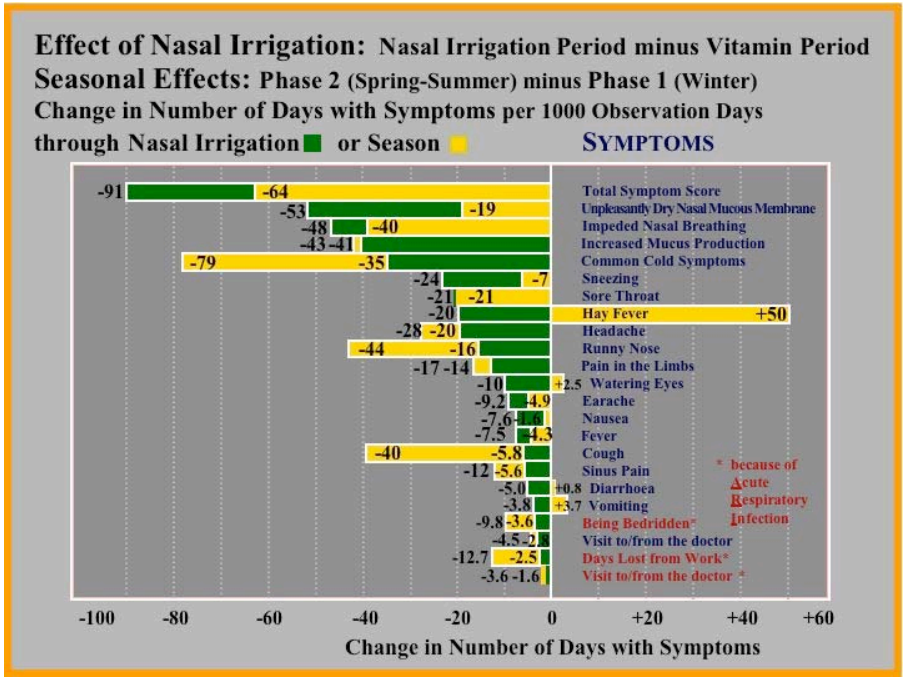

Figure 1

Daily nasal rinsing reduced the relative risk of 15 frequent respiratory symptoms and indicators of illness by 18 - 64% (table 1; figure 1):

Unpleasantly dry nasal mucous membrane, impeded nasal breathing (congested nose), increased mucus production, common cold symptoms, sneezing, sore throat, hay fever, headache, pain in the limbs, nausea, fever, being bedridden because of acute respiratory illness (ARI), visits to or from the doctor for any reason or because of ARI as well as the total symptom score.

Seasonal effects caused more symptoms during the winter in 14 variables (table 2; figure 1) such as total symptom score, impeded nasal breathing, increased mucus production, common cold symptoms, sore throat, headache, runny nose, pain in the limbs, cough, sinus pain, being bedridden (because of ARI), visits to or from the doctor (any cause and because of ARI) and days lost from work. Hay fever was more common during the spring-summer season.

Risk reduction by nasal irrigation was more pronounced than seasonal effects in six variables by a factor of 1.2 - 4.8: Total symptom score, unpleasantly dry nasal mucous membrane, impeded nasal breathing, sneezing, nausea and fever.

In eleven variables seasonal effects were stronger by a factor of 1.4 - 6.9, when compared to the effects of nasal irrigation:

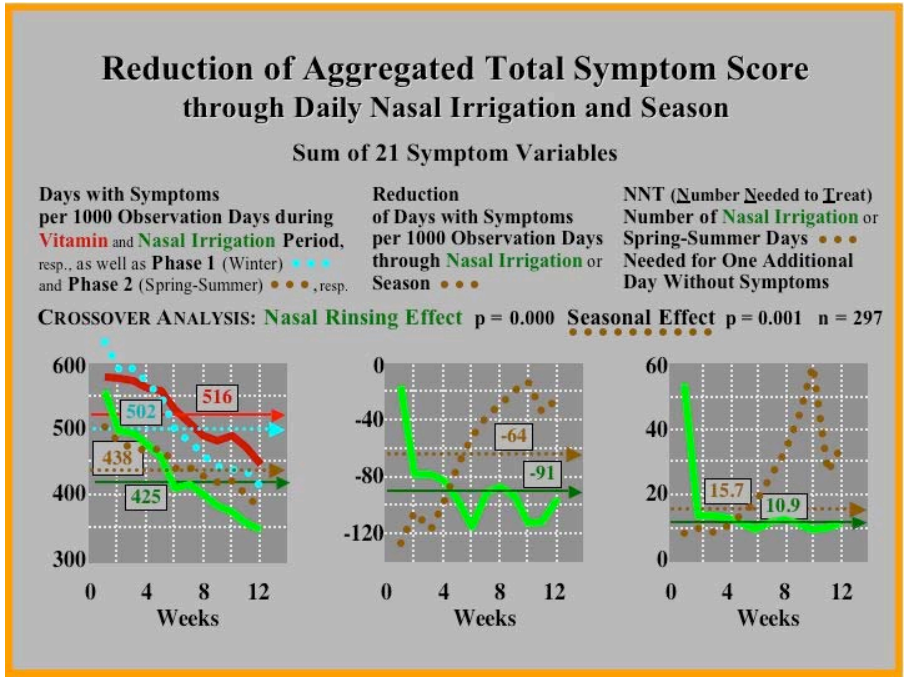

Figure 2

Common cold symptoms, hay fever, headache, runny nose, pain in the limbs, cough, sinus pain, being bedridden because of ARI, days lost from work, visits to or from the doctor (any cause and because of ARI).

