



RESEARCH ARTICLE

Preliminary efficacy of shallakyadi capsules (Ayurvedic intervention) on post-chikungunya chronic inflammatory rheumatism: Single-arm, open-label clinical trial

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Abstract

Over 40 % of chikungunya (CHIK) patients develop arthritic manifestations resembling amavata disease as described in Ayurveda. Therefore, a clinical trial was planned to establish the efficacy and safety of the Ayurvedic medicine shallakyadi capsules on post-chikungunya chronic inflammatory rheumatism (pCHIK-CIR). A single-centre, open-label, single-arm, clinical trial was conducted on the participants with pCHIK-CIR. A total of 90 participants were treated with shallakyadi capsule, in a dose of two capsules twice daily (each of 500 mg), orally before lunch and dinner for two months. The primary outcomes were disease activity score (DAS-28) and clinical disease activity index (CDAI), while secondary outcomes were health assessment questionnaire (HAQ) and changes in clinical symptoms. Mean changes were calculated using paired *t*-tests (for continuous data) and the Wilcoxon signed-rank test (ordinal data). A significant improvement was observed in the changes between before and after treatment for the primary and secondary outcomes, viz. DAS-28 (mean difference (MD) $\pm$ standard deviation (SD): 1.27 ± 0.74 , $p < 0.001$), CDAI (MD $\pm$ SD: 8.85 ± 4.34 , $p < 0.001$), HAQ (MD $\pm$ SD: 13.73 ± 5.71 , $p < 0.001$). In contrast, changes in C-reactive protein (CRP) (MD $\pm$ SD: 1.17 ± 9.3 , $p = 0.25$) and erythrocyte sedimentation rate (ESR) (MD $\pm$ SD: 2.1 ± 13.1 , $p = 0.14$) were statistically insignificant. No adverse drug reactions were observed. Shallakyadi capsule improves disease activity, quality of life and symptomatic relief with no adverse effects in pCHIK-CIR cases during a two-month treatment regimen. The study demonstrates the feasibility and potential of Ayurvedic treatment for post-chikungunya arthritis, underscoring the need for larger, well-designed multicentre trials.

Keywords: ayurveda; *Boswellia serrata*; chikungunya; post-chikungunya chronic inflammatory rheumatism; shallaki

Introduction

The chikungunya virus (CHIKV) is an arbovirus that is spread by Aedes mosquitoes. It causes CHIK fever (1). It is projected that 39% of the world's population lives in countries where CHIKV is common and is at risk of contracting it (2). Although CHIK fever typically resolves within 5–14 days in most patients (3), more than 40 % of patients develop arthritic manifestations. The CHIKV disease is associated with the onset of nonspecific post-viral arthritis, rheumatoid arthritis, seronegative spondylitis and other noninflammatory musculoskeletal manifestations such as persistent arthralgia. The rheumatic characteristics of CHIK include symmetrical polyarthritis, frequently involving the hands and feet, which resembles rheumatoid arthritis; nonspecific arthralgias indicative of post-viral arthritis; or asymmetric oligoarthritis or monoarthritis, akin to seronegative spondyloarthritis (3). Post-viral polyarthralgia, fibromyalgia, chronic joint pain, adhesive capsulitis and plantar fasciitis are some of the other features (4–6). If these arthritic symptoms remain for more than three months after the

start of CHIK fever, the disease is called post-chikungunya chronic inflammatory rheumatism (pCHIK-CIR) (7). The overall prevalence of pCHIK-CIR is 40.22 % [95 % CI, (31.11–49.34 %)], while in the Indian subcontinent, it is 27.27 % [95 % CI, (15.66–38.88 %)] (4). These clinical progressions affect the quality of life, considerably impact the strained health system (8) and subsequently increase direct and indirect economic loss (9,10).

Paracetamol (for mild symptoms), a short course of corticosteroids and disease-modifying antirheumatic drugs (DMARDs) (for moderate to severe symptoms) are the advised treatment protocol for this condition (11, 12). Long-term use of these medicines are associated with significant adverse effects and thus necessitates the quest for the role of traditional medicines (13–15). Ayurveda has been practiced in Southeast Asian regions for ages and provides details about the chronic musculoskeletal diseases.

