

Original Article

An open-label, prospective, pre–post comparison study to evaluate the efficacy of individualized homoeopathic medicines using Kent's repertory in the treatment of upper respiratory tract infections

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Received: 06 March 2024
Accepted: 01 August 2025
EPub Ahead of Print: 24 September 2025
Published:

DOI
10.25259/JISH_17_2024

Quick Response Code:



ABSTRACT

Objectives: Upper respiratory tract infections (URTIs) are a significant global concern. Work, school performance, productivity, and economic burden are linked to URTI. These need to be taken care of in time, as they can lead to various complications. To date, there have been no approved specific and safe therapies for URTIs. Hence, this research project aimed at testing the efficacy of individualized homeopathic medicines in URTIs using Kent's repertoire.

Material and Methods: An open-label, single-arm, experimental, prospective, non-randomized, non-controlled, before-and-after comparison study was done on 52 participants suffering from URTIs using Kent's repertory. Institutional ethical clearance was obtained; then, 58 consenting patients were enrolled after screening of 69 patients by eligibility criteria and were allocated to classical homeopathic treatment. Six cases were dropouts; 52 cases were regular. Outcome measures were assessed and analysed with the Wisconsin Upper Respiratory Symptom Survey-21 (WURSS-21) questionnaire.

Results: After homeopathic treatment, the WURSS-21 questionnaire score mean was gradually reduced. At baseline, the WURSS-21 questionnaire total score mean was 65.56 (standard deviation [SD] $\pm$ 8.15); at the first follow-up, the mean was 17.10 (SD $\pm$ 15.46); at the second follow-up, the mean was 7.23 (SD $\pm$ 12.30); and at the third follow-up, the mean was 2.58 (SD $\pm$ 6.90). Friedman's analysis of variance by rank test showed a significant result, where the χ^2 statistic is 147.1904 for the WURSS-21 total score at the level of significance 0.05 in a two-tailed hypothesis. Showing that individualized homeopathic medicines are efficacious in the treatment of URTIs. Overall, after treatment with individualized homeopathic medicines, 48 patients improved, 4 patients did not improve, and 8 patients dropped out of the study. No adverse effects and/or complications were observed. The most commonly used remedies are *Rhus toxicodendron*, *Bryonia alba*, *Belladonna*, etc.

Conclusion: Data suggest that individualized homeopathic treatment is useful for patients suffering from URTIs. The practical applicability of Kent's repertory in the treatment of URTIs is observed.

Keywords: Homoeopathy, Kent's repertory, Upper respiratory tract infection, Wisconsin upper respiratory symptom survey-21 questionnaire

INTRODUCTION

Respiratory tract infections are a persistent and pervasive health issue in developing countries, such as India.^[1] It refers to any of the infectious diseases involving the respiratory tract, broadly classified according to the parts of the respiratory tract affected, such as upper respiratory tract infections (URTI) and Lower respiratory tract infections (LRTI). The upper respiratory tract consists of the airway from the nostrils to the vocal cords in the larynx, including paranasal air sinuses and the middle ears.^[2] URTIs included - rhinitis, laryngitis, pharyngitis, laryngopharyngitis, sinusitis, and otitis media.^[2-4] It affects almost all age groups of patients- predominantly children, adolescents, and older adults. A great variety of pathogens are responsible for URTIs, mostly viral-like Influenza A and B viruses, Rhino virus, Adeno virus, Corona virus, Respiratory Syncytial virus, etc.,^[5] along with some bacteria such as Group - A *Streptococcus* beta-haemolyticus, *Haemophilus influenzae*, and *Moraxella catarrhalis*, etc., and fungi are also causing it. Symptoms usually include a runny nose, sneezing, sore throat, general malaise, hoarseness of voice, low-grade temperature at onset, followed by cough and nasal congestion.^[6,7] URTIs are usually a self-limiting disease, and generally recover patients within about 7–10 days but it may also cause various life-threatening complications like pneumonia and other LRTIs,^[2,6] acute glomerulo-nephritis, rheumatic fever, peritonsillar and retro pharyngeal abscess, septicemia, severe acute respiratory distress syndrome, even to death mainly among children and old peoples.^[5] Nowadays, modern systems of medicinal treatment to control URTIs are based on simple case-to-case management to diagnose and treat promptly using pharmaceutical therapies such as antibiotics, antipyretics, anti-inflammatory drugs, expectorants, decongestants, and cough suppressants, either alone or in combination.^[2-6,8-10] Till now, there is no approved specific and safe therapy for URTIs,^[2,5,6] and modern medicines sometimes may lead to adverse drug reactions.^[9] Homoeopathic literature shows the data on the efficacy of homoeopathic medicines in URTIs. There have been various studies done on URTIs in Homoeopathy to date. A trial to investigate the clinical effectiveness of a homoeopathic add-on therapy in a pediatric sub-population with URTIs in a randomised controlled multinational clinical trial by Haselen *et al.*, showing the efficacy of homoeopathic medicine in reducing symptoms over standard modern medicine treatment group.^[6] Another study showing the efficacy of homoeopathic medicine in preventing and treating pediatric acute URTI by Hawke *et al.*^[2] An international randomized controlled trial by Thinesse-Mallwitz *et al.* on 523 patients, published in 2015, showed that those taking homoeopathic medications had symptoms alleviated 1–2 days earlier than the standard treatment group.^[9] A recent study was done

