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Research Article

RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED CLINICAL STUDY OF *CYMBOPOGAN CITRATUS* IN INFLUENZA

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KEYWORDS: *Cymbopogan Citratus*, Influenza, Lemon Grass.

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ABSTRACT

Background: Influenza, or flu, is a respiratory illness that is caused by a virus. As Influenza is known to be highly contagious and there by affecting working community at large, a natural; cost effective remedy can help sail through the course of illness with much ease.

The plant *Cymbopogon citratus* (DC) Stapf. commonly known as Lemon grass belongs to Poaceae family and is a native of tropical countries. Various studies have been done on the plant to reveal its potential therapeutic effects. Thus this study untended to evaluate its efficacy in the management of Influenza and its symptoms.

Methodology: Randomized double blind placebo controlled clinical study. 62 patients of age group 20- 50 years, suffering from Influenza and fulfilling the diagnostic criteria were selected and randomly grouped into trial (Group I - 31 patients) and control group (Group II - 31 patients received the Placebo- Distilled water 25ml 3 times daily). Both the groups were given Paracetamol 500mg/kg body weight as rescue medicine if required.

Observation & Results: The signs and symptoms of Influenza which were exhibited in patients when subjected to the Trial medication showed good results. The quality of life in them was better compared to control group.

Conclusion: The current study helped to confirm the effect of the plant *Cymbopogon citratus* (DC) Stapf. in influenza. In Trial group, significantly better remission of associated signs and symptoms of influenza was found compared to control group. This would help us create an increased awareness amongst the public about the use of herbal medicines in either cure or as add on therapy in the management of Influenza.

INTRODUCTION

Influenza mostly referred as flu is an acute respiratory illness caused commonly by influenza A or B virus. It is one of the worst known pandemics which took the life of 50million people. The respiratory secretions of infected persons contain significant numbers of influenza virus particles, so infection can be transmitted by sneezing and coughing through large particle droplets[1].

The mean period of influenza virus shedding in immune competent adult patients is about 5 days but may continue for up to 10 days or more -especially in children, elderly adults, chronic disease patients and immune compromised hosts. Typically influenza starts with the abrupt onset of high-grade fever, myalgia, headache and malaise. These symptoms are followed by symptoms of respiratory issues like unproductive cough, sore throat or nasal congestion and discharge.

The illness varies from mild to severe suffering, sometimes ending up in complications too[2]. As Influenza is known to be highly contagious and there by affecting working community at large

a natural, cost effective remedy can help sail through the course of illness with much ease. *Cymbopogon citratus* (DC.) Stapf. is one such drug mentioned in Ayurveda classical texts as an antipyretic agent[3]. Many pharmacological studies done on this drug have revealed that it possesses anti-amoebic, antibacterial, antidiarrheal, anti-filarial, antimicrobial[4], anti-inflammatory[5], antimalarial, anti-mutagenicity, anti-mycobacterial, antioxidant, hypoglycemic and neurobehavioral properties[6]. In the coastal region of Uttara Kannada district this drug is used by labour class people for fever. Hence a clinical trial was conducted to evaluate the effect of *Cymbopogon citratus* (DC.) Stapf. on its anti-pyretic effects which is utmost necessity to benefit public at large.

Materials and Methods

1. Study Design: The present study was a Randomized, double blind, placebo controlled, clinical study.

2. Data Collection

Source of clinical data & Drug: A total of sixty patients in the age group of 20-50 years suffering from influenza and fulfilling the diagnostic criteria were selected from Kayachikitsa and other OPD's of Sri Sri College of Ayurvedic Science and Research, Bangalore. *Arka* of *Cymbopogan citratus* and Distilled water were used as the trial drug and placebo respectively.

3. Preparation of Medicine: The drug *Cymbopogan citratus* collected from the herbal garden of college was identified and authenticated by the senior scientist, taxonomist of the department of PG studies Dravyaguna, Sri Sri College of Ayurvedic Science and Research, Bangalore. The dosage form *Arka* was prepared at laboratory of Department of Dravyaguna using the distillation apparatus in the ratio of 1:5 (drug: water). The distilled water was prepared using distillation apparatus by means of double distillation process.

4. Grouping: Patients with complaints of fever ≥ 100.4°F with one respiratory complaint presenting within 48 hrs of onset of the condition were selected within the age group of 20-50 years of either genders.

