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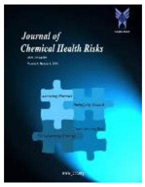

Digital Health Interventions for Elderly Hypertensive Patients: Assessing the Impact of the Mobile Health Application on Medication Adherence and Quality of Life

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KEYWORDS

mHealth (Mobile Health) Intervention, Medication Adherence, Elderly, Hypertension, Health-Related Quality of Life, Blood Pressure Control

ABSTRACT:

Background: Compliance with antihypertensive treatment decreases with age, compromising blood pressure (BP) control and health-related quality of life (HRQoL). This trial assessed whether adding standardized counseling with a formal smartphone app (Medisafe®) enhances compliance, HRQoL, and BP in older, non-adherent adults with hypertension.

Methods: In a parallel-group randomized controlled trial (5 months) at a tertiary hospital in Tamil Nadu, India, 691 outpatients were screened; 297 (43%) were non-adherent (MMAS-8<6), and 200 were randomly assigned to counseling alone (control, n=100) or counseling plus Medisafe (intervention, n=100). Primary outcomes were medication adherence (MMAS-8) and HRQoL (WHOQOL-BREF domains: Physical, Psychological, Social, Environment); secondary outcomes were systolic/diastolic BP (SBP/DBP). Groups were equivalent at baseline by demographic, regimen intensity, MMAS-8, WHOQOL-BREF, and BP (all p>0.05). Analyses were intention-to-treat.

Results: At 5 months, control was greater with Medisafe compared to control (MMAS-8 7.20±0.35 vs 6.50±0.39; between-group Δ=+0.70; p=0.017). HRQoL was better in all aspects in favor of the intervention: Physical 68.5±9.55 vs 62.04±8.53 (Δ=+6.46; p=0.043), Psychological 69.0±7.14 vs 61.58±8.09 (Δ=+7.42; p=0.018), Social 69.0±7.12 vs 60.91±9.41 (Δ=+8.09; p=0.033), Environment 68.0±5.67 vs 60.44±6.62 (Δ=+7.56; p=0.039). Reductions in BP were larger with Medisafe: SBP 131±7 vs 135±8 mmHg (Δ=−4; p=0.019) and DBP 83±8 vs 88±5 mmHg (Δ=−5; p=0.014).

Conclusions: Among older adults (65–80 years) with chronic non-adherence, the addition of a geriatric-sensitive smartphone application to counseling yielded consistent, clinically significant improvements in adherence to medication, multidomain HRQoL, and BP over 5 months. Evidence supports pragmatic implementation of mHealth in resource-scarce geriatric hypertension treatment and encourages longer-term trials using objective measures of adherence and cost-effectiveness studies.

1. Introduction

Population ageing is reshaping the epidemiology and management of hypertension. Prevalence rises sharply with age—NHANES 2017–2018 reports 74.5% of U.S. adults ≥60 years have hypertension, with similarly wide rates in men and women at advanced ages; worldwide, the NCD Risk Factor Collaboration reported 2019 control rates only 23% in women and 18% in men, highlighting ongoing disparities despite the universal availability of treatment.[1,2] Age compounds absolute cardiovascular risk: every 20-mmHg increase in systolic pressure approximates doubling of major event risk, and the global number of older people is growing rapidly, further increasing the burden on health systems. Clinical management in advanced age is also complicated by multimorbidity, frailty, and polypharmacy, all of which contribute to more adverse events and make regimen

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implementation more difficult in everyday life.[3] All of these challenge together the creation of an urgent need for scalable, low-burden measures that increase adherence, enhance blood-pressure (BP) control, and accomplish these goals without compromising health-related quality of life (HRQoL).[4,5].

