Open Access

OBM Integrative and Complementary Medicine

LIDSEN Publishing Inc.

Original Research

Open-Label Study to Evaluate the Response to Homeopathic Treatment of Psoriasis

Divya Taneja [1, *], Madhumita Sadhukhan [2], Padmalaya Rath [3], Manas R Sarangi [4, †], Renu Mittal [1, *], Akshaya Kumar Prusty [5], Deepthi Gilla [6], Ashish Shivadikar [7], Birendra Rawat [8], Ravi Kumar Sadarla [9], Gurudev Choubey [10], Nidhi Mahajan [11], Renu Bala [12, ‡], Neha Kalra [1], Anupam Mukherjee [1, §], Anil Khurana [1, ‖], Raj K. Manchanda [1, ¶]

1. Central Council for Research in Homoeopathy, Headquarters, Delhi; E-Mails: drdivyataneja@gmail.com; renumittal8@gmail.com; drnehamehta1985@gmail.com; anupam.dr.98@gmail.com; anil23101961@gmail.com; rkmanchanda@gmail.com
2. Dr Anjali Chatterjee Regional Research Institute for Homoeopathy, Kolkatta, West Bengal; E-Mail: dr.msadhukhan@gmail.com
3. Dr DP Rastogi Central Research Institute for Homoeopathy, Noida, Uttar Pradesh; E-Mail: drpadmalaya@gmail.com
4. Regional Research Institute for Homoeopathy, Agartala, Tripura; E-Mail: drmanas2k@gmail.com
5. Regional Research Institute for Homoeopathy, Puri, Odisha; E-Mail: prustyakshayakumar@gmail.com
6. National Homoeopathic Research Institute for Mental Health, Kottayam, Kerala; E-Mail: drdeepthigilla@gmail.com
7. Regional Research Institute for Homoeopathy, Gudivada, Andhra Pradesh; E-Mail: ashishshivadikar@gmail.com
8. Regional Research Institute for Homoeopathy, Mumbai, Maharashtra; E-Mail: rawatdrbirendrasingh@yahoo.co.in
9. Clinical Research Unit for Homoeopathy, Puducherry; E-Mail: drrvkumar64@gmail.com
10. Clinical Research Unit for Homoeopathy, Siliguri, West Bengal; E-Mail: gurudev.choubey@gmail.com
11. Regional Research Institute for Homoeopathy, Jaipur, Rajasthan; E-Mail: drnidhimahajan1@gmail.com
12. Regional Research Institute for Homoeopathy, Guwahati, Assam; E-Mail: drrenu3011@gmail.com

† Central Council for Research in Homoeopathy, Headquarters, Delhi

‡ Homoeopathic Drug Research Institute, Lucknow, Uttar Pradesh
§ West Bengal Homoeopathic Health Services, Department of Health and Family Welfare, Government of West Bengal
‖ National Commission for Homoeopathy, Delhi
¶ Directorate of Ayush, Government of NCT of Delhi

* **Correspondences:** Divya Taneja and Renu Mittal; E-Mails: drdivyataneja@gmail.com; renumittal8@gmail.com

Academic Editor: Bernard Poitevin

Special Issue: Homeopathy

OBM Integrative and Complementary Medicine
2022, volume 7, issue 3
doi:10.21926/obm.icm.2203044

Received: August 12, 2022
Accepted: September 12, 2022
Published: September 21, 2022

Abstract

Patients with psoriasis commonly opt for homeopathic treatment. However, no study has assessed the response to homeopathic treatment by using standardized disease-specific scales, and the findings are based on clinical assessments only. The objective of this study was to evaluate the response to the individualized homeopathic treatment of psoriasis with respect to changes in disease severity and quality of life based on Psoriasis Area and Severity Index (PASI) and Psoriasis Disability Index (PDI) scales, respectively. A multicentric study was conducted using a pragmatic model. The study participants were regularly followed up for 1 year. Subsequently, participants completing the 1-year follow-up were included in a long-term assessment for further 2 years. Three monthly assessments were made by using PASI, PDI, and Visual Analog scales for patient and physician general assessment. Data were analyzed to identify treatment effects and variables affecting treatment. In total, 384 patients were enrolled, out of whom 254 participants completed 1 year of treatment. Of these, 84 participants continued treatment for an additional 12 months. A significant reduction was observed in the scores of PASI (10.96 ± 10.67 at baseline to 4.24 ± 5.10 at 12 months, $p = 0.000$), PDI (10.19 ± 9.11 to 3.91 ± 4.44, $p = 0.000$), and patient and physician global assessment scales. Regarding PASI response at 12 and 24 months, PASI 75–89 was reported in 66 and 14 participants, whereas PASI 90–100 was reported in 29 and 17 participants, respectively. Baseline severity of psoriasis considerably affected treatment response, whereas age, gender, and duration of psoriasis did not. Furthermore, the severity of psoriasis and quality of life improved considerably with regular homeopathic treatment.

Keywords

PASI; PDI; pragmatic study; responders; homeopathy; psoriasis

1. Introduction

Psoriasis is a multisystem disease predominantly affecting the skin and joints. Psoriasis mainly manifests as a chronic inflammation of the skin, characterized by disfiguring scaling and erythematous plaques that may be painful or often severely pruritic and may considerably affect the quality of life [1]. Psoriasis, a systematic disease largely observed in adult populations with psychological, metabolic, arthritic, and cardiovascular comorbidities, is associated with social burden and high treatment costs to patients and health care systems [2].

An estimated 60 million people worldwide have psoriasis [3]. In India, the prevalence of psoriasis varies from 0.44% to 2.8% [4]. Psoriasis prevalence is the highest in high-income countries such as Australasia, western Europe, central Europe, and North America. However, the United States, India, and China were identified to have the largest adult population with psoriasis [2].

