

Supplementary File - 1



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chaitalibhowmik@gmail.com

Ref. F. No. 5-23/NIH/PG/Ethical Comm. 2009/Vol 5/2671(A/S) Date: 10 April 2018
To

Dr. Chintamani Nayak;

Lecturer, Dept. of Homoeopathic Materia Medica,
National Institute of Homoeopathy,
Kolkata - 700106

Ref Study: "Effectiveness of Individualized Homoeopathic Treatment and
Urtica Urens Mother Tincture in treatment of Hyperuricemia: An open
Randomized Pragmatic Trial" under the Guidance of Principal Investigator Dr.
Chintamani Nayak; Lecturer, Dept. of Homoeopathic Materia Medica, NIH, Kolkata.

Dear Dr. Nayak,

The Institutional Ethical Committee of the National Institute of Homoeopathy,
has in its meeting on 23rd March 2018 reviewed and discussed your study entitled
"Effectiveness of Individualized Homoeopathic Treatment and *Urtica Urens*
Mother Tincture in treatment of Hyperuricemia: An open Randomized
Pragmatic Trial"

The following Members of the Ethical Committee were present in the meeting
held on 23rd March 2018 at 11 AM in the Board Room of National Institute of
Homoeopathy, Kolkata.

1. Dr. Samir Kumar Pal - Chairman - Basic Medical Science
2. Prof. Dr. Gautam Ash - Ex-Officio - Member Secretary
3. Dr. Lokanath Behera - Ex - Officio - Member Convener
4. Prof. (Dr.) Dilip Panakkada - Member - Subject Expert Person
5. Dr. Subhas Singh - Member - Clinician (Homoeopathy)
6. Sh. Hemendra Kumar Pandey - Member - Basic Medical Science (Invitee)
7. Dr. Shyamal Kumar Mukherjee - Member - Subject expert person
8. Sh. Adhir Kumar Das - Member - Legal Expert
9. Sh. Amiya Sarkar - Member - Lay person from the Community
10. Sh. Raktim Das - Member - Journalist
11. Dr. Manabendra Sau - Member - Basic Medical Science
12. Dr. Kajal Bhattacharya - Member - Subject Expert
13. Prof. Dr. Satadal Das - Member - Social Worker/Scientist
14. Dr. Debabrata Sarkar - Member - Clinical Homoeopathy
15. Mrs. Chaitali Bhowmik - Member - NGO (Sparsh)

The following documents were reviewed -

1. Protocol (Proposed Research Proposal)
2. Informed consent Document

The study being a non-regulatory, investigatory - initiated one, the Ethical
Committee agreed to exempt from the audio-video recording of informed consent
process. The written informed consent process shall however apply. The NIH-IEC should
be informed about:

- a) The progress of the study every three months.
- b) Any serious adverse events occurring in the course of the study within 24
hours of their occurrence.
- c) Any change in the protocol and patient information/ informed consent
documents, prior to their implementation.
- d) The final report of the study shall have to be submitted to the NIH-IEC in
all cases, even when the study is abandoned for any reason(s).

**The Institutional Ethical Committee has allowed the research proposal with the above
mentioned points.**

Yours sincerely

Prof. (Dr.) S.K. Pal

Chairman, NIH-IEC

Institutional Ethical Committee

Supplementary File - 2

CLINICAL TRIALS REGISTRY - INDIA

ICMR - National Institute of Medical Statistics



PDF of Trial

CTRI Website URL - <http://ctri.nic.in>

Clinical Trial Details (PDF Generation Date :- Tue, 13 Aug 2019 07:12:00 GMT)

CTRI Number	CTRI/2018/05/014026 [Registered on: 21/05/2018] - Trial Registered Prospectively	
Last Modified On	13/08/2019	
Post Graduate Thesis	Yes	
Type of Trial	Interventional	
Type of Study	Homeopathy	
Study Design	Randomized, Parallel Group, Multiple Arm Trial	
Public Title of Study	Homoeopathic treatment of increased blood uric acid	
Scientific Title of Study	Effectiveness of individualized homoeopathic treatment and Urtica urens mother tincture in treatment of hyperuricemia: an open, randomized, pragmatic trial	
Secondary IDs if Any	Secondary ID	Identifier
	U1111-1214-2300	UTN
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Chintamani Nayak
	Designation	Lecturer
	Affiliation	National Institute of Homoeopathy, Ministry of AYUSH, Govt. of India
	Address	Department of Homoeopathic Materia Medica, OPD room no. 12 and 13, Block GE, Sector III, Salt Lake, Kolkata Kolkata WEST BENGAL 700106 India
	Phone	9433161854
	Fax	
	Email	drcnayak@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Harcharanjeet Kaur
	Designation	Dean, Faculty of Homoeopathy
	Affiliation	SGT University
	Address	Shree Guru Gobind Singh Tricentenary University, Gurugram Gurgaon HARYANA 122505 India
	Phone	9810018876
	Fax	
	Email	dr.harcharan@gmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Harcharanjeet Kaur
	Designation	Dean, Faculty of Homoeopathy
	Affiliation	SGT University
	Address	Shree Guru Gobind Singh Tricentenary University, Gurugram HARYANA 122505 India
	Phone	9810018876
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	Email	dr.harcharan@gmail.com



