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Original Article

Effect of a Family History– and Risk Score–Based Decision Aid on Shared Decision-Making and Screening Outcomes: A Precision Prevention Randomized Trial

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ABSTRACT

Background: Effective shared decision-making is central to cardiovascular disease prevention, yet patients frequently experience decisional conflict, limited confidence, and inadequate engagement when risk information is conveyed through usual care alone. Decision aids have been shown to improve decision quality, but comparative evidence on the impact of decision aid intensity remains limited, particularly in primary care settings within low- and middle-income countries. Objective: To evaluate the comparative effectiveness of two decision aid intensities, strong and moderate, versus usual care in improving decision quality among adults undergoing cardiovascular risk assessment. Methods: A single-center, parallel-group randomized controlled trial was conducted at Lahore General Hospital, Lahore, enrolling 39 participants allocated equally to control, moderate decision aid, or strong decision aid groups. Continuous outcomes included decisional conflict, decision self-efficacy, knowledge, decisional regret, and participation/satisfaction, while binary outcomes assessed decision attainment, family history behaviors, lifestyle changes, and screening completion. Group differences were analyzed using analysis of variance with effect sizes, followed by Bonferroni-adjusted pairwise comparisons, and categorical outcomes were evaluated using chi-square tests and odds ratios. Results: Significant between-group differences were observed across all continuous outcomes (all $p \leq 0.002$), with the strong decision aid demonstrating the largest effects, including marked improvements in decision self-efficacy ($d = 3.42$) and participation/satisfaction ($d = 2.82$), and substantial reductions in decisional conflict ($d = -1.45$) and regret ($d = -1.92$). Binary outcomes showed favorable trends for decision aids but were underpowered for statistical significance. Conclusion: Decision aids significantly enhance decision quality in cardiovascular risk assessment, with greater benefits observed with higher intervention intensity, supporting the clinical value of comprehensive decision aids in primary prevention. Keywords: shared decision-making; decision aids; cardiovascular risk; primary prevention; randomized controlled trial

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INTRODUCTION

Cardiovascular disease remains a leading cause of morbidity and mortality worldwide, with primary prevention increasingly relying on accurate risk stratification and informed patient participation in clinical decision-making. Contemporary prevention guidelines emphasize absolute cardiovascular risk estimation combined with shared decision-making to align preventive strategies with individual values, preferences, and risk tolerance (1). However, despite the availability of validated risk calculators and evidence-based preventive interventions, patients often experience decisional conflict, limited understanding of probabilistic risk information, and reduced confidence in choosing among preventive options, which can undermine both adherence and long-term outcomes (2,3). These challenges are particularly salient in primary care settings, where time constraints and variable health literacy further complicate effective risk communication.

Decision aids have emerged as structured tools designed to support shared decision-making by presenting personalized risk information, clarifying options, and facilitating value-congruent choices. Prior randomized trials have demonstrated that decision aids can significantly reduce decisional conflict, improve knowledge, and enhance decision self-efficacy across diverse preventive contexts, including cardiovascular risk management, cancer screening, and genetic risk disclosure (1,4–6). Additionally, interventions incorporating family history information have shown promise in improving risk perception accuracy, stimulating preventive behaviors, and increasing patient engagement with screening and lifestyle modification (4,5,7). Nevertheless, existing evidence suggests that the magnitude of benefit from decision aids may vary according to their intensity, depth of personalization, and behavioral reinforcement components, with limited comparative data evaluating different "strengths" or delivery intensities of decision aid interventions within the same clinical framework.

In low- and middle-income healthcare settings, where preventive cardiology resources are often constrained, identifying scalable decision aid strategies that maximize decision quality without excessive complexity is particularly important. While prior studies have largely compared decision aids against usual care, few randomized controlled trials have directly contrasted varying intensities of decision aid exposure to determine whether more comprehensive interventions yield proportionally greater benefits in decisional outcomes. Moreover, there remains a paucity of locally generated evidence from South Asian primary care populations, where cardiovascular risk profiles, family structures, and sociocultural decision-making dynamics may differ substantially from Western cohorts. Addressing this gap is essential to inform contextually appropriate shared decision-making strategies and to optimize preventive care delivery.