Ayurveda is a widely utilised traditional medicine system in Southeast Asia, particularly in the Indian subcontinent (16). The clinical manifestation of pCHIK-CIR can be associated with the

chronic phase of amavata disease as delineated in Ayurvedic literature. Ama is a product of incorrect metabolism, which is not homogenous for the body. When vata dosha (regulatory functional factors of the body responsible for movement and cognition), along with ama, involves various joints of the body, pain, stiffness and swelling occur, which get aggravated during the morning time and after movement of the affected joints. Amavata, in its chronic state, results in chronic inflammation and symmetrical polyarthritis, analogous to pCHIK-CIR. Ayurvedic literature contains numerous references to pharmacological agents employed in the management of amavata due to their specific activities, including deepana (digestion and metabolism enhancer), pachana (digestion enhancer), vedanahara (analgesic action) and shothahara (anti-inflammatory action). Herbs with these properties may help stop the condition from getting worse and manage the inflammation in the affected joints.

Considering these facts, a clinical trial to establish the clinical efficacy and safety of the shallakyadi capsule was planned. Shallakyadi capsules contain extracts of shallaki (*Boswellia serrata* Roxb.), nirgundi (*Vitex negundo* L.), triphala (fine powder of equal parts of fruits of three myrobalans; *Embolia officinalis* Gaertn. (amalaki), *Terminalia bellirica* (Gaertn.) Roxb. (bibhitaki) and *Terminalia chebula* Retz. (haritaki)), bhumyamalaki (*Phyllanthus niruri* Linn.) and kiratatikta (*Swertia chirayita* (Roxb.) H. Karst).

Materials and Methods

Trial design

This study was a single-centre, prospective, open-label, single-arm, before-and-after clinical trial conducted in the outpatient department (OPD) of the hospital.

Participants

Eligibility criteria

Eligible participants were individuals of either sex, regardless of their caste or religion, who were between 18 and 70 years of age and agreed to participate.

Inclusion criteria

The participants suffering from pCHIK-CIR and fulfilling the diagnostic criteria (17) i.e., involvement of more than 4 joints with arthritis for a duration of > 6 weeks, having synovitis or heat and/or erythema on the joint or morning stiffness > 30 min or inflammatory pain that improves with exercise and is worsens with rest or during the night were included.

For confirmation of past exposure to CHIK fever, any of the following criteria were followed: i) A patient has a history of an acute onset of fever, usually with chills/rigours, which lasts for 3–5 days with multiple joint pains/swelling of extremities that may continue. ii) Epidemiological criteria: individuals residing at or visiting an endemic or epidemic area 15 days before the onset of symptoms have an epidemiological connection to a confirmed area. iii) Biological proof of infection confirmed by any one of the following at the time of infection: a) Isolation of virus in culture, b) CHIKV RNA by real-time polymerase chain reaction (PCR), c) specific anti-CHIKV IgM antibody, d) demonstration of rising titre of IgG antibody.

Exclusion criteria

Participants who had a history of rheumatoid arthritis, gout, psoriatic arthritis, rheumatic fever, autoimmune diseases, thyroid dysfunction, sarcoidosis and systemic lupus erythematosus (SLE) before CHIK fever, suffering from malignant and accelerated hypertension, coronary artery disease and uncontrolled diabetes, were excluded.

Recruitment method

The recruitment process was carried out targeting patients suffering from pCHIK-CIR. Recruitment involved direct recruitment of patients at the Kayachikitsa OPD and referrals by other OPD physicians who screened patients presenting with joint-related complaints following a history of fever. Posters and institutional notice boards displaying trial information, inviting potentially eligible patients to contact the study coordinator, were displayed in part of the recruitment process. Eligibility was established by a screening process utilising the predefined criteria. The participants who met the inclusion criteria and were not subject to any exclusion criteria received comprehensive information about the trial in a comprehensible language. Written informed consent was obtained before enrolment. After getting the informed consent, baseline assessments were conducted and the participants were officially enrolled into the study for further treatment and evaluation as per the trial protocol.