Source of Monetary or Material Support	Source of Monetary or Material Support			
	> National Institute of Homoeopathy Ministry of AYUSH Govt of India Block GE, Sector 3, Salt Lake, Kolkata 700106, West Bengal			
Primary Sponsor	Primary Sponsor Details			
	Name	National Institute of Homoeopathy Ministry of AYUSH Govt of India		
	Address	Block GE, Sector III, Salt Lake, Kolkata, West Bengal 700106		
	Type of Sponsor	Government medical college		
Details of Secondary Sponsor	Name	Address		
	None	Nil		
Countries of Recruitment	List of Countries			
	India			
Sites of Study	Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
	Chintamani Nayak	National Institute of Homoeopathy Ministry of AYUSH Govt of India	Dept of Homoeopathic Materia Medica, OPD room no. 13, Block GE, Sector III, Salt Lake, Kolkata Kolkata WEST BENGAL	9433161854 drcnayak@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethical Committee of National Institute of Homoeopathy	Approved	10/04/2018	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Disorder of purine and pyrimidinemetabolism, unspecified	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Individualized homeopathic medicines plus Urtica urens mother tincture plus lifestyle modifications and dietary advices	Indicated homeopathic medicines in centesimal or fifty millesimal potencies, as decided appropriate to the case or condition. In centesimal scale, each dose shall consist of a single drop of the indicated medicine (preserved in 90% v/v ethanol) in 5 ml of distilled water; dosage and repetition depending upon the individual requirement of the cases. In 50 millesimal scale, a single medicated cane sugar globule of poppy seed size (no. 10) shall be dissolved in 90 ml distilled water with addition of 2 drops of 90% v/v ethanol; 16 doses to be marked on the vial; each dose of 5 ml to be taken after 10 uniformly forceful	



		<p>downward strokes to the vial in 45 ml normal water in a clean cup, to stir well, to take 5 ml of this liquid orally, and to discard rest of the liquid from the cup. Along with this, <i>Urtica urens</i> mother tincture shall be administered in personalized dosage (10-20 drops once-thrice daily in 30 ml of normal water); be taken orally on clean tongue with empty stomach. Lifestyle modification will be advised in terms of encouraging to have lacto-vegetarian diet, restriction or moderation of high purine content food, e.g. meat, fish, poultry, organ meat, oyster, sea food, yeast and yeast extracts, cauliflower, mushroom, lentils, spinach, beans, peas etc., moderation of alcohol consumption, adequate fluids (2 lit/day), hot or cold compress over the affected joint, rest in bed and immobilization of the affected joint in acute gout, moderate exercise, physiotherapy, and counselling and patient education. Duration of therapy: 6 months</p>
Comparator Agent	Indicated homeopathic medicines in centesimal or fifty millesimal potencies plus lifestyle modifications and dietary advices	<p>Indicated homeopathic medicines in centesimal or fifty millesimal potencies, as decided appropriate to the case or condition. In centesimal scale, each dose shall consist of a single drop of the indicated medicine (preserved in 90% v/v ethanol) in 5 ml of distilled water; dosage and repetition depending upon the individual requirement of the cases. In 50 millesimal scale, a single medicated cane sugar globule of poppy seed size (no. 10) shall be dissolved in 90 ml distilled water with addition of 2 drops of 90% v/v ethanol; 16 doses to be marked on the vial; each dose of 5 ml to be taken after 10 uniformly forceful downward strokes to the vial in 45 ml normal water in a clean cup, to stir well, to take 5 ml of this liquid orally, and to discard rest of the liquid from the cup. be taken orally on clean tongue with empty stomach. Lifestyle modification will be advised in</p>



		terms of encouraging to have lacto-vegetarian diet, restriction or moderation of high purine content food, e.g. meat, fish, poultry, organ meat, oyster, sea food, yeast and yeast extracts, cauliflower, mushroom, lentils, spinach, beans, peas etc., moderation of alcohol consumption, adequate fluids (2 lit/day), hot or cold compress over the affected joint, rest in bed and immobilization of the affected joint in acute gout, moderate exercise, physiotherapy, and counselling and patient education. Duration of therapy: 6 months
Comparator Agent	Urtica urens mother tincture plus lifestyle modifications and dietary advices	Urtica urens mother tincture shall be administered in personalized dosage (10-20 drops once-thrice daily in 30 ml of normal water); to be taken orally on clean tongue with empty stomach. Lifestyle modification will be advised in terms of encouraging to have lacto-vegetarian diet, restriction or moderation of high purine content food, e.g. meat, fish, poultry, organ meat, oyster, sea food, yeast and yeast extracts, cauliflower, mushroom, lentils, spinach, beans, peas etc., moderation of alcohol consumption, adequate fluids (2 lit/day), hot or cold compress over the affected joint, rest in bed and immobilization of the affected joint in acute gout, moderate exercise, physiotherapy, and counselling and patient education. Duration of therapy: 6 months