Therefore, the present randomized controlled trial was designed to evaluate the comparative effectiveness of two decision aid intensities—a strong decision aid and a moderate decision aid—against usual care in improving decision quality among adults undergoing cardiovascular risk assessment in a primary care setting. Guided by a PICO framework, the study aimed to assess whether exposure to decision aids, particularly a more intensive version, would reduce decisional conflict and regret, enhance decision self-efficacy and knowledge, and improve patient participation and satisfaction. The primary hypothesis was that both decision aid interventions would outperform usual care across decision-quality outcomes, with the strong decision aid producing the greatest magnitude of effect.

MATERIALS AND METHODS

This randomized controlled trial employed a parallel-group design with three arms, including two experimental intervention groups and one control group, to evaluate the impact of decision aid intensity on cardiovascular decision-making outcomes. The study was conducted at Lahore General Hospital, Lahore, a tertiary-level outpatient facility providing primary and preventive healthcare services. Participant recruitment and data collection were carried out over a predefined study period during routine clinical visits. Eligible participants were adults attending the clinic for cardiovascular risk assessment who were capable of providing informed consent and participating in structured decision-making activities. Individuals with established cardiovascular disease, cognitive impairment, or inability to comprehend the decision aid materials were excluded to ensure the validity of decisional outcome assessments.

Participants were recruited consecutively and randomly allocated in a 1:1:1 ratio to the control group, the moderate decision aid group, or the strong decision aid group using a computer-generated randomization sequence. Allocation concealment was maintained through sealed opaque envelopes opened after enrollment. All participants provided written informed consent prior to participation. The control group received standard care, which included routine cardiovascular risk counseling as per usual clinical practice. The moderate decision aid group received a structured decision aid presenting individualized cardiovascular risk information, preventive options, and brief value clarification

elements. The strong decision aid group received an enhanced version incorporating more detailed risk communication, extended educational content, explicit value clarification exercises, and behavioral prompts designed to reinforce engagement and reflection.

