

# Homeopathy as an Adjuvant to Chemotherapy Improves Clinical Outcome in Relapsed Pulmonary Tuberculosis

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## BACKGROUND OF THE STUDY

- TB is the Single largest infectious disease causing high mortality. Management is never simple endeavor, requires additional considerations in special situations like relapse, DR, MDR
- Chemotherapy is successful , but prolonged, costly and need to be directly observed. Otherwise relapse, drug resistance emerges. Toxicities are frequent
- Adjunctive treatment Garlic, herbs, nutrient supplements with anti-TB drugs found to be effective

Antimicrobial Effect of Chloroformic Garlic Extract on Mycobacterium Tuberculosis (Pakistan Journal of Biological Sciences 9 (12): 2381-2383, 2006)



# REVIEW OF LITERATURE

- Effectiveness of homeopathy for upper respiratory tract complaints including allergies; lower respiratory tract complaints; or ear complaints
- Case reports highlighted the successful use in Pulmonary TB.
- **Evaluation of Homoeopathic drugs in the treatment of tuberculosis** Nehru H. M. C. and Hospital, New Delhi.
- Homeopathic treatment of multidrug resistant tuberculosis patients  
**DP Rastogi<sup>1</sup>** New Delhi, India
- Randomized trials: individualized homeopathy has an effect over placebo. The evidence, however, is not convincing because of methodological shortcomings and inconsistencies.



## RESEARCH QUESTION

- Can Homeopathy improve **sputum conversion** in Relapsed Pulmonary Tuberculosis Patients following Conventional treatment .
- Can homeopathy improve the **quality of life** in Relapsed Pulmonary Tuberculosis Patients following Conventional treatment .
- Can Homeopathy improve **clinical symptoms** (haemoptysis, cough, chest pain, fever, and night sweating) .
- Can Homeopathy bring about favorable modulation in **weight, ESR and Hemoglobin**.



# SELECTION CRITERIA

## ■ Inclusion Criteria

1. age of 18-60 years,
2. Relapse pulmonary tuberculosis\* with acid-fast bacilli smear positive by microscopy, using ZiehlNeelsen staining as recommended by WHO,

## ■ Exclusion Criteria

1. Pregnancy, any concomitant disease I.e. diabetes mellitus, acute renal failure or
2. Infectious disease including TB/HIV and HIV positive,
3. Currently or taken any alternative therapies in past 6 months,

\*patients declared cured after one full course of Chemo and remaining well for some time become sputum smear + with radioactive lesion.

