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Original Article

Evaluation of Myostaal SB in Osteopenia Management through Bone Remineralization: A Proof-of-Concept, Open-Label, Single-Arm Study in Middle-Aged and Older Adults

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ABSTRACT

Background: Myostaal SB is a rational herbo-mineral Ayurveda formulation for management of *Asthikshaya* (~ osteopenia). It contains *Kukkutandatvak Bhasma* (Processed Hen-egg Shell), *Asthisamhruta* (*Cissus quadrangularis*), and *Shatavari* (*Asparagus racemosus*). Present proof-of-concept clinical study was planned to explore its efficacy in osteopenia management. The primary objective was to evaluate improvement of Bone Mineral Density (BMD) scores in DEXA scan. The effect on bone health biochemical markers viz., serum Alkaline Phosphatase, Parathyroid and Vitamin D were also assessed, along with clinical and quality of life improvement. **Materials and Methods:** Total 35 adults of either sex aged, 40-75 years suffering from osteopenia with BMD T-score between -1 to -2.5 were allocated to intervention. All participants had a documented history of fractures likely resulting from low-impact trauma or injuries. Tab. Myostaal SB was given in a dose of one tablet thrice a day for 180 days. The baseline parameters, laboratory investigations were done as per the protocol. Data generated through clinical study were subjected to appropriate statistical tests. **Results:** The results indicated significant BMD improvement in mean T-scores of AP spine and radius and marked improvement in femur and femur neck. Significant reduction in ALP and PTH; and marked improvement in Vitamin D levels were observed. Clinical improvement and improved quality of life were also noted. No adverse events were reported. **Conclusion:** The positive role of Myostaal SB in bone remodeling was confirmed with improvement in bone strength and bone resorption markers. Thus, Myostaal SB Tablets can play a positive role in the management of osteopenia.

Keywords: Osteoporosis, *Cissus quadrangularis*, DEXA, Bone Health, Bone Mineral Density, BMD.

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INTRODUCTION

Throughout lifetime, our skeletal system continuously goes through a transformation, the 'bone remodeling'. It safeguards the system's structural integrity and supports maintenance of body's Calcium (Ca) and Phosphorous (P) metabolism. This remodeling majorly comprises of activity for deposition of new bone material (osteoblast activity) after the resorption of old or damaged bone (osteoclast activity) (Siddiqui and Partridge, 2016). The repair of microdamage in the bone matrix also prevents the accumulation of old bone tissue. The plasma Ca homeostasis is chiefly maintained by Parathyroid Hormone (PTH) (Sherwood 1968). While raising serum Ca levels, PTH regulates osteoclast mediated bone resorption activity. PTH directly acts on bones via the influence of vitamin D. Thus, vitamin D plays a central role in calcium and bone homeostasis too. This interaction between hormones and bone cells can lead to a variety of pathological outcomes for bone health. Moreover, as the age advances, bone resorption surpasses bone production (Salari *et al.*, 2021). This ultimately lowers bone mass and bone density.

Osteopenia is a condition where Bone Mineral Density (BMD) T score is between -1 to -2.5, as the bone density is lower than the

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usual age-appropriate value. Its consequent form, osteoporosis, denotes more severe loss in BMD with T score < -2.5. Such loss weakens the bones, making them more prone to fracture. Every year, around 200 million individuals worldwide experience osteoporosis, with its exact incidence and prevalence unknown (Sözen 2017). According to multiple researches conducted on Indian women, the prevalence of osteoporosis ranges from 8 to 62%, with a wide regional variation. The prevalence of osteoporosis is 22.9% in Indian adults, and it is higher among females (26.3%) when compared to males (10.9%) (Sabat *et al*., 2022; Gupta *et al*., 2012; Schaafsma *et al*., 1999).

Osteopenia, considered as the initial step towards the progression of Osteoporosis, can be simulated with *Asthikshaya* in Ayurveda (Gabhane *et al*., 2020). Its management with numerous herbs and minerals singly and/or in combination is also mentioned. Tab. Myostaal SB is a herbo-mineral Ayurveda formulation developed rationally for the management of *Asthikshaya*. Its ingredients such as, *Kukkutandatvak Bhasma* (Processed Hen-egg Shell), *Asthisamhruta* (*Cissus quadrangularis*), and *Shatavari* (*Asparagus racemosus*) synergistically maintain and improve bone health (Kaur *et al*., 2021; Chitme *et al*., 2009).