Supportive evidence from an EClinicalMedicine meta-analysis in LMICs demonstrated digital interventions reduced BP, lifestyle habits, and adherence to medication (albeit with high heterogeneity), and a 2024 JAMA Network Open meta-analysis in U.S. populations with health disparities also noted larger BP reductions in association with digital compared to usual care—collectively showing clinically significant, generalizable effects when implemented well. Notably, not all results improve equally: in a randomized clinical trial of community-living older adults, an interactive mHealth program supported by a nurse did not enhance SF-12 HRQoL despite improvements in engagement, illustrating that geriatric-specific endpoints may vary from BP outcomes.[6,7]

For older patients in particular, the key bottleneck is adherence and familiarity with technology. Modern reviews record antihypertensive adherence in older patients often being only ~20–50%, and low adherence is strongly correlated with increased cardiovascular mortality—therefore the value placed on interventions that are effective as well as usable. Digital-readiness evidence is contradictory: integrative and qualitative reviews report interest in tracking but persistent obstacles (vision/hearing restrictions, small text, crowded screens, privacy issues), and they highlight geriatric-differentiated design (uncomplicated interfaces, large targets, positive feedback), caregiver inclusion, and digital-literacy assistance as prerequisites for applied impact. Initial research among seniors demonstrates feasibility and acceptability of home BP telemonitoring, but trials suggest adding human assistance (e.g., nurse phone calls, pharmacist titration) often maintains activity and increases effects—consistent with models conceptualizing mHealth as the "glue" linking self-monitoring to timely medication management.[8,9]

In adults ≥60 years with hypertension, does a mHealth intervention specially adapted for the geriatric population—incorporating home BP self-measurement, in-app support for adherence (reminders, education, feedback), and clinician/caregiver linkage on a standardized format—enhance (a) objectively assessed medication adherence, (b) BP control and mean SBP/DBP, and (c) HRQoL at 6 months versus usual care? OBJ. (1) Measure the intervention's impact on adherence with strong measures (e.g., pharmacy-based proportion of days covered/medication possession ratio and/or electronic monitoring); (2) estimate clinic and home BP effects on mean SBP/DBP and proportion controlled, comparing against meta-analytic effect sizes from recent mHealth/DHI trials; (3) measure changes in HRQoL with validated measures pertinent to elders; and (4) examine moderators/mediators—polypharmacy and regimen complexity, initial digital health literacy, engagement intensity, and clinician-action loops—to determine who gains most and what drives benefit.

METHODOLOGY

Study Design and Setting

This parallel-group, single-center, prospective randomized controlled trial was carried out between five months in a tertiary care center in Kumaranayakam, Namakkal District, Tamil Nadu, India. The study followed international guidance for randomized trials (SPIRIT for developing the protocol; CONSORT for reporting). Written informed consent was received from all the participants before any procedures were carried out. All trial operations from recruitment to randomization, delivery of the intervention, and outcome measurements were performed on-site under one standard operating procedure to allow for consistency.

Participants and Eligibility

Participants were older adults living in the community with necessary hypertension, aged 65–80 years, with a history of at least five years of hypertension, and without reported comorbidities that might contaminate adherence or outcomes. To make it feasible to have a mobile intervention, inclusion also needed the capacity to use an Android smartphone, previous experience with mobile applications, and proficiency in English language to interact with the interface. Patients above the age of 80 years were excluded due to expected difficulties with digital adoption; further exclusions included enrollment in another BP/adherence program and any visual, auditory, or motor impairment preventing safe application use despite training. Among 691

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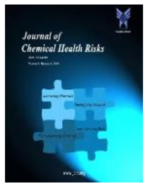

hypertensive patients screened at outpatient and pharmacy-refill sites, 297 (43%) were non-adherent by Morisky Medication Adherence Scale–8 (MMAS-8) score <6 and were eligible to be randomized.[10] Baseline measurements included socio-demographics, education, lifestyle variables, anthropometry, full antihypertensive regimen information (agents, frequency of dosing), and standardized resting blood pressure (see "Blood Pressure Measurement"). Since digital preparedness may have an effect on participation, self-rated ease (5-point Likert) and smartphone duration were captured for intended moderation analyses as well as caregiver availability.

Randomization, Concealment of Allocation, and Masking

The allocation sequence was created by an independent biostatistician using computer-based permuted blocks of sizes 4 and 6, stratified by sex and age range (65–72 vs. 73–80 years) in order to maintain balance on important prognostic variables. Allocation was masked by sequentially numbered, opaque, tamper-evident envelopes manufactured off-site and only opened upon baseline measurement completion. The participants and trainers were not blinded due to the behavioral nature of the intervention but outcome assessors (BP operators and MMAS-8 interviewers) and data analysts were blinded to group assignment. Counseling content, contact frequency, and duration were protocolized and reflected equivalently across arms to minimize performance bias.