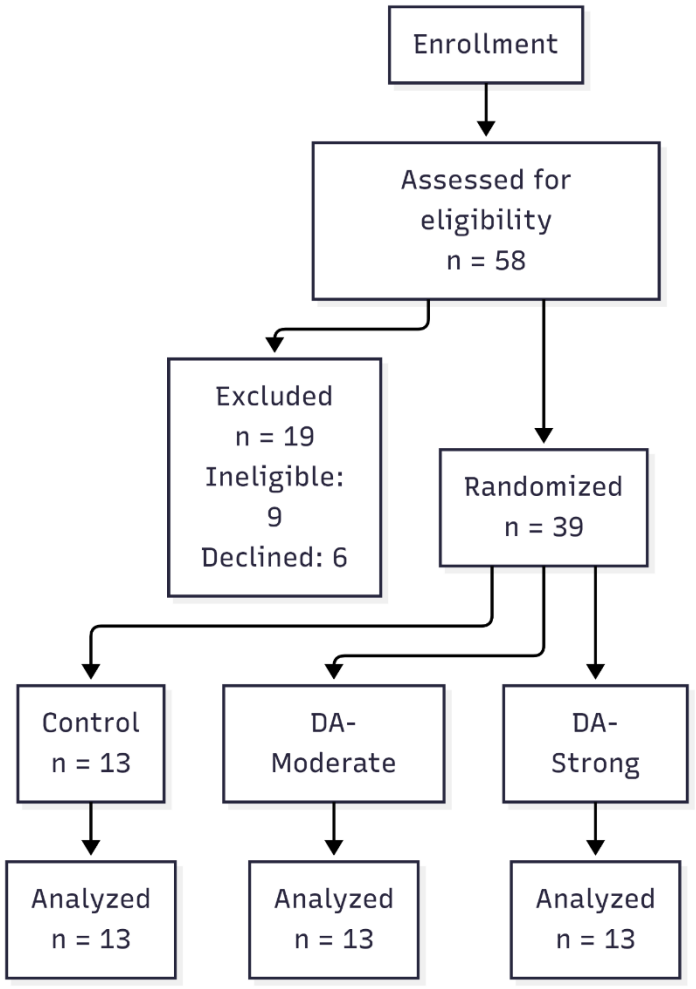

Figure 1 CONSORT Flowchart

Data collection was conducted immediately following the intervention exposure using validated instruments. Decisional conflict was measured using a standardized scale ranging from 0 to 100, with lower scores indicating less conflict. Decision self-efficacy was assessed on a 0–100 scale, with higher scores reflecting greater confidence in decision-making. Knowledge was evaluated using a structured questionnaire scored from 0 to 5. Decisional regret was measured on a 0–20 scale, with lower scores indicating less regret. Participation and satisfaction were assessed using a Likert-type scale ranging from 1 to 5. Binary outcomes included decision attainment, family history information gathering and sharing, lifestyle behavior changes, cholesterol screening completion, and risk classification status. All variables were operationally defined a priori to ensure consistency and reproducibility.

The sample size was fixed at 39 participants, with 13 individuals per group, reflecting the pilot nature of the trial and feasibility considerations. While not powered for definitive conclusions on binary endpoints, the sample was deemed sufficient to detect moderate-to-large effect sizes in continuous decisional outcomes. Statistical analysis was performed using standard statistical software. Continuous variables were summarized as mean ± standard deviation and analyzed using one-way analysis of variance with eta-squared reported as a measure of effect size. Pairwise comparisons versus control were conducted using independent-sample t-tests with Bonferroni adjustment and Cohen's d calculated to quantify effect magnitude. Categorical variables were summarized as counts and percentages, analyzed using chi-square tests, and supplemented with odds ratios and Fisher's exact tests where appropriate due to small cell sizes. Missing data were minimal and handled by complete-case analysis. Measures to minimize bias

included standardized intervention delivery, validated instruments, and prespecified analysis plans. The study protocol was approved by the relevant institutional ethics committee, and all procedures adhered to ethical principles for human research.

RESULTS

A total of 39 participants were analyzed (n = 13 per group). Continuous decision-quality outcomes demonstrated clear between-group differences favoring both decision aid arms, with the strongest and most consistent benefit observed in the DA-Strong arm. Across all continuous endpoints, omnibus ANOVA showed statistically significant group effects with moderate-to-large effect sizes (eta-squared range 0.292–0.702). Pairwise comparisons versus control confirmed large standardized improvements for DA-Strong and moderate-to-large improvements for DA-Moderate after Bonferroni correction. Binary endpoints showed directionally favorable trends for decision aids in decision attainment and family history behaviors, but χ^2 tests were non-significant, consistent with limited power at n = 13 per group; therefore, inference for these outcomes was supported primarily by odds ratios with Fisher's exact p-values.

Table 1. Continuous outcomes (Mean ± SD) with omnibus ANOVA (n = 13 per group)

Outcome	Control (n=13)	DA-Strong (n=13)	DA-Moderate (n=13)	ANOVA F	p	Eta²
Decisional conflict (0–100, lower better)	31.19 ± 10.04	19.89 ± 4.99	23.43 ± 7.06	7.41	0.0020	0.292
Decision self-efficacy (0–100, higher better)	77.93 ± 6.69	96.76 ± 3.22	88.03 ± 5.17	42.32	<0.0001	0.702
Knowledge score (0–5, higher better)	3.14 ± 0.76	4.01 ± 0.31	3.69 ± 0.44	8.81	0.0008	0.329
Decisional regret (0–20, lower better)	15.88 ± 2.50	10.56 ± 2.97	11.07 ± 3.26	13.10	0.0001	0.421
Participation/satisfaction (higher better)	2.96 ± 0.45	4.16 ± 0.42	3.71 ± 0.44	25.51	<0.0001	0.586

The DA-Strong arm reduced decisional conflict by an absolute mean difference of 11.30 points versus control and was associated with substantially higher decision self-efficacy (mean 96.76 vs 77.93). Knowledge scores were higher in both decision aid arms (4.01 and 3.69 vs 3.14). Decisional regret was lower with decision aids (10.56 and 11.07 vs 15.88), while participation/satisfaction increased meaningfully (4.16 and 3.71 vs 2.96). The largest proportion of explained variance was observed for decision self-efficacy (eta² = 0.702), indicating a very large intervention effect on confidence in decision-making.