5. Recruitment Strategies

Diagnostic criteria: Patients based on general physical examination for classical symptoms of influenza, rapid influenza diagnostic test (antigen detection) using Nasopharyngeal swab selected. Patients with complaints of fever ≥100.4°F with one respiratory complaint presenting within 48 hrs of onset of the condition were selected.

Inclusion Criteria: Verified cases of influenza were enrolled for the study with fever ≥100.4°F with at least one respiratory symptom of influenza which is within 48 hrs of onset.

Exclusion Criteria: Pregnant women, breast feeding ladies, suspected bacterial infections, H/o antiviral therapy, recent participation in any other clinical trial, patients with any other prior illness, who have received anti influenza and swine flu vaccination, suffering with any chronic diseases and high risk cases.

6. Randomization & Grouping: Randomly patients were grouped into trial and control group using simple random technique adopting random number generator. Group 1 contained 31 patients who received the trial drug (*Arka* of *Cymbopogan citratus*) and Group 2 contained 31 patients who received the placebo (distilled water).

7. Intervention: Written informed consent was taken from every patient recruited for the trial. *Arka* and distilled water were both administered in the dose of 25ml three times a day orally for a period of 5-7 days. Rescue medicine paracetamol was advised to be taken by both the groups only on having fever or any discomfort.

8. Assessment Criteria: The fever was recorded in degree Fahrenheit and other symptoms were recorded in the scoring scale of 10 to 0. Visual analogue scale was used to assess pain.

9. Follow Up and Assessment: alternate days follow up was done for 7 days and the findings were recorder.

10. Reporting of Complication/Side Effects/ Adverse Events: Proper recording of adverse events in the trial group if any was done in the case sheet.

CTRI registration number: Trial REF/2016/10/ 012456

Observations

- A total of 31 patients in both groups in each group were enrolled. Group I-31 patients received trail drug and Group II-31 patients received the Placebo (Distilled water 25ml 3 times daily).
- There were 15 male and 16 female in Group I and 19 male and 12 female in Group II.
- The age group of patients in Group I belonged to 21 to 50, whereas 28 to 50 in Group II.
- Fever being the main symptom, the temperature in the two groups ranged from a minimum of 100.6° F to maximum of 103° F in Group I and 101°F to 103° F in Group II.

- There was a drop in mean temperature in both groups seen before and after the treatment. (See details in Table 01 and Graph 1).
- The details of temperature of all the 31 patients of the two groups is charted in table 03 & 04 and graph.
- Other associated symptoms were recorded in the scoring scale of 10-0 and visual analogue scale for pains, details of their mean value of all 31 patients in each group is charted in Table 04 and diagrammatically represented in graph 04.
- Results of Statistical results: find the annexure.

Results

The signs and symptoms of Influenza showed improvement in patients when subjected to the Trial medication. The faster remissions of associated symptoms were seen in the trail group compared to the controlled group. The current study helped to prove the effect of *Cymbopogon citratus* (DC) Stapf in the disease influenza. This would help us create an increased awareness amongst the public about the use of herbal medicines in either cure or as add on therapy in the management of Influenza.

Table 1: Showing parameters

Parameters	**Group I**	**Group II**
Number of samples:	31	31
Age	21- 50	28-50
Gender		
Male	15	19
Female	16	12
Fever (Min- max)	100.6-103	101-103
Fever (Mean in Degree F)		
Before treatment	101.67	101.93
After treatment	99.60968	99.74839

Table 2: Showing- Temperature changes of the two groups, before and after treatment

Group I			**Group II**		
Fever (in Degree F)			**Fever (in Degree F)**		
Subjects	**BT**	**AT**	**Subjects**	**BT**	**AT**
1	102.2	100	1	102.2	100
2	101	100	2	102	100.2
3	100.8	99	3	102.8	100
4	102.6	100	4	102.4	100
5	100.6	100	5	101.8	99
6	102.5	100.1	6	102.2	100
7	100.6	98.6	7	101.2	100
8	102	99	8	102	100.2
9	101	99	9	101	99
10	101.8	100	10	102	98.8
11	102	100.2	11	102.6	100
12	102	100	12	101.2	100
13	103	100	13	101.8	99.2
14	102	100	14	101.6	100.1
15	101.6	99	15	102.1	100
16	102	100	16	102	100
17	100.9	99	17	101.8	99.8
18	100.8	99.8	18	101	100
19	101.8	99.6	19	103	99
20	101	100	20	102.4	100
21	102.8	99	21	102.2	99.6
22	102	98	22	102	100
23	100.6	98.6	23	102	99
24	101.2	100	24	102	100.1