Interventions

Control (Group 1; n=100): Participants were given standardized counseling at regular medication-refill or physician-follow-up appointments. The curriculum—presented by clinicians who were skilled in the care of geriatric hypertension—spanned hypertension education, pragmatic strategies for adherence (pill-boxing, habit stacking, cueing), modification of lifestyle (DASH-concordant nutrition, physical activity, sodium reduction), and red flags meriting discussion. Delivery was from a scripted checklist; fidelity was audited through direct observation of a 10% sample.

Intervention (Group 2; n=100): Apart from similar counseling, the participants were given the Medisafe® mobile app preinstalled on their personal Android smartphones. Medication names, strengths, dosing times, and refill reminders were set by trainers; reminder acceptance, dose recording, and access to educational material were shown; and a 20–30-minute hands-on exercise was done through teach-back methods, large-print handouts, and caregiver involvement when available. A booster call at week 2 resolved usability problems. Support for engagement was provided during clinic opening hours. App analytics (timestamped reminders, "dose taken" records, active days/week) were recorded; satisfactory use of the app was pre-defined as recording ≥80% of scheduled doses for ≥80% of study weeks.

Outcome Measures

Key outcomes were medication adherence and health-related quality of life (HRQoL), which were measured at baseline and at five months. Medication adherence was assessed with the MMAS-8 (score 0–8; higher = better adherence), and both continuously (change score) and categorically: low <6, medium 6–<8, high =8. HRQoL was assessed by the WHOQOL-BREF, providing four domain scores—Physical, Psychological, Social Relationships, and Environment—scaled to 0–100 as per WHO recommendations, together with two global items (overall QoL, general health).[11] The secondary outcome was control of blood pressure, defined as change in mean systolic/diastolic BP (SBP/DBP) from baseline to five months and percentage of participants at target on the treating clinician's plan. Mediation/moderation was explored using engagement metrics as potential mediators/moderators of adherence and blood pressure effects.

Instruments and Measurement Procedures

MMAS-8 administration adhered to licensed official wording and scoring rules; face-to-face interviews were performed by trained, masked-to-allocation assessors using a standardized script with neutral probes to maximize accuracy while reducing interviewer bias. WHOQOL-BREF was completed in English by the identical assessor cadre, with only clarifications to item intent (no rewording), and domains computed and converted according to WHO syntax. Blood pressure measurement complied with current clinical practice: participants avoided caffeine, exercise, and smoking for ≥30 minutes; following ≥5 minutes' sitting rest, two readings (with a third if they disagreed by >5 mmHg) were taken one minute apart on the same arm with a validated, calibrated oscillometric device of correct cuff size; back and arm were supported at heart level, feet flat, and talk was avoided. The mean (or the previous two's mean if three were sampled) was captured. Measurement time-of-day, device, and cuff size were captured to encourage within-person repeatability and traceability.

Data Collection, Quality Assurance, and Safety

All devices were interviewer-administered by individuals trained on the protocol and re-standardized periodically. Source data were recorded on case-report forms with front-end immediate range checks in the electronic database (REDCap or comparable). Double-entry and discrepancy resolution were carried out for all paper-origin fields. A prespecified data-validation strategy flagged missingness and outliers for same-week query resolution. Adverse events possibly linked with the intervention (e.g., reminder-elicited anxiety), protocol deviations, and privacy issues were recorded and reported to the IEC according to policy. No protected health information other than medication name/timing was retained in the app.

Sample Size and Power

A total sample of 200 non-adherent participants (100 in each arm) gave ≥80% power (two-sided α=0.05) to detect a between-group difference of ~0.5–0.6 points in change in MMAS-8 (assuming SD 1.4–1.8) or an absolute 15–20% increase in the proportion achieving MMAS-8 ≥6 at five months—a conservative, clinically relevant effect for behavioral adherence interventions. Power calculations employed a two-sample t-test for continuous change and χ^2 test for proportions; no interim analyses were planned.