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Patients suffering from hyperuricemia, with or without gout 2. Age between 18 and 65 years 3. Patients with known but controlled systemic diseases with medication 4. Patients giving written consent to participate in the study 5. Literate patients; ability to read Bengali and/or English

Exclusion Criteria

Exclusion Criteria	
Details	1. Secondary gout 2. Severe or advanced cases requiring surgical procedures or orthopedic corrections of deformities



	<ul style="list-style-type: none"> 3. Patients with psychiatric diseases 4. Cases suffering from uncontrolled systemic illness or life-threatening infections or any vital organ failure 5. Cases already undergoing homoeopathic treatment for any chronic disease 6. Substance abuse and/or dependence 7. Pregnant women and lactating mothers 						
Method of Generating Random Sequence	Permuted block randomization, fixed						
Method of Concealment	An Open list of random numbers						
Blinding/Masking	Open Label						
Primary Outcome	<table> <tr> <th>Outcome</th><th>Timepoints</th></tr> <tr> <td>Serum uric acid level</td><td>Baseline, 3 months, 6 months</td></tr> </table>	Outcome	Timepoints	Serum uric acid level	Baseline, 3 months, 6 months		
Outcome	Timepoints						
Serum uric acid level	Baseline, 3 months, 6 months						
Secondary Outcome	<table> <tr> <th>Outcome</th><th>Timepoints</th></tr> <tr> <td>Gout Assessment Questionnaire 2 (GAQ2) translated Bengali version</td><td>Baseline, 3 months, 6 months</td></tr> <tr> <td>Measure Yourself Medical Outcome Profile (MYMOP) translated Bengali version</td><td>Baseline, 3 months, 6 months</td></tr> </table>	Outcome	Timepoints	Gout Assessment Questionnaire 2 (GAQ2) translated Bengali version	Baseline, 3 months, 6 months	Measure Yourself Medical Outcome Profile (MYMOP) translated Bengali version	Baseline, 3 months, 6 months
Outcome	Timepoints						
Gout Assessment Questionnaire 2 (GAQ2) translated Bengali version	Baseline, 3 months, 6 months						
Measure Yourself Medical Outcome Profile (MYMOP) translated Bengali version	Baseline, 3 months, 6 months						
Target Sample Size	Total Sample Size=90 Sample Size from India=90 Final Enrollment numbers achieved (Total)=90 Final Enrollment numbers achieved (India)=90						
Phase of Trial	Phase 2/ Phase 3						
Date of First Enrollment (India)	28/05/2018						
Date of First Enrollment (Global)	No Date Specified						
Estimated Duration of Trial	Years=1 Months=0 Days=0						
Recruitment Status of Trial (Global)	Not Applicable						
Recruitment Status of Trial (India)	Completed						
Publication Details	None yet; to be published						
Brief Summary	<p>Gout, resulting from an inborn error of purine metabolism, manifests as a spectrum of clinical and pathologic features on a foundation of excess body burden of uric acid (overproduction of purine – primary gout; and/or overproduction and under-excretion of urate), manifested in part by hyperuricemia (serum urate greater than either 6.8 or 7.0 mg/dL) and frequently complicated by hypertension, obesity, dyslipidemia, metabolic syndrome, type 2 diabetes, renal calculus, and chronic kidney disease (CKD). Typically, the disease first presents as arthritis that is acute and episodic, but can become recurrent in the majority of individuals. Tophi, mainly in articular, periarticular, bursal, bone, auricular, and cutaneous tissues is a pathognomonic feature of gout, and are detectable by physical exam, and/or by imaging approaches and pathology examination. In the past few decades, gout has increased not only in incidence and prevalence, but also in clinical complexity, the latter accentuated in part by a dearth of novel advances in treatments for hyperuricemia and gouty arthritis. Epidemiologic studies indicate that the quality of gout management has remained suboptimal owing to both patient and physician issues. Urate-lowering therapy – allopurinol, probenecid, and recently, febuxostat, remains the mainstay</p>						



