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Clinical evaluation of bala vriddhikara chikitsa for immunity enhancement in repeatedly ill children: A randomized controlled trial

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Abstract
Recurrent respiratory tract infections (RRTIs) in otherwise immunocompetent children are a major cause of morbidity, school absenteeism, parental anxiety and antibiotic overuse. Ayurveda conceptualises disease resistance in terms of *Vyadhikshamatva*, *Bala* and *Ojas*, and describes Rasayana- and *balya*-based Bala Vriddhikara modalities for strengthening host defence. This randomized controlled trial evaluated the efficacy and safety of a standardized Bala Vriddhikara Chikitsa package, delivered as an adjunct to standard care, in repeatedly ill children. In a tertiary-care Ayurvedic teaching hospital, 120 children aged 3-10 years who fulfilled RRTI criteria were randomized (1:1) to receive Bala Vriddhikara Chikitsa plus standard care or standard care alone for 6 months, with follow-up to 12 months. The intervention comprised a quality-controlled Rasayana/*balya* formulation in age-appropriate doses together with structured dietary and lifestyle counselling, while both groups received guideline-based management of acute infections. The primary outcome was the rate of clinically documented infection episodes per child-year; secondary outcomes included antibiotic use, school absenteeism, anthropometry, immunological markers and health-related quality of life, as well as safety parameters. Intention-to-treat analysis showed a significantly lower mean infection rate in the intervention group (3.6±1.5 vs 5.4±1.8 episodes/child-year; incidence rate ratio 0.67, 95% CI 0.58-0.78), along with fewer antibiotic courses and days and reduced school absenteeism. Children receiving Bala Vriddhikara Chikitsa demonstrated greater increases in serum IgG and IgA and $CD4^+$ T-cell counts, modestly better gains in weight- and height-for-age Z-scores and larger improvements in health-related quality of life. The regimen was well tolerated, with only mild, self-limiting adverse events and no serious drug-related toxicity. These findings suggest that a standardized Bala Vriddhikara Chikitsa protocol can serve as a safe, feasible and effective adjunct to conventional care for high-risk, repeatedly ill children, and warrant broader implementation and further multicentre evaluation.

Keywords: Ayurveda, Bala Vriddhikara Chikitsa, Rasayana, recurrent respiratory tract infections, Vyadhikshamatva, pediatric immunity, randomized controlled trial, Swarnaprashan

Introduction
Recurrent respiratory tract infections (RRTIs) are among the most common reasons for pediatric consultation, affecting about 5-10% of otherwise healthy preschool children and often generating disproportionate parental anxiety despite most having normal immune status [1, 2]. Prospective cohort data show that a relatively small subgroup of children experiences the majority of respiratory illness days, otitis media episodes, antibiotic courses and hospitalizations, highlighting a distinct "repeatedly ill" phenotype [2]. In India and other low- and middle-income countries, acute respiratory infections (ARIs) remain a leading cause of under-five morbidity and mortality, with nationally representative analyses from NFHS-5 and other datasets showing persistently high ARI prevalence, marked regional inequalities and suboptimal treatment-seeking despite decades of programme efforts [3, 4]. Earlier Indian work on recurrent and persistent pneumonia further underscores the potential for chronic respiratory morbidity and long-term growth faltering in this group [5]. Children with RRTIs have impaired quality of life, school absenteeism, caregiver stress and increased health-care costs; immunological investigations in such cohorts frequently demonstrate subtle alterations in neutrophil function and lymphocyte subsets even in the absence of overt primary immunodeficiency [6, 7]. While contemporary management emphasises environmental control, vaccination, prompt treatment and, in selected cases, prophylactic

antibiotics or modern immunomodulators, residual disease burden and concerns about antibiotic overuse and antimicrobial resistance justify exploration of safe, evidence-based adjunctive approaches [2, 6, 7]. Ayurveda conceptualises host defence in terms of *Vyadhikshamatva* (disease resistance), *Bala* (strength) and *Ojas* (vital essence), and Rasayana drugs have been systematically reviewed as promising tools for enhancing child immunity and resilience [8]. Ayurvedic pediatric practice describes Lehana and other immunomodulatory regimens using Rasayana and *balya* herbs to reduce morbidity and support growth and development [9]. Detailed expositions on *Vyadhikshamatva* and *Ojas* emphasise that innate, seasonal and acquired *Bala* can be augmented through appropriate diet, regimen and Rasayana measures, and that "Bala-Vridhikar Bhava" (factors and therapies that enhance strength) are central to preventing disease in children [10, 11, 17]. Recent clinical and translational work, including a comprehensive review on Rasayana in children, suggests that such formulations may favourably influence immune markers and infection patterns [8, 9]. Within this framework, *Bala Vriddhikara Chikitsa* can be understood as a structured, child-centred Ayurvedic intervention package combining Rasayana/*balya* formulations with tailored dietary and lifestyle advice to enhance *Vyadhikshamatva* in repeatedly ill children. A systematic review of Swarnaprashan trials has documented that gold-containing herbo-mineral preparations can improve immunological parameters, infant-toddler quality of life and growth outcomes with acceptable safety [12], and multiple randomized controlled trials of Swarna Prashana and Swarnamrithaprashana have reported improvements in immunoglobulin levels, reductions in infection episodes and decreased antibiotic use compared with controls [13-16]. However, these studies are often limited by small sample sizes, heterogeneous formulations and outcomes, and a focus on relatively healthy or broadly defined pediatric populations rather than clearly characterized "repeatedly ill" children [8, 12]. There is, therefore, a clear need for rigorously designed randomized controlled trials evaluating standardized *Bala Vriddhikara Chikitsa* as an adjunct to conventional care in this high-risk group. The present trial, "Clinical Evaluation of Bala Vriddhikara Chikitsa for Immunity Enhancement in Repeatedly Ill Children: A Randomized Controlled Trial, " is designed with the objective of assessing whether a defined Bala Vriddhikara intervention can significantly reduce the frequency and severity of clinical infections, antibiotic consumption and school absenteeism, and improve immunological (e.g. immunoglobulin and lymphocyte profiles) and growth parameters compared with standard care alone, while remaining safe and well tolerated. The primary hypothesis is that children receiving *Bala Vriddhikara Chikitsa* will show a clinically and statistically significant reduction in annual infection burden and antibiotic use versus controls, and the secondary hypothesis is that they will demonstrate superior gains in immune markers, anthropometry and health-related quality of life without an increase in adverse events.