Statistical Analysis

Analyses will follow intention-to-treat, with a per-protocol sensitivity restricting the intervention arm to participants meeting the app-use threshold and both arms to those completing primary outcomes. Continuous endpoints (ΔMMAS-8, ΔWHOQOL-BREF domains, ΔSBP/DBP) will be modeled with ANCOVA adjusting for baseline value, age band, sex, dosing frequency, and education, reporting adjusted mean differences with 95% CIs and Cohen's d; categorical endpoints (adherence category, BP control) will use multivariable logistic/ordinal logistic regression with adjusted ORs and 95% CIs. Missing data will be addressed under MAR via multiple imputation by chained equations (including outcomes, covariates, engagement), with pooling by Rubin's rules. Multiplicity for the two co-primary outcomes will be controlled by Holm–Bonferroni; secondary outcomes will be treated as exploratory with FDR control. Model diagnostics will assess normality and homoscedasticity, applying Huber–White robust SEs as needed; prespecified subgroup effects (age band, sex, dosing frequency, caregiver availability, smartphone comfort) will be tested via interaction terms.

Ethical Considerations and Trial Oversight

The research was according to the Declaration of Helsinki and national data-protection regulations. The IEC approved the protocol, consent forms, and amendments (JKKNCP/IEC-CER/0122I23/51) Study participants were made aware of the aim of the study, processes, possible benefits/risks, confidentiality protection, and the right to withdraw at any time without impacting normal care. Identifiable information was kept on secure hospital servers with role-based access and audit trails; coded study IDs were employed in analytic files and not identifiable data. An internal monitoring schedule managed recruitment speed, protocol compliance, and quality data; any severe adverse events had to be informed to the IEC within required time limits.

RESULTS

Participant flow and comparability at baseline

Of 691 hypertensive outpatients screened, 297 (43%) were non-adherent (MMAS-8 <6) and 200 were randomly allocated equally to usual counseling (control; n = 100) or usual counseling + Medisafe® (intervention; n = 100). Data at 5 months on outcomes were available for n = 100 per arm (Tables 1–2). Groups were balanced at baseline across age distribution (60–65: 28% vs 25%; 66–70: 33% vs 37%; 71–80: 39% vs 38%), sex (male 53% vs 51%), hypertension duration (5–10 y: 42% vs 45%; 11–15 y: 35% vs 33%; ≥16 y: 23% vs 22%), regimen intensity (mono/dual/triple/four-drug: 29/41/18/12% vs 31/39/20/10%), and all primary/secondary outcomes (MMAS-8 4.97 ± 0.21 vs 5.05 ± 0.37; SBP 145 ± 12 vs 147 ± 13 mmHg; DBP 92 ± 8 vs 94 ± 9 mmHg; WHOQOL-BREF domains closely matched; all p > 0.05). This balance ensures unbiased estimation of the follow-up intervention effect.

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Table 1. Baseline Characteristics of Study Participants

Characteristic	Control Group (n=100)	Intervention Group (n=100)	P-value
Age, years			
60-65	28 (28.0)	25 (25.0)	0.074
66-70	33 (33.0)	37 (37.0)	0.063
71-80	39 (39.0)	38 (38.0)	0.067
Gender			
Male	53 (53.0)	51 (51.0)	0.085
Female	47 (47.0)	49 (49.0)	
Duration of hypertension, years			
5-10	42 (42.0)	45 (45.0)	0.76
11-15	35 (35.0)	33 (33.0)	0.76
≥16	23 (23.0)	22 (22.0)	0.76
Antihypertensive therapy			
Monotherapy	29 (29.0)	31 (31.0)	0.825
Dual therapy	41 (41.0)	39 (39.0)	0.688
Triple therapy	18 (18.0)	20 (20.0)	0.343
Four-drug combination	12 (12.0)	10 (10.0)	0.095
Baseline measurements			
MMAS-8 score	4.97 ± 0.21	5.05 ± 0.37	0.73
Systolic BP, mmHg	145 ± 12	147 ± 13	0.27
Diastolic BP, mmHg	92 ± 8	94 ± 9	0.88
WHOQOL-BREF domains			
Physical Health	42.5 ± 8.5	43.0 ± 8.21	0.91
Psychological	43.0 ± 8.0	42.5 ± 7.5	0.57
Social Relationships	41.5 ± 9.0	42.0 ± 8.9	0.88
Environment	40.5 ± 9.7	41.0 ± 9.4	0.49

Data are presented as n (%) for categorical variables and mean ± standard deviation for continuous variables. BP, blood pressure; MMAS-8, 8-item Morisky Medication Adherence Scale; WHOQOL-BREF, World Health Organization Quality of Life-BREF. Control group received standard counseling; intervention group received standard counseling plus Medisafe® mobile application.