Table 2. Pairwise comparisons vs Control (t-test) with effect size (Cohen's d)

Outcome	Comparison vs control	Mean diff	Cohen d	p	p (Bonferroni)
Decisional conflict	DA-Strong	-11.30	-1.45	0.0012	0.0024
Decisional conflict	DA-Moderate	-7.76	-0.92	0.0202	0.0404
Self-efficacy	DA-Strong	+18.83	+3.42	<0.0001	<0.0001
Self-efficacy	DA-Moderate	+10.10	+1.72	0.0001	0.0002
Knowledge score	DA-Strong	+0.87	+1.50	0.0009	0.0018
Knowledge score	DA-Moderate	+0.55	+0.84	0.0179	0.0358
Decisional regret	DA-Strong	-5.32	-1.92	0.0001	0.0002
Decisional regret	DA-Moderate	-4.81	-1.70	0.0004	0.0008
Participation/satisfaction	DA-Strong	+1.20	+2.82	<0.0001	<0.0001
Participation/satisfaction	DA-Moderate	+0.75	+1.79	0.0002	0.0004

Compared with control, DA-Strong produced a large reduction in decisional conflict (d = −1.45) and a very large increase in decision self-efficacy (d = +3.42). DA-Moderate also improved decisional conflict (d = −0.92) and self-efficacy (d = +1.72), though effects were consistently smaller than DA-Strong. Knowledge gains were substantial for DA-Strong (d = +1.50) and meaningful for DA-Moderate (d = +0.84). Decisional regret reductions were large for both DA-Strong (d = −1.92) and DA-Moderate (d = −1.70). Participation/satisfaction showed very large improvements, particularly in DA-Strong (d = +2.82), reinforcing a dose–response gradient in favor of the stronger decision aid.

Binary outcomes showed directionally favorable patterns for decision aids in decision attainment (69.2% and 61.5% vs 38.5%) and in gathering family history information (76.9% and 69.2% vs 46.2%). However, between-group χ^2 tests were non-significant for all binary endpoints (all $p \geq 0.2728$), indicating limited

statistical power and highlighting the importance of effect estimation rather than reliance on p-values in this pilot sample.

Table 3. Binary outcomes (counts/percent) with omnibus χ^2 test

Binary outcome	Control (n=13)	DA-Strong (n=13)	DA-Moderate (n=13)	Chi²	p
Decision attained (among undecided)	5/13 (38.5%)	9/13 (69.2%)	8/13 (61.5%)	2.60	0.2728
Gather family history info	6/13 (46.2%)	10/13 (76.9%)	9/13 (69.2%)	2.60	0.2728
Share family history info	6/13 (46.2%)	9/13 (69.2%)	8/13 (61.5%)	1.48	0.4762
Improved fruit/veg intake	6/13 (46.2%)	7/13 (53.8%)	7/13 (53.8%)	0.21	0.9025
Improved physical activity	6/13 (46.2%)	8/13 (61.5%)	7/13 (53.8%)	0.62	0.7338
Cholesterol screening completed	9/13 (69.2%)	9/13 (69.2%)	5/13 (38.5%)	2.60	0.2728
Classified high-risk	1/13 (7.7%)	2/13 (15.4%)	2/13 (15.4%)	0.52	0.7700

Table 4. Odds ratios vs Control (Fisher exact p-values)