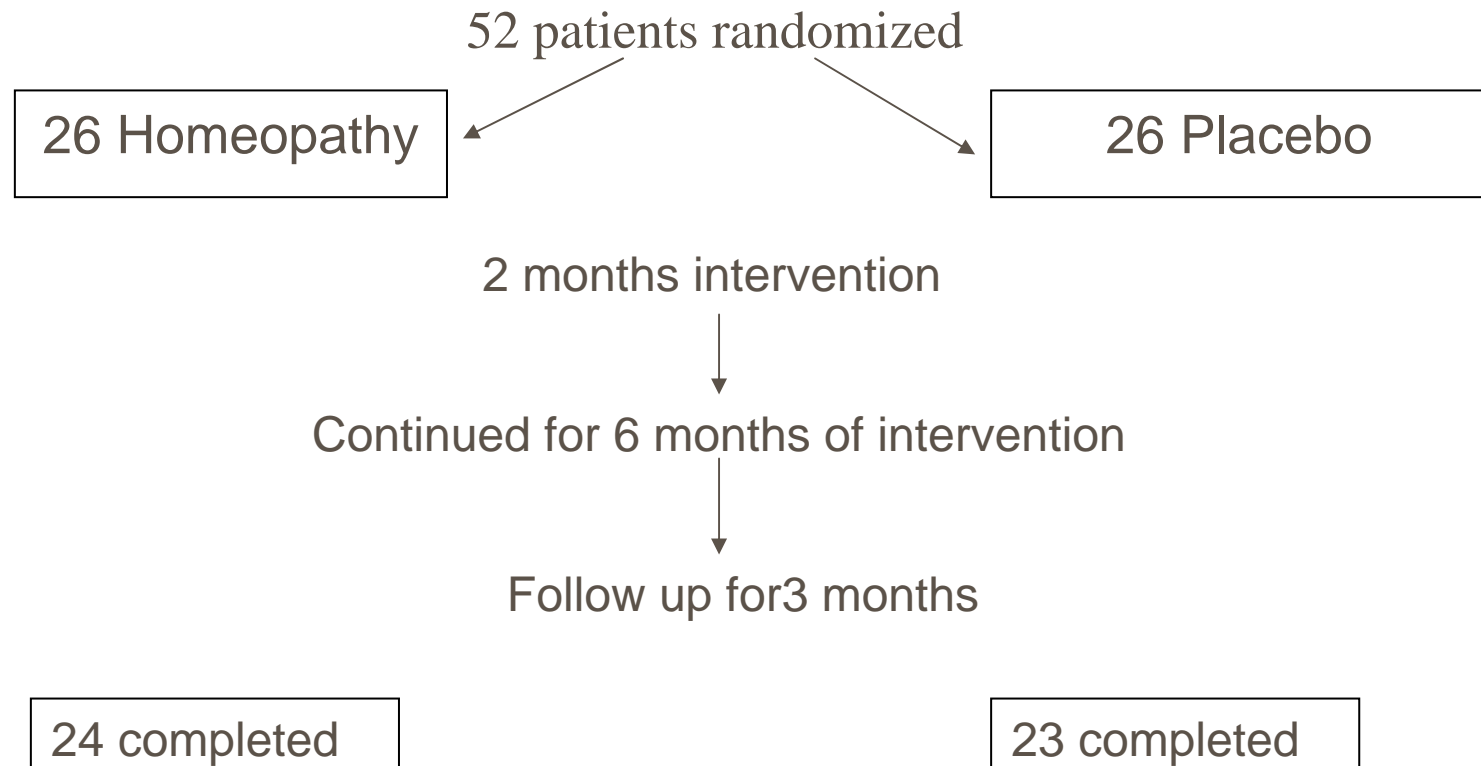


# MEASUREMENT

- **Clinical symptoms** (haemoptysis, cough, chest pain, fever, and night sweating)
- **Sputum AFB status** by microscopy was recorded
- **Weight**
- Blood samples for **Erythrocyte sedimentation rate and hemoglobin** analyses
- **Quality of life** was assessed using SF 36

# DESIGN OF STUDY-

## Clinical, Randomized, Double Blind Placebo Control Trial



# STRATEGIES

- Recruitment
- Randomization
- Blinding: Double blind study
- Placebo control
- Measurement approach: standard tools





# INTERVENTION

## Anti-TB Chemotherapy



- Conventional treatment was based on daily regimen with single dose empty stomach for 8 months
- For 2 months streptomycin along with R, Z, E, H. followed by HERZ 1 month with H,E and R.

	<30 kg	30-50 kg	>50 kg	Time
S	0.75 g	0-75 gm	1 gm	2 mo.daily
INH	300 mg	300 mg	300 mg	8 mo
R	300 mg	450 mg	600 mg	8 mo
E	600 mg	800 mg	1000 mg	8 mo
Z	800 mg	1200 mg	1500 mg	Initial 2 mo



# INTERVENTION

## Adjuvant therapy: HOMEOPATHY

- *"It is more important to know what kind of person has a disease than what kind of disease a person has"* - Sir William Osler
- Combinations of medicines ("complex homoeopathy") on the basis of conventional diagnosis and totality of symptoms.
- Build up a "symptom picture" of the patient. This is matched with a "drug picture" described in the homoeopathic *Materia medica*
- only one or two doses or a regular daily dose was used according to patient's constitution, temperament, and susceptibility.