Interventions

All the ingredients of the shallakyadi capsule were procured in aqueous extract form from a local pharmacy. The details of the ingredients and their proportions are presented in Table 1. Drugs were authenticated in the Pharmacognosy laboratory of the institute. Quality control data and safety analyses were conducted prior to clinical use and all parameters were found to be within normal limits as per Ayurvedic Pharmacopoeia of India (API) standards. Extracts were encapsulated under aseptic conditions into gelatin-based capsules.

Table 1. Ingredients of the shallakyadi capsule

Sl. No.	Name of the drug	Botanical name	Part used ^a	Proportion [*] (mg)
1	Shallaki	<i>Boswellia serrata</i> Roxb.	Resin	200
2	Nirgundi	<i>Vitex negundo</i> Linn.	Leaf	75
3	Triphala	Equal parts of: Haritaki- <i>Terminalia chebula</i> Retz. Vibhitaki- <i>Terminalia bellirica</i> (Gaertn.) Roxb. Amalaki- <i>Embolia officinalis</i> Gaertn.	Fruits	75
4	Bhumyamalaki	<i>Phyllanthus niruri</i> Linn.	Whole plant	75
5	Kiratatikta	<i>Swertia chirayita</i> (Roxb. ex Flem.) Karsten	Whole plant	75

^{*} Each capsule of 500 mg; ^a in extract form.

The intervention drug was given to the enrolled participants in a dose of two capsules twice a day (each of 500 mg), before lunch and dinner with lukewarm water orally for two months. Records of the dispensed medicine were maintained in a drug inventory form. Disease-modifying antirheumatic drugs, corticosteroids and other immunosuppressive or anti-inflammatory therapies were not permitted during the study period. A minimum washout period of seven days was required before enrollment for restricted medications. Analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs) were allowed only as rescue medication and their use was recorded in the case record form (CRF) at each follow-up visit.

Outcomes

Primary outcome

Change in mean at the end of treatment from baseline for disease activity score (DAS-28) (18): Evaluated using a 28-joint count, incorporating tender joint count (TJC-28), swollen joint count (SJC-28), patient's global assessment of disease activity (VAS scale) and erythrocyte sedimentation rate (ESR).

Change in mean at the end of treatment from baseline for clinical disease activity index (CDAI) (19): Calculated based on TJC-28 and SJC-28 patient's global disease activity assessment and physician's global disease activity assessment.

Secondary outcome

Quality of life assessment: Evaluated using the health assessment questionnaire (HAQ) to assess functional disability in patients with pCHIK-CIR (20). The mean change in HAQ scores from baseline to the end of the treatment period was considered.

Symptomatic relief in clinical features: Change in median score of chief clinical symptoms of pCHIK-CIR, including multiple joint pain (assessed using the visual analog scale), morning stiffness, joint tenderness, redness, elevated joint temperature, joint swelling and

restricted joint movements, was assessed. These symptoms were scored using a standardised 0–3 severity scale as described in Table 2.

Adverse events

The number and nature of adverse events, both serious and non-serious, were recorded and monitored throughout the study period to assess the safety of the intervention.

Data management

A CRF was developed and designed to include the required demographic, clinical and outcome data according to the research question and the objectives of the study. The CRF was paper-based and filled out during the hospital visit of the participant by the senior research fellow (SRF) of the project. Data from the CRF were entered into pre-specified Excel sheets by the SRF. The data entry was verified with the double data entry method. The data on the personal details of the participants were kept confidential by the principal investigator of the project.

Statistical analysis

The IBM SPSS software was used to analyse all of the data that was gathered. Continuous data were presented as means and standard deviations (SDs), rank data as medians and interquartile ranges (IQR) and categorical variables as frequencies and percentages. The Wilcoxon signed-rank test was employed for paired ordinal data, while paired *t*-tests were administered to assess within-group changes for continuous data. A *p*-value of less than 0.05 was deemed statistically significant. The Wilcoxon test was performed to evaluate the magnitude of changes. The rank-biserial correlation coefficient (*r*) was used to compute effect sizes, with *r* = 0.1 representing a small effect, 0.3 a medium effect and ≥ 0.5 a large effect. Cohen's *d* was used for paired *t*-tests. A value of 0.2 indicates a minor effect, 0.5 a medium effect and ≥ 0.8 a large effect, reflecting the level of treatment influence.