Based on the above background, present proof-of-concept study was planned to explore the therapeutic potential of Myostaal SB tablets in osteopenic individuals. The primary objective here was to evaluate efficacy of Myostaal SB in middle aged and elderly participants suffering from osteopenia in terms of change in their BMD scores after six months of treatment. Also, changes in Ayurvedic symptom scores for *Asthikshaya* assessment, biochemical markers for bone health (Serum vitamin D, PTH and Alkaline Phosphatase-ALP) were noted for a comprehensive evaluation.

MATERIALS AND METHODS

Study Design

This was an open-label, prospective, single group, non-randomized, single-center study.

Study setting

The study was carried out among individuals attending the Special OPD for Clinical Trials at D. Y. Patil Ayurvedic hospital, Navi Mumbai, Maharashtra, India. In this open-labelled study of six-months (180 days) duration, eligible participants were provided with test medication, i.e., Myostaal SB tablets. The outcome assessment for BMD was done at baseline and on study completion, while the estimation of biochemical markers for bone health was done at baseline, day 90 and on study completion. The hematological parameters for safety assessment were assessed at baseline and on study completion (CONSORT flow diagram-Annexure 1).

Ethical Considerations and Registration Details

Ethical approval from Institutional Ethics Committee of study centre was obtained (letter no. DYPUSA /21/2021 dated 17th May 2021). The study was registered on Clinical Trials Registry-India (CTRI) vide registration number, CTRI/2021/06/034249, dated 11th June 2021. The findings of study were reported according to CONSORT statement guidelines (Hopewell *et al*., 2025).

Selection of study participants

Participants attending the Special OPD were screened in accordance with the eligibility criteria as per study protocol. Participants of either sex in the age group of 40-75 years (both years inclusive) suffering from osteopenia with BMD T- score between -1 to -2.5, with a history of fractures that may have occurred with a minor injury or fall and who voluntarily provided written informed consent and willingly ready to follow procedures as per the study protocol were included in the study. The participants consuming any drugs known to affect bone metabolism, such as Selective Estrogen Receptor Modulators (SERMs), bisphosphonates, calcitonin, Vit. D (more than 60,000 units), methotrexate, anti–epileptic drugs, loop diuretics, corticosteroids (more than 5 mg/day of prednisolone or equivalent) etc., for more than 3 months were not considered eligible. Those suffering from osteomalacia, tumor, osteonecrosis, osteomyelitis, or any other bone-softening metabolic disorders, congenital disorders (Dysosteogenesis and Marfan's syndrome) were also excluded from the study.

Participants with documented history of leukemia, lymphoma, metastases (bony and other), pathologic fractures secondary to bone metastases from cancer, pediatric osteogenesis imperfecta or renal osteodystrophy, malabsorption syndrome were excluded. Moreover, those with documented history of endocrine disorders such as, hyperthyroidism, hyperparathyroidism, untreated Cushing's syndrome was not considered eligible. The participants with history of any organ transplantation, immobilization for > six weeks, past history of atrial fibrillation, acute coronary syndrome, myocardial infarction, heart failure stroke or severe arrhythmia in the last six months were excluded. The participants with auto-immune disease, uncontrolled hypertension, diabetes mellitus requiring insulin injections and chronic severe respiratory disease were considered ineligible. The participants with history of alcohol or drug abuse, receiving any other treatment for osteopenia other than vitamin supplements, those who have taken study drug or any herbal medication in the past 4 weeks and pregnant and lactating women were excluded.

Intervention details

The participants were administered Myostaal SB tablets at dose of one tablet thrice, i.e., in morning and after both meals, for 180 days. Myostaal SB tablets were provided by M/s. Solumiks Herbaceuticals Ltd., manufactured according to GMP standards

(Batch no. SL012112, Date of manufacturing: 06/2021 & Date of expiry: 05/2024). The following ingredients are included in each coated Myostaal SB tablet, viz., 333.333 mg of powdered *Kukkutandatvak Bhasma* (processed hen-egg shell); 500 mg each of extracts derived from *Asthisamhruta* (*Cissus quadrangularis*) and *Shatavari* (*Asparagus racemosus*). The dispensed containers clearly mentioned that these were for clinical trial use.