# Homeopathy: Drug picture

## ■ PHOSPHORUS

Talk, Indisposed to be silent

Heat vital lack of

Desire for cold drinks

Haemoptysis

Chest pain, lying on left

Expectoration L froathy

Numbness : toes

Fever : Evening

Perspiration : night

## ■ LYCOPODIUM

Company, desire for

Confidence, want of self

Appetite increased

:afternoon Respiration :

difficult, exertion after

Cough : dry

Chest pain, lying while

# RESULTS

## Baseline characteristics of relapsed TB patients treated with homeopathy or placebo

<b>Characteristic</b>	<b>Homeopathy group (N=24)</b>	<b>Placebo group (N=23)</b>
<b>Age yrs, mean <math>\pm</math> SD</b>	<b>30.17 <math>\pm</math> 4.94</b>	<b>31.13 <math>\pm</math> 4.87</b>
<b>Sex M/F, no.</b>	<b>14/10</b>	<b>16/7</b>
<b>Educational status, literate</b>	<b>70%</b>	<b>57.15 %</b>
<b>Work status</b>		
<b>Farming</b>	<b>50%</b>	<b>43.75%</b>
<b>Industries</b>	<b>28.25%</b>	<b>31.25</b>
<b>Construction</b>	<b>18.75%</b>	<b>21%</b>
<b>Unemployed</b>	<b>3%</b>	<b>4 %</b>

# RESULTS

Comparing Homeo and placebo at 0,2,8,11 mo.

parameter	0 mo. H/P	2 mo. H/P ( p<)	8 mo. H/P ( p<)	11 mo. H/P ( p<)
Sputum(-)	0/0	19/11(0.02)	21/11 (0.004)	21/10(0.002)
Haemoptysis(+)	22/ 22	1/14 (0.000)	1/10 (0.002)	1/10(0.002)
Cough(Severe)	24/23	3/23(0.000)	3/3	3/14(0.001)
Fever (freq)	18/23	3/11(0.009)	4/9	3/11(0.009)
Night sweat (+)	21/22	2/12(0.001)	1/11 (0.001)	2/12(0.000)
Chest pain (Mean ±SD)	7.46±1.7/ 7.83±1.5	5.75± 1.39/ 6.56 ± 1.44	4.04±1.04 5.17±1.19 (0.005)	2.75±1.11 4.52±1.95 (0.002)