of treatment in spite of having certain unavoidable toxicities and limitations. Complementary and Alternative Medicine (CAM) therapies like acupuncture, herbal extracts and formulations, injections of dilute formic acid, traditional Chinese medicine and diet therapy, Unani medicine and homoeopathy have, but limited research evidences in treatment of hyperuricemia and/or gout. Though traditionally being claimed as highly efficacious in treating such conditions, homoeopathy research in hyperuricemia remains seriously compromised. In this prospective, open-label, randomized, three parallel arms, pragmatic clinical trial, the investigators intend to explore whether individualized homoeopathic (IH) treatment, *Urtica urens* mother tincture (UUMT), and both (i.e. IH + UUMT) have any significantly different effect in treatment of hyperuricemia. Following preliminary and detailed screening using specified selection (inclusion and exclusion) criteria, 90 eligible patients will be recruited in the trial. Following that, baseline outcome data (serum uric acid, GAQ2 scores and MYMOP scores) will be obtained and the patients will be randomized either of the three trial arms in 1:1:1 ratio and will be assessed at baseline, after 3 months and 6 months. Comparative analysis will be carried out in the end to detect group differences, if any. Results will be published in scientific journals.

Supplementary File - 3

REVISED GOUT IMPACT (GI) SECTION OF GAQ_{2.0}

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Please answer every question. Read every question carefully and choose the best answer for you.

Questions may be answered by filling in a bubble to indicate your choice.

Some questions in this survey are about your gout overall and some are about only the times you are experiencing pain or swelling of your joints due to your gout. Two important terms are used in this survey:

Gout Attack = time when you are experiencing pain or swelling of your joints because of gout. When a question is about a Gout Attack please only think about what it is like for you when you have joint pain or swelling because of your gout.

Gout Overall = times you have a Gout Attack AND the time Between Attacks when you do not have joint pain or swelling because of gout.

ABOUT HOW GOUT AFFECTS YOUR DAILY LIFE OVERALL

1. Please indicate how much you agree or disagree with each of the statements below.

(Mark one answer for each statement.)

	Strongly Agree	Agree	Not Certain	Disagree	Strongly Disagree
a. I am worried that I will have a gout attack within the next year.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. I am afraid that my gout will get worse over time.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. I feel anxious that my gout will interfere with my future activities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. I worry that I will not be able to continue to enjoy my leisure activities as a result of my gout.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. I am bothered by side effects from my gout medications.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. I am mad or angry when I experience a gout attack.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. It is difficult to plan ahead for events or activities because I may have a gout attack.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. I feel depressed when I experience a gout attack.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. My current medications are effective for treating a gout attack when I have one.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. I miss planned or important activities when I have a gout attack.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k. I worry about long term effects of gout medications.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l. My current medications do not work well to prevent gout attacks from happening.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
m. I have control over my gout.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. During your last gout attack, how much of the time did you experience the following?

(Mark one answer for each statement.)

	All of the Time (100%)	Most of the Time (about 50%)	Some of the Time (about 50%)	A Little of the Time	None of the Time (0%)
a. Miss work because of your gout symptoms?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Have difficulty working because of your gout symptoms?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Have difficulty with recreational or social activities because of your gout symptoms?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Have difficulty with self care activities such as feeding, bathing, or dressing yourself because of your gout symptoms?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

During your last gout attack, how much did your symptoms interfere with the following things? (Mark one answer for each statement.)

	Not a Bit	A Little Bit	Moderately	Quite a Bit	Extremely
a. Your mood?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Your ability to move about?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Your sleep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Your normal work? (including both work outside the home and housework)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Your recreational activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Your enjoyment of life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Your ability to do what you want to do?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Scales and items: Gout concern overall (4 items, 1 a-d); Gout medication side effects (2 items, 1 e & k); Unmet gout treatment need (3 items, 1 i,l,m); Well being during attack (11 items, 2 a-d 3 a-g); Gout concern during attack (4 items, 1 f,g,h,j)

Supplementary File - 4

Gout Assessment Questionnaire: গাউট (গেঁটেবাত) পরিমাপক প্রশ্নাবলী

[অনুবাদিত বাংলা সংস্করণ]

রোগীর নাম:

রেজিস্ট্রেশন নং:

তারিখ:

নিদেশিকা: যে সকল রোগীদের রক্তে ইউরিক অ্যাসিডের পরিমাণ বেশি থাকে ও গাউটে (এক ধরনের গেঁটেবাত) ভোগেন, তাঁদের নিম্নলিখিত উপসর্গগুলি দেখা যায়। কিছু প্রশ্ন সামগ্রিকভাবে আপনার উপরে রোগটির প্রভাব (Gout overall) জানতে চাইবে। আবার কিছু প্রশ্ন শুধুমাত্র যে সময়ে আপনার গাঁটগুলিতে (অস্থিসন্ধি) ফোলা বা ব্যথা অনুভব করেন (Gout attack), সেই তীব্রতা সম্পর্কিত। আপনার ক্ষেত্রে এই রোগলক্ষণগুলির যথার্থতার কথা মনে রেখে প্রত্যেক প্রশ্নের সঙ্গে দেওয়া উপযুক্ত যে কোনো একটি বক্সে টিক চিহ্ন দিয়ে আপনার উত্তরটি জানান।

