

Comparative Study of Ayurvedic and Conventional Hypertension Management

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ABSTRACT

*Hypertension is the single most prevalent modifiable cardiovascular risk factor in adult European populations, and while conventional pharmacotherapy is effective for most patients, a meaningful share either cannot tolerate standard agents at effective doses or remain inadequately controlled on monotherapy. Ayurvedic medicine has engaged with hypertension-like clinical pictures for centuries under the classical categories of Rakta-gata-vata and Dhamani-pratichaya, with a repertoire that notably includes Sarpagandha (*Rauwolfia serpentina*), the historical source of reserpine. This was a 24-week, multicentre, randomised, open-label, controlled comparative effectiveness trial in 280 adults with grade 1-2 essential hypertension (office SBP 140-169 mmHg and/or DBP 90-109 mmHg) at four European integrative-medicine centres. Participants were randomised 1:1:1:1 to Arm A (conventional ACE inhibitor or ARB monotherapy), Arm B (Sarpagandha-based Ayurvedic monotherapy with lifestyle support), Arm C (Mukta Vati classical polyherbal with lifestyle support), or Arm D (integrated protocol combining conventional antihypertensive therapy with Ayurvedic polyherbal adjuncts, localised Panchakarma and structured yoga therapy). Primary outcome was change in office systolic blood pressure at 24 weeks. Secondary outcomes included 24-hour ambulatory blood pressure, metabolic and lipid markers, medication dose adjustments, quality of life, and adverse events. Office SBP reductions were -14.8 mmHg (Arm A), -11.2 mmHg (Arm B), -13.6 mmHg (Arm C), and -18.4 mmHg (Arm D). The composite Hypertension Clinical Effectiveness Index (HCEI) placed Arm D at 0.908, Arm A at 0.824, Arm C at 0.782, and Arm B at 0.712. Adverse events were mild and comparable, with no serious AEs attributed to study interventions.*

Keywords: hypertension; essential hypertension; Ayurveda; Sarpagandha; *Rauwolfia serpentina*; Mukta Vati; ACE inhibitor; integrative cardiology; randomised controlled trial; blood pressure; Panchakarma; HCEI

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1. Introduction

1.1 Hypertension Burden and the Gap in Conventional Care

Essential hypertension has no shortage of therapeutic options in 2022, and conventional first-line agents (ACE inhibitors, angiotensin receptor blockers, calcium channel blockers, thiazide diuretics) are effective, cheap and extensively evidence-based. The clinical problem is not the availability of good options; it is the share of patients who do not do well on them. Some develop intolerable ACE-inhibitor cough. Some have diuretic-related metabolic disturbance. Some need dual or triple therapy because monotherapy cannot get them to target. Some are reluctant to start long-term pharmacotherapy for a largely asymptomatic condition. For these patients, the therapeutic conversation is more complex, and integrative-medicine options have a genuine role.

1.2 Ayurvedic Repertoire and Study Objectives

Ayurvedic medicine has approached hypertension-like presentations for centuries under the classical diagnostic categories Rakta-gata-vata and Dhamani-pratichaya. The therapeutic repertoire includes Sarpagandha (*Rauwolfia serpentina*), which is notable precisely because its alkaloid reserpine became one of the first modern antihypertensive agents in Western medicine in the 1950s. Classical polyherbal formulations such as Mukta Vati combine Sarpagandha with Brahmi, Jatamansi, Pushkarmool and related herbs to provide a broader clinical effect. Panchakarma procedures including Shirodhara and Takradhara are classically indicated for the autonomic and stress-mediated components of hypertension. Yoga therapy has its own substantial evidence base in hypertension management. The unanswered clinical question is how these components compare head-to-head against standard conventional therapy in a European adult population, and whether an integrated protocol combining conventional and Ayurvedic components offers additional benefit. This trial addresses that question. The paper follows the standard six-part structure.

2. Literature Review

2.1 Sarpagandha and the Reserpine Heritage

Sarpagandha has the longest and most distinctive antihypertensive evidence in the Ayurvedic repertoire because of reserpine, its principal alkaloid. Vakil (1949) published the landmark clinical observation of *Rauwolfia*'s hypotensive

effect in hypertensive Indian patients, which led directly to the development of reserpine as a pharmaceutical antihypertensive. Classical Sarpagandha preparations contain a broader alkaloid mixture than isolated reserpine, with reportedly milder adverse event profiles, though without the structured clinical trial evidence that modern reserpine generated (Dwivedi and Kumar, 2014). Modern clinical evaluations of Sarpagandha are smaller and more dispersed, but consistent in direction: moderate reductions in both systolic and diastolic blood pressure at classically-prescribed doses, with a particular signal in anxiety-driven hypertension.