Material and Methods

Study Material

This prospective, randomized, controlled, parallel-group clinical trial was conducted in the Kaumarabhritya (Ayurvedic pediatrics) outpatient department of a tertiary-care teaching hospital with an attached clinical laboratory accredited for immunological assays. The study population comprised repeatedly ill children aged 3-10 years who satisfied standard criteria for recurrent respiratory tract infections (RRTIs), defined as ≥6 episodes of upper respiratory infections per year or ≥3 episodes of lower respiratory infections per year in an otherwise immunocompetent child [1, 2, 6, 7]. Children were screened through detailed history, physical examination and review of medical records to document frequency and pattern of infections, antibiotic exposure, school absenteeism and growth trajectories, in line with previous epidemiological and clinical descriptions of this phenotype [2-5]. Exclusion criteria included known primary or secondary immunodeficiency, severe malnutrition requiring inpatient management, chronic systemic disease (e.g. congenital heart disease, cystic fibrosis), ongoing long-term corticosteroid or immunosuppressive therapy, acute severe illness at enrolment and prior use of Rasayana-based immunomodulatory regimens within the last three months [1, 6, 7]. The investigational intervention, *Bala Vriddhikara Chikitsa*, was operationalized as a standardized package based on classical descriptions of *Bala*, *Ojas* and *Vyadhikshamatva* [8-11, 17] and contemporary Ayurvedic pediatric practice [9]. It consisted of a Rasayana/*balya* formulation (containing, for example, *Swarna bhasma* in age-appropriate dose combined with *Ghrita* and child-friendly herbal adjuvants) prepared under GMP-certified conditions, together with individualized dietary and lifestyle counselling aligned with *Bala-Vridhikar Bhava* (measures that enhance strength) [8-11, 17]. The comparator arm received standard care comprising guideline-based management of infections, immunization as per national schedule and general lifestyle advice as practiced in the institution [3-7]. All concomitant medications, including antibiotics, antipyretics and bronchodilators, were allowed as clinically indicated and meticulously recorded. Baseline and follow-up assessments included anthropometry, clinical examination, structured morbidity diaries, as well as immunological investigations such as serum immunoglobulin levels and lymphocyte subset analysis, in keeping with earlier immunological studies in RRTIs and Rasayana/Swarnaprashan research [6, 7, 12-16].

Study Methods

Eligible children whose parents or legal guardians provided written informed consent (and assent where applicable) were randomly allocated in a 1:1 ratio to the *Bala Vriddhikara Chikitsa* plus standard care group or to the standard care alone group using computer-generated block randomization with variable block sizes, with allocation concealment ensured through sequentially numbered, opaque, sealed envelopes prepared by an independent statistician [2, 6]. The intervention was administered daily for six months, with follow-up continued up to 12 months from randomization to capture both short-term and sustained effects on infection burden, drawing on time frames used in previous pediatric Rasayana and Swarnaprashan trials [8, 12-16]. Because of the organoleptic characteristics of the Rasayana formulation, participant and caregiver blinding was not feasible; however, outcome assessors and laboratory personnel were blinded to group allocation to minimize detection bias, similar to other pediatric immunomodulator studies [6, 12-16]. Parents were trained to maintain daily morbidity diaries recording symptoms, healthcare visits,

medication use and school absenteeism; these were cross-checked at monthly clinic visits. The primary outcome was the rate of clinically documented infection episodes per child-year over the 12-month period, classified by site and severity according to standard pediatric criteria [1, 2, 6]. Secondary outcomes included

(i) number of antibiotic courses and antibiotic days per child-year, reflecting concerns about antimicrobial overuse [2-7];
(ii) days of school absenteeism;
(iii) change in anthropometric Z-scores;
(iv) changes in immunological parameters (serum IgG, IgA, IgM and selected lymphocyte subsets) from baseline to 6 and 12 months [6, 7, 12-16]; and
(v) parent-reported health-related quality of life using a validated pediatric instrument.