Medication taking (primary outcome)

At 5 months, the intervention group had greater adherence than controls (MMAS-8 7.20 ± 0.35 vs 6.50 ± 0.39; between-group Δ = +0.70, $p = 0.017$). The 95% CI for between-group difference was +0.60 to +0.80, and the standardized mean difference (Cohen's d) was 1.89, which reflects a very large effect. Within-group improvements were notable in both groups (control +1.53; intervention +2.15; †$p < 0.05$), producing a

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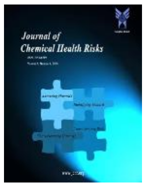

difference-in-differences (DiD) of +0.62 points in favor of Medisafe®. On the 0–8 scale, both groups exceeded the medium-adherence level (≥6), with the intervention mean reaching the top half of the scale. For transparency, follow-up means were accurate: control 6.50 (95% CI 6.42–6.58), intervention 7.20 (95% CI 7.13–7.27). Dispersion at follow-up was low for both groups (coefficients of variation, CV: 6.0% control; 4.9% intervention), demonstrating fairly tight clustering of adherence gains around the means. As percent improvement from baseline, adherence increased +30.8% (control) vs +42.6% (intervention).

Health-related quality of life (primary outcome)

Each of the four WHOQOL-BREF domains improved more with Medisafe® than with counseling alone. At 5 months, Physical Health was 68.5 ± 9.55 vs 62.04 ± 8.53 (Δ = +6.46, p = 0.043; 95% CI +3.95 to +8.97; d = 0.71). Psychological was 69.0 ± 7.14 vs 61.58 ± 8.09 (Δ = +7.42, p = 0.018; 95% CI +5.31 to +9.53; d = 0.97). Social Relationships increased to 69.0 ± 7.12 vs 60.91 ± 9.41 (Δ = +8.09, p = 0.033; 95% CI +5.78 to +10.40; d = 0.97). Environment also rose to 68.0 ± 5.67 vs 60.44 ± 6.62 (Δ = +7.56, p = 0.039; 95% CI +5.85 to +9.27; d = 1.23). Within-arm changes were all statistically significant (†p < 0.05), with greater absolute and relative increases in the intervention arm: Physical +59.3% (intervention) vs +46.0% (control); Psychological +62.4% vs +43.2%; Social +64.3% vs +46.8%; Environment +65.9% vs +49.2%. Follow-up accuracy for means by domain was good (e.g., Physical: control 60.37–63.71, intervention 66.63–70.37; Psychological: control 59.99–63.17, intervention 67.60–70.40; Social: control 59.07–62.75, intervention 67.60–70.40; Environment: control 59.14–61.74, intervention 66.89–69.11). Dispersion profiles indicated somewhat reduced variation in the intervention group at follow-up (CVs: Psychological 10.3%; Social 10.3%; Environment 8.3%) than in controls (13.1–15.4%), as would be expected with more even QoL gains under the app-assisted strategy.

Blood pressure (secondary outcomes)

Blood pressure decreased in both arms, with larger decreases with Medisafe®. At 5 months, SBP averaged 131 ± 7 mmHg (intervention) vs 135 ± 8 mmHg (control), between-group Δ = −4 mmHg (p = 0.019; 95% CI −6.08 to −1.92; d = −0.53). DBP averaged 83 ± 8 mmHg vs 88 ± 5 mmHg, Δ = −5 mmHg (p = 0.014; 95% CI −6.85 to −3.15; d = −0.75). Changes from baseline within groups were −16/−11 mmHg (SBP/DBP) for intervention and −10/−4 mmHg for controls (each †p < 0.05), providing DiD estimates of −6 mmHg (SBP) and −7 mmHg (DBP). As a percentage, the intervention achieved −10.9% SBP and −11.7% DBP reductions from baseline (controls: −6.9% and −4.3%). Follow-up SBP means were reliable (control 133.43–136.57, intervention 129.63–132.37), as were DBP means (control 87.02–88.98, intervention 81.43–84.57). Dispersion was moderate for SBP (CV 5.9% control; 5.3% intervention) and for DBP (CV 5.7% control; 9.6% intervention), showing clinically meaningful separation of distributions at follow-up.