আপনার প্রাত্যহিক জীবনযাপনে গাউটের প্রভাব:

নিদেশিকা: নিম্নলিখিত বক্তব্যগুলির সঙ্গে আপনি কতটা সহমত, তা উপযুক্ত বক্সে টিক চিহ্ন দিয়ে জানান। কোনো বক্তব্য আপনার ক্ষেত্রে প্রযোজ্য না হলে অপ্রাসঙ্গিক বক্সে টিক দিন।

উপসর্গসমূহ	প্রবলভাবে সম্মত	সম্মত	অনিশ্চিত	অসম্মত	প্রবলভাবে অসম্মত	অপ্রাসঙ্গিক
১. আমার দুশ্চিন্তা হয় যে আগামী বছরের মধ্যেই আমার গাঁটগুলি আবার ফুলে উঠবে ও ব্যথা হবে	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
২. আমার ভয় হয় যে সময়ের সঙ্গে আমার গেঁটেবাত আরও বেড়ে যাবে	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৩. গেঁটেবাতের কারণে ভবিষ্যতে আমার কাজকর্ম করতে অসুবিধা হবে বলে আশঙ্কা হয়	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৪. আমার দুশ্চিন্তা হয় যে এই গেঁটেবাতের কারণে আমি অবসরকালীন কাজকর্মগুলি উপভোগ করতে পারবো না	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৫. আমি গেঁটেবাতের ওষুধের পার্শ্বপ্রতিক্রিয়ায় বিব্রত বোধ করছি	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৬. যখন আমার গাঁটগুলি ফুলে ওঠে ও ব্যথা হয়, আমি প্রায় ক্ষিপ্ত হয়ে উঠি	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৭. আমার গাঁটগুলি ফুলতে পারে ও ব্যথা হতে পারে এই ভয়ে আমার কোনো কাজকর্মের পরিকল্পনা করতে সমস্যা হয়	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৮. যখন আমার গাঁটগুলি ফুলে ওঠে ও ব্যথা হয়, আমি হতাশ বোধ করি	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৯. যখন আমার গাঁটগুলি ফুলে ওঠে ও ব্যথা হয়, বর্তমানে চলাকালীন ওষুধগুলি সেই অবস্থায় কার্যকরী	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
১০. যখন আমার গাঁটগুলি ফুলে ওঠে ও ব্যথা হয়, আমাকে পরিকল্পিত বা গুরুত্বপূর্ণ কাজগুলি বাতিল করতে হয়	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
১১. আমার গেঁটেবাতের ওষুধের দীর্ঘমেয়াদী প্রভাবের কথা ভেবে দুশ্চিন্তা হয়	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
১২. আমার বর্তমান ওষুধগুলি রোগটির নতুনভাবে হওয়াকে ভালোভাবে আটকাতে পারছে না	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
১৩. আমার গেঁটেবাত সবমিলিয়ে নিয়ন্ত্রিত	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

নির্দেশিকা: শেষবার যখন আপনার গাঁটগুলি ফুলে উঠেছিল ও ব্যথা হয়েছিল, কতটা সময় আপনি নিম্নলিখিত সমস্যাগুলি অনুভব করেছিলেন, তা উপযুক্ত বক্সে টিক চিহ্ন দিয়ে জানান।

উপসর্গসমূহ	সকল সময়	বেশিরভাগ সময়	অর্ধেক সময়	অল্প সময়	কখনোই না
১. গাউটের কষ্টের জন্যে কাজ বন্ধ রাখতে হয়েছে	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
২. গাউটের কষ্টের জন্যে কাজ করতে কষ্ট হয়েছে	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৩. বিনোদনমূলক বা সামাজিক কাজকর্মে কষ্ট হয়েছে	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৪. ব্যক্তিগত কাজকর্মে (যেমন খাওয়াদাওয়া, স্নান করা, জামাকাপড় পড়া) বাধা পেয়েছি	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

নির্দেশিকা: শেষবার যখন আপনার গাঁটগুলি ফুলে উঠেছিল ও ব্যথা হয়েছিল, নিম্নলিখিত বিষয়গুলিতে তা কতটা বাধা দিয়েছিল, উপযুক্ত বক্সে টিক চিহ্ন দিয়ে জানান।

বিষয়সমূহ	সামান্যও না	খুব অল্প	মোটামুটি	বেশ কিছুটা	খুব বেশি
১. আপনার মেজাজ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
২. আপনার চলাফেরা করার ক্ষমতা	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৩. আপনার ঘুম	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৪. আপনার স্বাভাবিক কাজকর্ম (ঘরোয়া বা বাইরের কাজ)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৫. আপনার বিনোদনমূলক কাজকর্ম	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৬. আপনার জীবনের উপভোগ্যতা	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
৭. আপনি যা চাইছেন তা করার ক্ষমতা	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

অংশগ্রহণের জন্যে ধন্যবাদ । অনুগ্রহ করে দেখে নিন যে প্রত্যেক প্রশ্নের উত্তর দিয়েছেন কিনা ।

.....