On the basis of age at onset, disease severity, and morphological evaluation, psoriasis is classified into the following subtypes: plaque, guttate, pustular, and erythrodermic. Unlike other autoimmune diseases, psoriasis is not diagnosed through histopathological examination and blood tests [5]. The diagnosis is usually based on clinical examination only, and the staging/severity of the condition is adjudged clinically on standardized scales [6].

Patients with dermatologic diseases commonly use alternative treatments, with homeopathy being one of the most common [7].

The homeopathic literature identifies numerous medicines for the treatment of psoriasis, which are detailed in the standard books on therapeutics [8, 9]. The commonly used Repertory of the Homoeopathic Materia Medica by Dr. JT Kent [10] mentions psoriasis as rubric "Eruptions – psoriasis" in the chapter of "Skin" with 52 drugs, whereas Synthesis Repertorium Homeopathicum Syntheticum [11], mentions 65 more drugs in this rubric. Homeopathic practitioners have frequently reported treating psoriasis [12-16]. These reports detail patient presentation and the remission of psoriasis over a variable period based on the clinical assessment and photographs of the dermatological condition. However, they have lacked details on the use of validated scales for the assessment of patients and the relapse and progression of psoriasis under homeopathic treatment.

Observational studies have reported that homeopathic treatment is useful based on clinical assessments (Supplementary Table S1) [17-20]. However, none of these studies have used standardized disease-specific scales for the assessments.

Considering homeopathy has the potential to treat psoriasis, but empirical data on case response to homeopathic treatment on standardized disease-specific scales are lacking, this multicentric study was conducted using a pragmatic model. The primary objective was to evaluate response to the individualized homeopathic treatment of psoriasis concerning changes in disease severity and the quality of life during 1 year. Subsequently, the participants who completed 1 year of follow-up were included in the long-term follow-up for the assessment of relapse for further 2 years.

The study was approved by the Institutional Ethical Committee of the Central Council for Research in Homoeopathy (CCRH) and retrospectively registered with the Clinical Trial Registry of India under CTRI/2018/11/016481. All procedures were in accordance with the ethical standards

of the responsible committee on human experimentation and with the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects [21].

2. Materials and Methods

2.1 Trial Design

This was an open, observational [22], real-time, pragmatic study conducted from February 2014 to December 2019.

2.2 Participants

Research institutes and units of CCRH have outpatient departments (OPDs) providing health care services. At 11 centers, dermatology OPDs were initiated, which provide routine OPD care to patients with dermatological disorders by using homeopathic medicines only. This study was conducted in these dermatology clinics. Patients with psoriasis were requested to participate in the study. Voluntary written informed consent was obtained from them, and those consenting to participate were included in the study. The details of these patients were recorded at baseline and subsequent follow-ups in a specific format composed of homeopathic case recording details and assessment questionnaires. Those who refused to participate were provided similar treatment in the OPD, except that their case details were recorded in their OPD cards only and were not used for study assessments.

After the completion of 1-year follow-up, the participants were requested to continue treatment in the OPD, and the treatment and status of the patients were recorded at each follow-up on the same parameters as in the observational study for another 2 years.

The study included male and female participants in the age group of 18–60 years presenting with plaque-type psoriasis, that is, well-defined, erythematous, scaly lesions that become silvery if scraped.

Patients with guttate psoriasis or pustular psoriasis and psoriatic arthritis (identified based on the Psoriasis Epidemiology Screening Tool (PEST) questionnaire) [23] were excluded. Patients were excluded from the study if they were undergoing any treatment for psoriasis during the past 6 months; unwilling to refrain from using systemic allopathic treatment and phototherapy; having evidence of skin conditions (i.e., eczema, lichen planus, tinea) other than psoriasis that would interfere with the evaluations of study; and eligible for systemic immune-suppressive therapy, such as those with generalized pustular psoriasis or psoriatic erythroderma with significant functional impairment, and high levels of distress. The diagnosis was made by a trained consulting dermatologist, who is a practitioner of modern medicine with a master's degree in dermatology. The participants' case recordings, assessments, and follow-ups were made by homeopathic investigators. The study investigators were institutionally trained homeopathic practitioners with a postgraduate degree in homeopathy with a minimum of 5 years of research experience.

2.3 Intervention

The homeopathic investigators obtained a detailed case history, analyzed and repertorized the case details, and selected medicines in consultation with Materia Medica. Medicines were provided from the pharmacy in the OPD at the study centers of CCRH. The medicines are procured

from SBL Pvt. Ltd., a good manufacturing practices–compliant pharmaceutical firm approved by CCRH. Medicines were dispensed in sugar globules of standard size 30 (this number denotes the number in millimeters required to cover the space occupied by 10 equal-sized globules placed in close contact with each other) [24].

Only single medicines were permitted to be used at a time. At treatment initiation, the selected medicine was prescribed in 6C potency. During the study period, the potencies were raised sequentially as needed in pursuance with the homeopathic principles. The 30C potency, as and when prescribed, was given once a day, and ≥200C potencies were used once a week. Each dose of the selected medicine consisted of four pills of size 30. The medicines were given orally. No local applicants were prescribed. During the study period, the participants were advised not to use any medicated local applicants.

All the participants were followed up every month (or more frequently, if required) for 1 year. Subsequently, the participants completing 1-year follow-up were requested to continue with the treatment in the OPD, and the assessments were made monthly; data were recorded in the same manner until they discontinued reporting at the OPD.