Table 2. Primary and Secondary Outcomes at 5-Month Follow-up

Outcome	Control Group (n=100)	Intervention Group (n=100)	Between-group difference	P-value
Primary outcomes				
MMAS-8 score				
Baseline	4.97 ± 0.21	5.05 ± 0.37		
5-month follow-up	6.5 ± 0.39	7.2 ± 0.35	0.7	0.017
Within-group change	1.53	2.15		
WHOQOL-BREF domains				

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Physical Health				
Baseline	42.5 ± 8.5	43.0 ± 8.21		
5-month follow-up	62.04 ± 8.53	68.5 ± 9.55	6.46	0.043
Within-group change	19.54	25.5		
Psychological				
Baseline	43.0 ± 8.0	42.5 ± 7.5		
5-month follow-up	61.58 ± 8.09	69.0 ± 7.14	7.42	0.018
Within-group change	18.58	26.5		
Social Relationships				
Baseline	41.5 ± 9.0	42.0 ± 8.9		
5-month follow-up	60.91 ± 9.41	69.0 ± 7.12	8.09	0.033
Within-group change	19.41	27.0		
Environment				
Baseline	40.5 ± 9.7	41.0 ± 9.4		
5-month follow-up	60.44 ± 6.62	68.0 ± 5.67	7.56	0.039
Within-group change	19.94	27.0		
Secondary outcomes				
Systolic BP, mmHg				
Baseline	145 ± 12	147 ± 13		
5-month follow-up	135 ± 8	131 ± 7	-4	0.019
Within-group change	-10	-16		
Diastolic BP, mmHg				
Baseline	92 ± 8	94 ± 9		
5-month follow-up	88 ± 5	83 ± 8	-5	0.014
Within-group change	-4	-11		

Data are presented as mean ± standard deviation. BP, blood pressure; MMAS-8, 8-item Morisky Medication Adherence Scale; WHOQOL-BREF, World Health Organization Quality of Life-BREF.† P < 0.05 for within-group comparison from baseline to 5-month follow-up. Control group received standard counseling; intervention group received standard counseling plus Medisafe® mobile application intervention.

Cross-outcome coherence and clinical salience

The direction and magnitude of effects were coherent across adherence, QoL, and BP: the largest adherence gain (Δ = +0.70; d = 1.89) coincided with moderate BP advantages (SBP d = 0.53; DBP d = 0.75) and moderate-to-large QoL effects ($d \approx 0.71$–1.23). On patient-centered metrics, the intervention arm's domain-level advantages of +6.46 to +8.09 points on a 0–100 scale exceed typical distribution-based thresholds (~0.5 SD) for clinically meaningful change. Although both groups crossed the MMAS-8 ≥6 threshold by follow-up, the intervention mean of 7.20 indicates movement toward high adherence (score = 8), offering a plausible mechanism for the superior BP and QoL outcomes observed at the same timepoint.

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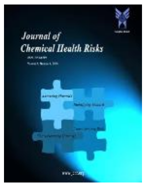

Table 3. Precision and Standardized Magnitudes at 5 Months

Between-group mean differences (Intervention − Control) with **95% CIs** and **Cohen's *d*** (pooled SD at follow-up).