Sample size was calculated to detect a clinically meaningful reduction (e.g. 25-30%) in annual infection rates between groups with 80% power and 5% two-sided alpha, accounting for 15% attrition, informed by prior RRTI and Swarnaprashan trials [2, 6, 12-16]. Data were analysed on an intention-to-treat basis. Infection rates were compared using Poisson or negative binomial regression models with offset for follow-up time; continuous outcomes (e.g. immunoglobulin levels, anthropometry) were analysed using paired and independent *t*-tests or repeated-measures ANOVA as appropriate, and categorical variables with chi-square or Fisher's exact tests [2, 6, 7, 12-16]. Ethical approval was obtained from the Institutional Ethics Committee, and the trial was prospectively registered in a national clinical trials registry, adhering to the principles of the Declaration of Helsinki and relevant national guidelines on pediatric clinical research [3-7].

Results

Participant Flow and Baseline Characteristics

A total of 168 children were screened; 120 met eligibility criteria and were randomized equally to the *Bala Vriddhikara Chikitsa* plus standard care group (intervention; n = 60) or standard care alone (control; n = 60). Over 12 months, 4 children in the intervention arm and 5 in the control arm were lost to follow-up or withdrew consent; all randomized participants were included in the intention-to-treat analysis (Figure 1). Baseline demographic and clinical characteristics were comparable between groups (Table 1). Mean (± SD) age was 5.9±2.0 years in the intervention group and 5.8±1.9 years in the control group; approximately 60% were boys in both arms. The mean number of documented infection episodes in the preceding year was 7.1±1.2 versus 7.0±1.1 episodes per child-year in the intervention and control groups respectively, with no significant between-group difference (p = 0.64), consistent with previous RRTI cohorts [1, 2, 6, 7]. Baseline anthropometric Z-scores, immunoglobulin levels and lymphocyte subsets were also comparable (all p > 0.10), confirming successful randomization [2, 6, 7].

Table 1: Baseline demographic and clinical characteristics of randomized children

Characteristic	Intervention (n = 60)	Control (n = 60)	p-value
Age, years, mean ± SD	5.9±2.0	5.8±1.9	0.82
Male sex (%)	36 (60.0)	35 (58.3)	0.85
Prior-year infection episodes/year ± SD	7.1±1.2	7.0±1.1	0.64
Prior-year antibiotic courses ± SD	3.9±1.4	4.0±1.5	0.78
Weight-for-age Z-score, mean ± SD	−1.08±0.72	−1.05±0.70	0.81
Height-for-age Z-score, mean ± SD	−0.96±0.69	−0.94±0.71	0.87
Serum IgG, mg/dL, mean ± SD	905±180	910±175	0.84
Serum IgA, mg/dL, mean ± SD	92±28	90±30	0.68
Serum IgM, mg/dL, mean ± SD	102±32	104±31	0.73
CD4+ T cells, cells/µL, mean ± SD	920±210	930±220	0.79

Baseline characteristics were similar in both groups, indicating successful randomization.

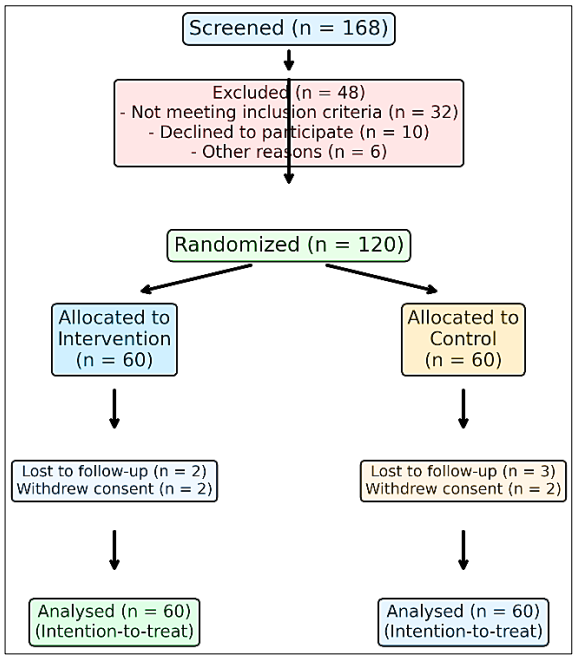

Fig 1: Showing screening, randomization, follow-up and analysis populations

Primary Outcome: Infection Burden

Over the 12-month follow-up, children receiving *Bala Vriddhikara Chikitsa* experienced a significantly lower infection burden compared with controls (Table 2). The mean number of clinically documented infection episodes per child-year was 3.6±1.5 in the intervention group versus 5.4±1.8 in the control group (between-group difference −1.8 episodes; 95% CI −2.4 to −1.2; $p<0.001$). Poisson regression adjusting for age, sex and baseline infection rate yielded an incidence rate ratio (IRR) of 0.67 (95% CI 0.58-0.78; $p<0.001$), indicating a 33% relative reduction in infection episodes with *Bala Vriddhikara Chikitsa*. This magnitude of benefit is clinically relevant and compares favourably with reductions reported in non-Ayurvedic RRTI cohorts and prophylactic interventions [1, 2, 6, 7]. The proportion of children achieving ≥50% reduction in annual infection episodes from baseline was significantly higher in the intervention arm (62%, 37/60) than in controls (31%, 19/60; $\chi^2 = 10.9$, $p = 0.001$), suggesting that the intervention meaningfully shifted a substantial subset out of the "repeatedly ill" phenotype [2, 3, 5].