25	102.6	99.6	25	103	100
26	101	100	26	102	99.4
27	102.3	100	27	101	100
28	100.8	100	28	102.2	99
29	100.8	100	29	101.4	99.8
30	103	100	30	101.2	100
31	102.6	99.4	31	101.8	100

Table 3: Showing- mean of the grades in associated symptoms of the two group, before and after treatment on a scoring scale of 10-0

Associated Symptoms - (Average/ Mean)		
Extreme coldness (chills shivering, shaking (rigor)		
Before treatment	0.7742	1.17
After treatment	0	0
Cough		
Before treatment	1.19	1.871
After treatment	0	0.16129
Nasal congestion		
Before treatment	0.29032	1.06452
After treatment	0	0.03226
Running nose		
Before treatment	2.67742	1.74194
After treatment	0	0.0645
Sneezing		
Before treatment	1.903	1.516
After treatment	0	0
Fatigue		
Before treatment	0.484	1.774
After treatment	0	0.03
Irritated, watering eyes		
Before treatment	0	0.3871
After treatment	0	0.0645
Redness in eyes/face/ mouth/throat/nose		
Before treatment	0.29032	0.3871
After treatment	0	0.0645
Body aches		
Before treatment	1.90323	3.19355
After treatment	0	0
Pain in Joints		
Before treatment	0.8065	1.2903
After treatment	0	0
Throat Ache		
Before treatment	0.6129	0.2903
After treatment	0	0
Headache		
Before treatment	1.871	1.1613
After treatment	0	0

Lemon Grass

Statistical Analysis of the study

General Linear Model

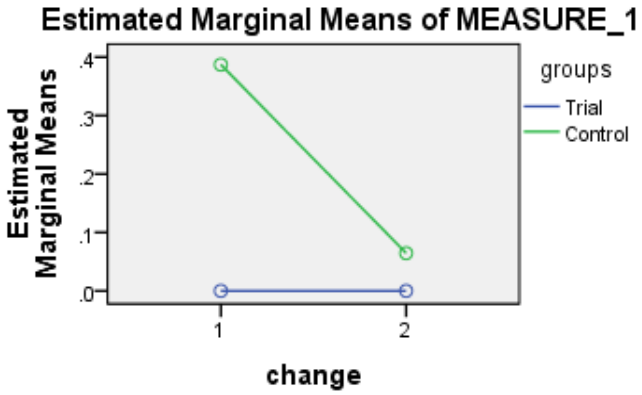
Descriptive Statistics				
	Groups	**Mean**	**Std. Deviation**	**N**
Irrit_BT	Trial	.00	.000	31
	Control	.39	1.230	31
	Total	.19	.884	62
Irrit_AT	Trial	.00	.000	31
	Control	.06	.359	31
	Total	.03	.254	62

Tests of Within-Subjects Effects

Measure: Measure_1					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	.806	1	.806	3.614	.062
Change * groups	.806	1	.806	3.614	.062
Error (change)	13.387	60	.223		

The above table shows there is no significant difference found between the parameter of irritability between the trial group and control group.

Profile Plots



T-Test

Group Statistics					
	Groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Irrit_remission	Trial	31	.00	.000	.000
	Control	31	.61	1.706	.306

Independent Samples Test				
	t-test for Equality of Means			
	t	**df**	**Sig. (2-tailed)**	**Mean Difference**
Irrit_remission	-2.000	60	.050	-.613

The above table shows there is significant difference found between the parameter of fatigue remission with P value 0.050. The trial group was significantly better in irritability remission than control group.