Outcome assessment

Primary outcome variable with assessment method

Estimation of changes in BMD- It was assessed using Dual-energy X-ray absorptiometry (DEXA) scan. The T- score was assessed at four sites viz. Anteroposterior Spine (L1-L4 region), Left Femur Total, Left Femur Neck and Left Forearm (Radius 33%). The DEXA scan was done at baseline and on completion of study.

Secondary outcome variables and their assessment methods

a) The Ayurvedic symptom score for *Asthikshaya* assessment- This score for assessment of *Asthikshaya* was designed by the investigators based on the classical Ayurveda texts viz., Charaka Samhita and Ashtanga Sangraha and published literature. The score assessment was done at baseline and on completion of study. The assessment proforma and scoring grades is provided in Annexure-2.

b) Assessment of quality of life and enjoyment- It was assessed by the validated questionnaire viz., Quality of Life Enjoyment and Satisfaction Questionnaire - Short Form (Q-LES-Q-SF) on baseline and after completion of study (Endicott *et al.*, 1993) (Annexure-3).

c) Biochemical markers for bone health- The laboratory investigations for estimation of Vit. D, ALP and PTH were done on baseline, on day 90 and on completion of study.

d) Assessment of safety by hematological parameters- The safety assessment by hematological profile including Hemoglobin (Hb), Complete Blood Count (CBC), Aspartate Aminotransferase (AST), Alanine Transaminase (ALT), Blood Urea Nitrogen (BUN), and Serum Creatinine were carried out at baseline and on completion of study.

Sample size determination

In this study, a sample size of 30 study participants was taken. This sample size was empirically decided owing to proof-of-concept nature of study.

Statistical methods

Data was analyzed using IBM SPSS Statistics software version 26 & GraphPad Instat software version 3.06. Descriptive statistics were assessed. Data were expressed in percentages and Mean±SD. Shapiro Wilk test was used to assess the Normality of data. Data at more than two intervals was compared using ANOVA test (data with normal distribution)/Kruskal Wallis test (data with non-normal distribution).

RESULTS

Baseline Data

Demographic data

Forty-two participants were screened for eligibility after obtaining their written informed consent. Of these, seven participants were not found ineligible. Thus, 35 participants were recruited. Of these recruited participants, 30 participants completed the study. Five participants dropped out from the study, of which three were lost to follow-up and two were withdrawn due to poor compliance. At baseline, majority (70%) of participants were females (n=21) and in the age group of 40-49 years.

Effect on Primary outcome parameter- Change in the BMD T-score before and after intervention (Day 0 to Day 180)

Out of the 30 participants who completed the study, 27 participants had baseline T-scores suggestive of osteopenia (between -1 to -2.5) of AP Spine, 22 participants had osteopenia of Radius, 12 participants had osteopenia of Femur while, seven participants had Femur neck osteopenia. Improvement in mean T-score at visit 8 (After 180 days of treatment), as compared to baseline visit was observed in all the 30 participants, as presented in Table 1. At visit 8, significant (p<0.05) improvement in mean T-scores of AP Spine and Radius regions was observed. However, improvement in mean T-score of Femur and Femur Neck was statistically insignificant.

Table 1: Changes in T-score of AP Spine, Radius, Femur and Femur Neck.

Region	T-score at Visit 1 (Baseline) Mean±SD	T-score at Visit 8 (Visit 8) Mean±SD	*p*-value
AP Spine (n=27)	-1.61±1.1	-1.25±0.61	*0.041
Radius (n=22)	-1.62±0.41	-1.25±0.42	*0.045
Femur (n=12)	-1.58±0.42	-1.42±0.39	^{NS}0.897
Femur Neck (n=7)	-1.84±0.54	-1.72±0.62	^{NS}0.087

*p<0.05 at Visit 8 (Final Visit - After 180 days of treatment) vs. Visit 1 (Baseline - Before Treatment). NS - Not Significant.