Table 2. Scoring pattern for grading subjective parameters

I	Stiffness (sandhigraha)	
1	No stiffness	0
2	Stiffness lasted for 5–15 min	1
3	Stiffness lasted for 15–30 min	2
4	Stiffness lasted for more than 30 min	3
II	Tenderness (sparshasayata)	
1	No tenderness	0
2	Wincing of the face on pressure	1
3	Wincing of the face and withdrawal of the affected part on pressure	2
4	Resists to touch	3
III	Redness (raktima)	
1	No redness	0
2	Redness over one joint	1
3	Redness over two joints	2
4	Redness over more than two joints	3
IV	Temperature over joint skin (ushnata)	
1	Normal body temperature	0
2	Feeling warmth compared to normal body temperature in one joint	1
3	Feeling warmth compared to normal body temperature in two joints	2
4	Feeling warmth compared to normal body temperature in more than 2 joints	3
V	Swelling (shotha)	
1	No swelling	0
2	Swelling in one joint	1
3	Swelling in two joints	2
4	Swelling in more than two joints	3
VI	Restriction of movement (sandhigraha)	
1	Normal movement	0
2	Normal movement with pain	1
3	Slight movement with pain	2
4	Unable to move	3

Results

Recruitment

The patients were enrolled from July 2021 to August 2022. For the present clinical trial, 90 participants were registered. Out of these 84 (93.3 %) participants completed the two months of treatment with shallakyadi capsules as prescribed in the protocol, 6 (6.7 %) participants discontinued treatment due to various personal reasons (Fig. 1).

Baseline demographics

Demographic data, viz. gender, age, religion, dietary practices, socio-economic status, educational qualification, occupation and chronicity were collected on the first day of the recruitment. The details of the demographic characteristics of the participants at the baseline are mentioned in Table 3.

The baseline demographic profile of the 90 participants showed that the majority were female (80 %) and predominantly in the age group of 51–60 years (26.6 %). Most participants (98.9 %) were Hindu and followed a vegetarian diet (83.33 %). Socio-economically, 94.4 % belonged to the middle class. In terms of education, over half (54.4 %) fell into the 'others' category, with a smaller proportion having completed higher secondary or higher education. The occupational distribution demonstrated that 71.1 % of the people were housewives. The rest were servicemen, retired

people, merchants, students and labourers. Most participants (67.8 %) reported that they had been sick for less than three months, indicating that their symptoms were relatively recent. Only 24.4 % of patients reported symptoms for 3–6 months, 4.4 % for 6–12 months and 3.3 % for 1–2 years. A smaller proportion of patients reported symptoms for a prolonged duration of disease. None of the patients reported regular use of corticosteroids, NSAIDs or any anti-inflammatory drugs at the baseline.

Primary outcomes

Table 4 illustrates the effect of therapy on primary outcomes. The mean score for DAS-28 before treatment (BT) was 4.06 ± 0.87 , which reduced significantly to 2.78 ± 0.87 . The statistical significance of this mean difference (MD) of 1.27 ± 0.74 was highly significant ($t = 15.61$, $p < 0.001$). The CDAI score was also reduced from 17.58 ± 6.27 BT to 8.73 ± 5.38 after treatment. The average difference was 8.85 ± 4.34 and the reduction was also highly statistically significant ($t = 18.66$, $p < 0.001$). In conclusion, both DAS-28 and CDAI scores exhibited substantial reductions in post-intervention, suggesting a favourable treatment effect.