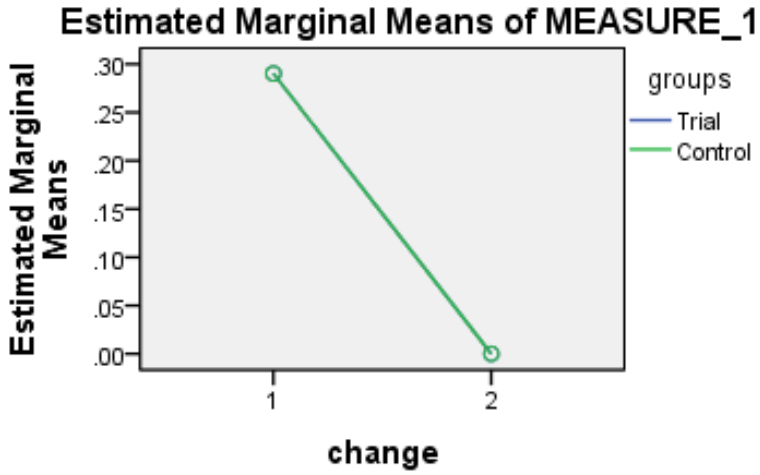
General Linear Model

Descriptive Statistics				
	groups	**Mean**	**Std. Deviation**	**N**
Redness_BT	Trial	.29	.938	31
	Control	.29	.783	31
	Total	.29	.857	62
Redness_AT	Trial	.00	.000	31
	Control	.00	.000	31
	Total	.00	.000	62

Tests of Within-Subjects Effects					
Measure: MEASURE_1					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	2.613	1	2.613	7.003	.010
Change * groups	.000	1	.000	.000	1.000
Error (change)	22.387	60	.373		

The above table shows there is no significant difference found between the parameter of redness in between the trial and control group

Profile Plots



T-Test

Group Statistics					
	groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Redness_remission	Trial	31	.32	1.013	.182
	Control	31	.45	1.207	.217

The above table shows there is no significant difference found between the parameter of redness remission with the trial group and control group with P value 0.650

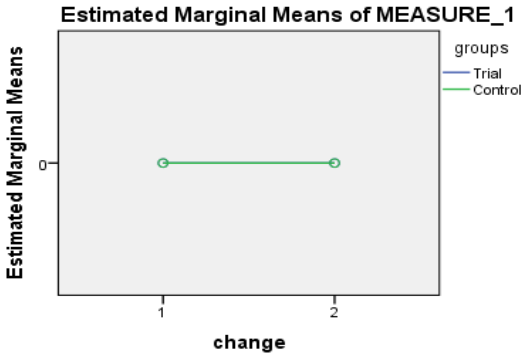
General Linear Model

Descriptive Statistics				
	Groups	**Mean**	**Std. Deviation**	**N**
Pete_rash_BT	Trial	.00	.000	31
	Control	.00	.000	31
	Total	.00	.000	62
Pete_rash_at	Trial	.00	.000	31
	Control	.00	.000	31
	Total	.00	.000	62

Tests of Within-Subjects Effects						
Measure: MEASURE_1						
Source		**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	Sphericity Assumed	.000	1	.000	.	.
Change * groups	Sphericity Assumed	.000	1	.000	.	.
Error (change)	Sphericity Assumed	.000	60	.000		

The above table shows no change

Profile Plots



T-Test

Group Statistics					
	groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Pete_rash_remission	Trial	31	.00	.000a	.000
	Control	31	.00	.000a	.000
a. t cannot be computed because the standard deviations of both groups are 0.					

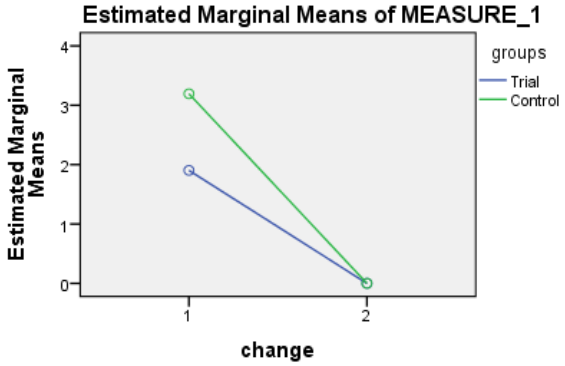
General Linear Model

Descriptive Statistics				
	Groups	**Mean**	**Std. Deviation**	**N**
Bodyache_BT	Trial	1.90	2.226	31
	Control	3.19	2.212	31
	Total	2.55	2.295	62
Bodyache_AT	Trial	.00	.000	31
	Control	.00	.000	31
	Total	.00	.000	62