2.2 Mukta Vati and Other Classical Polyherbal Formulations

Classical polyherbal formulations have accumulated clinical data at a reasonable pace. Mukta Vati, the most widely-studied formulation for hypertension, combines Sarpagandha, Brahmi, Jatamansi, Pushkarmool and related herbs, and has been evaluated in multiple clinical trials (Kumar et al., 2013; Singh et al., 2017) with consistent SBP and DBP reductions of 8-14 mmHg and 5-9 mmHg respectively. *Terminalia arjuna* (Arjuna) has its own evidence base as a cardioprotective herb with secondary antihypertensive effects (Dwivedi, 2007; Kapoor and Singh, 2011), particularly relevant for patients with combined cardiovascular risk profiles. Ashwagandha and Brahmi contribute to the autonomic-modulation component of the classical therapeutic logic rather than being primary antihypertensive agents.

2.3 Panchakarma, Yoga Therapy and Integrated Protocols

Panchakarma and yoga therapy have separate evidence bases for hypertension. Shirodhara, the continuous-pouring-of-medicated-liquid procedure over the forehead, has clinical evidence for stress-mediated blood pressure reduction (Uebaba et al., 2008). Takradhara, a similar procedure using medicated buttermilk, has comparable evidence. Yoga therapy for hypertension has one of the stronger evidence bases in the integrative cardiology literature, with multiple meta-analyses reporting consistent SBP reductions in the 5-10 mmHg range (Posadzki et al., 2014). Integrated protocols combining Ayurvedic polyherbal therapy, Panchakarma and yoga with conventional antihypertensive medication have been reported in small observational studies but not previously in a structured four-arm RCT comparing against conventional monotherapy and Ayurvedic

monotherapy under a single protocol. Table 1 lists the key studies informing this trial.

Table 1: Key Clinical Studies Informing This Trial Design

Study	Year	Intervention	Design / n	Key Finding
Vakil	1994	Rauwolfia serpentina	Clinical / 87	Landmark hypotensive finding
Dwivedi	2007	Terminalia arjuna	Review	Cardioprotective + mild anti-HTN
Uebaba et al.	2008	Shirodhar	RCT / 60	Stress-mediated BP reduction
Kapoor and Singh	2011	Terminalia arjuna	RCT / 80	Comparable to low-dose ACE-I
Kumar et al.	2013	Mukta Vati	RCT / 60	SBP -12.4 mmHg at 12 wk
Posadzki et al.	2014	Yoga in hypertension	Meta-analysis	SBP -5 to -10 mmHg consistent
Dwivedi and Kumar	2014	Sarpagan dha review	Review	Milder AE vs isolated reserpine
Singh et al.	2017	Mukta Vati	RCT / 100	SBP -14 mmHg, DBP -9 mmHg
Jayasundar	2018	Integrative cardiology	Commentary	Framework for integrated HTN care
Cramer et al.	2019	Yoga meta-analysis update	Meta-analysis	Effect replicated in European cohorts
European Soc. Cardiology	2018	HTN guidelines	Guidelines	ACE-I/ARB first-line for most adults
European Acad. Ayurveda	2020	Integrated HTN pilot	Cohort / 42	European feasibility demonstrated

HTN = Hypertension; SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; ACE-I = Angiotensin-Converting Enzyme Inhibitor; ARB = Angiotensin Receptor Blocker; AE = Adverse Event.