2.4 Outcomes

The primary outcome of the disease was estimated based on a change in the mean Psoriasis Area and Severity Index (PASI) score, ranging from 0–72 [25], and the number of participants achieving a specific percentage reduction in their individual scores. A 75% reduction in the PASI score (PASI 75) is the current benchmark of primary endpoints for most clinical trials of psoriasis. Many researchers consider this endpoint to be too stringent as it places potentially useful therapies at risk of failing to demonstrate efficacy. Some studies have suggested that a 50% reduction in the PASI score (PASI 50) represents a meaningful change in a person's life and therefore is a better primary endpoint [26]. In this study, the participants with a ≥75% (PASI 75–100), <75 and ≥50% (PASI 50–74.9), and <50% (PASI 0–49.9) reduction in the PASI score from baseline were recorded as responders, partial responders, and non-responders, respectively. Also, change in participant quality of life was measured using the Psoriasis Disability Index (PDI), a validated psoriasis-specific quality of life scale [27].

Furthermore, patient and physician global assessments were measured on a 0–10 Visual Analog Scale from very good (0) to very bad (10) based on how they were doing. Photographic records of participants were obtained with due consideration to confidentiality and sensitivity of the areas affected at baseline and subsequent visits.

2.5 Sample Size

In a clinical audit study, out of 157 patients with dermatological conditions, 32 (20%) had psoriasis [28]. Considering psoriasis prevalence to be 20%, alpha 0.05, and power of study 90, the sample size identified was 246. To cover for 10% dropout, a minimum sample of 270 was calculated. Because this was a pragmatic study, all participants reporting at the clinical set-up who fulfilled the inclusion criteria were enrolled as a large sample size allows precise estimation of the treatment effect, and it is usually easy to assess the representativeness of the sample and to generalize the results [29].

2.6 Statistical Methods

Data are presented as mean ±standard deviation for continuous variables (age, duration of illness PASI at baseline, PDI at baseline, and baseline patient and physician global assessments) and as number (percentage) for categorical variables (gender). Repeated measure analysis of variance (ANOVA) was conducted to identify a change in continuous variables, which were measured every 3 months. Correlation analysis was performed between outcome parameters at baseline and change in outcome parameters after 12 and 24 months of treatment.

Psoriasis severity at baseline was categorized as severe, moderate, and mild for PASI scores >12, 7–12, and <7, respectively [30]. The associations of percentage change in PASI (dependent variable) with participant's age, illness duration, and baseline PASI score were evaluated using the chi-square test.

A p-value of <0.05 was considered statistically significant. All analyses were performed using STATCRAFT version 2.0.3.

3. Results

3.1 Participant Flow

In total, 566 patients with psoriasis were screened, out of whom 384 patients were enrolled (Figure 1). All the enrolled participants completed the initial 3 months of treatment; furthermore, 365, 296, and 254 participants completed 6 months, 9 months, and 1 year of treatment, respectively. The number of patients continuing treatment in the extended period of 15, 18, 21 and 24 months was 164, 139, 106, and 84 respectively. At 36 months, the number of patients undergoing regular treatment reduced to 15. For the analysis, follow-up up to 24 months only was included because most of the patients continuing beyond 2 years were highly irregular and had missed follow-ups for >3 consecutive months.

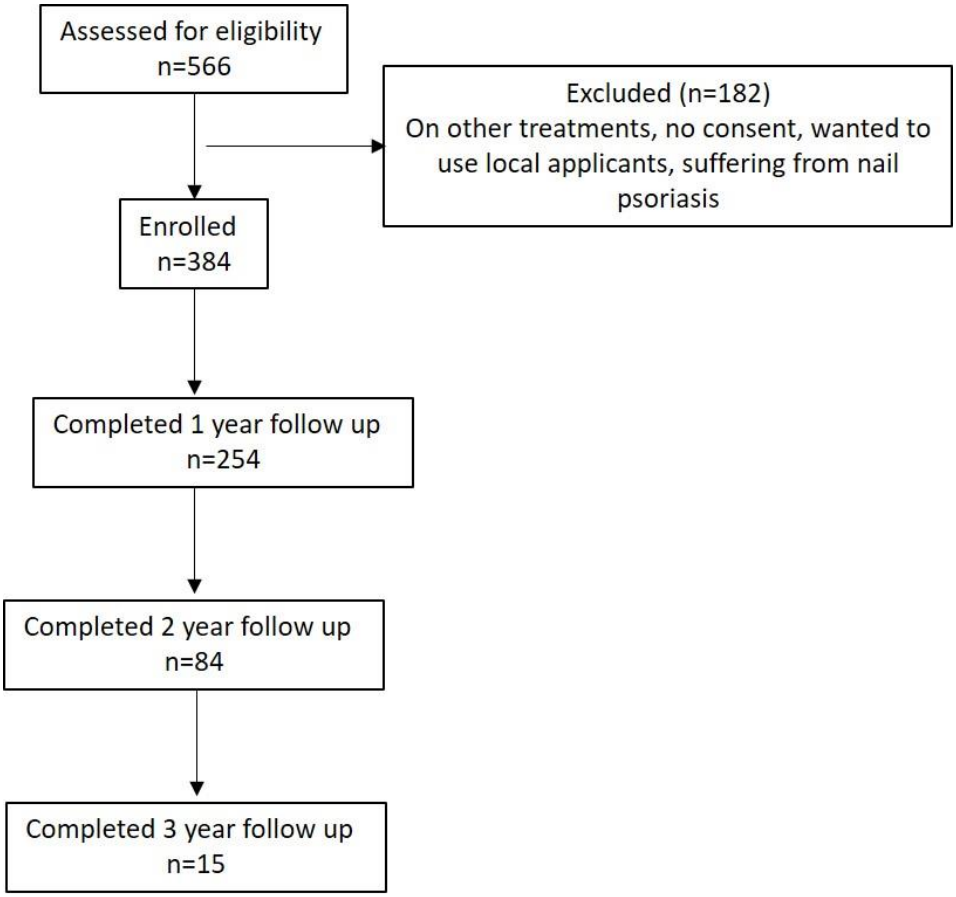

Figure 1 Strobe flowchart.