# RESULTS

## Comparing Homeo and placebo at 0,2,8,11 mo

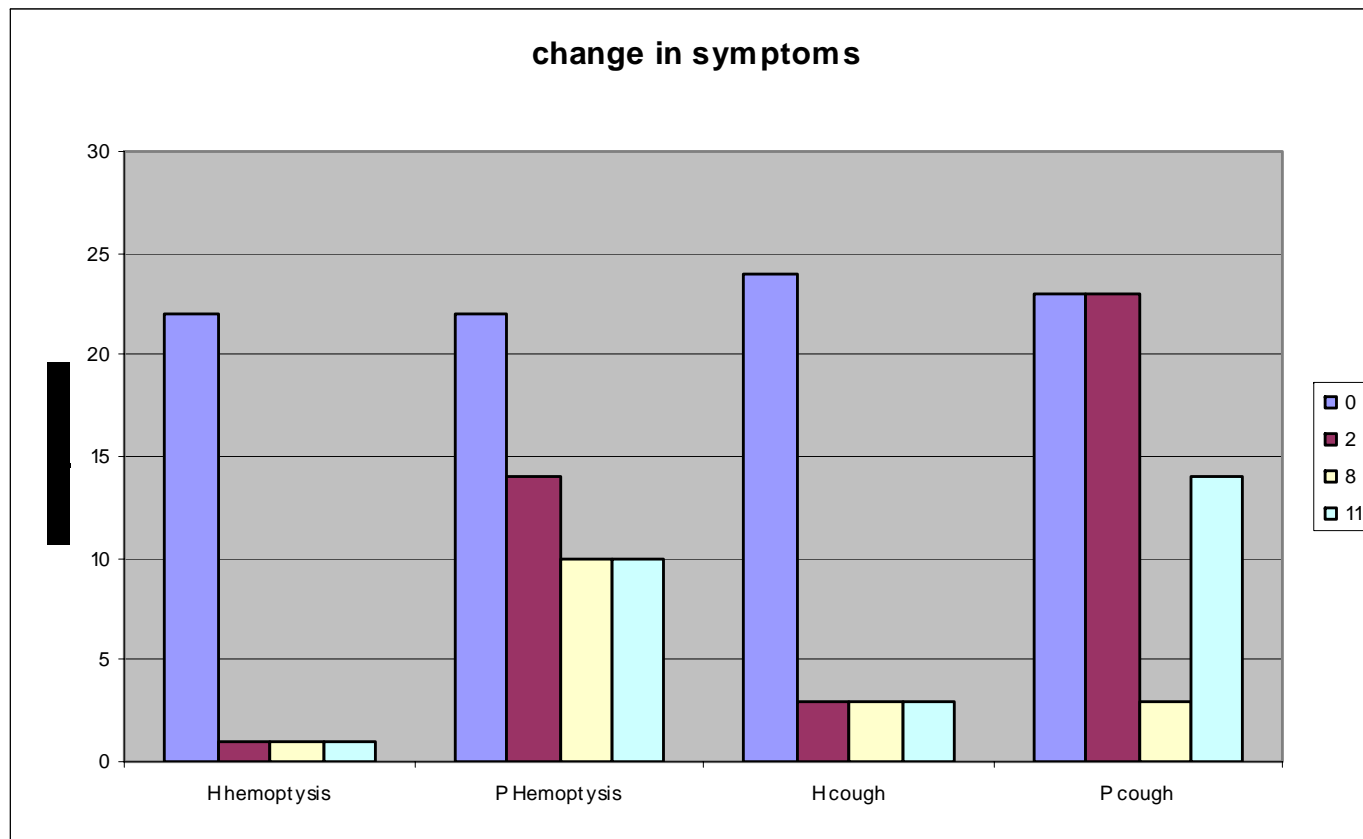
Parameter	0 mo. H/P	2 mo. H/P	8 mo. H/P	11 mo. H/P
Breathless-ness	7.67±1.3/ 7.83±1.2	5.62±0.57/ 7.00±1.83 ( p<0.02)	4.29±0.46/ 6.30±2.30 (p< 0.002)	3.42±1.32/ 5.48±2.86 (p< 0.01)
Weight/kg	41.62±4.58/ 40.39±4.63	43.00±4.30/ 39.65± 4.42 ( p<0.01)	46.21±3.23/ 41.04±4.26 (p< 0.000)	50.17±3.64/ 41.48±4.06 (p< 0.000)
Hb gm%	8.88±1.29/ 9.08±1.19	9.75±1.26/ 9.16±1.24	11.12±0.85/ 9.21±0.80 (p< 0.000)	11.87±0.80/ 9.95±1.46 (p< 0.000)
ESR Mm/hr	75.46±8.73/ 74.21±6.71	49.58±6.76/ 66.17±9.61 ( p<0.001)	11.33±3.79/ 37.17±27.64 (p< 0.001)	9.87±1.57/ 36.91±30.96 (p< 0.05)