Tests of Within-Subjects Effects					
Measure: MEASURE_1					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	201.323	1	201.323	81.742	.000
Change * groups	12.903	1	12.903	5.239	.026
Error (change)	147.774	60	2.463		

The above table shows there is significant difference found between the parameter of body pain in between trial and control group. The trial group was found to be significantly better than control group

Profile Plots



T-Test

Group Statistics					
	Groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Bodyache_remission	Trial	31	1.81	1.815	.326
	Control	31	3.71	2.003	.360

Independent Samples Test				
	t-test for Equality of Means			
	t	**df**	**Sig. (2-tailed)**	**Mean Difference**
Bodyache_remission	-3.920	60	.000	-1.903

The above table shows there is significant difference found between the parameter of fatigue remission. The trial group was significantly better in body ache remission than control group

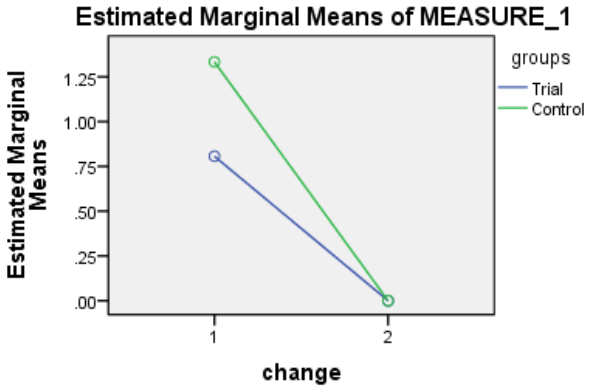
General Linear Model

Descriptive Statistics				
	groups	**Mean**	**Std. Deviation**	**N**
Pain_BT	Trial	.81	1.515	31
	Control	1.33	1.768	30
	Total	1.07	1.652	61
Pain_AT	Trial	.00	.000	31
	Control	.00	.000	30
	Total	.00	.000	61

Tests of Within-Subjects Effects					
Measure: MEASURE_1					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	34.903	1	34.903	25.821	.000
Change * groups	2.116	1	2.116	1.566	.216
Error (change)	79.753	59	1.352		

The above table shows there is no significant difference found between the parameter of pain in between the trial and control group

Profile Plots



T-Test

Group Statistics					
	Groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Pain_remission	Trial	31	.84	1.485	.267
	Control	31	1.97	2.415	.434

Independent Samples Test				
	t-test for Equality of Means			
	t	**df**	**Sig. (2-tailed)**	**Mean Difference**
Pain_remission	-2.217	60	.030	-1.129

The above table shows there is significant difference found between the parameter of pain remission with P value 0.030.The trial group was significantly better in body ache remission than control group

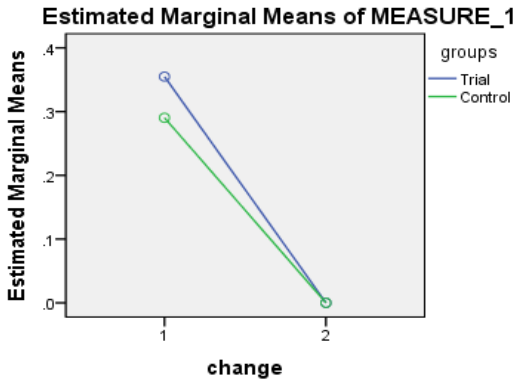
General Linear Model

Descriptive Statistics				
	groups	**Mean**	**Std. Deviation**	**N**
TThroat_BT	Trial	.35	.950	31
	Control	.29	1.006	31
	Total	.32	.971	62
Throat_AT	Trial	.00	.000	31
	Control	.00	.000	31
	Total	.00	.000	62

Tests of Within-Subjects Effects					
Measure: MEASURE_1					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	3.226	1	3.226	6.734	.012
Change * groups	.032	1	.032	.067	.796
Error (change)	28.742	60	.479		

The above table shows there is no significant difference found between the parameter of throat pain in between the trial and control group

Profile Plots



T-Test

Group Statistics					
	groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Throat_remission	Trial	31	.48	1.151	.207
	Control	31	.35	1.142	.205