3.2 Baseline Characteristics

Out of the 384 patients, 89 were aged 18 to 30 years, 113 were 31 to 40 years, 98 were 41 to 50 years, and 84 were 51 to 60 years. Furthermore, 233 were men, and 151 were women. Among the participants, 31 had had psoriasis for <1 year, 127 for 1 to 5 years, 95 for 5 to 10 years, 97 for 10 to 20 years, and 34 for ≥20 years. The severity of psoriasis in 196, 87, and 101 patients was mild, moderate, and severe, respectively.

Baseline characteristics are given in Table 1.

Table 1 Baseline characteristics of the participants.

Parameter (n = 384)	Mean + SD
Age	40.24 ± 11.49
Duration of illness	7.76 ± 6.75
Baseline PASI	10.21 ± 10.17
Baseline PDI	9.61 ± 8.84
Baseline patient global assessment	6.18 ± 2.06
Baseline physician global assessment	4.92 ± 2.85

3.3 Change in Outcome Parameters

A significant reduction was observed in mean PASI scores during the 12-month treatment period from 10.96 ± 10.67 at baseline to 7.63 ± 8.38, 5.71 ± 6.66, 4.74 ± 5.69, and 4.24 ± 5.10 at 3, 6, 9, and 12 months, respectively (Table 2). The reduction in mean PDI and patient and physician global assessment scores was significant during 12 months (Figure 2).

Table 2 Change in PASI and PDI mean scores during 12 months.

		PASI				PDI			
		Mean Difference	95% Confidence Interval for Difference Lower Bound	Upper Bound	Sig.[b]	Mean Difference	95% Confidence Interval for Difference Lower Bound	Upper Bound	Sig.[b]
Baseline	3 months	3.327*	2.559	4.096	0.000	2.897*	2.206	3.589	0.000
	6 months	5.252*	4.367	6.136	0.000	5.047*	4.213	5.882	0.000
	9 months	6.222*	5.191	7.252	0.000	5.909*	5.015	6.803	0.000
	12 months	6.718*	5.684	7.752	0.000	6.285*	5.373	7.196	0.000
3 months	6 months	1.925*	1.422	2.428	0.000	2.150*	1.627	2.674	0.000
	9 months	2.894*	2.140	3.649	0.000	3.012*	2.332	3.691	0.000
	12 months	3.391*	2.596	4.185	0.000	3.387*	2.699	4.076	0.000
6 months	9 months	0.970*	0.458	1.481	0.000	0.862*	0.472	1.252	0.000
	12 months	1.466*	0.877	2.055	0.000	1.237*	0.744	1.730	0.000
9 months	12 months	0.496*	0.051	0.941	0.029	0.375	-0.020	0.771	0.063

Repeated measure ANOVA based on estimated marginal means.

*The mean difference is significant at 0.05 with repeated measure ANOVA.

bAdjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

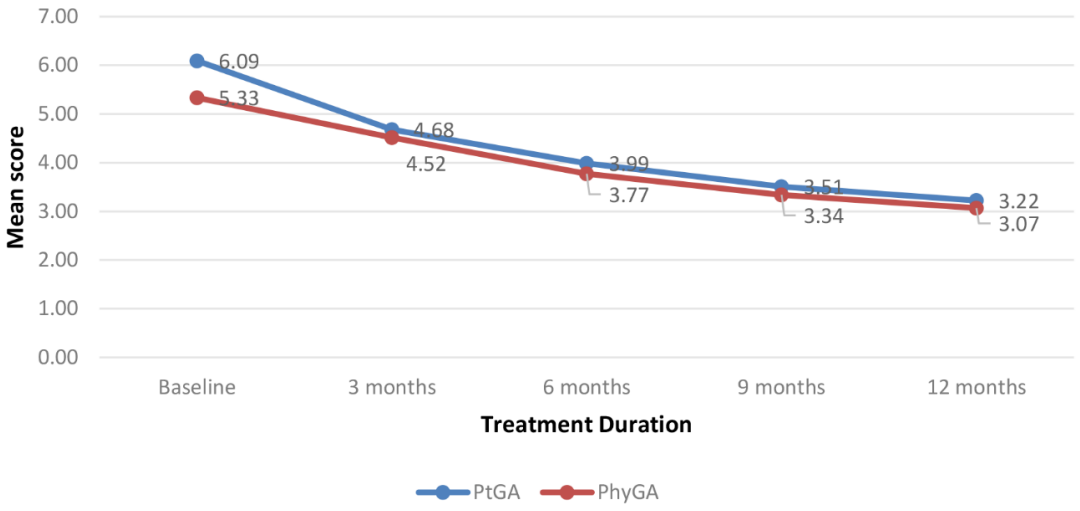

Figure 2 Mean patient global assessment (PtGA) and physician global assessment (PhyGA) over 12 months.

3.4 Change in Scores at 24 Months of Treatment

Data of 84 patients completing 2 years of treatment were analyzed. Reductions in PASI and PDI scores in these patients were significant in the first 12 months but not thereafter (Figure 3).