Effect on secondary outcome parameters

Change in Ayurvedic symptom score before (Day 0), during (Day 90) and after intervention (Day 180)

The mean total Ayurvedic symptom score at Day 0 was 15.40±2.61, which progressively significantly reduced to 10.17±2.51 ($p<0.01$) on Day 90 and 2.40±1.25 ($p<0.001$) at Day 180. A significant reduction was observed in the individual domains of *Asthi Shoola* (bone pain/tenderness), *Sandhi Shoola* (joint pain) and *Kesha Patana* (hair fall) at Day 90 ($p<0.001$) and Day 180 ($p<0.001$) as compared to Day 0. Also, the *Shrama* (tiredness) score, significantly improved at Day 90 ($p<0.01$) and Day 180 ($p<0.001$) as compared to Day 0. Significant reduction was observed in the individual domains of *Nakha Vikara* and *Patana* (nail deformities) ($p<0.001$), *Danta Vikara* and *Patana* (dental deformities) ($p<0.001$) and *Sandhi Shaithilya* (laxity of joints) ($p<0.001$) only at Day 180 days when compared Day 0. For the domains of *Loma Patana* (Loss of body hairs) and *Meda Kshaya* (Depletion of body fat), statistical tests could not be applied as only three participants reported these symptoms at Day 0. The domain-wise reduction in symptom score is presented in Table 2.

Change in Total Q-LES-Q-SF score before (Day 0), during (Day 90) and after intervention (Day 180)

The mean Total Q-LES-Q-SF Score at Day 0 was 45.63±1.65, which significantly improved to 51.73±4.97 ($p<0.01$) after 90 days of treatment and 59.47±1.87 ($p<0.001$) after 180 days of treatment.

Change in levels of biochemical markers (ALP, PTH and vitamin D) before (Day 0), during (Day 90) and after intervention (Day 180)

Progressive reduction in mean ALP and PTH levels was observed, which was statistically significant. The serum vitamin D levels were on rise from Day 0 till Day 180; however, this increase was statistically insignificant. The changes in biomarker levels are presented in Table 3.

Effect on safety parameters

No adverse events were reported / observed at all time-points of measurement in any of the participants. All vital parameters i.e., temperature, blood pressure, heart rate and respiratory rate were within normal ranges, at all-time points of measurement. No statistically significant change was observed in any vital parameter of any participant, measured from baseline visit till end of study visit.

No statistically significant changes were observed in any of the hematological parameters after completion of 180 days treatment, as presented in Table 4.

Overall, the efficacy of Myostaal SB on improvement of bone health in terms of improved BMD, reduced ALP and PTH levels, betterment in Ayurvedic symptom score suggestive of osteopenia and enhanced quality of life suggested its beneficial role in osteopenia management.

Table 2: Change in Ayurvedic symptom score-domain-wise.

Domains of Ayurvedic Symptom Score	Day 0 (V2)	Day 90 (V5)	Day 180 (V8)	*p*-value (V5 vs. V2)	*p*-value (V8 vs. V2)	*p*-value (V8 vs. V5)
Asthi Shoola (n=30)	2.97±0.18	1.83±0.46	0.26±0.44	*$p<0.001$	*$p<0.001$	*$p<0.001$
Sandhi Shoola (n=30)	2.5±0.51	1.53±0.51	0.33±0.48	*$p<0.001$	*$p<0.001$	*$p<0.001$
Kesha Patana (n=30)	2.06±0.44	1.06±0.86	0.20±0.48	*$p<0.001$	*$p<0.001$	*$p<0.01$
Nakha Vikara and Patana (*n*=24)	1.53±0.81	1.06±0.73	0.30±0.53	^{NS} $p>0.05$	*$p<0.001$	*$p<0.01$
Danta Vikara and Patana (*n*=26)	1.89±0.73	1.53±0.73	0.50±0.73	^{NS} $p>0.05$	*$p<0.001$	*$p<0.001$
Shrama (*n*=30)	2.56±0.67	1.63±0.61	0.36±0.55	*$p<0.01$	*$p<0.001$	*$p<0.001$
Sandhi Shaithilya (*n*=27)	1.66±0.67	1.26±0.78	0.33±0.47	^{NS} $p>0.05$	*$p<0.001$	*$p<0.001$
Loma Patana (n=3)	0.17±0.53	0.10±0.40	0.03±0.18	-	-	-
Meda Kshaya (n=3)	0.17±0.53	0.13±0.51	0.07±0.25	-	-	-

*- Significant, NS - Not Significant.

Table 3: Changes in biochemical marker levels.