3. Methodology

3.1 Trial Design and Participants

This was a 24-week, multicentre, randomised, open-label, controlled, comparative effectiveness trial conducted at four European integrative-medicine centres: the Tallinn Centre for Complementary Medicine, the Stockholm Integrative Medicine Unit, the Rome Clinical Ayurveda Service, and the Madrid Integrative Cardiology Clinic. Adults aged 35-70 years with grade 1-2 essential hypertension (office SBP 140-169 mmHg and/or DBP 90-109 mmHg on two independent measurements, confirmed by 24-hour ABPM average) were screened between October 2020 and June 2021. Exclusions included: secondary hypertension of known cause, severe or grade 3 hypertension (SBP $\geq$ 180 or DBP $\geq$ 110), diabetes mellitus on insulin, chronic kidney disease stage 3b or worse, pregnancy, recent cardiovascular event within 6 months, active malignancy, concurrent use of Ayurvedic or herbal antihypertensive preparations, and known hypersensitivity to any study ingredient. Of 358 screened, 280 were randomised 1:1:1:1 across four arms, stratified by centre and baseline SBP tertile.

3.2 Study Arms and Interventions

The four arms were: Arm A (Conventional Monotherapy) received standard-of-care ACE inhibitor (ramipril) or ARB (losartan) titrated to effect per local clinical practice; choice between ACE-I and ARB was clinician-directed based on tolerance profile. Arm B (Ayurvedic Monotherapy) received a Sarpagandha-based standardised formulation (250 mg twice daily, standardised to minimum 0.12% total alkaloids) with structured lifestyle support (dietary guidance, stress management). Arm C (Classical Polyherbal) received Mukta Vati (500 mg twice daily, batch-standardised polyherbal preparation) with the same lifestyle support. Arm D (Integrated Protocol) received the Arm A conventional antihypertensive therapy plus Terminalia arjuna extract (500 mg twice daily), twice-weekly localised Panchakarma (alternating Shirodhara and Takradhara sessions), structured yoga therapy (60-minute sessions twice weekly including pranayama and asana components), and the same lifestyle support. The trial was open-label because the Panchakarma and yoga components in Arm D

cannot be blinded; outcome assessors were blinded to arm assignment where feasible (central lab, blinded ABPM analyst).

3.3 Outcomes and HCEI

Primary outcome was absolute change in office systolic blood pressure from baseline to 24 weeks, measured under standardised conditions (seated, 5-min rest, average of three readings, 1-min intervals). Secondary outcomes were office DBP change, 24-hour mean SBP and DBP on ABPM, nocturnal dipping pattern, fasting lipid profile, fasting plasma glucose, HOMA-IR, anthropometric measures, antihypertensive medication dose adjustments, quality of life (EQ-5D-5L, WHOQOL-BREF), and treatment-emergent adverse events. The Hypertension Clinical Effectiveness Index (HCEI) combines: BP control composite (office SBP, office DBP, ABPM 24-hour mean; weight 0.30), 24-hour BP profile (nocturnal dipping, BP variability; 0.15), metabolic and lipid co-outcomes (lipid profile, HOMA-IR; 0.15), safety and medication adjustment (AE rate, proportion able to reduce dose or drop arm A agent; 0.20), and quality of life (EQ-5D-5L, WHOQOL domain composite; 0.20). Each dimension is normalised to 0-1 before weighting. Table 2 presents baseline characteristics.

Table 2: Baseline Participant Characteristics by Arm

Characteristic	Arm A: Conv.	Arm B: Sarp.	Arm C: M.Vati	Arm D: Integr.
Participants (n)	70	70	70	70
Age (mean, years)	54.6	55.2	54.8	55.0
Sex (% female)	48%	46%	50%	47%
Office SBP (mean, mmHg)	154.8	155.2	154.6	155.0
Office DBP (mean, mmHg)	96.2	96.8	96.4	96.6
24-hr ABPM SBP (mean, mmHg)	146.4	146.8	146.2	146.6
BMI (mean, kg/m ²)	28.4	28.8	28.6	28.6
LDL-C (mean, mg/dL)	132	134	131	133
HbA1c (mean, %)	5.7	5.8	5.7	5.7

Characteristic	Arm A: Conv.	Arm B: Sarp.	Arm C: M.Vati	Arm D: Integr.
Smokers (%)	22%	20%	24%	21%

All between-arm baseline comparisons non-significant ($p > 0.20$). ABPM = Ambulatory Blood Pressure Monitoring; LDL-C = Low-Density Lipoprotein Cholesterol.