Independent Samples Test				
	t-test for Equality of Means			
	t	**df**	**Sig. (2-tailed)**	**Mean Difference**
Throat_remission	.443	60	.659	.129

The above table shows there is no significant difference found between the parameter of throat pain remission in between the trial and control group

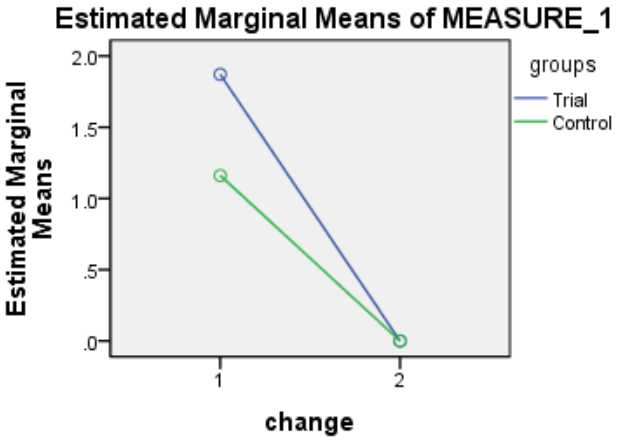
General Linear Model

Descriptive Statistics				
	Groups	**Mean**	**Std. Deviation**	**N**
Headache_BT	Trial	1.87	2.109	31
	Control	1.16	2.018	31
	Total	1.52	2.078	62
Headache_AT	Trial	.00	.000	31
	Control	.00	.000	31
	Total	.00	.000	62

Tests of Within-Subjects Effects					
Measure: MEASURE_1					
Source	**Type III Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
Change	71.258	1	71.258	33.444	.000
Change * groups	3.903	1	3.903	1.832	.181
Error (change)	127.839	60	2.131		

The above table shows there is no significant difference found between the parameter of headache in between the trial and control group

Profile Plots



T-Test

Group Statistics					
	groups	**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Headache_remission	Trial	31	1.65	1.582	.284
	Control	31	1.29	2.101	.377

Independent Samples Test				
	t-test for Equality of Means			
	t	**df**	**Sig. (2-tailed)**	**Mean Difference**
Headache_remission	.751	60	.455	.355

The above table shows there is no significant difference found between the parameter of headache remission in between the trial and control group

DISCUSSION

The efficacy of the drug *Cymbopogon citrates* (DC.) Stapf in Influenza may be attributed to its pharmacological properties like *Rasa Panchaka* namely *Katu,Tikta Rasa, Laghu Teekshna Guna, Katu Vipaka, Ushna Veerya* and *Karmas* like *Swedajanana, Jwaraghana, Deepana Paachana, Ruchya, Vatashamana, Shleshmaghna* as mentioned in the Ayurveda classics[7]. The phyto constituents present in the drug like alkaloids, saponins, tannins and flavanoids are also supportive for the therapeutic activity of the drug. As there is faster remission seen in the trial group with respect to the associated symptoms of influenza this drug can be tried on a bigger sample size to prove its effectiveness on a wider scale. The drug being abundantly available makes it even more cost effective. Hence as shown in the current study due its better tolerance amongst the patients it can be aptly used as add on therapy in the management of influenza cases.

CONCLUSION

In Trial group, significantly better remission of associated signs and symptoms of influenza was found compared to control group. As paracetamol was used as rescue medicine in both the groups, no much significant difference was found between the trial and control group in the reduction of fever. The current study helped to confirm the effect of the plant *Cymbopogon citrates* (DC) Stapf in the disease influenza and proved to help sail through the course of illness with much ease.