at the National Institute of Homoeopathy, India, which compared the efficacy of homoeopathic individualised medicines versus homoeopathic specific medicine Sabadilla in the management of URTI in children.^[11] The studies mentioned above mostly focus on paediatric URTIs, neglecting other age groups with URTIs. Some of the studies were conducted in combination with modern medicinal treatments. The efficacy of individualised homoeopathic medicine has not been thoroughly evaluated and requires further study. According to the 'law of similia' and the maxim 'similia similibus curentur', homoeopathy treats patients with a remedy that is capable of producing similar symptoms in a healthy individual.^[12] Therefore, in homoeopathy, the same disease can be treated with different remedies in different patients through 'individualisation,' which depends on the physical, mental and miasmatic symptoms of an individual.^[13] In this study, the patients with acute URTI were being treated with individualised homoeopathic medicines. URTI symptoms were assessed using the Wisconsin upper respiratory symptom survey-21 (WURSS-21), which is a 21-item illness-specific symptom and health related quality of-life questionnaire widely used in different clinical study related to URTI^[14] by using this scoring scale, the condition of the health of the patient was assessed whether the patient was improved or deteriorated or remained as before. In this study, 'Repertory of the Homoeopathic Materia Medica' by Dr. Kent^[15] was used to arrive at the similimum. It is a widely used repertoire and effective in different clinical studies and day-to-day practice, with efficacy. According to Dr. Barthel- 'The Repertory of the Homoeopathic Materia Medica' by JT Kent^[15] is the most appropriate, most complete and most reliable of all.^[16] Here, in the study in Kent's repertory, we have consulted the various rubrics and sub-rubrics on URTIs in each of the cases.

MATERIAL AND METHODS

Study design

Open-label, prospective, pre–post comparison study.

Study setting

OPD Patients of Mahesh Bhattacharyya Homoeopathic Medical College and Hospital.

Selection of sampling

Those patients who were suffering from URTIs and fulfilled the specified eligibility criteria had been selected from the patients who came to the outpatient department (OPD) of Mahesh Bhattacharyya Homoeopathic Medical College and Hospital.

Sampling method

The patient should be selected for the study using a simple random sampling method.

Sample size

Fifty-eight patients meeting eligibility criteria from the OPD of Mahesh Bhattacharyya Homoeopathic Medical College and Hospital were enrolled. Six patients dropped out, and the analysis was done on 52 patients who met the eligibility criteria.

Study duration

Each patient got a follow-up for 15 ± 2 days.

Selection criteria

Inclusion criteria

1. URTI cases with the presence of the following symptoms, equal or <24 h
 - a. At least 1 URTI symptom
 - Nasal symptoms (plugged nose, runny nose, sneezing),
 - Pharyngeal symptom (scratchy throat, sore throat, pharyngeal hyperemia),
 - Cough (ordinary cough without suspicion of acute lower respiratory tract disease)
 - b. At least 1 general symptom
 - Feeling tired
 - Weakness
 - Body ache
 - Irritable or whiney
 - Less active
2. Age 5–65 years
3. Both sexes
4. Written informed consent
5. Willingness and ability to comply with all trial procedures.