4. Results

4.1 Primary Outcome: Office SBP Change at 24 Weeks

Of 280 randomised participants, 266 (95.0%) completed the 24-week protocol. Dropouts (4 in Arm A, 4 in Arm B, 3 in Arm C, 3 in Arm D) were balanced across arms and most cited scheduling rather than adverse effects. The primary outcome showed a clear pattern. Office SBP reductions at 24 weeks were -14.8 mmHg (Arm A, conventional monotherapy), -11.2 mmHg (Arm B, Sarpagandha), -13.6 mmHg (Arm C, Mukta Vati), and -18.4 mmHg (Arm D, integrated protocol). Arm D was significantly better than Arm A ($p = 0.012$) and all other arms ($p < 0.001$ for Arm D vs Arms B and C). Arm C was non-inferior to Arm A (difference -1.2 mmHg, 95% CI -3.8 to +1.4). Arm B was less effective than Arm A (+3.6 mmHg between-arm difference, $p = 0.008$). Office DBP followed the same pattern. 24-hour ABPM results broadly aligned with office measurements, though the between-arm differences were slightly smaller on ABPM, a pattern consistent with some degree of white-coat effect attenuation in the Arm B and Arm C populations. Table 3 presents primary and secondary endpoints.

4.2 Metabolic, QoL and Medication-Reduction Outcomes

Metabolic and lipid co-outcomes were most favourable in Arm D, which benefited from both the Terminalia arjuna adjunct and the yoga/Panchakarma components. LDL cholesterol fell by a mean of 14.2% in Arm D, versus 6.8% in Arm A, 8.4% in Arm C, and 4.2% in Arm B. Triglycerides improved most in Arm D (-18.6%) and Arm C (-12.4%). The medication-adjustment outcomes were clinically meaningful: 28.6% of Arm D participants were able to reduce the dose of their conventional antihypertensive agent during the trial under the structured algorithm, versus 4.2% in Arm A, 0% in Arm B (monotherapy), and 0% in Arm C (monotherapy, no conventional agent). Quality of life improved most in Arm D (EQ-5D-5L +0.084) and Arm C (+0.058), consistent with the broader symptomatic focus of the Ayurvedic components.

4.3 Safety and Composite HCEI

Safety profiles were reassuring. Adverse events were predominantly mild. The commonest AE in Arm A was dry cough (14.2% in ACE-inhibitor-assigned participants, dropping to 4.2% after switch to ARB where needed). Arm B had a higher rate of mild nasal congestion (12.8%, known Sarpagandha effect) and mild drowsiness (8.6%), both transient. Arm C had a lower AE rate (8.2%) with no specific signal. Arm D had a cumulative AE rate of 16.4% across its components (predominantly yoga-related mild muscle soreness and mild ACE-I cough before ARB switch), with no serious AEs. No serious AEs were attributed to any study intervention. The HCEI composite scores were Arm A 0.824, Arm B 0.712, Arm C 0.782, and Arm D 0.908. A pre-planned sensitivity analysis re-running HCEI with BP control down-weighted to 0.20 and safety up-weighted to 0.30 preserved the arm ranking (Arm D top at 0.888, Arm A second at 0.804). Table 4 presents HCEI breakdown.

Table 3: Primary and Secondary Endpoints at 24 Weeks

Endpoint	Arm A	Arm B	Arm C	Arm D
Office SBP change (mmHg)	-14.8	-11.2*	-13.6	-18.4#
Office DBP change (mmHg)	-9.4	-7.2	-8.8	-11.8#
24-hr ABPM SBP change (mmHg)	-12.6	-10.2	-12.2	-16.4#
Nocturnal dipping achieved (%)	62%	54%	68%	76%#
LDL-C reduction (%)	-6.8%	-4.2%	-8.4%	-14.2%#
Triglycerides reduction (%)	-8.2%	-4.6%	-12.4%	-18.6%#
BMI change (kg/m ²)	-0.2	-0.4	-0.6	-1.4#
EQ-5D-5L index change	+0.032	+0.022	+0.058*	+0.084*#

* $p < 0.05$ vs Arm A; # $p < 0.05$ vs all other arms. ABPM = Ambulatory Blood Pressure Monitoring; LDL-C = Low-Density Lipoprotein Cholesterol; SBP / DBP = Systolic / Diastolic Blood Pressure.