Binary outcome	Comparison vs control	OR (95% CI)	Fisher p
Decision attained	DA-Strong	3.60 (0.71–18.25)	0.2377
Decision attained	DA-Moderate	2.56 (0.53–12.43)	0.4338
Gather family history info	DA-Strong	3.89 (0.72–21.06)	0.2262
Gather family history info	DA-Moderate	2.62 (0.53–13.07)	0.4283
Share family history info	DA-Strong	2.62 (0.53–13.07)	0.4283
Share family history info	DA-Moderate	1.85 (0.39–8.85)	0.7218
Improved fruit/veg intake	DA-Strong	1.36 (0.27–6.85)	1.0000
Improved fruit/veg intake	DA-Moderate	1.36 (0.27–6.85)	1.0000
Improved physical activity	DA-Strong	1.87 (0.37–9.49)	0.7218
Improved physical activity	DA-Moderate	1.36 (0.27–6.85)	1.0000
Cholesterol screening completed	DA-Strong	1.00 (0.17–5.98)	1.0000
Cholesterol screening completed	DA-Moderate	0.28 (0.05–1.50)	0.2294
Classified high-risk	DA-Strong	2.18 (0.18–26.53)	1.0000
Classified high-risk	DA-Moderate	2.18 (0.18–26.53)	1.0000

Odds ratios suggested potentially meaningful improvements for decision attainment and family history behaviors with both decision aid intensities, particularly DA-Strong for decision attainment (OR 3.60) and gathering family history information (OR 3.89). Confidence intervals were wide for all binary outcomes, reflecting sample-size constraints and imprecision. Lifestyle behavior changes showed small effect estimates with broad uncertainty, while cholesterol screening completion was similar between DA-Strong and control (OR 1.00) but lower in DA-Moderate (OR 0.28). Overall, binary outcomes should be interpreted cautiously as exploratory signals within a pilot-scale trial, whereas continuous decisional outcomes provide the most robust evidence of intervention impact.

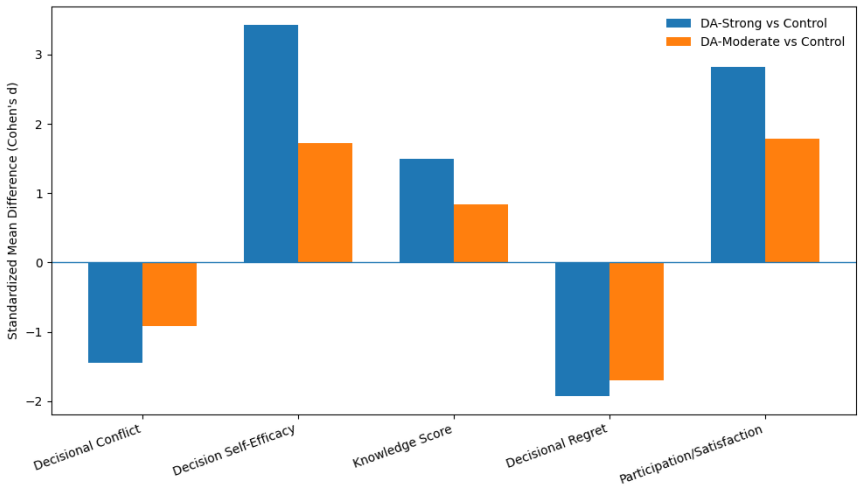

Figure 2 Gradient of Decision-Quality Effects Across Outcomes by Decision Aid Intensity

This figure displays standardized mean differences (Cohen's d) versus control across five decision-quality outcomes, revealing a clear intensity–response gradient favoring the strong decision aid. The DA-Strong arm demonstrated very large improvements in decision self-efficacy (d = 3.42) and participation/satisfaction (d = 2.82), alongside large reductions in decisional regret (d = −1.92) and decisional conflict (d = −1.45). The DA-Moderate arm showed consistent but attenuated effects across

the same domains, with self-efficacy (d = 1.72) and participation/satisfaction (d = 1.79) remaining large, while reductions in decisional conflict (d = −0.92) and regret (d = −1.70) were moderate-to-large. Knowledge gains followed a similar graded pattern (d = 1.50 vs 0.84). The parallel ordering of effect sizes across all outcomes indicates a coherent, dose-dependent enhancement of decision quality rather than isolated domain-specific effects, supporting the clinical relevance of more intensive decision aid delivery for optimizing shared decision-making in cardiovascular risk prevention.