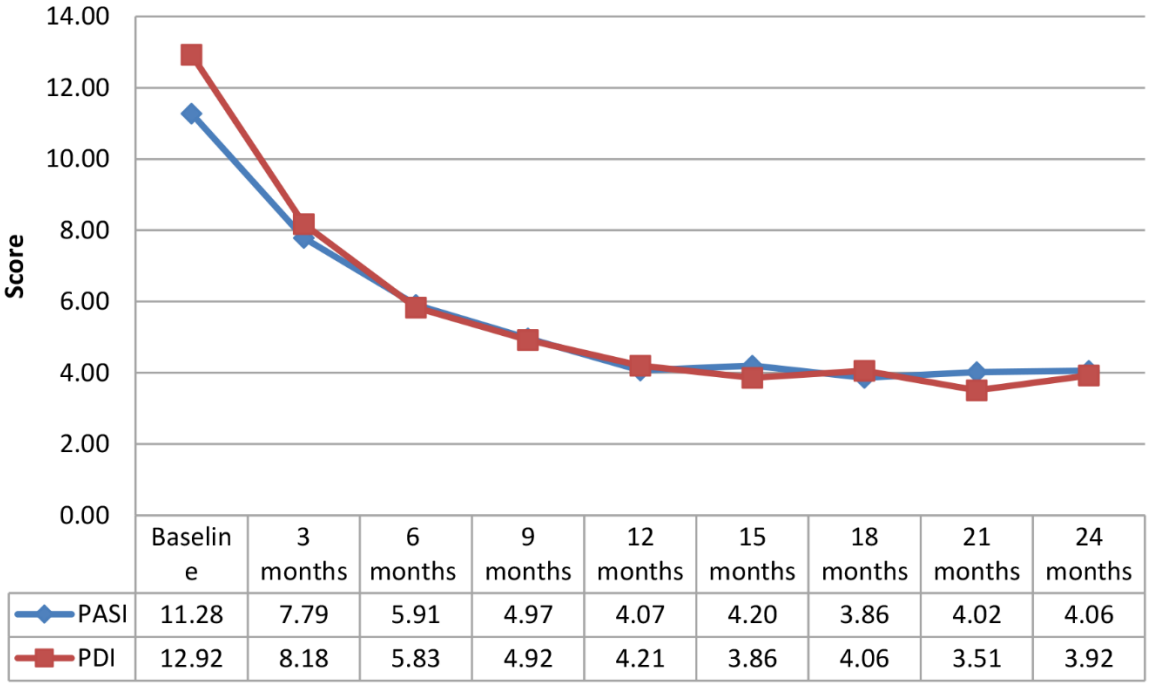

Figure 3 Mean PASI and PDI scores during 24 months (n = 84).

Both patient and physician global assessment scores reduced significantly (Table 3). Post hoc analysis revealed that the change was significant only in the initial 12 months but not subsequently.

Table 3 Mean PtGA and PhyGA scores in the participants completing 2 years of treatment.

n = 84	PtGA	p-value*	PhyGA	p-value
Baseline	6.00 ± 2.25		5.44 ± 2.74	
3 months	4.53 ± 2.28		4.42 ± 2.17	
6 months	3.91 ± 1.98		3.73 ± 1.94	
9 months	3.32 ± 2.13		3.20 ± 1.91	
12 months	2.95 ± 2.09	0.000	2.67 ± 1.90	0.000
15 months	2.92 ± 2.24		2.65 ± 2.09	
18 months	3.15 ± 2.31		2.92 ± 2.27	
21 months	3.09 ± 2.25		2.83 ± 2.08	
24 months	3.63 ± 2.35		3.40 ± 2.32	

*Repeated measure ANOVA.

3.5 Treatment Response

Acute flares were seen in 157 participants, out of which 117 had a single episode, and 40 had multiple episodes. In total, 42 participants did not report back for treatment after the aggravation of complaints.

The numbers of participants with PASI 90–100, 75–89, and 50–74 at 3, 6, 9, and 12 months of treatment are presented in Figure 4. At 3 months, only 7% of the participants achieved PASI 90–100, which increased to 29% at 12 months. Furthermore, the percentage of participants achieving PASI 75–89 increased with treatment duration.

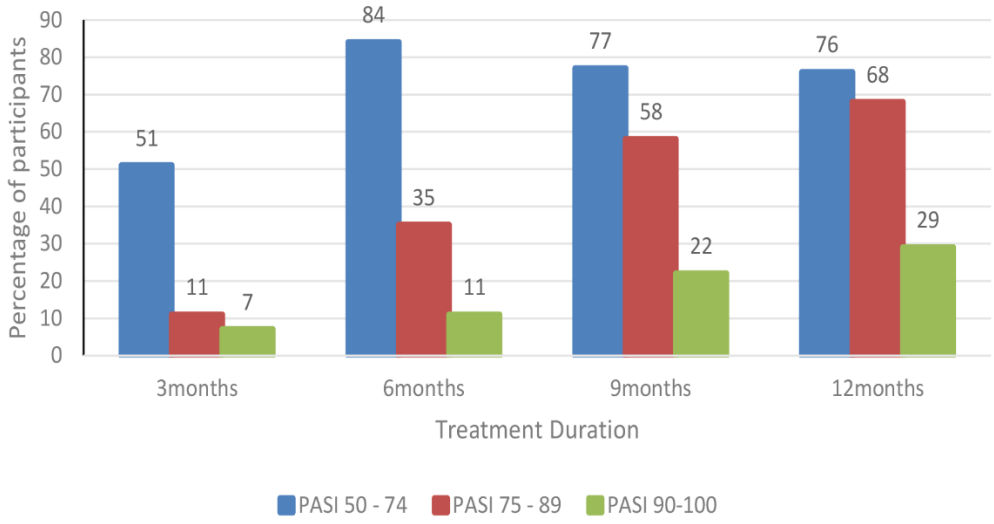

Figure 4 Percentages of participants achieving PASI reduction over the treatment period.

The difference between responders, partial responders, and non-responders at 12 and 24 months was not significant (Table 4). Among the responders, PASI 75–89 was observed in 66 and 14 participants at 12 and 24 months, respectively. Furthermore, PASI 90–100 was observed in 29 and 17 participants at 12 and 24 months, respectively.

Table 4 Response to treatment based on PASI scores in participants completing 12 and 24 months of treatment.