Biochemical Marker	Day 0 (V2)	Day 90	Day 180	*p*-value (V5 vs. V2)	*p*-value (V8 vs. V2)	*p*-value (V8 vs. V5)
ALP (µg/L)	10.24±2.37	9.23±2.82	8.49±2.38	^{NS} $p>0.05$	$^{*}p<0.05$	^{NS} $p>0.05$
PTH (pg/mL)	58.35±9.11	54.08±8.88	51.41±8.68	^{NS} $p>0.05$	$^{*}p<0.05$	^{NS} $p>0.05$
Vit. D(ng/mL)	19.16±4.31	21.43±4.33	23.23±4.69	^{NS} $p>0.05$	^{NS} $p>0.05$	^{NS} $p>0.05$

*- Significant, NS - Not Significant.Normal ranges; ALP (Male: 6.50-20.10 µg/L, Premenopausal Female: 4.50-16.90 µg/L, Postmenopausal Female: 7.00-22.40 µg/L), PTH (14.00-72.00 pg/mL) and vitamin D (Normal Range: 30 - 100 ng/mL).

Table 4: Assessment of hematological parameters.

Investigation	Day 0	Day 180	*p*-value
Hb (g/dL)	12.61±1.54	12.60±1.62	p=0.933
RBC (10^6/µL)	4.58±0.48	4.58±0.41	p=0.794
WBC (mm^3)	7946.67±2219.31	7570±2234.86	p=0.132
Neutrophils (%)	63.43±5.73	61.9±6.07	p=0.160
Lymphocytes (%)	33.63±5.33	32.87±5.32	p=0.436
Eosinophils (%)	2.03±0.85	3.10±1.06	p=0.703
Basophils (%)	0.00±0.00	0.00±0.00	-
Monocytes (%)	0.90±0.71	2.13±1.07	p=0.391
Platelets (lakhs/mm^3)	2.95±0.86	2.87±0.79	p=0.387
AST (IU/L)	22.27±6.48	18.41±5.94	p=0.801
ALT (IU/L)	21.60±6.26	20.30±6.15	p=0.312
BUN (mg/dL)	9.85±2.18	8.68±2.01	p=0.754
Sr. Creatinine (mg/dL)	1.00±0.18	0.96±0.16	p=0.108

DISCUSSION

The results of present study indicate promising role of Myostaal SB tablets in osteopenia management and prevention against its progression to osteoporosis. The improvement in bone strength was specified by increased T-scores, while, reduction in ALP and PTH levels indicated its anti-resorptive action. Overall, role of Myostaal SB in bone remodeling through remineralization was proclaimed. The absence of adverse effects as well as maintenance of normal hematological profile indicates good safety profile.

Slowly yet steadfastly, prevalence of osteopenia and osteoporosis are on rise in India and worldwide despite availability of various pharmacological agents. Under-diagnosis, poor patient compliance due to adverse effects and expensive cost of therapy, etc. are some of the important reasons for it. Moreover, rather than fatality, the outcomes of these conditions lead to disabilities and loss of healthy life years with economic, social and emotional afflictions (Aibar-Almazán *et al.*, 2022). In such situation, preventive treatment with traditional systems of medicine, such as Ayurveda can offer hope to the patients by means of reducing the risk of associated fractures.

Osteoporosis, a chronic disorder of bone metabolism is majorly asymptomatic in initial stages. It can directly manifest itself with enhanced bone fragility and proneness to bone fractures. It is thus important to diagnose and treat it preferably in its precursor stage, i.e., osteopenia (Kanis 2002). The deterioration of bone mass can be assessed by measuring the BMD by DEXA scan, a gold standard diagnostic method. Thus, in present work, it was used as objective assessment parameter.

Ayurveda therapies were shown to be effective in osteopenia management in previous studies. Munshi *et al.*, demonstrated efficacy of *Panchatikta Ghrita* as adjuvant to Ca and Vitamin D3 supplements in slowing down bone degeneration in elderly adults with osteopenia (Munshi *et al.*, 2019). In a study by Kumar *et al.*, stand-alone treatment with tablet *Asthiposhak* was found to be effective in improving BMD T Score and clinical symptoms of osteopenic adults (Kumar *et al.*, 2023). A randomized, standard-controlled clinical study among osteopenic adults was undertaken by Kadlimatti *et al.*, to compare efficacy of Ayurveda Rasayana compound (consisting of *Ashwagandha* (*Withania somnifera*), *Shatavari* (*Asparagus racemosus*), *Lakshadi Guggulu* and *Shukti Bhasma*) with a Ca and Vitamin D3 supplement, Shelcal. The symptomatic improvement due to Ayurveda interventions were significantly better. The improvement in BMD, on the other hand, was notable yet insignificant (Kadlimatti *et al.*, 2011).