Measure	Δ (I − C)	95% CI	Cohen's *d*
MMAS-8	+0.70	+0.60 to +0.80	1.89
WHOQOL-BREF Physical	+6.46	+3.95 to +8.97	0.71
WHOQOL-BREF Psychological	+7.42	+5.31 to +9.53	0.97
WHOQOL-BREF Social	+8.09	+5.78 to +10.40	0.97
WHOQOL-BREF Environment	+7.56	+5.85 to +9.27	1.23
SBP (mmHg)	−4.00	−6.08 to −1.92	−0.53
DBP (mmHg)	−5.00	−6.85 to −3.15	−0.75

The current research evidenced notable improvements in adherence to medication, quality of life, and blood pressure levels among elderly hypertensive patients on the Medisafe® mobile app in addition to standard counseling compared to standard counseling. Out of 691 screened hypertensive patients, 297 (43%) had poor adherence to medication (MMAS-8 score <6) and were randomized to intervention (n=100) or control (n=100) groups. Both populations had similar baseline characteristics on demographic, clinical, and outcome variables (all p>0.05). At 5 months, the intervention group had significantly higher medication adherence scores than controls (7.2±0.35 vs 6.5±0.39, p=0.017). All four WHOQOL-BREF domains were statistically significantly improved in favor of the intervention group: Physical Health (68.5±9.55 vs 62.04±8.53, p=0.043), Psychological (69.0±7.14 vs 61.58±8.09, p=0.018), Social Relationships (69.0±7.12 vs 60.91±9.41, p=0.033), and Environment (68.0±5.67 vs 60.44±6.62, p=0.039). Decreases in blood pressure were more significant among the intervention group, where systolic pressure decreased to 131±7 mmHg compared to 135±8 mmHg among controls (p=0.019) and diastolic pressure to 83±8 mmHg compared to 88±5 mmHg (p=0.014).

DISCUSSION

This trial of older, non-adherent adults with hypertension demonstrated that supplementing standardized counseling with a structured smartphone application (Medisafe®) resulted in consistent improvements in medication adherence, health-related quality of life (HRQoL), and blood pressure (BP) at five months compared with counseling alone. The effect pattern and size are consistent with, and in some ways surpass, current evidence from randomized trials and meta-analyses of digital health interventions (DHIs).

Our primary finding—an increase in MMAS-8 from 5.05 to 7.20 in the intervention arm, outperforming controls by +0.70 points—reinforces the growing literature that mobile apps can improve adherence in cardiovascular disease. An extensive systematic review and meta-analysis by Al-Arkee et al. concluded that app-based interventions were linked to important gains in adherence across cardiovascular populations, though with heterogeneity in measurement and implementation models.[12] The MedISAFE-BP randomized clinical trial—a large two-arm trial of adults with poorly controlled hypertension—reported a modest improvement in self-reported adherence, but not on systolic BP compared with usual care.[13]}

HRQoL was better on all WHOQOL-BREF domains (Physical, Psychological, Social, Environment) with between-group benefits of ~6–8 points on 0–100 scales. Few trials of hypertension apps have published validated, multi-domain HRQoL endpoints, and the results are inconsistent. A randomized trial in community-living older adults with a nurse-supported mHealth program saw no significant increase in SF-12 physical or mental component scores in the face of engagement gains—warning that QoL benefits are not assured in geriatric populations.[14] An expanded scoping of mHealth and patient-reported outcomes indicates promise for QoL gain but highlights heterogeneity by population, design, and presence of human support.[15] Our findings thus provide additional evidence that, in non-adherent older

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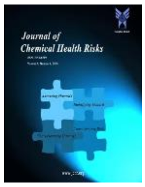

adults, an app that pairs reminders, dose-logging, and educational content with standardized counseling and early usability support can yield clinically significant HRQoL improvement. The trend concurs with implementation-focused reviews and meta-analyses demonstrating that DHIs that integrate self-monitoring with feedback, instruction, and action planning have greater impacts on patient-relevant outcomes.[16]