# RESULTS

## Quality of life

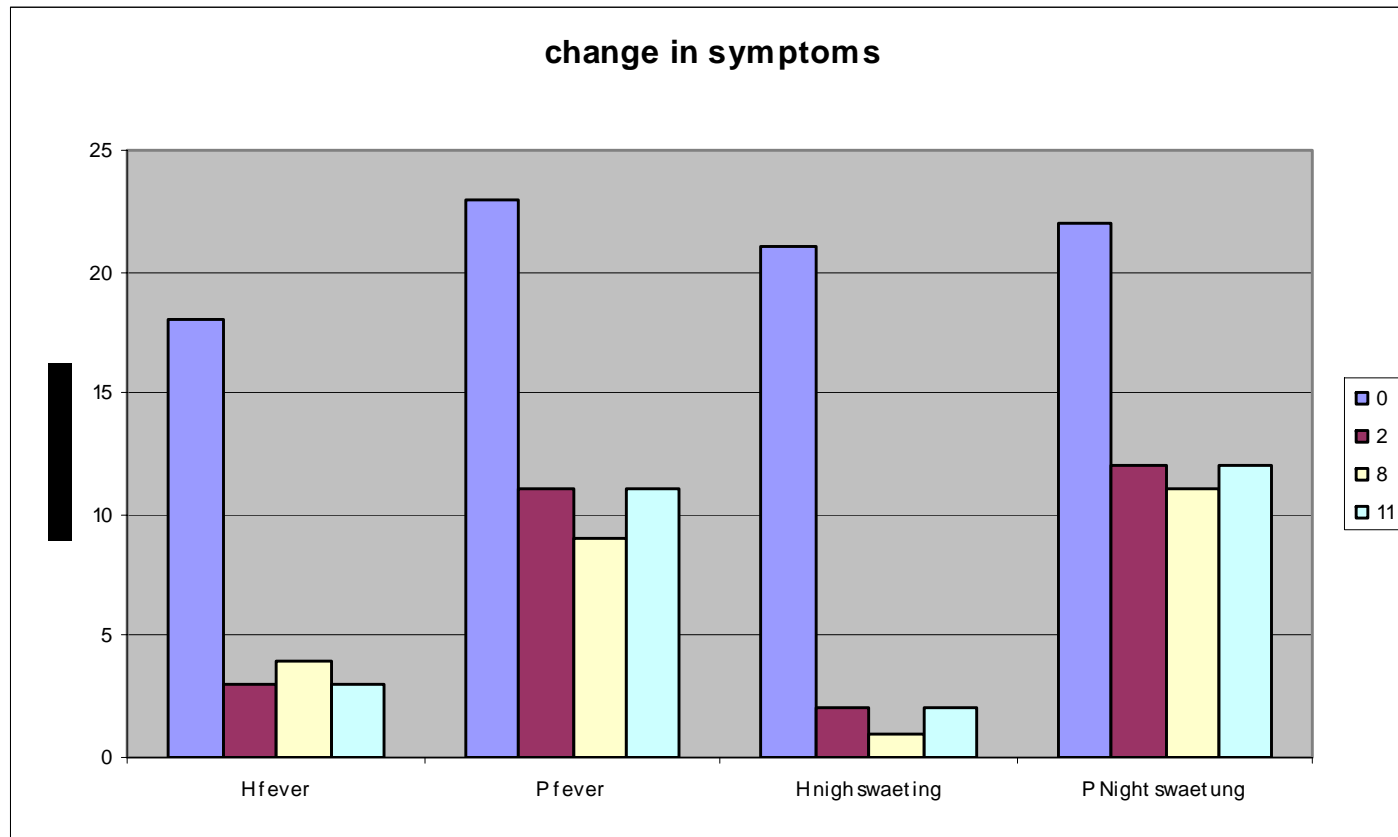
<b>SF 36 domain</b>	<b>Homeopathy</b>	<b>Placebo</b>	<b>p value</b>
<b>Physical function</b>	<b>80.33±8.72</b>	<b>56.30± 13.76</b>	<b>0.000</b>
<b>Body pain</b>	<b>74.42±10.34</b>	<b>63.74±7.10</b>	<b>0.000</b>
<b>General health</b>	<b>87.50±8.52</b>	<b>69.36±18.43</b>	<b>0.000</b>
<b>Vitality/energy</b>	<b>79.83±15.99</b>	<b>65.69±12.60</b>	<b>0.000</b>
<b>Social function</b>	<b>84.87±7.99</b>	<b>72.22±10.63</b>	<b>0.000</b>
<b>Mental health</b>	<b>79.83±10.95</b>	<b>62.30± 14.44</b>	<b>0.000</b>
<b>Role limitation physical</b>	<b>80.58±7.36</b>	<b>64.52±12.71</b>	<b>0.000</b>
<b>Role limitation emotional</b>	<b>85.04±8.89</b>	<b>58.61±14.38</b>	<b>0.000</b>