Exclusion criterias

1. Severe or complicated cases of the URTIs present with symptoms such as severe respiratory distress, severe chest pain, and violent headache,
2. Known case of obstructive anatomic lesions in the nasopharynx,
3. Severe co-morbidity, including previous malignant disease during the past 5 years before enrolment,
4. Self-reported immune-compromised state,
5. Patient with psychiatric disorders,
6. On active treatment from any other system of medicine,

7. Undergoing homoeopathic treatment for chronic disease within last 6 months,
8. Heavy smoking or known or suspected drug addiction,
9. Pregnancy, lactation, or wish for pregnancy or breast feeding,
10. Participation in another clinical trial during the past 3 months prior to enrolment,
11. Patients unable to read the patient information sheet
12. Patients were unwilling to take part or were not given consent to join the study.

Withdrawal criteria

Those who were facing any severity or complications during treatment or did not benefit from our treatment could withdraw from the study.

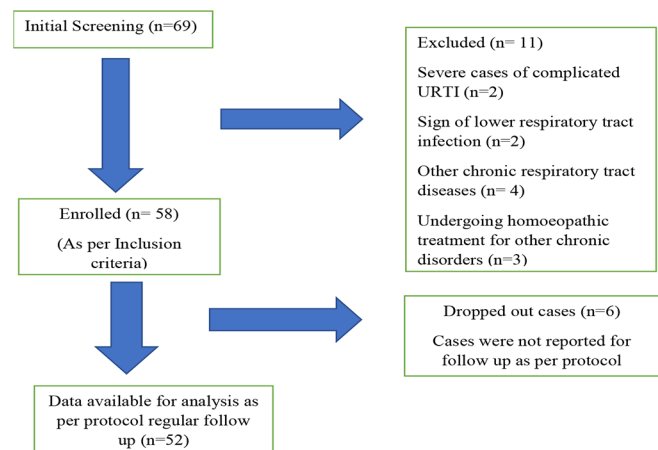
Intervention

The following intervention was taken-

- Proper case taking was done
- Selection of medicine was done based on the totality of symptoms after proper analysis, evaluation, and repertorisation using 'Repertory of the homoeopathic materia medica'^[17,18] by Dr. Kent^[15] and after final consultation with the materia medica.
- Indicated homoeopathic remedies were given in centesimal potencies as per the case.
- Along with several lifestyle changes as
 - (a) All the participants were encouraged to take water vapour inhalation as and when needed
 - (b) Maintain local hygiene
 - (c) They also advised to stop smoking
 - (d) Adequate sleep
 - (e) Regular and nutritious diet
 - (f) Promote exercise, etc.

Flow chart of the Brief procedure:

The brief procedure of the study is mentioned below in the Flowchart 1.



Flow chart 1: Brief procedure.

- Follow up of the cases at 4th (± 1) day, 8th (± 1) day and on day 15th (± 2).
- The outcome of the Individualised Homoeopathic Medicine was assessed using the WURSS 21 questionnaire.
- Subsequent prescriptions were generated according to 'Kent's 12 observations', and 'second prescription', 'Remedy relationship' etc.

Outcome measures

Using the WURSS-21 scoring scale, the patient's health condition was assessed to determine whether the patient had improved, deteriorated, or remained unchanged.

RESULTS

In the socio-demographic characteristics, it has been found that the mean age of patients suffering from URIs is 30, and a maximum (23.08%) of the total patients are age group of 05–15 years. The females, 29 (55.77%), were more affected than the males, 23 (44.23%). Maximum (48.08%) of them belong to middle-class socioeconomic status. 40.38% of the patients were students. In this study the maximum number of patients who have been suffering from URIs were having no addiction (76.92%).