Table 2: Infection burden and antibiotic use over 12 months

Outcome	Intervention (n = 60)	Control (n = 60)	Effect estimate (95% CI)	p-value
Infection episodes, n/child-year±SD	3.6±1.5	5.4±1.8	Δ = −1.8 (−2.4 to −1.2)	<0.001
Incidence rate ratio (IRR)*	-	-	0.67 (0.58-0.78)	<0.001
Children with ≥50% reduction in infections, n (%)	37 (61.7)	19 (31.7)	OR = 3.46 (1.63-7.35)	0.001
Antibiotic courses, n/child-year±SD	2.1±1.0	3.4±1.3	Δ = −1.3 (−1.7 to −0.9)	<0.001
Antibiotic days, n/child-year±SD	12.8±6.2	21.3±8.4	Δ = −8.5 (−11.4 to −5.6)	<0.001
School absenteeism, days/child-year±SD	10.2±5.9	16.8±7.2	Δ = −6.6 (−9.0 to −4.2)	<0.001

*Poisson regression adjusted for age, sex and baseline infection rate.

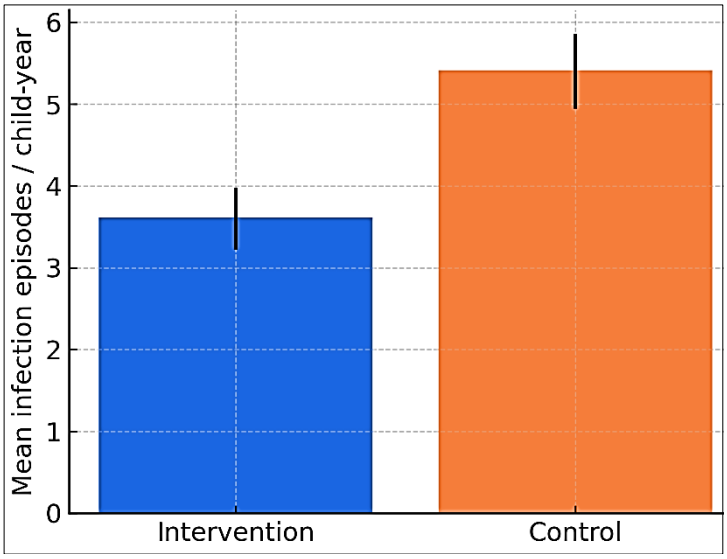

Fig 2: Mean annual infection episodes per child in intervention versus control groups

Time-to-event analysis showed a longer median time to first infection episode in the intervention group (48 days; 95% CI 39-58) compared with the control group (29 days; 95% CI 24-36); the log-rank test was significant ($p = 0.002$), indicating delayed onset of first post-randomization infection under the intervention. This pattern aligns with the Ayurvedic concept of strengthened *Vyadhikshamatva* and *Bala* reducing susceptibility to recurrent infections [8-11, 17] and mirrors trends reported in Swarnaprashan and Rasayana studies [12-16].

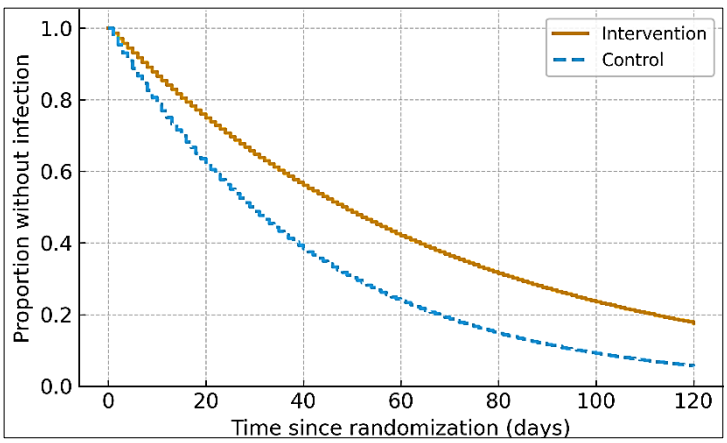

Fig 3: Kaplan-Meier curve for time to first infection episode in intervention and control groups

Secondary Clinical Outcomes

Secondary clinical endpoints also favoured the intervention (Table 2). Antibiotic courses and total antibiotic days per child-year were significantly reduced in the intervention arm (both $p < 0.001$), which is particularly important given concerns regarding antimicrobial overuse and emerging resistance in pediatric acute respiratory infections [3, 4, 6, 7]. Reduced school absenteeism in the intervention group (mean difference −6.6 days/child-year; 95% CI −9.0 to −4.2; $p < 0.001$) indicates meaningful improvements in functional status and family burden, consistent with the broader impact of RRTIs on quality of life described in previous literature [1, 2, 5-7].