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REFERENCES

1. Dan L. Longo, Anthony S. Fauci, Dennis L. Kasper, Stephen L. Hauser, J. Larry Jameson, Joseph Loscalzo. Harrison's Principles of Internal Medicine. 18th ed. US; McGraw Hill Professional; 2011.p.1493-99.
2. Michael Swash, Michael Glynn. Hutchison's Clinical Methods-An Integrated Approach to clinical practice. 23rd ed. China; Saunders Elsevier; 2007.
3. Chaudhary GCK, Dhar BP, Joseph GVR, Mangal AK, Dabur R, Mandal TK et al. Database on Medicinal Plants In Ayurveda, New Delhi; Documentation and Publication Division CCRAS; 1990;3:p.140-56.
4. Danlami, U Rebecca A, Machan DB, Asuquo TS. Comparative study on the Antimicrobial activities of the Ethonolic extracts of lemon grass and Polyalthia longifolia. Journal of Applied Pharmaceutical Science. 2011 Nov 1; 1(9): 174-6.
5. V. Francisco, A. Figueirinha, B. Neves, C. García Rodríguez, M. Lopes, M. Cruz, M. Batista MT. Cymbopogon citratus as source of new and safe anti-inflammatory drugs: bio-guided assay using lipopolysaccharide-stimulated macrophages. Journal of Ethnopharmacology. 2011 Jan 27; 133(2):818-27.
6. Shah G, Shri R, Panchal V, Sharma N, Singh B, Mann AS. Scientific basis for the therapeutic use of Cymbopogan citratus, stapf (Lemon grass). Journal of Advanced Pharmaceutical Technology & Research. 2011 Jan-Mar; 2(1):3-8.
7. Chunekar KC, commentator, Bhavaprakasha Nighantu, Pandey GS, Varanasi; Choukambha Bharti Academy; 2015.p.370.