In this study, the outcome measurement was done by the WURSS-21 score, comparing at the baseline and various follow-ups, mainly the 1st follow-up. In this study, a non-parametric test for WURSS-21 scores was shown. The mean $\pm$ standard deviation (SD) values are reduced from 65.48 ± 7.97 – 17.17 ± 15.17 to 7.52 ± 12.15 – 3.12 ± 6.32 in WURSS-21 total score for baseline, first follow-up, second follow-up and third follow-up, respectively.

WURSS-21 scores

The mean total WURSS-21 score reduced gradually from base line to different subsequent follow ups which was at the baseline was 65.56, at first follow up 17.10, 2nd follow up 7.52 and third follow up reduced to 3.12.

The WURSS-21 Score is represented in Figure 1.

Statistical analysis and interpretation of the study

Data from each patient was obtained by measuring the WURSS-21 questionnaire before and during every follow-ups of treatment.

Selection of test

As the score calculated using WURSS-21 questionnaire score is qualitative in nature, sample size is 52 and same sample is evaluated before and after treatment, and the data sets are not normally distributed so 'Friedman's analysis of variance (ANOVA) by Rank' test is used for analysis.^[19]

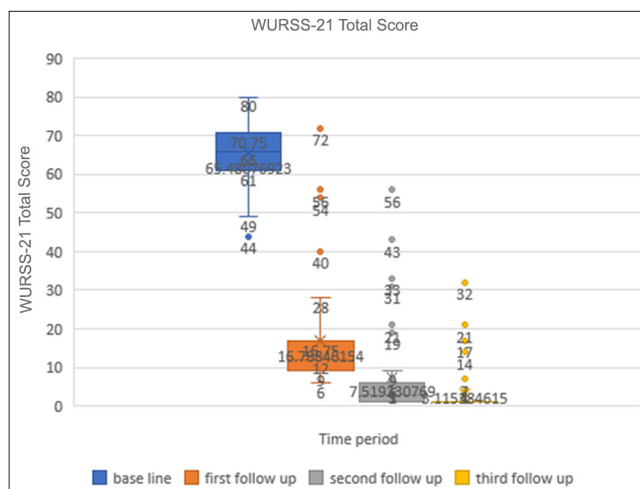


Figure 1: Box and Whisker plot showing mean Wisconsin upper respiratory symptom survey-21 (WURSS) 21 symptoms score at baseline and 4th (± 1) day, 8th (± 1) day and on day 15th (± 2) visit of treatment. It is shown that Baseline Scores (blue box) show high symptom burden (median ~65–70). First Follow-Up (orange box) shows a large drop (median ~15). Second and third follow-up (gray and yellow) show further reduction, with the third follow-up nearing 0 in many cases. Outliers decrease over time, indicating less variability and fewer extreme scores, which supports treatment efficacy.

Table 1: Post hoc analysis in between different follow ups and baseline.

	Baseline and first follow up	Base line and second follow up	Baseline and third follow up
Summation of positive rank ($\Sigma +R$)	1374	1378	1378
Summation of negative rank ($\Sigma -R$)	4	0	0
Mean difference	53.48	62.48	64.48
Standard deviation	109.81	109.81	109.81
Z-value	6.2382	6.2714	6.2717
P-value	<0.00001	<0.00001	<0.00001
Significance level of 0.05			

At the Significance Level of 0.05 in two tailed hypothesis testing calculated The X^2 statistic is 147.1904 ($df = 3, n = 52$). The $P < 0.00001$. The result is significant at $P < 0.05$. So, we can reject the null hypothesis (H_0) and accept the alternative hypothesis (H_A).^[20]

Effect size

The effect size for Kendall's W, used with the Friedman test, is calculated as $W = \chi^2 / \{N \times (k - 1)\}$, where χ^2 is the Friedman test statistic, N is the number of subjects, and k is the number of measurements per subject.

Table 2: Clinically verified rubrics from Kent's repertory during the study ($n=52$).