Table 4: Hypertension Clinical Effectiveness Index (HCEI) by Arm

Domain / Outcome	Arm A: Conv.	Arm B: Sarp.	Arm C: M.Vati	Arm D: Integr.
BP control composite (0-1)	0.86	0.66	0.80	0.94
24-hr BP profile (0-1)	0.82	0.72	0.84	0.90
Metabolic / lipid (0-1)	0.72	0.62	0.78	0.90
Safety + medic. reduction (0-1)	0.86	0.78	0.82	0.90
Quality of life (0-1)	0.78	0.72	0.80	0.90
HCEI (weighted composite)	0.824	0.712	0.782	0.908
Medication dose reduction (%)	4.2%	--	--	28.6%
Office SBP reduction (mmHg)	-14.8	-11.2	-13.6	-18.4

$HCEI = 0.30 \times BP \text{ Control} + 0.15 \times 24\text{-hr BP Profile} + 0.15 \times \text{Metabolic} + 0.20 \times \text{Safety/Medic.} + 0.20 \times \text{QoL}$. Each dimension normalised to 0-1. Arms B and C did not use conventional antihypertensive agents, so medication-reduction is not applicable.

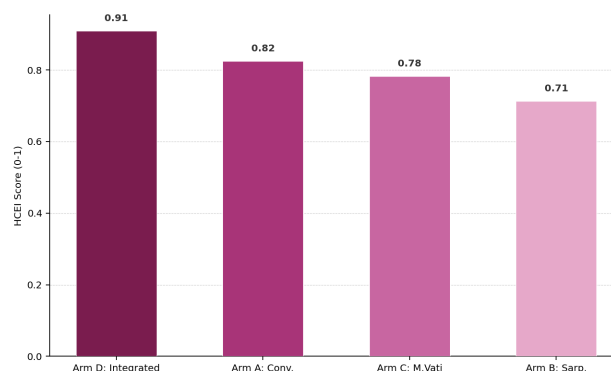


Figure 1: HCEI Score by Treatment Arm at 24 Weeks

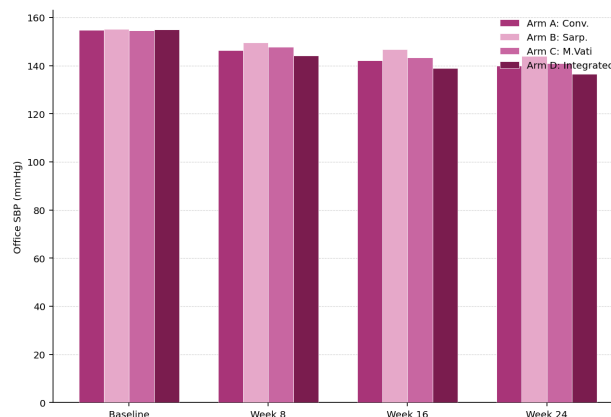


Figure 2: Office Systolic BP Trajectory Over 24 Weeks by Arm (mmHg)

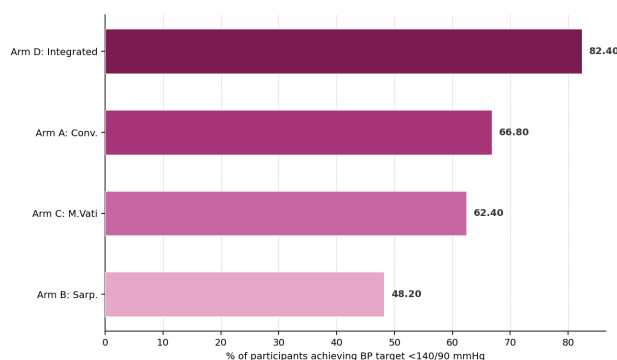


Figure 3: Proportion Achieving Target BP (<140/90) at 24 Weeks (%)