Being a proof-of-concept study, there were certain limitations regarding the methodological aspect. Based on these results, studies with larger sample size and diverse population can be more beneficial. Additionally, the exclusion criteria may be broadened, and further investigation into the potential applications of Myostaal SB can be undertaken. The present study was carried out in single group, without any comparator, leading to probability of bias. Further studies with multiple randomized groups and standard treatment comparators can provide more robust evidence base.

CONCLUSION

The results of this study indicate a positive role of Myostaal SB Tablets in bone remodeling. The improvement in T-score gives an indication of improvement in bone strength and reduction in ALP and PTH levels indicate its probable anti-resorptive action. Myostaal SB Tablets can play a positive role in the management of osteopenia, which if not treated can further lead to osteoporosis and increase the risk of developing fractures.

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None.

ABBREVIATIONS

BMD: Bone mineral density; **ALP:** Alkaline phosphatase; **CTRI:** Clinical Trials Registry India; **DEXA:** Dual-energy X-ray absorptiometry; **Q-LES-Q-SF:** Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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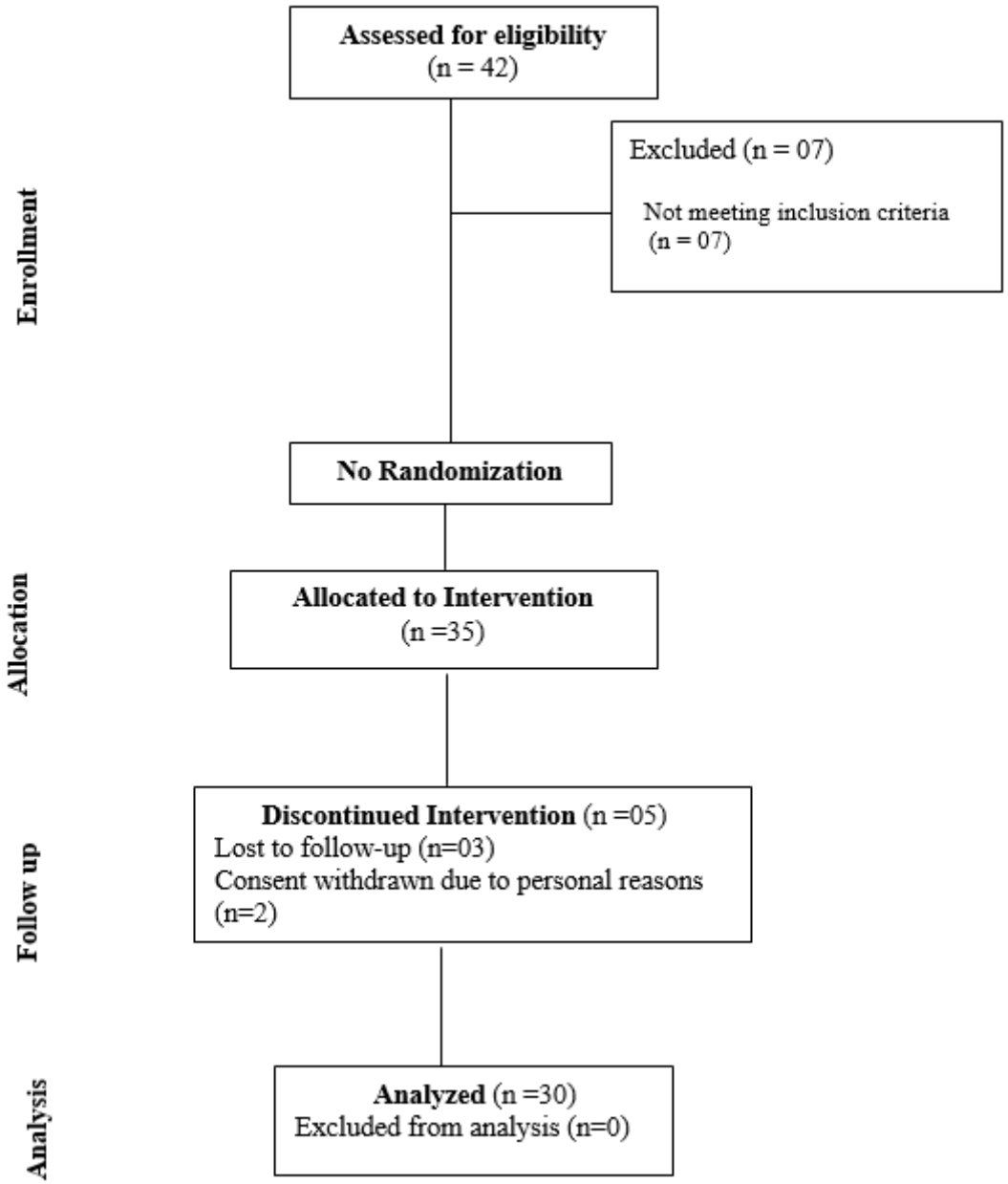