রোগীর স্বাক্ষর

.....

ডাক্তারের স্বাক্ষর

Supplementary File - 5

* MYMOP2 *

Full name Date of birth

Address and postcode.....

Today's date Practitioner seen

Choose one or two symptoms (physical or mental) which bother you the most. Write them on the lines.

Now consider how bad each symptom is, over the last week, and score it by circling your chosen number.

SYMPTOM 1: 0 1 2 3 4 5 6
..... As good as it could be As bad as it could be
.....

SYMPTOM 2: 0 1 2 3 4 5 6
..... As good as it could be As bad as it could be
.....

Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevents you doing. Score how bad it has been in the last week.

ACTIVITY: 0 1 2 3 4 5 6
..... As good as it could be As bad as it could be
.....

Lastly how would you rate your general feeling of wellbeing during the last week?

0 1 2 3 4 5 6
As good as it could be As bad as it could be

How long have you had Symptom 1, either all the time or on and off? Please circle:

0 - 4 weeks 4 - 12 weeks 3 months - 1 year 1 - 5 years over 5 years

Are you taking any medication FOR THIS PROBLEM? Please circle: YES/NO

IF YES:

1. Please write in name of medication, and how much a day/week

.....

2. Is cutting down this medication: Please circle:

Not important a bit important very important not applicable

IF NO:

Is avoiding medication for this problem:

Not important a bit important very important not applicable

*** MYMOP2 Follow up ***

Full name Today's date

Please circle the number to show how severe your problem has been IN THE LAST WEEK.

This should be YOUR opinion, no-one else's!

SYMPTOM 1:	0	1	2	3	4	5	6
.....	As good as it could be					As bad as it could be	
.....							

SYMPTOM 2:	0	1	2	3	4	5	6
.....	As good as it could be					As bad as it could be	
.....							

ACTIVITY:	0	1	2	3	4	5	6
.....	As good as it could be					As bad as it could be	
.....							

WELLBEING:	0	1	2	3	4	5	6
How would you rate your general feeling of wellbeing?	As good as it could be					As bad as it could be	

If an important new symptom has appeared please describe it and mark how bad it is below.

Otherwise do not use this line.

SYMPTOM 3:	0	1	2	3	4	5	6
.....	As good as it could be					As bad as it could be	
.....							

The treatment you are receiving may not be the only thing affecting your problem. If there is anything else that you think is important, such as changes you have made yourself, or other things happening in your life, please write it here (write overleaf if you need more space):

Are you taking medication FOR THIS PROBLEM ? Please circle: YES/NO

IF YES:

Please write in name of medication, and how much a day / week

.....

Supplementary File - 6

MYMOP-2 (Initial) Bengali version

রোগীর নাম:

বয়স:

রেজিস্ট্রেশন নং:

তারিখ:

নির্দেশিকা একটি বা দুটি উপসর্গ বা রোগলক্ষণ (শারীরিক বা মানসিক) বেছে নিন যা আপনাকে সবথেকে বেশি কষ্ট দিচ্ছে। ধারণা করুন যে গত সপ্তাহে প্রতিটি সমস্যার তীব্রতা কতটা ছিল এবং উপযুক্ত সংখ্যায় গোল দাগ দিয়ে তা নির্দেশ করুন।

উপসর্গ ১:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো			সবথেকে খারাপ			
.....	যা হতে পারে			যা হতে পারে			
উপসর্গ ২:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো			সবথেকে খারাপ			
.....	যা হতে পারে			যা হতে পারে			

নির্দেশিকা এইবারে যে কোনো একটি কাজকর্ম (শারীরিক, সামাজিক, বা মানসিক) বেছে নিন যেটি আপনার কাছে গুরুত্বপূর্ণ এবং রোগের কারণে আপনি তা করতে পারছেন না বা করতে কষ্ট হচ্ছে।

কাজকর্ম:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো			সবথেকে খারাপ			
.....	যা হতে পারে			যা হতে পারে			

সবমিলিয়ে আপনি গত সপ্তাহে আপনার সার্বিকভাবে ভালো থাকার অনুভূতিকে কিভাবে বর্ণনা করবেন, তা উপযুক্ত সংখ্যায় গোল দাগ দিয়ে নির্দেশ করুন।

০	১	২	৩	৪	৫	৬
সবথেকে ভালো			সবথেকে খারাপ			
যা হতে পারে			যা হতে পারে			

কত দিন ধরে আপনি প্রথম উপসর্গটিতে ভুগছেন (সকল সময় বা মাঝেমধ্যে)?