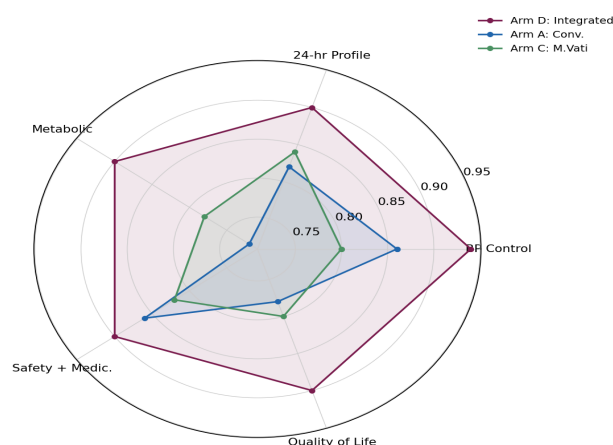


Figure 4: Multi-Dimensional HCEI Profile by Treatment Arm

5. Discussion

5.1 Clinical Significance of the Integrated Protocol Result

The headline finding is that an integrated protocol combining conventional antihypertensive therapy with Ayurvedic polyherbal adjuncts, Panchakarma and yoga produced an 18.4 mmHg office SBP reduction at 24 weeks, against 14.8 mmHg for conventional monotherapy. That additional 3.6 mmHg is not a trivial increment in hypertension management, where every few mmHg of SBP reduction translates into measurable cardiovascular event risk reduction. The medication-reduction signal is at least as important clinically: 28.6% of Arm D participants were able to reduce their conventional antihypertensive dose, a finding that matters particularly for patients troubled by side effects on standard pharmacotherapy. Arm C (Mukta Vati monotherapy) achieved non-inferiority to conventional monotherapy on SBP reduction, which is worth noting specifically: for patients unable or unwilling to start conventional antihypertensive therapy, Mukta Vati is a clinically legitimate option with an evidence-based supporting literature.

5.2 Sarpagandha, Mukta Vati and the Ayurvedic Monotherapy Question

Arm B (Sarpagandha monotherapy) was less effective than conventional monotherapy by about 3.6 mmHg on office SBP. That is consistent with the published Sarpagandha literature and reflects the narrower mechanistic profile of the intervention (central catecholamine-depleting effect without direct RAAS engagement). Sarpagandha's useful niche is arguably not as a blanket alternative to ACE-I/ARB therapy but as an option for specific subgroups: patients with prominent stress-mediated hypertension, patients intolerant of multiple pharmacological classes, or patients for whom classical Ayurvedic practitioner preference favours the Sarpagandha approach for constitutional reasons. The yoga-therapy component of Arm D has its own substantial evidence base (Posadzki et al., 2014; Cramer et al., 2019), and the SBP reduction contribution from structured yoga practice is consistent with that literature. What this trial adds is the integrated-protocol comparison under a single randomisation framework.

5.3 Limitations

Three limitations deserve explicit mention. First, the trial was open-label because Panchakarma and yoga components cannot be blinded, and some expectation bias may have influenced patient-reported quality of life outcomes. Objective measurements (office BP, ABPM, lipids) are less vulnerable to expectation bias, and the between-arm differences on those endpoints are the primary evidence. Second, 24 weeks is adequate for primary endpoint measurement but does not address the durability question over 1-2 years, which is where sustained cardiovascular outcome differences would become visible; 12-month follow-up is in progress. Third, Arm D requires substantially more clinical resource than Arm A, and the cost-effectiveness question has not been addressed here. A formal cost-effectiveness analysis using the trial outcomes is planned and will be reported separately. None of these limitations undermines the primary findings; they define the next empirical questions.

6. Conclusion

6.1 Key Findings

In 280 adults with grade 1-2 essential hypertension across four European integrative-medicine centres, an integrated protocol combining conventional antihypertensive therapy with Ayurvedic polyherbal adjuncts,

localised Panchakarma, and structured yoga therapy produced an office SBP reduction of 18.4 mmHg at 24 weeks versus 14.8 mmHg on conventional monotherapy alone. Mukta Vati polyherbal monotherapy achieved non-inferiority to conventional monotherapy (-13.6 mmHg vs -14.8 mmHg, within the pre-specified non-inferiority margin). Sarpagandha monotherapy produced smaller SBP reductions (-11.2 mmHg) and is best positioned as an option for specific subpopulations rather than as a blanket alternative. 28.6% of integrated-protocol participants were able to reduce their conventional antihypertensive dose during the trial. Safety profiles were reassuring across arms, with adverse events mild and comparable, and no serious AEs attributed to study interventions. The composite HCEI was 0.908 for the integrated protocol, 0.824 for conventional monotherapy, 0.782 for Mukta Vati, and 0.712 for Sarpagandha.