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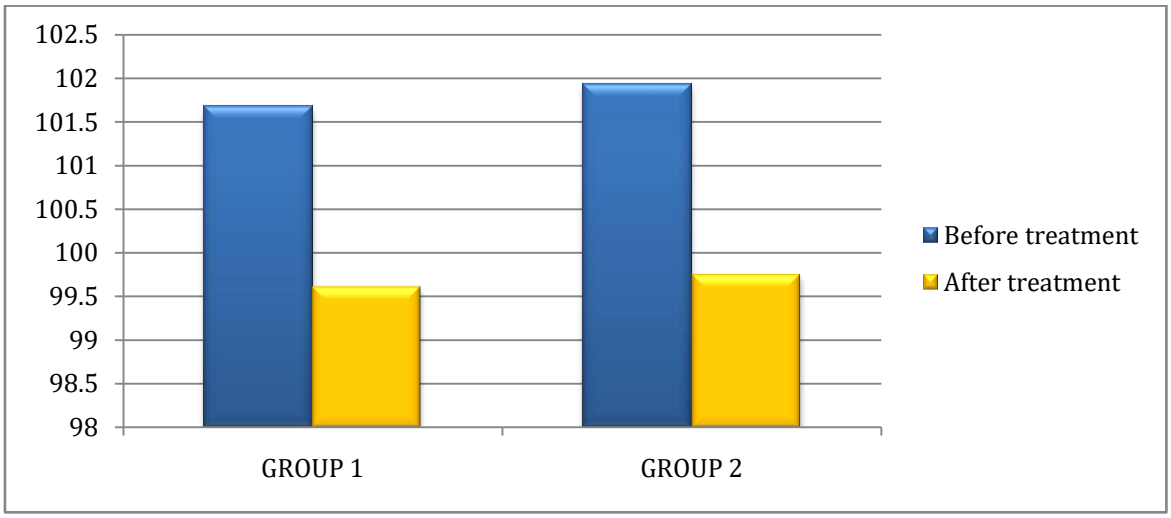
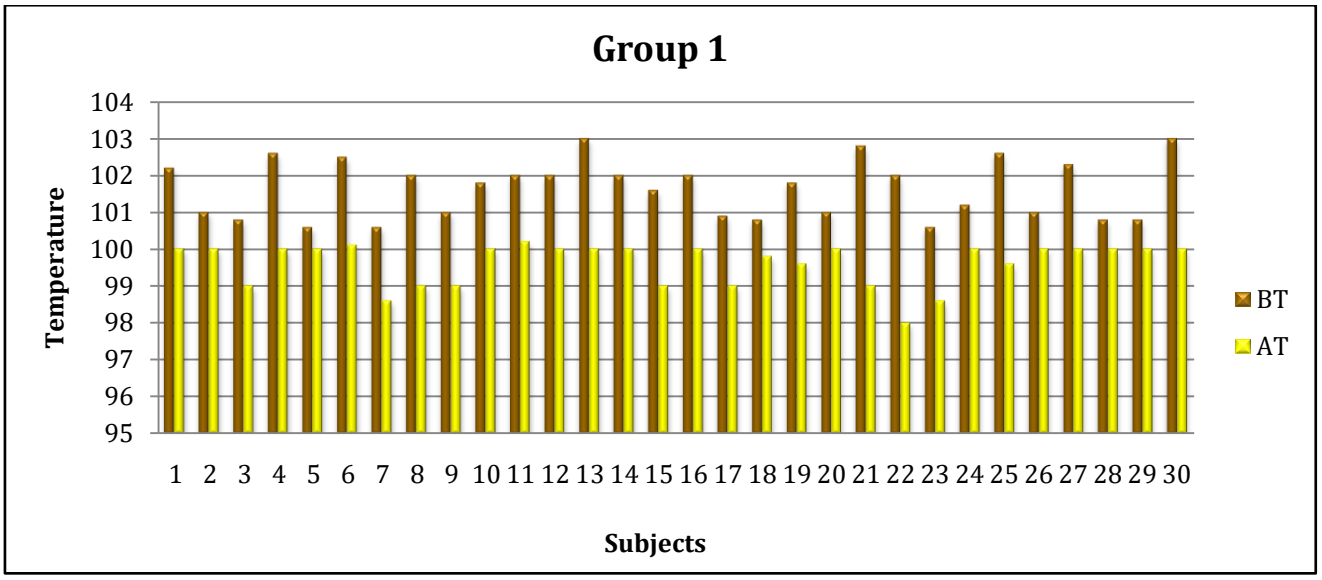
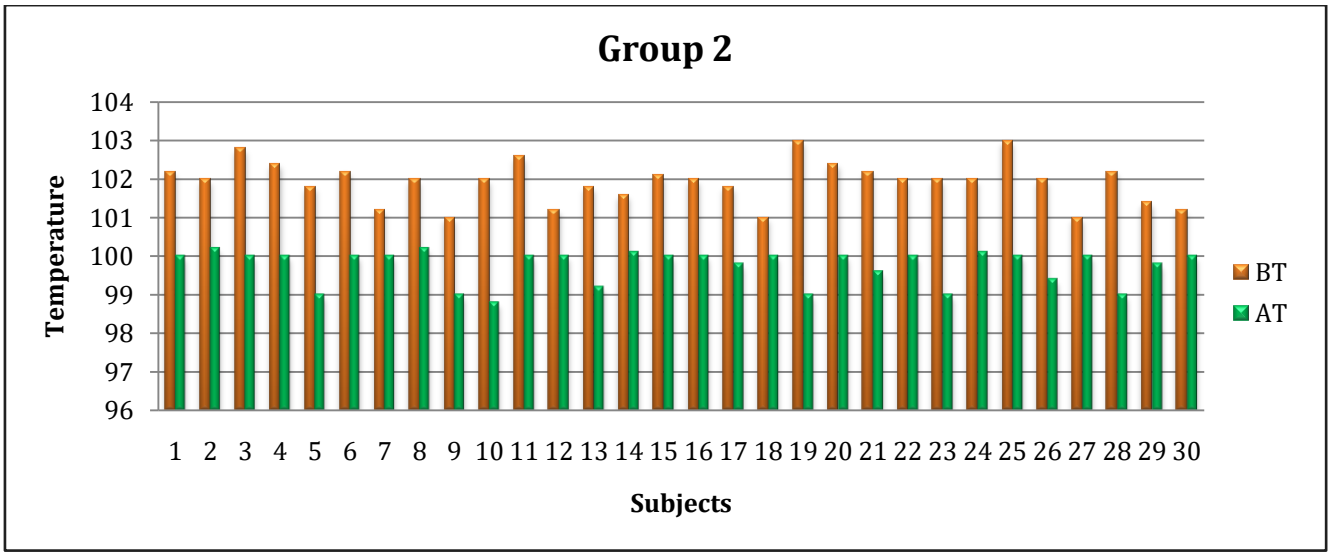
Graph 1: Showing - Changes in temperature in the two groups: before and after treatment



Graph 2: Showing - Changes in temperature of subjects in Group I : before and after treatment



Graph 3: Showing - Changes in temperature of subjects in Group II: before and after treatment



Graph 4: Showing - Baseline characteristics of 62 patients their symptoms, who were randomized to receive the drug (Group I) and Placebo (Group II)