S. No.	Chapter	Rubrics/ Sub-rubrics	Frequency	Percentage
1	Eye	Itching, coryza, during	12	23.08
2	Eye	Lachrymation, coryza, during	15	28.85
3	Eye	Lachrymation, cough, with	10	19.23
4	Ear	Inflammation, eustachian tube	5	9.62
5	Nose	Blow the, constant inclination to	22	42.31
6	Nose	Catarrh	21	40.38
7	Nose	Coryza	43	82.69
8	Nose	Discharge	46	88.46
9	Nose	Obstruction	23	44.23
10	Nose	Smell, diminished	12	23.08
11	Nose	Smell, wanting, lost	4	7.69
12	Nose	Sneezing	37	71.15
13	Nose	Snuffles	20	38.46
14	Throat	Elongated uvula	7	13.46
15	Throat	Enlargement of tonsils	16	30.77
16	Throat	Inflammation, tonsils	16	30.77
17	Throat	Inflammation, uvula	10	19.23
18	Throat	Pain	19	36.54
19	Throat	Scratching	23	44.23
20	Larynx and trachea	Catarrh	7	13.46
21	Larynx and trachea	Croup	11	21.15
22	Larynx and trachea	Inflammation	10	19.23
23	Larynx and trachea	Irritation in air passages	21	40.38
24	Larynx and trachea	Mucus in the air passages	26	50
25	Larynx and trachea	Voice. Hoarseness, coryza, during	14	26.92

(Contd...)

Table 2: (Continued).

S. No.	Chapter	Rubrics/ Sub-rubrics	Frequency	Percentage
26	Larynx and trachea	Voice. Hoarseness, cough, during	9	17.31
27	Larynx and trachea	Voice. Hoarseness, croup, after	5	9.62
28	Cough	Daytime	18	34.62
29	Cough	Morning	16	30.77
30	Cough	Evening	12	23.08
31	Cough	Night	21	40.38
32	Cough	Dry, coryza, during	10	19.23
33	Cough	Lying agg.	22	42.31
34	Cough	Rattling	9	17.31
35	Expectoration	Daytime only	11	21.15
36	Expectoration	Evening	16	30.77
37	Expectoration	Night	21	40.38
38	Expectoration	Air agg.	15	28.85
39	Expectoration	Copious	17	32.69
40	Expectoration	Difficult	11	21.15
41	Expectoration	Thick	14	26.92
42	Expectoration	Watery	21	40.38

Here $W = 147.1904 / \{52 \times (4-1)\}$
 $= 147.1904 / 156$
 $= 0.944$

This indicates a large effect size, signifies stronger agreement.^[21]

Post hoc analysis

For *post hoc* analysis here we have done a Wilcoxon match pair signed rank test between baseline and each follow ups values are listed in the below Table 1.

At the, significance level of 0.05 in two tailed hypothesis testing calculated Z-value is greater than the tabulated Z-value (1.96) in between the different follow ups and baseline. So, we can reject the null hypothesis (H_0) and accept the alternative hypothesis (H_A).^[22]

DISCUSSION

Pre-post-comparison was an open-label, prospective, pre-post-comparison clinical trial conducted at MBHMCH involving 52 patients from the OPD as per the eligibility criteria. The purpose of this study was to show the efficacy of

Table 3: Prescribed homoeopathic medicines ($n=52$).

Name of the medicine	Frequency	Percentage
Rhus toxicodendron	16	30.77
<i>Bryonia alba</i>	13	25
Belladonna	4	7.69
Arsenicum album	2	3.85
Coccus cacti	2	3.85
Spongia tosta	2	3.85
<i>Aconitum napellus</i>	1	1.92
Allium cepa	1	1.92
Arsenicum iodatum	1	1.92
Arum triphyllum	1	1.92
Causticum	1	1.92
Cina	1	1.92
<i>Drosera rotundifolia</i>	1	1.92
Hepar sulphur	1	1.92
<i>Hyoscyamus niger</i>	1	1.92
<i>Lachesis</i>	1	1.92
Phosphorus	1	1.92
<i>Pulsatilla</i>	1	1.92
Teucrium marum verum	1	1.92
Rhus toxicodendron had covered in maximum no. of patients 16 (30.77%), followed by <i>Bryonia alba</i> 13 (25.00%)		