Secondary outcomes

Table 5 presents changes in cardinal symptoms and biomarkers before and after treatment. The scores on the HAQ revealed a significant improvement, improving from a mean of 29.1 ± 6.6 at the outset to 15.3 ± 7.5 after treatment. The mean change was

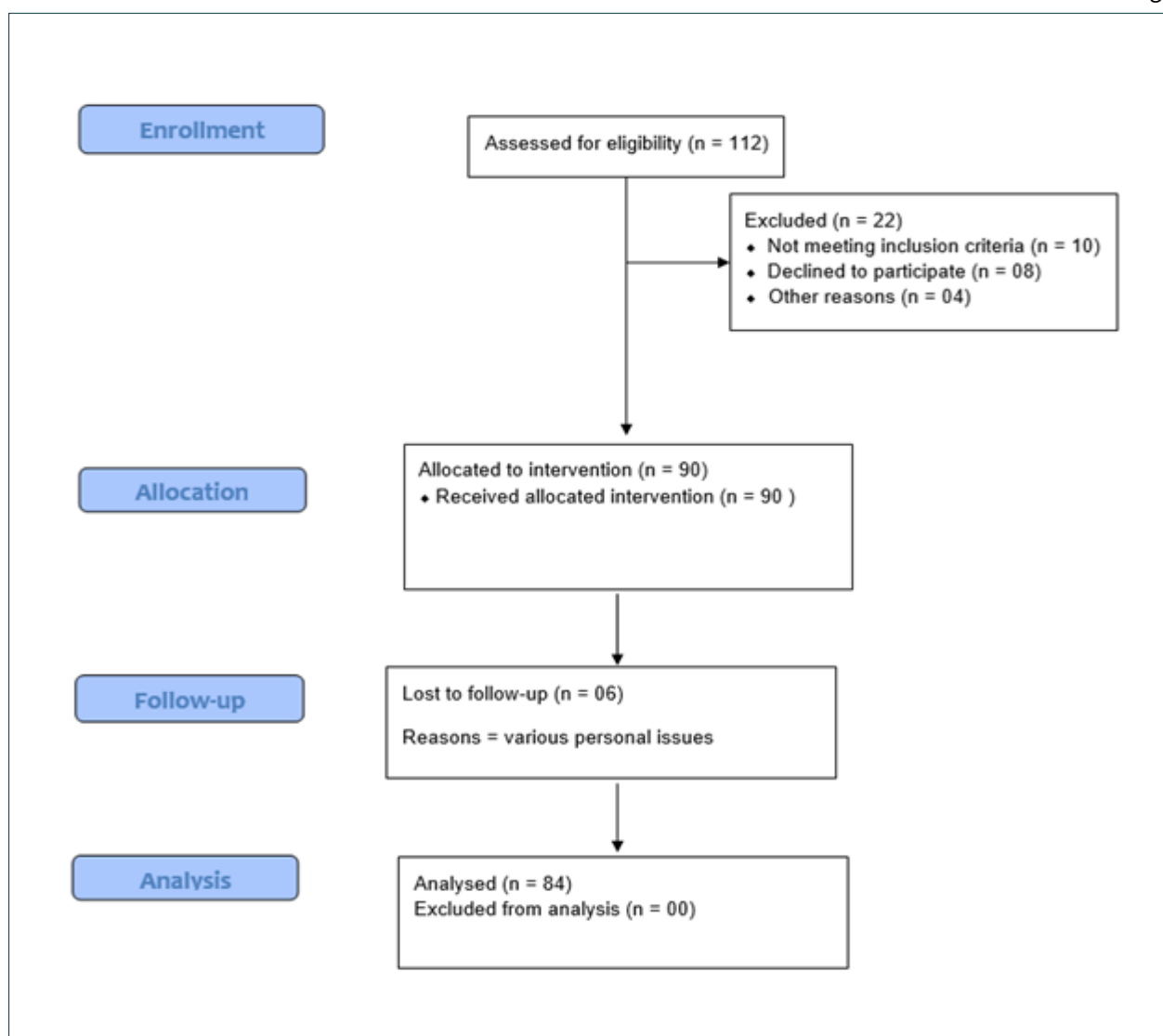


Fig. 1. Participant flow chart.