# Change in the symptoms

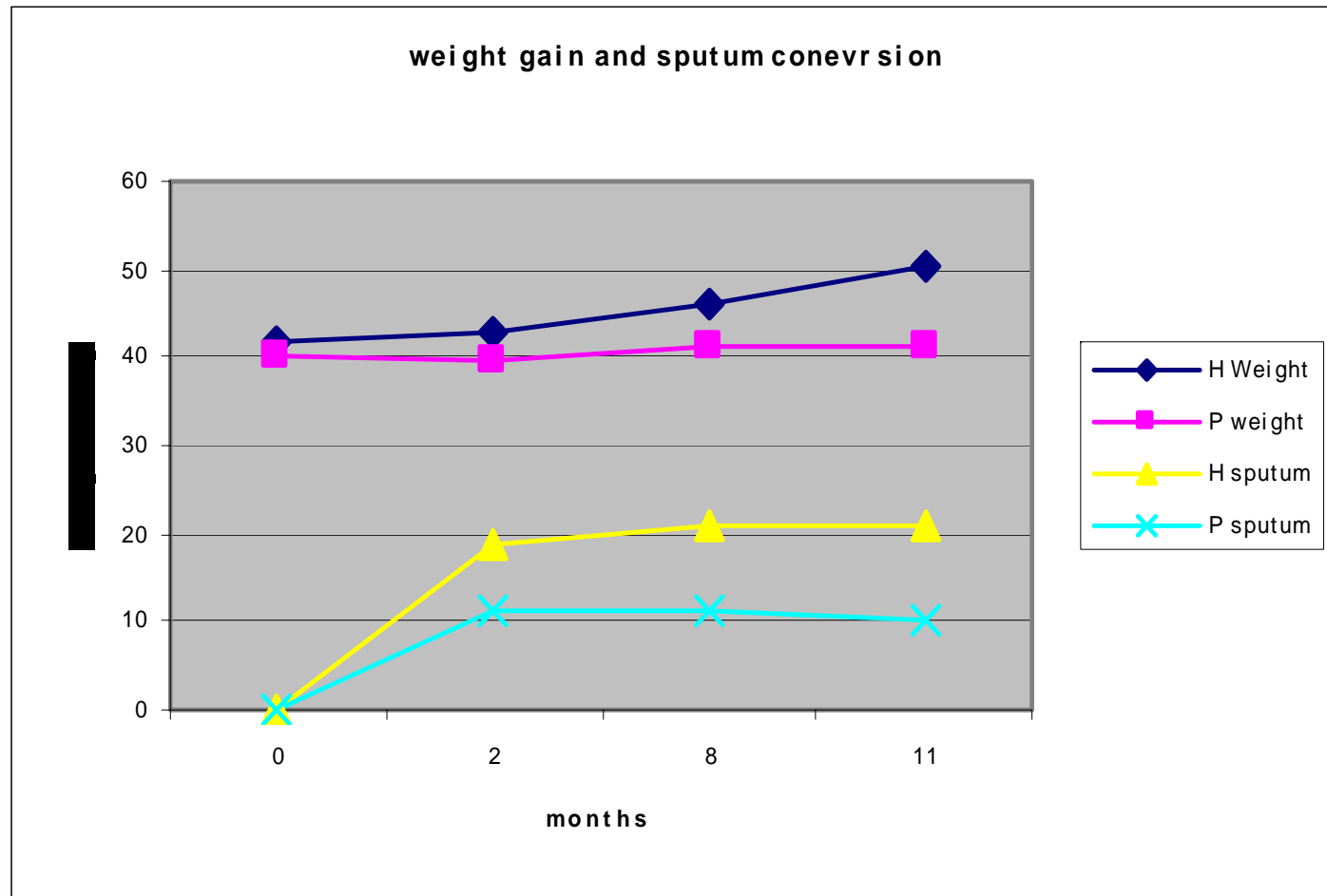




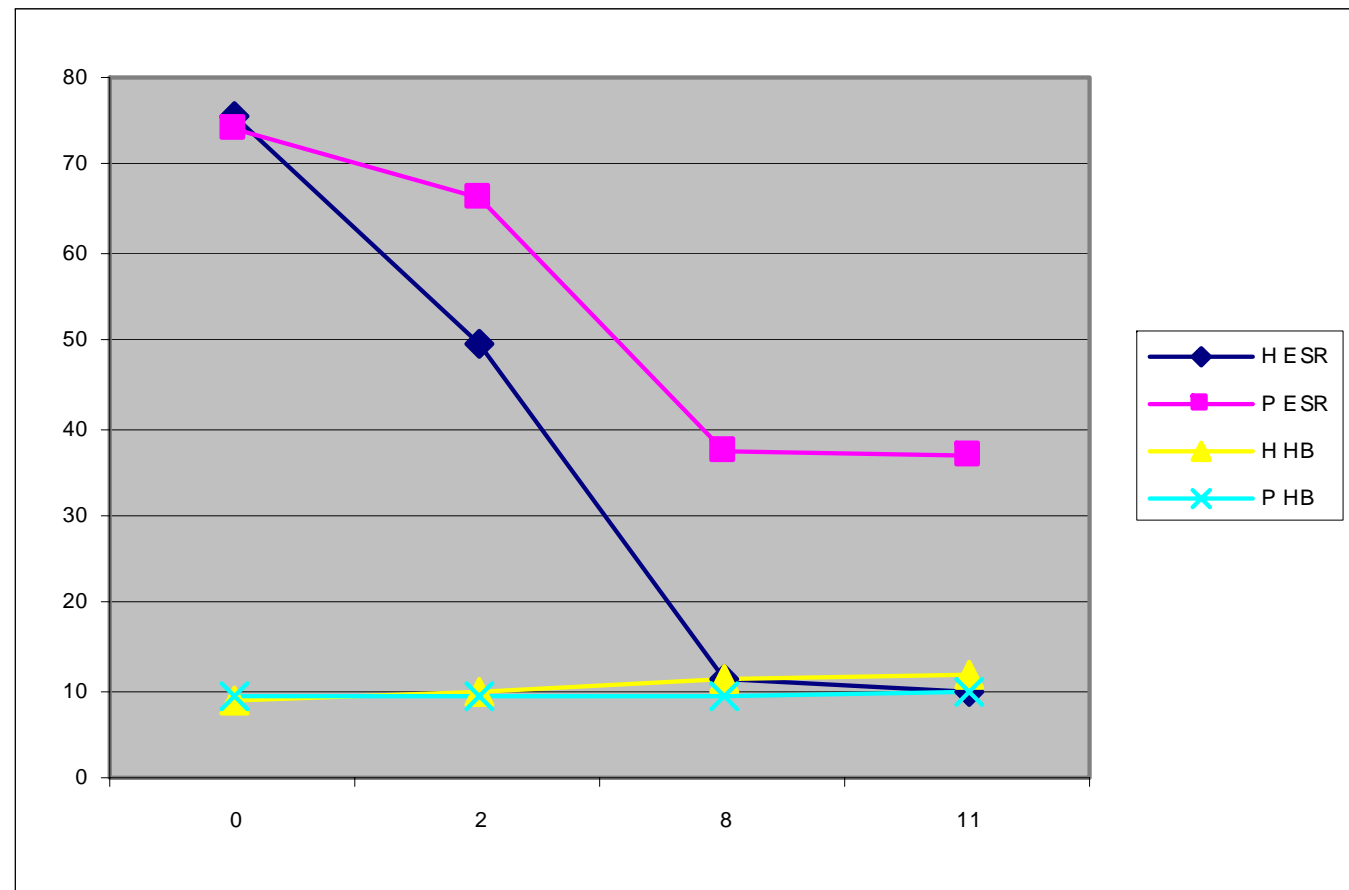
# Change in the symptoms



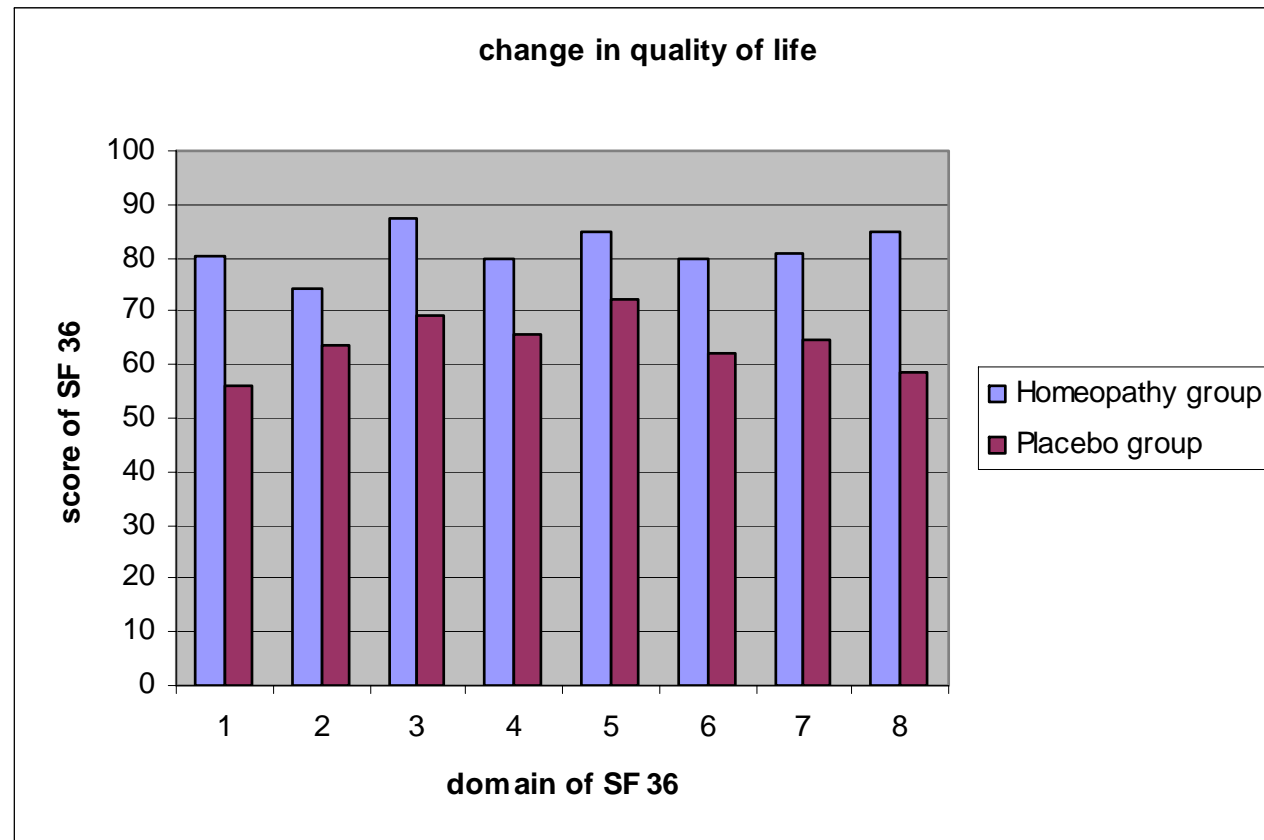
# Change in weight and sputum



# Change in the Hematology



# Comparing quality of life



**1-physical function, 2-body pain, 3-general health, 4-vitality/energy, 5-social functioning, 6-mental health, 7-role limitation physical, 8-role limitation emotional.**

# DISCUSSION

- Homeopathy supplementation has a significant and favorable effect on **weight gain, sputum conversion, and reduction of symptoms like cough.**
- **Reduced cough and increased Mycobacterial clearance in Sputum** observed at 2 month.
- There wasn't any significant side effect or worsening symptoms were recorded.





# STRENGTH OF STUDY

- **Homeopathy in the form in which it is commonly practiced rather than in a form specially modified for clinical trials.**
- **More than one homeopath, as negative result might have been attributed to lack of competence of a single therapist.**
- **Study design**
- **Good adherence**



# WEAKNESS OF STUDY

- **Limitations of sputum culture of the study population**
- **Shorter follow up period of 3 months**
- **Study design would have been improved by conducting sample size calculation, by stratifying by tuberculosis conditions, and by choosing outcome measures (or modifying those used) to be more sensitive to change.**

# WHAT'S NEXT?



- **Resistance or multi drug resistance**
- **Longer follow up**
- **Comparing different approach of Homeopathy**



# Questions? Comments?

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THANK YOU  
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