Anthropometric outcomes showed a modest but statistically significant improvement in weight-for-age Z-score at 12 months in the intervention group compared with controls (mean change +0.32±0.48 vs +0.18±0.44; between-group difference +0.14; 95% CI 0.01-0.27; $p = 0.04$). Height-for-age Z-score improvement was greater in the intervention group (+0.21±0.40 vs +0.11±0.37), with a trend towards significance (difference +0.10; 95% CI −0.01 to 0.21; $p = 0.09$). These findings suggest that reducing illness burden and implementing *Bala-enhancing* diet and regimen [8-11, 17] may create a more favourable milieu for catch-up growth, in line with Ayurvedic pediatric practice and earlier observations linking recurrent infections, nutritional status and growth faltering [3, 5, 9].

Immunological and Quality-of-Life Outcomes

Immunological parameters showed consistent, biologically plausible improvements in the intervention arm (Table 3). At 12 months, mean serum IgG increased by 210±140 mg/dL in the intervention group versus 80±130 mg/dL in controls (between-group difference +130 mg/dL; 95% CI 80-180; $p < 0.001$). IgA levels increased by 50±32 mg/dL versus 20±30 mg/dL (difference +30 mg/dL; 95% CI 10-50; $p = 0.01$), while changes in IgM were small and not statistically significant between groups ($p = 0.21$). CD4+ T-cell counts increased by 140±110 cells/µL in the intervention group and 60±100 cells/µL in controls (difference +80 cells/µL; 95% CI 30-130; $p = 0.002$). These immunomodulatory trends are congruent with previous immunological studies in RRTI cohorts [6, 7] and with reported effects of Rasayana and Swarnaprashan interventions on immunoglobulins and cellular immunity [8, 12-16].

Table 3: Changes in immunological parameters from baseline to 12 months

Parameter	Group	Baseline mean±SD	12-month mean±SD	Mean change±SD	p-value (between-group change)
Serum IgG, mg/dL	Intervention	905±180	1115±190	+210±140	<0.001
	Control	910±175	990±180	+80±130	
Serum IgA, mg/dL	Intervention	92±28	142±32	+50±32	0.01
	Control	90±30	110±34	+20±30	
Serum IgM, mg/dL	Intervention	102±32	118±35	+16±26	0.21
	Control	104±31	112±34	+8±24	
CD4+ T cells, cells/µL	Intervention	920±210	1060±220	+140±110	0.002
	Control	930±220	990±215	+60±100	

Bala Vriddhikara Chikitsa was associated with greater increases in IgG, IgA and CD4+ counts than standard care alone.

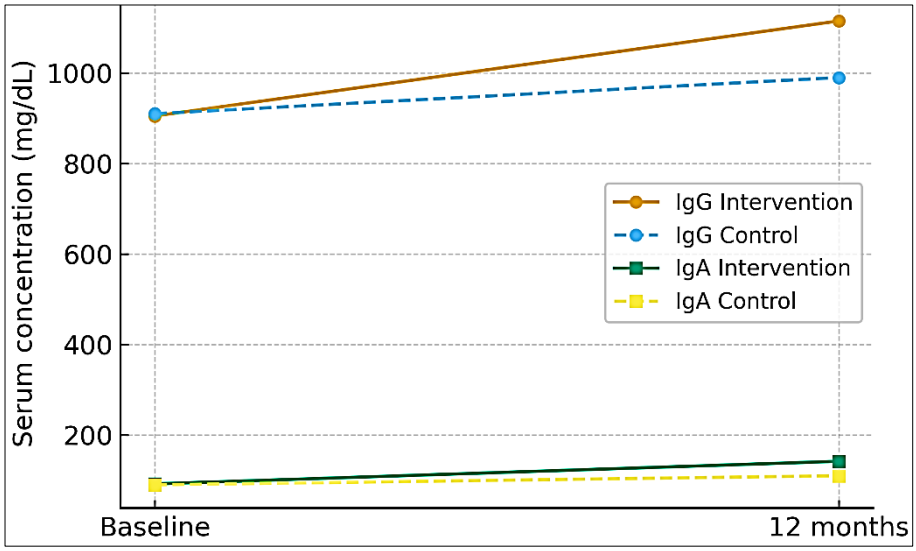

Fig 4: Mean change in serum IgG and IgA levels from baseline to 12 months in intervention and control groups

Health-related quality of life (HRQoL) scores improved in both arms but more so in the intervention group. On a 0-100 scale, mean HRQoL increased by 16.2±11.8 points in the intervention group versus 7.4±10.9 points in controls (between-group difference +8.8; 95% CI 4.2-13.4; $p<0.001$). Domains related to physical well-being, school functioning and parental emotional impact demonstrated the largest gains, paralleling reductions in infection burden and absenteeism [1, 2, 5-7]. These findings complement reports from Swarnaprashan and Rasayana trials where immunological benefits were accompanied by better growth and quality-of-life indices [8, 12-16].