Table 3. Demographic characteristics of the study participants at baseline

Sl. No.	Variable	Category	Number of participants (%)
1	Gender	Male	18 (20)
		Female	72 (80)
2	Age	18–30 years	15 (16.6)
		31–40 years	19 (21.1)
		41–50 years	21 (23.3)
		51–60 years	24 (26.6)
		61–70 years	11 (12.2)
3	Religion	Hindu	89 (98.9)
		Muslim	1 (1.1)
4	Dietary practices	Vegetarian	75 (83.33)
		Mixed	15 (16.66)
5	Socio-economic status	Poor	5 (5.6)
		Middle class	85 (94.4)
		Illiterate	5 (5.6)
6	Educational status	Higher Secondary	17 (18.9)
		Graduate	13 (14.4)
		Postgraduate	6 (6.7)
		Others	49 (54.4)
		Serviceman	7 (7.8)
7	Occupational status	Businessman	5 (5.6)
		Labourer	3 (3.3)
		Student	4 (4.4)
		Housewife	64 (71.1)
		Retired	7 (7.8)
8	Chronicity	< 3 months	61 (67.8)
		3–6 months	22 (24.4)
		6–12 months	4 (4.4)
		1–2 years	3 (3.3)

Table 4. The effect of shallakyadi capsule on primary outcomes (DAS-28 and CDAI score)

Outcomes	n	BT (Mean ± SD)	AT (Mean ± SD)	Difference (Mean ± SD)	t	p
DAS-28	84	4.06 ± 0.87	2.78 ± 0.87	1.27 ± 0.74	15.61	< 0.001
CDAI score	84	17.58 ± 6.27	8.73 ± 5.38	8.85 ± 4.34	18.66	< 0.001

DAS-28: disease activity score 28; CDAI: clinical disease activity index (CDAI) for rheumatoid arthritis; BT: before treatment; AT: after treatment; SD: standard deviation; t: test statistic value of paired t test; p: p-value.

13.73 ± 5.71, suggesting considerable functional improvement ($t = 22.0, p < 0.001$). C-reactive protein (CRP) levels exhibited a slight decrease from 5.59 ± 8.9 mg/dL to 4.4 ± 3.5 mg/dL, with a MD of 1.17 ± 9.3, which was not statistically significant ($t = 1.1, p = 0.25$). The ESR also decreased slightly, from 22.0 ± 15.2 mm/hr to 19.8 ± 12.7 mm/hr, with a MD of 2.1 ± 13.1, which was likewise not statistically significant ($t = 1.5, p = 0.14$). Clinically, all values were within normal ranges. The HAQ had a large effect size (Cohen's $d = 2.40$), indicating a substantial improvement in function. The CRP ($d = 0.13$) and ESR ($d = 0.16$) had minimal to no effect sizes, which means that the changes in inflammatory markers were very small.

After treatment, all the cardinal symptoms improved significantly. The median pain score dropped from 6 (IQR: 5–7) to 3 (2–5), the edema from 2 (0–3) to 0 (0–2) and the morning stiffness from 3 (2–3) to 1 (1–2). Tenderness reduced from 1 (1–1) to 0 (0–0.75),

redness from 3 (0–3) to 0 (0–2), temperature from 3 (2–3) to 0 (0–2) and mobility restriction from 2 (2–2) to 1 (1–1). All improvements were statistically significant ($p < 0.001$), with effect sizes (r) between -0.79 and -0.89, which means that the intervention had significant effects on physical well-being. Table 6 shows a summary of all changes.

Haematological safety

Table 7 illustrates haematological parameter changes before and during the intervention. There were no statistically significant differences in hemoglobin, total leukocyte count, differential counts (neutrophils, lymphocytes, eosinophils, monocytes and basophils), red blood cells (RBC) count, or packed cell volume (PCV) (all $p > 0.05$ except for basophils, $p = 0.02$, which was not clinically pertinent). These results show that the intervention did not have any adverse or potentially hazardous impacts on blood parameters, which supports its haematological safety.

Table 5. The effect of shallakyadi capsule on secondary outcomes (HAQ, CRP and ESR)

Outcomes	n	BT (Mean ± SD)	AT (Mean ± SD)	Difference (Mean ± SD)	t	p	Cohen's d
HAQ	84	29.1 ± 6.6	15.3 ± 7.5	13.73 ± 5.71	22.0	< 0.001	2.4
CRP (mg/dL)	83	5.59 ± 8.9	4.4 ± 3.5	1.17 ± 9.3	1.1	0.25	0.13
ESR (mm/1 st hr)	83	22.0 ± 15.2	19.8 ± 12.7	2.1 ± 13.1	1.5	0.14	0.16

BT: before treatment; AT: after treatment; SD: standard deviation; HAQ: health assessment questionnaire; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; t: test statistic value of paired t test; p: p-value.