	At 12 months (n = 254)	At 24 months (n = 84)
Responders	99 (38.97%)	31 (36.90%)
Partial responders	77 (30.31%)	24 (28.57%)
Non-responders	60 (23.62%)	17 (20.23%)
Aggravation	18 (7.08%)	12 (14.28%)

Chi-square statistic is 4.1379; p-value is 0.25.

3.6 Effect of Demographic Variables on Treatment Response

The treatment responses were not related to age, gender, and illness duration at 12 and 24 months (Table 5) except for baseline severity, which was statistically significant. Out of 74 patients

with a severe presentation, 36.49% were responders, 40.54% were partial responders, and 22.97% were non-responders. The corresponding percentages for 61 patients with moderate presentations were 47.54%, 27.87%, and 24.59%, whereas those for 119 patients with mild presentations were 36.13%, 25.21%, and 38.66%, respectively.

Table 5 Distribution of factors in responders, partial responders, and non-responders completing 12 months of treatment.

		Non-responder n = 78	Partial responder n = 77	Responder n = 99	p-value*
Age	18–30 years	14	17	17	0.50
	31–40 years	27	26	27	
	41–50 years	18	23	30	
	51–60 years	19	11	25	
Gender	Male	49	40	65	0.16
	Female	29	37	34	
Duration of illness	Less than 1 years	5	2	7	0.40
	1 to Less than 5 years	25	19	36	
	5 to less than 10 years	20	24	26	
	10 years to less than 20 years	24	22	22	
	More than 20 years	4	10	8	
Baseline severity	Mild	46	30	43	0.04
	Moderate	15	17	29	
	Severe	17	30	27	

*Chi-square test.

3.7 Medicines Used

A total of 29 medicines were used as the first prescription (Table 6). Most of the medicines used were in 6C potency initially. No adverse events from treatments were identified. The assessments of the patients were made clinically as well as with scales to identify subsequent prescriptions (Figure 5, Figure 6, Figure 7). Among the patients completing 12 months of treatment, 26 continued with the same medicine in 6C potency. In 161 patients, the potency was increased progressively. In 67 patients, the medicine was changed. The prescriptions following the first prescription, both for the medicine and dosage, were as per the principles of homeopathy based on the symptoms of the patients.

Table 6 Medicines used.

Sl No.	Name of the Medicine	Prescribed	Responder	Partial responder	Nonresponder	Dropped out before completing 12 months of treatment
1	Sulphur	75	13	15	23	24

2	Natrum muriaticum	56	13	10	11	22
3	Phosphorus	37	12	4	8	13
4	Lycopodium	35	9	8	8	10
5	Arsenicum album	25	7	5	2	11
6	Pulsatilla	22	7	7	2	6
7	Sepia	18	3	6	1	8
8	Calcarea carbonicum	17	3	3	7	4
9	Kali arsenicum	10	7	1	2	0
10	Graphites	10	4	1	2	3
11	Nitric acid	6	3	1	0	2
12	Mercurius solubilis	6	2	1	0	3

The symptoms of the participants responding to medicines at 1 year were compiled for the medicines, where >35% of the participants were responders or partial responders (Supplementary Table S2).

Figure 5 Photographs of a 49 year old woman at the start, during and at end of treatment.

A 49-year-old woman presented with psoriasis on soles on January 25, 2017, at Regional Research Institute in Gudivada. She experienced excessive itching on the lesions. She was sensitive to people's remarks and tended to weep and get anxious easily. She had scanty sweat. She craved for sour food items and liked drinking milk. Arsenicum album 6C was prescribed to her. Medicine was repeated in the same potency as and when improvement stopped. Her PASI score reduced from 5.6 at baseline to 0.8 after 2 years of treatment.

Figure 6 Photographs of a 53 year old man at the start, during and at end of treatment.

A 53-year-old man was enrolled at Clinical Research Unit in Puducherry on November 16, 2017. His complaints started after a financial setback, and he was worried about money and related matters. He was an introvert and avoided asking for help. He was religious, did regular meditation, and was always willing to help others. His sleep was disturbed due to his worries. He had difficulty passing stool. He was a hot patient and craved for salt, curd, and spinach. He was prescribed natrum muriaticum 6C at baseline and at 2 months, natrum muriaticum 30C at 4 and 6 months, and natrum muriaticum 200 at 15 months. In between, a placebo was prescribed for as long as he showed improvement. Potency was raised when improvement stopped. The baseline PASI score

was 6.8, which reduced to 0.4 after 18 months of treatment and further reduced to 0 at 21 months, which continued to 2 years when the patient last reported.

Figure 7 Photographs of a 40 year old female at the start, during and at end of treatment.

A 40-year-old woman was enrolled at Regional Research Institute in Puri on December 21, 2017, with a baseline PASI score of 14.5, which increased to 31.9 at 3 months, 31 at 6 months, and 30.8 at 9 months and then reduced to 25.3 at 12 months, 25.5 at 15 months, and 18.6 at 18 months. She had erythematous scaly lesions with itching on the extremities, back, scalp, and abdomen, which aggravated during perspiration and ameliorated with the application of something warm. The patient had a burning sensation on lesions, which would aggravate on scratching and ameliorate on the application of something warm. She was sad and depressed because of her abusive husband. She had an aversion to milk, was thirstless, and had disturbed sleep. Arsenicum album 6C was prescribed initially, followed by arsenicum album 30 when the psoriasis lesion spread. Subsequently, she was prescribed natrum muriaticum 6C on April 19, 2018, the potency of which was increased to 30 and then 200, after which her lesions decreased gradually, and the PASI score reduced to 10.4 by November 21, 2019.

4. Discussion

The study is pragmatic in its approach to identifying the practice of homeopathic physicians in psoriasis treatment.