In seven of these nasal rinsing reduced the relative risk by 20 - 43%: Common cold symptoms, hay fever, headache, pain in the limbs, being bedridden because of ARI, visits to or from the doctor (any cause and because of ARI).

Daily nasal irrigation is associated with 33.4 additional days without any of 21 daily documented respiratory symptoms or indicators of illness within one year (NNT: 10.9 days) (figure 2).

There is a high incidence of respiratory symptoms and disease in the winter at the beginning of the year, with more than 640 days of recorded symptoms per 1000 days of observation pointing to a high impact also in the general population. It is, however, reduced during the following twelve weeks by more than 200 days with symptoms per 1000 days of observation (fig. 2, **blue dotted lines** in diagram 1). During the twelve weeks without nasal rinsing, on average there are still one or more symptoms recorded on at least every second day (fig. 2, **red line** in diagram 1). The full protective effect of nasal rinsing can be seen quite soon, after two to four weeks (fig. 2, **green lines** in diagram 2 and 3).

Young boy during nasal rinsing using the JALA NETI SET

Naturally occuring seasonal effects were evaluated by comparing the documented symptoms in phase 1 (January-April) with phase 2 (April-July). 163 compliant participants rinsed their noses in phase 1 (group A) and 134 took vitamins (group B). In phase 2 the interventions were exchanged in group A and B accordingly.

Crossover analysis (ANOVA) was performed on the basis of average weekly symptom scores. Reduction of symptoms was evaluated by absolute risk reduction as additional days without symptoms per 1000 documented observation days in the nasal rinsing period compared to the vitamin period as well as by relative risk reduction in percent in the nasal rinsing period (table 1, figure 1).

Seasonal effects were determined in a similar way by changes in absolute and relative risk during the spring-summer period (phase 2) compared to the winter period (phase 1) (table 2, figure 1).

On average participants rinsed their noses 1.1 ± 0.4 times daily and took vitamins 0.9 ± 0.2 times per day. About 95% of the participants reported their experience with nasal irrigation as predominantly easy, pleasant and comfortable. During the nasal rinsing period they were bedridden for less days, contacted the doctor less frequently, and used less medication as well as less decongestant nasal drops and sprays. Their general well-being was better when practising nasal rinsing than during the vitamin period.

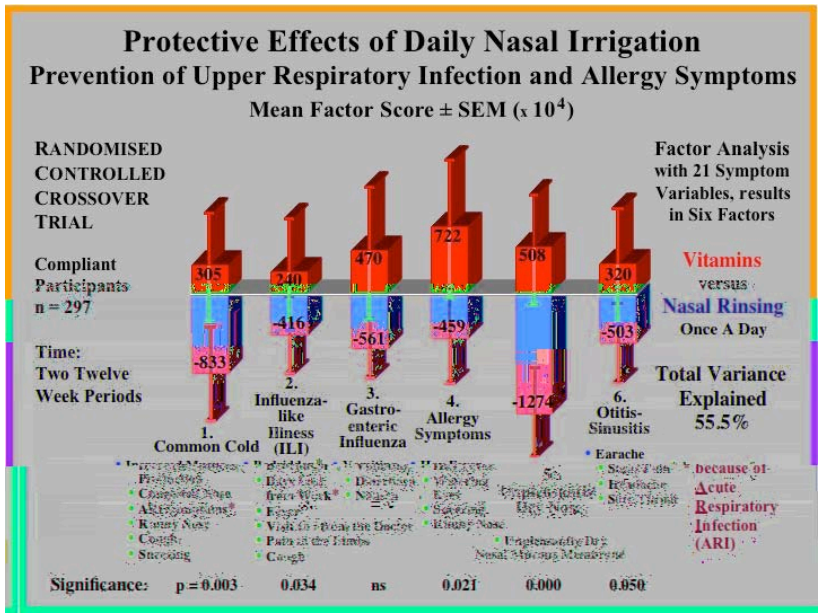

Figure 4

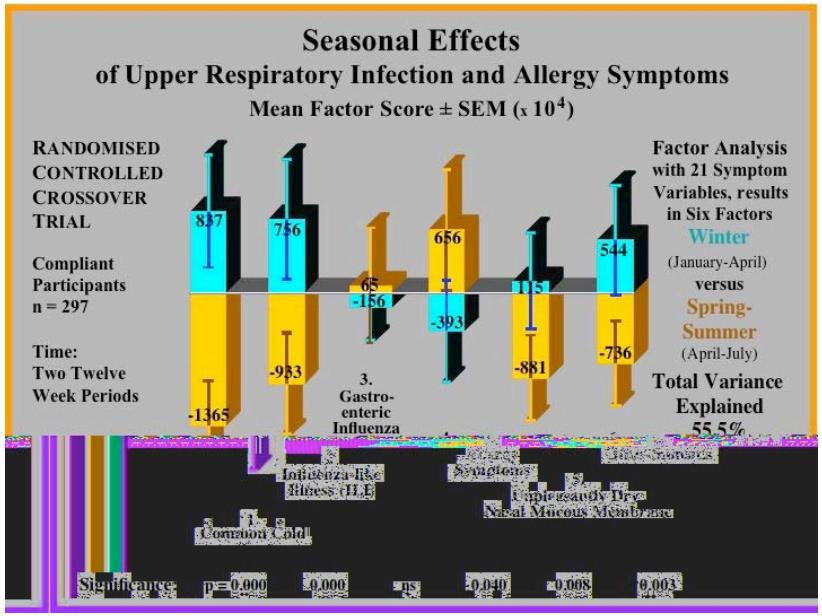

Figure 5