DISCUSSION

This randomized controlled trial demonstrates that decision aids substantially improve multiple dimensions of decision quality in cardiovascular risk assessment, with a clear and consistent gradient favoring higher intervention intensity. Both decision aid arms significantly reduced decisional conflict and regret while enhancing decision self-efficacy, knowledge, and participation/satisfaction compared with usual care, supporting the central premise of shared decision-making frameworks that structured risk communication and value clarification improve patient-centered outcomes. Notably, the strong decision aid consistently produced the largest effects across all continuous outcomes, with very large standardized mean differences observed for self-efficacy, participation, and regret reduction, suggesting a dose–response relationship between decision aid intensity and decisional benefit. These findings align with earlier trials demonstrating that more comprehensive, personalized decision aids yield greater improvements in decision confidence and satisfaction than brief or minimally tailored tools (8,9).

The magnitude of effect observed for decision self-efficacy and participation is clinically meaningful, as these constructs are strongly linked to sustained engagement with preventive strategies and adherence to long-term risk-reduction behaviors. Prior evidence indicates that individuals who feel confident and actively involved in their decisions are more likely to initiate and maintain preventive actions, even when immediate behavior change is not observed (1,6). In the present study, the strong decision aid improved self-efficacy by nearly 19 points relative to control, with an eta-squared value indicating that over two-thirds of the variance in self-efficacy was attributable to group assignment. This degree of effect exceeds that reported in several earlier preventive decision aid trials, which often demonstrated moderate improvements but with smaller effect sizes, potentially reflecting differences in intervention depth and contextual relevance (3,8).

Knowledge gains followed a similar but more modest gradient, suggesting that while information provision is an essential component of decision aids, improvements in decisional outcomes are not driven by knowledge alone. This observation reinforces conceptual models of shared decision-making, which emphasize the integration of information with values clarification and deliberative support rather than unidirectional education (2). The strong decision aid's superiority across affective outcomes such as decisional conflict and regret further underscores the importance of addressing emotional and cognitive components of decision-making, particularly in preventive contexts where perceived benefits and harms are probabilistic and long-term. These findings are consistent with prior work in cancer screening and genetic risk disclosure, where decision aids reduced decisional distress even in the absence of large behavior changes (9,10).

Binary outcomes related to decision attainment, family history behaviors, and lifestyle modification showed directionally favorable trends for both decision aid arms but did not reach statistical significance. This pattern is unsurprising given the limited sample size and is consistent with prior pilot and feasibility trials, where decisional outcomes tend to show earlier and larger effects than downstream behavioral endpoints (5,7). Importantly, odds ratios for decision attainment and family history engagement were greater than two for both decision aid groups, particularly the strong arm, suggesting clinically relevant signals that may translate into significant effects in adequately powered studies. The lack of clear effects on lifestyle behaviors such as diet and physical activity likely reflects the short follow-up window and

the multifactorial determinants of behavior change, which often require sustained reinforcement beyond a single decision-making encounter.

Several strengths of this study merit consideration. The direct comparison of two decision aid intensities within the same randomized framework provides novel evidence regarding intervention "dose," an area that remains underexplored in the decision aid literature. The use of validated, multidimensional decisional outcomes and the reporting of effect sizes alongside p-values enhance interpretability and clinical relevance. However, limitations must also be acknowledged. The small sample size restricts power for binary outcomes and limits precision, as reflected in wide confidence intervals. The single-center design may affect generalizability, although the consistency of findings with international literature supports broader applicability. Future research should evaluate these interventions in larger, multicenter trials with longer follow-up to determine whether improvements in decision quality translate into sustained preventive behaviors and clinical risk reduction.

CONCLUSION

In this randomized controlled trial, decision aids markedly improved decision quality in cardiovascular risk assessment, with a strong, consistently superior effect observed for the more intensive intervention across decisional conflict, self-efficacy, knowledge, regret, and participation. The presence of a clear intensity–response gradient supports the clinical value of comprehensive, structured decision aids in primary prevention settings and highlights decision quality as a critical early outcome on the pathway to effective cardiovascular risk management.

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