A progressive decrease in the scales' scores was observed, indicating a reduction in the severity of the condition and improvement in the quality of life during the initial treatment period of 12 months. Thereafter, no further decrease or increase in the scale scores was observed in the next 12 months. Psoriasis is a long-term clinical condition and requires long-term treatment. A large percentage of the participants continuing treatment achieved a reduction in the PASI scale score by >75%. The treatment response in the participants was independent of age, gender, and illness duration. Baseline severity was identified as the only factor affecting the treatment response. Other factors are likely responsible for the treatment effect, and the identification of such variables in future studies can lead to the development of models that can govern the treatment effect and can be moderated to improve the treatment effect. Among the participants who continued treatment for >12 months, no further reduction in disease severity was observed; moreover, the complaints remained static, and the treatment response seen in the initial months was sustained.

The treatment strategy involved having an understanding of the case in totality, including mental and physical (general and particular) symptoms in addition to skin-specific symptoms, and medicines were prescribed after considering these. In all the patients, 6C potency was used initially and was subsequently changed as per the requirement. Because patients with psoriasis present with physical complaints, treatment initiation with a low potency was decided at the time of protocol development.

The focus here is on individualized oral medicine and not on topical medicine, which is not recommended as per the principles of classical homeopathy. The pragmatic approach of the study reflects a high modal validity of the study, and the response identified is likely to be similar to treatment in clinical settings. However, newer treatment strategies, particularly philosophical concepts such as obstacles to cure, miasms, and second prescriptions, can be tested in future studies to improve response rates. This is especially important considering that although a response is achieved in the initial year of treatment and the treatment effect is sustained, the complaints do not improve further.

The symptoms of patients responding to the treatment can be validated in future studies on mathematical models. Several new symptoms have been identified in contemporary language and settings and can be a valuable addition to the *Materia Medica* and repertory after validation in other studies.

The duration of complaints varied markedly from less than a month to 38 years and going by the conventional approach, the treatment required is different for different stages of the condition and varies based on responses to previous medication. The treatment profile remains essentially the same in homeopathy, irrespective of the illness duration. The disease severity assessed by PASI in terms of the percentage area of involvement and type of lesion may determine the initial response, with patients with moderately severe presentations achieving >75% reduction in the scale compared with those with very severe and mild presentations.

However, a major limitation of this study is the high participant attrition, particularly during the second and third years of treatment. The participant attrition rate was 33.85% in the first year and

78.12% by the end of 2 years. The reasons for attrition were not detailed with participant data. However, some reasons for attrition were identified to be the long duration of treatment during which the participants lost patience, the disease reached a stable level, or the condition aggravated after a long period of stability or improvement, leading to disappointment with the treatment. Some participants had moved residences to places away from the treatment center, because of which they discontinued the treatment. However, these factors were identified only during a routine conversation with the patients and were not systematically collected data for patient attrition. In long-term studies, strategies for patient retention need to be additionally devised along with enrollment strategies.

Conducting randomized controlled trials on psoriasis is difficult as the standard treatment for the condition is different at different stages of the disease, and is not without side effects. Patients have different outlooks toward treatment acceptance and side effects. Long-term pragmatic studies on psoriasis have a higher translational value in clinical settings to identify not only treatment response but also prescription strategies to increase the response percentage.

Despite these limitations, this study identifies key considerations for homeopathic treatment in psoriasis, namely that the treatment response is not dependent on age, gender, and illness duration. The treatment must be based on symptoms in totality. The safety profile of the treatment is high, and the treatment response is high in patients undergoing treatment for 1 year, with a significant improvement after initial regular treatment for 6 months. The participants must be followed closely; a changing response may warrant a change in potency, dosage, and medicine.

The strengths of the study include large sample size, the use of a pragmatic approach, and the identification of medicines most useful for treatment. Changes in objective parameters measured with validated scales were used to identify the scope of homeopathic treatment in psoriasis.

5. Conclusion

The severity of psoriasis and the quality of life improved significantly with regular homeopathic treatment, with disease severity affecting the treatment effect.

Acknowledgments

We acknowledge the contribution of investigators associated with the project viz. Dr B Indira, NHRIMH Kottayam, Dr MS Ghosh, DACRRIH Kolkata, Dr JS Arya, CRUH, Siliguri, Dr M Prakash Rao, CRUH Puducherry, Dr Sarabjit Sarkar, RRIH Guwahati, for their contribution in enrollment of cases. Dr Rehana Prasad, Dr Madhumita Nath, Dr Sudeshna Saha, Dr Pranati Saha, Dr Santi Adhikary, Dr Abhiram Bannerjee, Dr Sangeetha, Dr P Madhappan were the research fellows who assisted the investigator at the centres during enrolment and follow up of cases. Dr Atul Juneja, former Scientist, ICMR-National Institute of Medical Statistics, New Delhi, provided guidance for statistical analysis. Mr Anurag Bajpai, statistical assistant, helped in statistical analysis. Ms Nisha Devi, Office Assistant, CCRH headquarters, provided secretarial assistance throughout the conduct of the project and in the manuscript development.

Author Contributions

Divya Taneja: Protocol development; Analysis and interpretation of data; Drafting the article; Final approval of the version to be submitted. **Madhumita Sadhukhan:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Padmalaya Rath:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Manas R Sarangi:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Renu Mittal:** Coordination for implementation of study; Compilation and consolidation of data; Drafting the article; Final approval of version to be submitted. **Akshaya Kumar Prusty:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Deepthi Gilla:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Ashish Shivadikar:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Birendra Rawat:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Ravi Kumar Sadarla:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Gurudev Choubey:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Nidhi Mahajan:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Renu Bala:** Acquisition of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Neha Kalra:** Compilation of data; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Anupam Mukherjee:** Compilation of symptoms of drugs; Drafting the article; Final approval of the version to be submitted. **Anil Khurana:** Conception and design of the study; Coordination for Study implementation; Framework for data consolidation and analysis; Revising the article critically for important intellectual content; Final approval of the version to be submitted. **Raj K. Manchanda:** Conception and design of the study; Approvals for study implementation; Revising the article critically for important intellectual content; Final approval of the version to be submitted.