individualised homoeopathic medicines in the treatment of URTIs by using Kent's repertory. Case taking of the patients was done according to the guidelines of the organisation of medicine, and a standard case taking pro forma was followed. Repertorisation was done using Kent's Repertory. Frequently consulted rubrics [Table 2] in cases related to URTIs are mentioned along with frequently prescribed medicines [Table 3]. The socio-demographic data from the study are very useful. In this study, non-parametric tests for WURSS-21 scores showed that the mean $\pm$ SD values were reduced from 65.48 ± 7.97 – 17.17 ± 15.17 to 7.52 ± 12.15 – 3.12 ± 6.32 in WURSS-21 total score for baseline, first follow-up, second follow-up and third follow-up, respectively. In the non-parametric Friedman's ANOVA by Rank test at the Significance Level of 0.05 in two-tailed hypothesis testing, the χ^2 statistic is 147.1904 ($df = 3$, $n = 52$). The result is significant at $P < 0.05$. In a *post hoc* analysis with baseline and each follow-up using the Wilcoxon signed rank test, the Z-value was higher than the table value, which signifies that in each follow-up the result was significant. The effect size of the study was calculated by using Kendall's W, where the W-value is 0.944, which represents a stronger agreement.

In the study, we have seen that individualised homoeopathic medicines in cases of URTIs are also more effective than any combination medicines or a specific one. These do not follow

the homoeopathic laws and principles that were observed in various previous clinical studies. Hence, it provides enough evidence regarding the efficacy of homoeopathic medicine in reducing the signs and symptoms of URTI after receiving the treatment, and also the practical utility of Kent's Repertory in the treatment of URTI was observed through a reportorial approach, different important related rubrics that were clinically listed above [Table 2].

Limitations of the study

- The limitations of the present study are that the sample size was small (although kept small due to COVID pandemic constraints), involving only 52 patients.
- The period of treatment (15) was limited.

As statistical analysis becomes more logical and the inferences become stronger in large samples and for sufficiently prolonged periods of study, the statistical conclusions drawn in the present study could have given a more encouraging outcome with a larger sample and longer follow-up schedule. Though the limitations of time and other aspects could not unravel the study in all its aspects.

Recommendations

- The sample size is small, so it is suggested that in the future, a study on many patients should be conducted along with an appropriate investigation. Such a study will help to draw a more definite conclusion
- The data regarding socio-demographic characteristics can be used in other demographic studies
- Fifty millesimal potencies may be used to show any differences between centesimal potencies
- This study would have been better if a comparative arm had also been used in this study
- The data may help in the planning of further research projects in Homoeopathy, especially randomized controlled trials
- Use of more questionnaires would improve the genuineness of findings and inferences drawn.

Thus, more extensive and repeated research study in a similar setup is needed to generalise the results and to find a more rational conclusion about the significance of this topic.

CONCLUSION

This was an open-label, prospective, pre-post-comparison study that was conducted on 52 patients suffering from URTI. There was an improvement in symptoms of URTIs as evident from statistically significant differences in the WURSS-21 score. The study suggests that the individually chosen homoeopathic medicines for the cases of URTIs, following the laws and principles of homoeopathy, are much more

effective than any specific medicine and/or combinations of it. It also shows that Kent's repertory is very useful for this kind of acute disease.

The sample size of this study was small, so it is suggested that in the future, a study on large numbers of patients should be conducted along with appropriate investigation. Such a study will help to draw a more definite conclusion. Furthermore, research by a randomised controlled trial is also required. It is expected that this study will create great awareness among patients, the general population, as well as homoeopathic physicians to establish a firm belief that URTIs can be treated effectively through proper individualised homoeopathic medicines.

Ethical approval: The Institutional Review Board has approved the study at the Mahesh Bhattacharyya Homoeopathic Medical College and Hospital, Howrah, West Bengal, India, number 908/MBHMCH/CH/PRIN/ADM/20, date 06th October 2020.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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How to cite this article: Pramanik S, Bairi PK, Pandit RK, Sarkar S, Billah MA, Chowdhury D. An open-label, prospective, pre-post comparison study to evaluate the efficacy of individualized homoeopathic medicines using Kent's repertory in the treatment of upper respiratory tract infections. *J Intgr Stand Homoeopathy*. doi: 10.25259/JISH_17_2024