Table 6. The effect of shallakyadi capsule on chief symptoms

Cardinal symptoms	n	BT MD (IQR)	AT MD (IQR)	test statistic (Z)	p-value (p)	Effect size (r)
Pain in joints	84	6 (5–7)	3 (2–5)	-8.03	< 0.001	-0.87
Swelling in joints	46	2 (0–3)	0 (0–2)	-5.35	< 0.001	-0.79
Morning stiffness	84	3 (2–3)	1 (1–2)	-7.75	< 0.001	-0.84
Tenderness	76	1 (1–1)	0 (0–0.75)	-7.78	< 0.001	-0.89
Redness	60	3 (0–3)	0 (0–2)	-6.43	< 0.001	-0.83
Temperature	71	3 (2–3)	0 (0–2)	-7.02	< 0.001	-0.83
Restriction of movement	84	2 (2–2)	1 (1–1)	-7.82	< 0.001	-0.85

Wilcoxon signed ranks test (based on positive ranks); BT: before treatment; AT: after treatment; MD: median; IQR: inter quartile range.

Table 7. The effect of shallakyadi capsule on haematological safety

Parameters	n	BT (Mean ± SD)	AT (Mean ± SD)	Difference (Mean ± SD)	t	p
Hb	83	12.02 ± 1.57	12.07 ± 1.63	-0.042 ± 0.77	-0.49	0.62
TLC	83	7282.9 ± 2160.5	7251.8 ± 2143.2	31.09 ± 2068.69	0.13	0.89
Neutrophils	83	59.3 ± 8.5	59.07 ± 8.6	0.24 ± 9.26	0.24	0.80
Lymphocytes	83	31.8 ± 8.16	32.3 ± 8.15	-0.59 ± 8.88	-0.60	0.54
Eosinophils	83	2.9 ± 1.79	2.7 ± 1.67	0.15 ± 1.71	0.81	0.41
Monocytes	83	5.4 ± 1.87	5.3 ± 1.40	0.14 ± 1.33	0.97	0.33
Basophils	83	0.5 ± 0.22	0.4 ± 0.22	0.04 ± 0.19	2.2	0.02
Total RBC	83	4.5 ± 0.62	4.5 ± 0.61	-0.05 ± 0.27	-1.7	0.09
PCV	83	37.3 ± 4.22	37.5 ± 4.31	-0.13 ± 2.46	-0.48	0.63

BT: before treatment; AT: after treatment; SD: standard deviation; t: test statistic value of paired t test; p: p-value; Hb: hemoglobin; TLC: total leukocyte count; RBC: red blood cells; PCV: packed cell volume.

Adverse events

During the full course of treatment with the shallakyadi capsule and in the follow-up period, none of the participants reported any untoward complaints related to the medicine. All the haematological parameters were within normal limits and the administration of trial drugs did not produce any clinically relevant changes in them. No rescue medicines or any supportive medicines were needed during the period of the study or the follow-up of the study. This factor establishes the safety profile of the drug.

Discussion

This study is the first clinical trial in the Ayush system to evaluate the safety and efficacy of shallakyadi capsules in people with pCHIK-CIR. To the best of the authors' knowledge, no previous clinical research has investigated the role of Ayurvedic herbs in post-chikungunya arthritis, except for a few isolated case reports (21). While a few preclinical studies have indicated the possible effects of ashwagandha (*Withania somnifera* (Linn.) Dunal) (22) and andrographolide (23) in *in vivo* models, as well as a Siddha formulation (24) explored in a comparable way, clinical evidence is mostly uncharted. This work aims to address this deficiency by proposing an Ayurvedic therapeutic approach for a condition that significantly impacts quality of life and places a strain on the healthcare system.