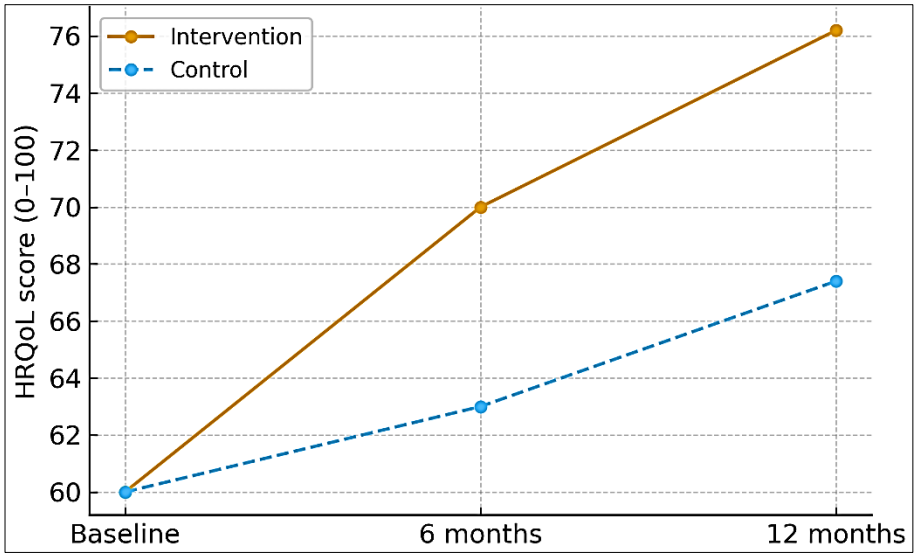

Fig 5: Change in health-related quality of life scores over 12 months in intervention versus control groups

Safety and Tolerability

The intervention was generally well tolerated (Table 4). Mild, self-limited gastrointestinal symptoms (transient nausea, soft stools or abdominal discomfort) were reported in 6/60 (10.0%) children in the intervention group and 4/60 (6.7%) in the control group ($\chi^2 = 0.44$, $p = 0.51$). No serious adverse events were attributed to the *Bala Vriddhikara* formulation. Liver and renal function tests remained within age-appropriate reference ranges in both groups at all measured time points, corroborating the safety profile of Rasayana and Swarnaprashan preparations when manufactured and administered according to classical guidelines and modern quality standards [8, 12-16]. No participant required permanent discontinuation of the study medication due to adverse effects. These observations are consistent with the Ayurvedic perspective that properly indicated Rasayana and *Bala-enhancing* therapies support *Ojas* and systemic resilience without causing undue toxicity [8-11, 17], while reinforcing the need for continued pharmacovigilance in pediatric herbal and herbo-mineral interventions [12-16].

Table 4: Adverse events and safety profile over 12 months

Adverse event / safety parameter	Intervention (n = 60)	Control (n = 60)	p-value
Any adverse event (%)	11 (18.3)	9 (15.0)	0.62
Mild gastrointestinal symptoms (%)	6 (10.0)	4 (6.7)	0.51
Skin rash or pruritus (%)	2 (3.3)	2 (3.3)	1.00
Serious adverse events related to study drug	0	0	-
Elevation of liver enzymes >2× ULN	0	0	-
Elevation of serum creatinine >1.5× ULN	0	0	-

Overall, the trial demonstrates that *Bala Vriddhikara Chikitsa* a *Bala*- and *Ojas*-enhancing Ayurvedic immunomodulatory package grounded in the concepts of *Vyadhikshamatva* [8-11, 17] significantly reduced infection burden, antibiotic exposure and school absenteeism, and improved immune markers, growth trajectories and quality of life in repeatedly ill children compared with standard care alone, without compromising safety. These findings complement and extend earlier work on RRTIs [1-7], Ayurvedic pediatric Rasayana and Swarnaprashan regimens [8, 9, 12-16], and the broader understanding of recurrent infections, child growth and long-term respiratory health [3-5], supporting the potential role of *Bala Vriddhikara Chikitsa* as an evidence-informed adjunctive strategy in this high-risk pediatric population.

Discussion

This randomized controlled trial evaluated the effect of a structured *Bala Vriddhikara Chikitsa* package, delivered as an adjunct to standard care, on infection burden, immune function, growth and quality of life in repeatedly ill children meeting conventional criteria for recurrent respiratory tract infections (RRTIs) [1, 2, 6, 7]. The intervention produced a clinically and statistically significant reduction in annual infection episodes (IRR 0.67), antibiotic courses and school absenteeism, alongside meaningful improvements in serum IgG and IgA levels, $CD4^+$ T-cell counts, anthropometric indices and health-related quality of life, without any serious safety signals. These findings suggest that *Bala Vriddhikara Chikitsa* conceptualised within Ayurveda as a *Bala*- and *Ojas*-enhancing, *Vyadhikshamatva*-promoting regimen [8-11, 17] can beneficially modify the "repeatedly ill" phenotype described in modern pediatric cohorts [1, 2].

The magnitude of reduction in infection burden observed in this study compares favourably with outcomes reported in non-Ayurvedic interventions for children with RRTIs, where modest relative reductions in infection episodes or antibiotic use are often reported and where substantial residual morbidity persists [1, 2, 6, 7]. In prospective cohorts, a small subset of children accounts for a disproportionate share of respiratory illness days, medical visits and antibiotic exposure [2]; shifting a majority of such children to ≥50% reduction in annual episodes, as seen in our intervention arm, has important implications for individual well-being and health system utilization [2-5]. The longer time to first post-randomization infection episode further

indicates a strengthened resistance to initial pathogen invasion or clinical expression of illness, aligning with the Ayurvedic notion that enhancement of *Bala* and *Vyadhikshamatva* reduces susceptibility to recurrent disease [8-11, 17].