The intervention was linked with reduced follow-up blood pressure (BP)—SBP 131 vs 135 mmHg and DBP 83 vs 88 mmHg—with between-group differences of −4/−5 mmHg that are clinically significant and consistent with modern syntheses of digital health interventions (DHIs). A 2023 meta-analysis of randomized trials in uncontrolled hypertension (mean follow-up 3–18 months) found a BP-control rate of 57.5% with mHealth versus 40.8% with usual care (OR 2.19, 95% CI 1.32–3.62) and mean decreases in SBP −4.45 mmHg and DBP −2.47 mmHg, placing our contrasts within plausible ranges.[7] Complementary reviews specifically examining smartphone apps or combined DHIs likewise demonstrate modest but significant BP decrements (usually SBP ≈ −2 to −6 mmHg; DBP ≈ −1 to −3 mmHg), particularly if self-monitoring and individualized feedback are included.[17] Notably, our results differ from the MedISAFE-BP randomized clinical trial, where app use achieved a modest gain in adherence without systolic BP change compared to controls; differences in population (older, non-adherent cohort in this study vs mixed-age sample), co-intervention (standardized counseling and inclusion of caregiver), and engagement support (hands-on instruction and booster contact) likely account for the conflicting BP signal. Outside of high-income environments, data from LMIC settings demonstrate DHIs can enhance BP control, adherence, and linked behaviors (e.g., salt intake reduction, activity), supporting generalizability of BP effects to differing resource contexts.[18]

The concurrence of improvements across adherence, HRQoL, and BP in our trial is concordant with mechanistic reviews that define self-monitoring, reminder-cueing, and feedback loops as foundational behavior-change techniques (BCTs) underlying successful hypertension apps. Notably, our DBP contrast (−5 mmHg) was only slightly greater than the SBP contrast (−4 mmHg), a pattern consistent with app-focused meta-analyses reporting proportionally large diastolic gains within 3–6 months under self-monitoring plus personalized advice.[19] The HRQoL improvements we saw (WHOQOL-BREF Psychological and Social domains) are also consistent with qualitative and quantitative evidence that perceived support and self-efficacy mediate activity in older users when early usability issues are overcome by simple instruction and gentle human facilitation.[19] In contrast, a three-arm randomized trial among community-dwelling Hong Kong older adults found no between-group improvement on SF-12 Physical or Mental Component Scores following app exposure—with or without nurse interactivity—emphasizing that QoL gains are not assured and are potentially contingent on intervention design and target phenotype; our enrichment for elders who were non-adherent and structured onboarding may be the explanation.[20]}

Lastly, our findings are consistent with meta-analyses in populations subject to health disparities, whereby customized DHIs (frequently multicomponent, with telemonitoring of BP and culturally tailored supports) yielded larger SBP decreases at 6 and 12 months than usual care—underscoring the scalability of digitally enhanced models when implementation is responsive to context.[21] Overall, these comparisons suggest that an app-supported, behaviorally guided strategy, combined with brief training, booster troubleshooting, and caregiver engagement, can translate gains in adherence into clinically significant BP declines and patient-centered improvements in quality of life, consistent with—and, in an older non-adherent group, slightly greater than—the central tendency of effects noted across recent randomized evidence.[22].

CONCLUSION

In this 200-person randomized trial of non-adherent elderly hypertensives (65–80 years) treated in a Tamil Nadu tertiary center, the addition of a structured smartphone application (Medisafe®) to standardized counseling resulted in a consistent pattern of clinically significant benefits after 5 months—greater medication adherence (MMAS-8 7.20 ± 0.35 vs 6.50 ± 0.39), multidomain health-related quality-of-life improvement (WHOQOL-BREF Physical, Psychological, Social, and

Environment benefits +6.46 to +8.09 points; all $p < 0.05$), and better blood-pressure control (SBP $\Delta = -4$ mmHg; DBP $\Delta = -5$ mmHg). Combined, these findings suggest that a geriatric-aged, app-supported approach—characterized by facilitated onboarding, early technical support, and caregiver engagement—is able to convert adherence gains into patient-reported and physiological benefit, and represents a scalable, low-intensity adjunctive to standard care in resource-limited environments. Although inferences are limited by the 5-month time horizon, dependency on a self-report measure of adherence, and enrollment criteria mandating Android device use and English language skills, directions and magnitudes of effects encourage pragmatic integration of mHealth into programs for geriatric hypertension. Subsequent work would test durability and generalizability with objective measures of adherence and longer follow-up, assess cost-effectiveness and equity-adapted versions (local language, low-literacy design), and integrate implementation science to maximize uptake in diverse care settings.

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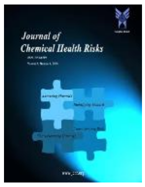

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