According to the results of this single-centre, open-label, before-and-after study, shallakyadi capsules provide significant enhancements in disease activity, quality of life and symptomatic alleviation for individuals with pCHIK-CIR. Notably, substantial enhancements were noted in DAS, including DAS-28 and the CDAI

scale, while patient-reported outcomes, such as the HAQ and a standardised 0–3 symptom severity scale, also exhibited clinical significance. The intervention appeared to confer sustained analgesia because no rescue or supportive medications were needed during the treatment phase.

Even though inflammatory markers like CRP and ESR only changed a little, the participants felt a lot better and got better at doing things, which suggests that the drug's effects may go beyond just lowering inflammation in the body. The lack of significant change in CRP and ESR may be explained by several factors. First, the baseline values of these markers were not markedly elevated in many participants, which may have produced a floor effect and limited the possibility of detecting a meaningful decline after treatment. Second, pCHIK-CIR may persist in some patients with predominant pain, stiffness, fatigue and functional limitation rather than active systemic inflammation (25).

While CHIK is not specifically discussed in Ayurvedic classics, its clinical appearance of fever and joint issues might be theoretically associated with sandhigata sannipata jwara in the acute phase (26) and the amavata stage (27). Shallakyadi capsules, which contain herbs such as *B. serrata* (shallaki) and *V. negundo* (nirgundi), have been well-documented for their efficacy in osteoarthritis and rheumatoid arthritis, having analgesic and anti-inflammatory effects (28–30). Other substances, such as bhumyamalaki (31), kiratatikta (32) and triphala (33) are commonly utilised in the treatment of Jwara (hyperthermia) due to their tikta rasa (bitter taste), laghu guna (light property) and rasa dhatu (the body's component with nutrients and essence) affinity. The formulation's combination of jwaraghna, amapacana and shoolahara activities aids in resolving the pathophysiology of pCHIK-CIR by targeting both residual ama

and associated inflammatory symptoms.

Its acceptability and preliminary safety are further supported by the low dropout rate and no adverse drug reactions or laboratory abnormalities were recorded during the trial. These findings establish a vital baseline for subsequent randomised controlled trials by providing effect-size estimates and insights into feasibility and demographic variables.

However, there are significant limitations to the study. The open-label, uncontrolled design creates the potential for selection and information bias; therefore, the findings of this study should be considered preliminary, exploratory and hypothesis-generating. Furthermore, it was a short-term (two months) study conducted at a single centre with a small sample size of 90 individuals, limiting the generalisability and strength of the findings. Future controlled studies with a larger sample sizes, longer follow-up and stratification based on baseline inflammatory marker levels are required to determine whether shallakyadi capsules have a measurable effect on systemic inflammation in pCHIK-CIR.

Conclusion

The present single-arm before-and-after clinical study observed significant improvements in disease activity score (DAS-28), clinical disease activity index (CDAI), health assessment questionnaire (HAQ) and clinical symptom scores among patients with post-chikungunya chronic inflammatory rheumatism (pCHIK-CIR) following treatment with shallakyadi capsules for two months. The formulation was well tolerated, with no reported adverse events or clinically relevant haematological abnormalities. However, C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) did not show significant changes; therefore, the findings should be interpreted as preliminary evidence of symptomatic and functional improvement rather than definitive anti-inflammatory efficacy. Further adequately powered randomised controlled trials with longer follow-up are required to confirm these findings.

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Authors' contributions

MG, KP, RK and GA contributed to conceptualisation and methodology/study design. MG, KP, RK and SDP contributed to investigation and data curation. MG and KP contributed to writing—review and editing and writing—original draft, respectively. KP and RK contributed to visualisation, while MG contributed to visualisation, supervision, project administration and funding acquisition. GA contributed to supervision and project administration. All authors read and approved the final manuscript.

Compliance with ethical standards

Conflict of interest: Authors do not have any conflict of interests to declare.

Ethical issues: The trial was prospectively registered under the Clinical Trials Registry, India (CTRI/2021/04/033079) after obtaining ethical approval from the Institutional Ethics Committee (PGT/7/-A/Ethics/2020-21/2158).

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