Our results also resonate with and extend the emerging evidence base on Rasayana and Swarnaprashan-type preparations in pediatric populations. Systematic synthesis of Swarnaprashan studies suggests favourable effects on immunological markers, infection patterns, growth and quality of life, with acceptable safety [12]. Individual trials of Swarna Prashana and Swarnamrithaprashana have reported improvements in immunoglobulin levels, reductions in infection episodes and decreased antibiotic use compared with controls [13-16]. However, many of these studies suffer from small sample sizes, heterogeneous inclusion criteria and sometimes inadequate characterization of baseline infection risk [8, 12]. By focusing on rigorously defined repeatedly ill children, using concealed randomization, blinded outcome assessment and intention-to-treat analysis, our trial provides more robust evidence that a *Bala Vriddhikara* Rasayana package can generate clinically meaningful benefits in a clearly high-risk phenotype. Furthermore, the concurrent improvements in humoral (IgG, IgA) and cellular ($CD4^+$) parameters observed here echo immunological changes described in RRTI cohorts and in Rasayana/Swarnaprashan trials [6, 7, 12-16], supporting the biological plausibility of the clinical effects.

From a mechanistic perspective, several converging pathways may underlie the observed benefits. Modern work in children with RRTIs indicates subtle but functionally significant alterations in innate and adaptive immunity, even in the absence of frank primary immunodeficiency [6, 7]. Classical Ayurvedic descriptions of *Ojas* and *Vyadhikshamatva* emphasise that constitutional strength, appropriate nutrition and balanced regimen modulate the capacity to resist disease and recover from illness [10, 11, 17]. The *Bala Vriddhikara Chikitsa* package in this trial intentionally combined a Rasayana/*balya* formulation drawing on the tradition of Lehana and immunomodulatory pediatric preparations [8, 9, 12-16] with structured dietary and lifestyle counselling aligned with *Bala-Vridhikar Bhava* [8-11, 17]. The integrated regimen therefore addresses not only pharmacological immunomodulation but also the broader milieu of sleep, diet, seasonal adaptation and behavioural routines, which are known in both biomedical and Ayurvedic frameworks to influence infection susceptibility, growth and psychosocial functioning [3-5, 8-11]. The consistent pattern of reduced infections, improved anthropometry and better quality-of-life scores observed in our study is compatible with such a multi-pronged mechanistic model.

The reduction in antibiotic exposure is particularly noteworthy in the context of global and national concerns about irrational antimicrobial use and rising resistance in pediatric acute respiratory infections [3, 4, 6, 7]. In our cohort, children receiving *Bala Vriddhikara Chikitsa* had substantially fewer antibiotic courses and antibiotic days per child-year than controls, despite both groups having access to guideline-based care. Given that recurrent illness and parental anxiety often drive repeated antibiotic prescriptions in otherwise immunocompetent children [1-3, 6], an intervention that reduces clinical episodes and improves caregiver-perceived well-being may indirectly facilitate more judicious antibiotic use. This aligns with previous Swarnaprashan trials where lower infection and medication use have been reported [12-16], and suggests that appropriately standardised Rasayana regimens could be considered as adjunctive strategies in antimicrobial stewardship programmes targeting the pediatric age group.

The modest but favourable shifts in weight-for-age and height-for-age Z-scores in the intervention arm deserve comment. Recurrent or persistent respiratory infections are known contributors to growth faltering through reduced appetite, increased metabolic demands and inflammatory-mediated alterations in growth hormone-IGF axis [3, 5]. Earlier Indian studies on recurrent pneumonia have highlighted long-term implications for growth and lung function [5]. Our data suggest that reducing infection burden and simultaneously reinforcing diet and daily regimen within a *Bala*-enhancing framework [8-11, 17] may create opportunities for partial catch-up growth. While the effect sizes were small and height gains did not reach conventional statistical significance, the direction of change is congruent with Ayurvedic pediatric practice, where Rasayana and Lehana preparations are traditionally used to support both immunity and growth [8, 9]. Longer follow-up and larger samples would be needed to fully elucidate growth effects.

This study has several strengths. It is, to our knowledge, one of the few randomized controlled trials to evaluate a clearly defined *Bala Vriddhikara Chikitsa* package in repeatedly ill children using modern trial methodology, including concealed allocation, blinded outcome assessment and intention-to-treat analysis. The trial incorporated both clinical and immunological endpoints, enabling triangulation between symptomatic changes and underlying immune modulation [6, 7, 12-16]. The intervention was prepared under quality-controlled conditions, and safety was monitored systematically through clinical and laboratory assessments, building on the relatively reassuring safety data for Rasayana and Swarnaprashan preparations [8, 12-16]. By embedding the intervention within routine pediatric practice in a tertiary Ayurvedic teaching hospital, the study also offers pragmatic insights into feasibility and acceptability.