০ - ৪ সপ্তাহ ☐ ৪ - ১২ সপ্তাহ ☐ ৩ মাস - ১ বছর ☐ ১ - ৫ বছর ☐ ৫ বছরের বেশি ☐

আপনি কি এই উপসর্গটির জন্যে কোনো চিকিৎসা করাচ্ছেন? হ্যাঁ ☐ না ☐

যদি উত্তর 'হ্যাঁ' হয়, আপনার ওষুধের নাম লিখুন ও দিনে/সপ্তাহে কতটা ওষুধ খাচ্ছেন জানান:

ওষুধের পরিমাণ যদি কমানো হয়: গুরুত্বপূর্ণ নয় ☐ কিছুটা গুরুত্বপূর্ণ ☐ খুব গুরুত্বপূর্ণ ☐ অপ্রাসঙ্গিক ☐

যদি উত্তর 'না' হয় এবং যদি ওষুধ বন্ধ রাখা হয়:

গুরুত্বপূর্ণ নয় ☐ কিছুটা গুরুত্বপূর্ণ ☐ খুব গুরুত্বপূর্ণ ☐ অপ্রাসঙ্গিক ☐

অংশগ্রহণের জন্যে ধন্যবাদ। অনুগ্রহ করে দেখে নিন যে প্রত্যেক প্রশ্নের উত্তর দিয়েছেন কিনা।

রোগীর স্বাক্ষর

ডাক্তারের স্বাক্ষর

MYMOP-2 (Follow-up) Bengali version

রোগীর নাম:

বয়স:

রেজিস্ট্রেশন নং:

তারিখ:

নিদেশিকা গত সপ্তাহে আপনার নিম্নলিখিত সমস্যাগুলির তীব্রতা কতটা ছিল, উপযুক্ত সংখ্যায় গোল দাগ দিয়ে তা নির্দেশ করুন।

উপসর্গ ১:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো						সবথেকে খারাপ
.....	যা হতে পারে						যা হতে পারে
উপসর্গ ২:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো						সবথেকে খারাপ
.....	যা হতে পারে						যা হতে পারে
কাজকর্ম:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো						সবথেকে খারাপ
.....	যা হতে পারে						যা হতে পারে
সবমিলিয়ে ভালো থাকা:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো						সবথেকে খারাপ
.....	যা হতে পারে						যা হতে পারে

যদি নতুন করে কোনো উপসর্গ এসে থাকে, তাহলে তার তীব্রতা কতটা?

উপসর্গ ৩:	০	১	২	৩	৪	৫	৬
.....	সবথেকে ভালো						সবথেকে খারাপ
.....	যা হতে পারে						যা হতে পারে

আপনি কি এই উপসর্গটির জন্যে কোনো চিকিৎসা করাচ্ছেন? হ্যাঁ ☐ না ☐

যদি উত্তর 'হ্যাঁ' হয়, আপনার ওষুধের নাম লিখুন ও দিনে/সপ্তাহে কতটা ওষুধ খাচ্ছেন জানান:

হতে পারে আপনি যে চিকিৎসা করাচ্ছেন, সেটি ছাড়া অন্য কিছু আপনার উপসর্গগুলিকে প্রভাবিত করছে। যদি আপনার এইরকম কিছু গুরুত্বপূর্ণ মনে হয়ে থাকে (যেমন আপনি নিজের জীবনে যা কিছু পরিবর্তন এনেছেন), তা লিখে জানান।

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অংশগ্রহণের জন্যে ধন্যবাদ । অনুগ্রহ করে দেখে নিন যে প্রত্যেক প্রশ্নের উত্তর দিয়েছেন কিনা ।

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রোগীর স্বাক্ষর

ডাক্তারের স্বাক্ষর

**CONSORT 2010 checklist of information to include when reporting a randomised trial***

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2-3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	4-5
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	6-7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
Statistical methods	11b	If relevant, description of the similarity of interventions	5-6
	12a	Statistical methods used to compare groups for primary and secondary outcomes	7-8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	8
	13b	For each group, losses and exclusions after randomisation, together with reasons	8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tables 1, 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10-11
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11
Other information			
Registration	23	Registration number and name of trial registry	2, 4
Protocol	24	Where the full trial protocol can be accessed, if available	2, 4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	12

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Supplementary File - 8

RedHot checklist of information to include when reporting randomised trials of homeopathy

Item	Treatment (CONSORT item number)	Description	Reported on page No
1	Rationale (2)	<i>Type of homeopathy</i> Individualized Formula Isopathy <i>Evidence base</i> Sources, references	<hr/> 2-4 - - <hr/> 2-4
2	Participants (3)	Knowledge condition Baseline health definition in proving	<hr/> 2-4 <hr/> NA
3	Medications (4)	<i>Manufacture</i> ▪ Manufacturer, Pharmacopoeia (or process), references ▪ Potency and scale ▪ Dilution method <i>Nomenclature</i> ▪ Individualized: list or frequency table ▪ Formula: constituents, trade name <i>Dosage</i> ▪ Dose, timing, form	<hr/> 5-6 <hr/> 5-6 <hr/> 5-6 <hr/> <hr/> 10 <hr/> NA <hr/> 4 <hr/> 5-6
4	Consultations (4)	Setting Clinical history detail Duration, frequency Number needed to agree prescription Group process or expert consultation Confidence in prescriptions	<hr/> <hr/> 5 <hr/> 5 <hr/> 5 <hr/> 5 <hr/> 5
5	Practitioners (4)	Number in study Experience, accreditation, qualifications Current schools or styles of homeopathy	<hr/> 5-6 <hr/> 5-6 <hr/> 5-6