Annexure 1: CONSORT diagram showing the flow of participants through each stage of the study.

i. *Asthi Shoola* (Pain in bones):

No pain in bones	Score 0
Mild pain in bones not affecting by daily activities	Score 1
Moderate pain in bones not affecting by daily activities.	Score 2
Frequent severe pain in bones affecting daily activities.	Score 3

ii. *Sandhi Shoola* (Pain in joints):

No pain in joints	Score 0
Mild pain in joints not affecting by daily activities	Score 1
Moderate pain in joints not affecting by daily activities.	Score 2
Frequent severe pain in joints affecting daily activities.	Score 3

iii. *Kesha Patana* (Hair fall):

No Hair fall	Score 0
Hair fall once in the morning while washing/combing	Score 1
Hair fall on every time of combing	Score 2
Hair fall even without combing and raised hairline in frontal region	Score 3

iv. *Shrama* (Tiredness):

No tiredness	Score 0
Tiredness with excessive exertion	Score 1
Tiredness with moderate exertion	Score 2
Tiredness with mild exertion	Score 3

v. *Nakha Vikara* and *Patana* (Nail deformity):

No nail deformity	Score 0
Mild loss of natural texture and elasticity of nails	Score 1
Moderate loss of natural texture and elasticity of nails	Score 2
Visible brittleness of nails	Score 3

vi. *Danta Vikara* and *Patana* (Dental deformity):

No dental deformity	Score 0
Occasional dental pain with dental caries or loosening of at least one tooth	Score 1
Dental pain that doesn't responds to analgesics along with caries / loosening / loss of 2-4 teeth.	Score 2
Loosening / loss of 4-8 teeth.	Score 3

vii. *Sandhi Shaithilya* (Laxity/looseness in joints):

No feeling of laxity / looseness in joints	Score 0
Mild feeling of laxity / looseness in joints. Patient can stand/walk independently without difficulty.	Score 1
Moderate feeling of laxity / looseness in joints. Patient can stand/walk independently with difficulty.	Score 2
Severe feeling of laxity / looseness in joints. Patient can stand/walk only with support. (crutches, cane, walkers)	Score 3

viii. *Loma Patana* (Loss of body hair):

No	Score 0
Mild	Score 1
Moderate	Score 2
Severe	Score 3

ix. *Meda Kshaya* (Depletion of fat tissue):

No	Score 0
Mild	Score 1
Moderate	Score 2
Severe	Score 3

Sources:

a. Charaka Samhita, Sutrasthana 28/16. (Chaukhambha Surabharati Prakshan, Varanasi)

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Annexure 2: Ayurvedic Symptom Score. The Ayurvedic Symptom Score for Asthikshaya adopted by the Clinical Trial Site was designed based on the approved classical Ayurved texts (Charaka Samhita and Ashtanga Sangraha) and published literatures.

Participant Study Number	
Participant Initials	
Date of Evaluation	

Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF)

Taking everything into consideration, during the past week how satisfied have you been with your.....

	Very Poor	Poor	Fair	Good	Very Good
.....physical health?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....mood?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....work?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....household activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....social relationships?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....family relationships?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....leisure time activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....ability to function in daily life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....sexual drive, interest and/or performance?*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....economic status?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....living/housing situation?*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....ability to get around physically without feeling dizzy or unsteady or falling?*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....your vision in terms of ability to do work or hobbies?*	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....overall sense of well being?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....medication? (If not taking any, check here ☐ and leave item blank.)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
.....How would you rate your overall life satisfaction and contentment during the past week?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

*If satisfaction is very poor, poor or fair on these items, please UNDERLINE the factor(s) associated with a lack of satisfaction.

Annexure 3: Q-LES-Q-SF.