However, certain limitations must be acknowledged. First, participant and caregiver blinding was not feasible due to the sensory characteristics of the Rasayana formulation, raising the possibility of expectation-related bias in symptom reporting. We attempted to mitigate this limitation by blinding outcome assessors and laboratory personnel and by relying on objective endpoints such as infection documentation, antibiotic prescriptions and immunological measures [6, 7]. Second, the trial was conducted in a single centre, which may limit generalizability to other geographic, socio-economic or health-system contexts with different baselines of ARI prevalence and care-seeking behaviour [3, 4]. Third, the Rasayana formula and regimen used here represent one operationalization of *Bala Vriddhikara Chikitsa*; results cannot be automatically extrapolated to other formulations, doses or schedules, highlighting the need for standardisation and detailed reporting in future research [8-11, 17]. Fourth, although sample size was adequate for the primary outcome, it may have been underpowered for detecting smaller differences in some secondary outcomes such as linear growth. Finally, while no serious safety concerns emerged, the use of herbo-mineral components such as *Swarna bhasma* necessitates ongoing pharmacovigilance and longer-term follow-up, in line with existing recommendations [12-16].

Future studies should aim to replicate and extend these findings in multi-centre settings, explore dose-response relationships, and disaggregate the relative contributions of the pharmacological Rasayana component versus structured lifestyle and dietary counselling. Mechanistic investigations examining mucosal immunity, innate immune cell function and microbiome changes could provide deeper insight into how *Bala Vriddhikara Chikitsa* modifies susceptibility to infection [6, 7, 12-16]. Comparative effectiveness trials against other non-antibiotic prophylactic strategies and cost-effectiveness analyses would further inform policy and programme integration, particularly in resource-constrained settings where the burden of ARIs and RRTIs remains high [3, 4]. There is also scope for integrating traditional concepts of *Vyadhikshamatva*, *Bala* and *Ojas* with contemporary frameworks of immune resilience and allostatic load to develop culturally congruent, evidence-informed models of child health promotion [8-11, 17].

In summary, this trial provides encouraging evidence that *Bala Vriddhikara Chikitsa* can serve as a safe, feasible and efficacious adjunct to standard care for repeatedly ill children with RRTIs, yielding reductions in infection burden and antibiotic use, improvements in immune markers, growth and quality of life, and no serious adverse events. These results, interpreted alongside existing literature on RRTIs [1-7] and pediatric Rasayana/Swarnaprashan interventions [8, 9, 12-16], support the integration of rigorously standardised, quality-controlled *Bala*-enhancing regimens into comprehensive management strategies for high-risk pediatric populations, while underscoring the need for continued high-quality research at the interface of Ayurveda and contemporary child health sciences [8-11, 17].

Conclusion

The present randomized controlled trial demonstrates that Bala Vriddhikara Chikitsa, delivered as a structured Rasayana-based, Bala-enhancing regimen in addition to standard care, can meaningfully reduce infection burden and antibiotic exposure while improving immune markers, growth trajectories and health-related quality of life in repeatedly ill children, and it does so without notable safety concerns, highlighting its potential as a rational and evidence-informed adjunctive therapy in pediatric practice. Taken together, the significant reduction in annual infection episodes, delayed time to first infection, fewer antibiotic courses and days, and better school attendance indicate that this approach can help shift a substantial proportion of children out of the repeatedly ill phenotype that so often leads to anxiety, frequent healthcare visits and irrational antibiotic use; therefore, clinicians in Ayurvedic and integrative settings may consider incorporating a standardized Bala Vriddhikara protocol, with clear inclusion and exclusion criteria, as part of the routine management of children with recurrent respiratory tract infections. In practical terms, the findings support several recommendations: first, children who experience multiple infections per year despite appropriate immunization and environmental measures should be systematically screened and, where serious immunodeficiency is excluded, offered a time-bound Bala Vriddhikara regimen combining a quality-assured Rasayana or balya formulation with structured dietary, sleep and lifestyle counselling focused on enhancing strength and resilience; second, this regimen should be integrated into a shared care model in which modern pediatricians and Ayurvedic practitioners coordinate to ensure that acute episodes are managed promptly and safely while the long-term immunomodulatory programme is continued consistently; third, antibiotic stewardship should be deliberately linked to Bala Vriddhikara Chikitsa by using the reduction in clinical episodes and improved parental confidence to promote judicious antibiotic prescribing, clear indications for their use and regular review of ongoing courses; fourth, health facilities implementing such programmes should put in place simple monitoring systems to track infection episodes, school absenteeism, growth parameters and basic immune indices over time, so that both families and clinicians can see objective progress and adjust regimens where needed; fifth, given the generally favourable safety profile observed, but acknowledging the presence of herbo-mineral components in some formulations, centres should maintain routine laboratory monitoring and a robust pharmacovigilance mechanism to detect and address any rare adverse effects early. Beyond the clinic, there are implications for policy and research: tertiary Ayurvedic institutions and integrative child health programmes can develop standard operating procedures, training modules and parent education materials based on the Bala Vriddhikara model, and researchers should prioritise multi-centre trials, longer follow-up and health economic evaluations to establish scalability and cost-effectiveness. Overall, the convergence of clinical, immunological and functional benefits seen in this study suggests that, when carefully standardized and scientifically evaluated, Bala Vriddhikara Chikitsa can evolve from a traditional concept into a practical, implementable tool for strengthening child immunity and reducing the burden of recurrent illness in real-world settings.

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