Funding

The study was funded by the Central Council for Research in Homoeopathy, New Delhi, India from its own funds.

Competing Interests

The authors have declared that no competing interests exist.

Additional Materials

The following additional materials are uploaded at the page of this paper.

1. Table S1: Observational studies conducted on Psoriasis.
2. Table S2: Symptoms of Medicines used.

References

1. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS, Leonardi CL, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008; 58: 826-850.
2. Parisi R, Iskandar IYK, Kontopantelis E, Augustin M, Griffiths CEM, Ashcroft DM. National, regional, and worldwide epidemiology of psoriasis: Systematic analysis and modelling study. BMJ. 2020; 369: m1590.
3. Raharja A, Mahil SK, Barker JN. Psoriasis: A brief overview. Clin Med. 2021; 21: 170-173.
4. Dogra S, Yadav S. Psoriasis in India: Prevalence and pattern. Indian J Dermatol Venereol Leprol. 2010; 76: 595-601.
5. Raychaudhuri SK, Maverakis E, Raychaudhuri SP. Diagnosis and classification of psoriasis. Autoimmun Rev. 2014; 13: 490-495.
6. Kim WB, Jerome D, Yeung J. Diagnosis and management of psoriasis. Can Fam Physician. 2017; 63: 278-285.
7. Smolle J. Homeopathy in dermatology. Dermatol Ther. 2003; 16: 93-97.
8. Lilienthal S. Homoeopathic therapeutics. 5th ed. New Delhi: B. Jain Publishers (P) Ltd.; 2004. 910p.
9. Clarke J. The prescriber. 3rd ed. New Delhi: B. Jain Publishers (P) Ltd.; 2009. 267p.
10. Kent JT. Repertory of the homoeopathic Materia medica. 3rd ed. New Delhi: B. Jain Publishers (P) Ltd.; 2010. 1316p.
11. Barthel H, Klunker W. Synthesis RepertoriumHomeopathicum. Edition 9.1. New Delhi: B. Jain Publishers (P) Ltd.; 1991. pp. 1857-1858.
12. Nwabudike LC. Palmar and plantar psoriasis and homeopathy–Case reports. Our Dermatol Online. 2017; 8: 66-69.
13. Gupta G, Gupta N, Pandey DK, Gupta G. Psoriasis: Best case series. Homœopathic Links. 2019; 32: 064-076.
14. Mahesh S, Shah V, Mallappa M, Vithoulkas G. Psoriasis cases of same diagnosis but different phenotypes—Management through individualized homeopathic therapy. Clin Case Rep. 2019; 7: 1499-1507.
15. Panchal M. A case of chronic psoriasis. Homoeopath Links. 2006; 19: 22-24.
16. Jurj G. A case report of palmoplantar psoriasis treated with homeopathic Secale cornutum. Int J Complement Alt Med. 2020; 13: 74-77.
17. Witt CM, Ludtke R, Willich SN. Homeopathic treatment of patients with psoriasis–A prospective observational study with 2 years follow-up. J Eur Acad Dermatol Venereol. 2009; 23: 538-543.
18. Singh H, Manchanda RK, Arora S. Evaluation of homoeopathic drugs in Psoriasis. CCRH Q Bull. 1993; 15: 24-27.
19. Gupta, G. Evidence based clinical study on effect of homoeopathic drugs in psoriasis. Asian J Homoeopath. 2007; 1: 14-24.
20. Mohan GR. Clinical study of different types of psoriasis and homeopathic management. Homoeopath Links. 2013; 26: 135-138.

21. World Medical Association. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. JAMA. 2013; 310: 2191-2194.
22. WHO. Clinical Research. In: General guidelines for methodologies on research and evaluation of traditional medicine. Geneva: WHO; 2000. pp. 11-16.
23. Ibrahim GH, Buch MH, Lawson C, Waxman R, Helliwell PS. Evaluation of an existing screening tool for psoriatic arthritis in people with psoriasis and the development of a new instrument: The Psoriasis Epidemiology Screening Tool (PEST) questionnaire. Clin Exp Rheumatol. 2009; 27: 469-474.
24. Bannerjee DD. Augmented textbook of homoeopathic pharmacy. 2nd ed. New Delhi: B. Jain Publishers Pvt Ltd.; 2007. p. 76.
25. Psoriasis Area and Severity Index (PASI). Psoriasis area and severity index (PASI) worksheet [Internet]. London: British Association of Dermatologists. Available from: https://cdn.bad.org.uk/uploads/2021/12/29200150/Psoriasis-Area-and-Severity-Index-PASI-01.10.12.pdf.
26. Carlin CS, Feldman SR, Krueger JG, Menter A, Krueger GG. A 50% reduction in the Psoriasis Area and Severity Index (PASI 50) is a clinically significant endpoint in the assessment of psoriasis. J Am Acad Dermatol. 2004; 50: 859-866.
27. Psoriasis Disability Index [Internet]. Cardiff: Cardiff University; [cited date 2021 November 12]. Available from: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/psoriasis-disability-index.
28. Sevar R. Audit of outcome in 829 consecutive patients treated with homeopathic medicines. Br Homeopath J. 2000; 89: 178-187.
29. Biau DJ, Kernéis S, Porcher R. Statistics in brief: The importance of sample size in the planning and interpretation of medical research. Clin Orthop Relat Res. 2008; 466: 2282-2288.
30. Schmitt J, Wozel G. The psoriasis area and severity index is the adequate criterion to define severity in chronic plaque-type psoriasis. Dermatology. 2005; 210: 194-199.