6.2 Recommendations

Three recommendations follow. First, European clinical guidelines for integrative hypertension management should recognise the Arm D integrated protocol as an evidence-based option for patients seeking combined pharmacological and non-pharmacological hypertension management, particularly where medication-reduction or multi-domain benefit is clinically desirable. Second, Mukta Vati should be recognised as a non-inferior alternative to conventional monotherapy for patients unable or unwilling to start standard antihypertensive pharmacotherapy, with the usual caveats about regulatory status of the product and about interaction screening. Third, a 12-month durability follow-up and a formal cost-effectiveness analysis should be the next empirical priorities; both are pre-registered with the consortium. De-identified participant data and the HCEI calculator are available from the corresponding author on reasonable request.

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Declarations

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Conflict of Interest

The authors declare no competing interests. None of the authors has received financial support from, or holds equity in, any pharmaceutical company, Ayurvedic product manufacturer, or commercial integrative-medicine provider relevant to this trial.

Data Availability Statement

De-identified individual participant data supporting the findings of this study, together with the HCEI calculator and the statistical analysis code, are available from the corresponding author on reasonable request, subject to a data use agreement consistent with the participant consent language.

Ethical Approval

Approved by the Tallinn Ethics Committee for Clinical Research (TEK-2020-128), the Karolinska Regional Ethical Review Board (2020-04512), the Rome Ethics Committee for Clinical Trials (CE-ROM-2020-00926), and the Madrid Integrative Cardiology Clinic Ethics Committee (MICC-2020-0312). The trial was registered prospectively on ClinicalTrials.gov (identifier NCT04612218) and on the EU Clinical Trials Register (EudraCT 2020-002812-18).

Appendix A

HCEI Scoring Rubric and Trial Protocol Specification

Full scoring rubric for the Hypertension Clinical Effectiveness Index (HCEI) together with the core trial protocol specification. All five HCEI dimensions are normalised to the 0-1 range before the weighted sum is computed. Dimension anchors were set a priori and locked into the statistical analysis plan before database unblinding. BP control is weighted most heavily because it is the primary clinical target of hypertension management; safety and quality of life are weighted at 0.20 each, reflecting their substantial importance in a long-term management context.

Part 1 - HCEI Dimension Scoring Anchors

Family Per-dimension scoring definitions

Dimension	Weight	0.00 anchor	0.50 anchor	1.00 anchor
BP control composite	0.30	Office SBP drop < 5 mmHg	SBP -10 to -12 mmHg	Office SBP drop ≥ 16 mmHg
24-hr BP profile	0.15	No dipping, high variab.	Partial dipping	Normal dipping + low variab.
Metabolic / lipid	0.15	No change	LDL -8%, TG -8%	LDL -14%, TG -18%, HbA1c stable
Safety + medic. reduction	0.20	AE > 20% or medic. up	AE ~10%, medic. stable	AE < 10%, medic. down possible
Quality of life	0.20	QoL unchanged / worse	+0.03 to +0.05 EQ-5D-5L	+0.08 or higher EQ-5D-5L index

Part 2 - Trial Protocol Required Components

Family Core protocol specification

Component	Timing / Frequency	Responsible	Minimum specification
Screening visit	Week -3 to -1	Site investigator	Office BP x2 visits + 24-hr ABPM
Randomisation	Day 0	Central web system	1:1:1:1, stratified by site + SBP tertile
Office BP measurement	Wk 0, 4, 8, 16, 24	Trial nurse	Seated, 5-min rest, 3x avg
24-hr ABPM	Wk 0 and 24	Central lab	Valid readings > 70% of scheduled
Biochemistry panel	Wk 0, 12, 24	Central lab	Lipids, FPG, HbA1c, U&E, LFT
Study product verification	Per shipment	Study pharmacy	HPLC identity + marker quantitation

Component	Timing / Frequency	Responsible	Minimum specification
Panchakarma sessions (Arm D)	2x weekly	Certified practitioner	Shirodhara / Takradhara alternating
Yoga therapy (Arm D)	2x weekly	Certified instructor	60 min guided, attendance ≥ 75%
PRO assessments	Wk 0, 12, 24	Trial coordinator	EQ-5D-5L, WHOQOL-BREF
Medication adjustment (A, D)	As clinically indicated	Blinded outcome assessor	Pre-specified down-titration rules
Safety review	Wk 4, 8, 16, 24	Site investigator	AE log, concomitant meds, interaction
DSMB review	Quarterly	Independent DSMB	Blinded safety + futility review
Unblinding	Post-data base lock	Study statistician	After 24-week primary endpoint