6	Co-interventions (4)	<i>Included</i>	
		Rationale, intended effect, references	6-7
		Duration, frequency	6-7
		<i>Excluded</i>	
7	Control interventions (4)	Stopping of mainstream interventions	NA
		Antidotes	NA
		<i>Active</i>	
		Rationale, references	6-7
		<i>Placebo</i>	-
8	Adverse events (8)	Manufacturing process	NA
		Aggravations	10

Statement, to be included with checklist:

These guidelines are intended as a supplement to, not a substitute for, the CONSORT Statement, to improve the reporting of homeopathic treatments. We strongly recommend that reports of clinical trials of homeopathy follow the CONSORT guidelines, particularly the flowchart.

The points above are specific to homeopathy. All points refer to controlled clinical trials, all but item 7 to uncontrolled outcome studies.

Supplementary File - 9

Indications of prescribed medicines

1. **Benzoic acid:**

- Tearing in joints with clear urine, old nodes become painful. As the pain abates, palpitation sets in, ceasing only when pain increases.
- Gout going from left to right or commencing in great toe.
- Urine is of offensive urinous odor, highly intensified, depositing reddish cloudy sediment.
- Prone to dwell on unpleasant things of the past. Omits words in writing.

2. **Bryonia alba:**

- Best adapted to the persons of gouty or rheumatic diathesis; prone to so-called bilious attacks. Rheumatic pains and swellings. Hot swelling of feet. Joints red, swollen, hot, with stitches and tearing. Every spot is painful on pressure. Pain produced is stitching and tearing, agg. by motion, touch, amel. by absolute rest, lying on painful side.
- Affects the right side.
- Mucous membranes are all dry with thirst for large quantities of water.
- Urine dark and scanty.
- Complains apt to develop slowly, especially appear during warm weather after cold days.
- Tongue white down the center.
- Patient is unbearably cross. Exceedingly irritable, with ailments form chagrin, mortification, anger, violence, with chilliness and coldness.

3. **Colchicum autumnale:**

- Adapted to the rheumatic, gouty, uric acid diathesis. Gout in persons of vigorous constitutions. Gout attacking many joints; shifting from one to another, with burning and tearing pains. The joint becomes inflamed, dark red, hot and intensely painful and swollen, patient nearly beside himself with agony. Tearing pains, agg. in the evening, at night, and from touch. Stubbing the toe hurts exceedingly. Inflammation of the great toe, gout in the heel, cannot bear to have it touched or moved. Edema and coldness of legs and feet, with weariness, heaviness and inability to move.
- Urine acid, dark and scanty.
- Pain goes from left to right, light or superficial during warm weather, affects the bones and deeper tissues, when air is cold.
- The smell of food nauseates.
- Ailments from grief or misdeed of others. Ailments from any external impressions, light, noise, strong odors, contact, bad manners, make him almost beside himself.

4. **Ledum palustre:**

- Adapted to rheumatic, gouty diathesis; constitutions abused by alcohol.

- Edematous swelling of joint, which may feel cold to touch, but not cold subjectively to patient; affects chiefly left shoulder and right hip joint. Begins in lower limbs and ascends. Habitual gout in the articulations of hands and feet. Ball of great toe swollen and painful. Gouty nodosities in joints. Fine tearing pain in toes.
- Pain are sticking, tearing, throbbing; rheumatic pains are agg. by motion, night, by warmth of bed; amel. only when holding feet in ice-cold water.

5. Lycopodium clavatum:

- Uric acid diathesis with ailments develop gradually and failure of digestive powers.
- Tophi; nocturnal pains, agg. by heat. Tearing in the limbs at night and on alternate days, agg. at rest. Joints rigid painful and numb. Finger joints inflamed with arthritis nodes. Swelling of the dorsa of the feet, amel. by warmth.
- Red sand in the urine, must rise often at night to pass urine.
- For persons intellectually keen, but physically weak; upper part of the body emaciated. Lower part semi-dropsical.
- Sour eructation; frequent belching without relief. Symptoms move from right to left, and worse from about 4 to 8 pm.
- Ailments from fright, anger, mortification, or vexation with reserved displeasure.
- Avaricious, greed, miserly, pusillanimous, irritable and peevish. Loss of self-confidence.