

Use of digital patient decision-support tools for atrial fibrillation treatments: a systematic review and metaanalysis

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Abstract

Objectives To assess the effects of digital patient decision-support tools for atrial fibrillation (AF) treatment decisions in adults with AF.

Study design Systematic review and metaanalysis.

Eligibility criteria Eligible randomised controlled trials (RCTs) evaluated digital patient decision-support tools for AF treatment decisions in adults with AF. Information sources We searched MEDLINE, EMBASE and Scopus from 2005 to 2023. Risk-of-bias (RoB) assessment: We assessed RoB using the Cochrane Risk of Bias Tool 2 for RCTs and cluster RCT and the ROBINS-I tool for quasi-experimental studies. Synthesis of results We used random effects meta-analysis to synthesise decisional conflict and patient knowledge outcomes reported in RCTs. We performed narrative synthesis for all outcomes. The main outcomes of interest were decisional conflict and patient knowledge. Results 13 articles, reporting on 11 studies (4 RCTs, 1 cluster RCT and 6 quasi-experimental) met the inclusion criteria. There were 2714 participants across all studies (2372 in RCTs), of which 26% were women and the mean age was 71 years. Socioeconomically disadvantaged groups were poorly represented in the included studies. Seven studies (n=2508) focused on non-valvular AF and the mean CHAD2DS2-VASc across studies was 3.2 and for HAS-BLED 1.9. All tools focused on decisions regarding thromboembolic stroke prevention and most enabled calculation of individualised stroke risk. Tools were heterogeneous in features and functions; four tools were patient decision aids. The readability of content was reported in one study. Meta-analyses showed a reduction in decisional conflict (4 RCTs (n=2167); standardised mean difference -0.19; 95% CI -0.30 to -0.08; p=0.001; I²=26.5%; moderate certainty evidence) corresponding to a decrease in 12.4 units on a scale of 0 to 100 (95% CI -19.5 to -5.2) and improvement in

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Treatment decisions in atrial fibrillation (AF) are complex. Patient decision-support tools, including educational tools and patient decision aids, can support shared decisionmaking.

WHAT THIS STUDY ADDS

⇒ Digital patient decision-support tools for treatment decisions in AF, likely reduce decisional conflict but make little to no difference in patient knowledge, compared with usual care. Implementation in healthcare delivery was low.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Digital patient decision-support tools may be warranted in shared decision-making for AF treatment choices. Studies are needed to understand barriers and enablers to implementation.

patient knowledge (2 RCTs (n=1057); risk difference 0.72, 95% CI 0.68, 0.76, p<0.001; I²=0%; low certainty evidence) favouring digital patient decision-support tools compared with usual care. Four of the 11 tools were publicly available and 3 had been implemented in healthcare delivery. Conclusions In the context of stroke prevention in AF, digital patient decisionsupport tools likely reduce decisional conflict and may result in little to no change in patient knowledge, compared with usual care. Future studies should leverage digital capabilities for increased personalisation and interactivity of the tools, with better consideration of health literacy and equity aspects. Additional robust trials and implementation studies are warranted. PROSPERO registration number CRD42020218025

Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia and a key risk factor for embolic stroke and heart failure, with an increasing global burden as the population continues to age.^{1 2} AF treatment involves stroke prevention, symptom management, and cardiovascular and comorbidity optimisation.^{2 3} Treatment decisions in AF are complex because there are multiple treatment options and evidence gaps, often with more than one medically appropriate option. Recent AF guidelines acknowledge this uncertainty and emphasise the importance of shared decision-making in AF treatment decisions, considering patients' values, goals and preferences.^{2 4}

A key component of shared decision-making is providing evidence-based information on the benefits and harms of existing treatment options, which can be supported by patient education tools.⁵ Patient education tools aim to increase the patient's (ie, decision-maker) knowledge to enable discussion and informed uptake of a treatment choice.^{2 4 6} Whereas, when there are two or more reasonable treatment alternatives, a patient decision aid may be more appropriate (eg, patients at 'moderate stroke risk').² Patient decision aids support preference-sensitive decisions by describing the health problem and making explicit the decision, providing information on options' benefits and harms, and helping patients clarify which benefits and harms matter most to them.⁷ Patient education tools and patient decision aids (ie, patient decisionsupport tools) can facilitate shared decision-making and improve treatment adherence, leading to better outcomes.^{6.8 9}

To date, four systematic reviews^{10–13} (only one with metaanalysis)¹¹ have evaluated patient decision-support tools for anticoagulation and stroke prevention in AF, suggesting improvements in decisional conflict. However, these reviews included mostly non-digital tools (eg, paper-based), which are limited in their ability to personalise and present information. Digital health—the development and use of digital technologies to improve health¹⁴ offers new opportunities to deliver personalised and engaging information to support patients in shared decision-making. At present, it is uncertain whether digital delivery of patient decisionsupport tools for AF treatment decisions can improve decisional conflict and patient knowledge. The aim of this systematic review was to assess the effects of digital patient decision-support tools for AF treatment decisions in adults with AF.

Methods

We followed the Cochrane handbook¹⁵ for conducting this systematic review and reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses¹⁶ (online supplemental file 1). We registered the systematic review protocol with PROS-PERO (CRD42020218025) and was modified on 7 February 2023 (online supplemental file 2).

Eligibility criteria

Eligible studies were experimental trials (randomised controlled trials (RCTs) or quasi-experimental), where adults diagnosed with AF were provided with digital patient decision-support tools to facilitate decision-making regarding treatment options for the management of AF. We classified patient decision-support tools as a patient decision aid if reported as such in the article; otherwise, the tool was classified as an educational tool. All these tools had to be delivered in a digital format (ie, app, web-based or desktop) to meet study inclusion. We excluded clinician decisionsupport tools, which are focused on supporting clinicians in choosing the most ideal therapy based on patient characteristics. Any comparisons were accepted, including usual care. Outcomes of interest included decision-related measures (eg, decisional conflict), patient knowledge, change in treatment and medication adherence. The Decisional Conflict Scale is the most commonly used measure related to decision-making¹⁷ and consists of a 16-item scale that evaluates an individual's degree of uncertainty about the choice (4 subscales: informed; values clarity; support; uncertainty; effective decision), with a score ranging from 0 to 100, and higher scores indicating greater decisional conflict.¹⁸

Information sources

We searched MEDLINE (PubMed interface), EMBASE (Ovid platform) and Scopus (Elsevier platform) in October 2020 and updated the search in February 2023, for eligible studies published in English since 2005 (online supplemental file 3). We restricted the search to English studies published from 2005 onwards because the consensus on criteria for judging the quality of patient decision aids was established in 2005 by the International Patient Decision Aids Standards (IPDAS) collaboration.

Selection of studies and data extraction

Two reviewers independently performed title and abstract screening and subsequent full-text screening. Disagreements were resolved with a third reviewer. We used Cohen's κ to measure the intercoder agreement in each screening phase. Two researchers conducted data extraction, and a third researcher reviewed the extracted data. We contacted authors if any data were missing and reported unavailable data.

Two reviewers independently assessed the reporting of patient decision aid evaluation studies using the Standards for UNiversal reporting of patient Decision Aid Evaluations (SUNDAE check-list), a 26-item checklist that aims to ensure that reports of these studies are understandable, transparent and of high quality.¹⁹

Risk of bias assessment

Two reviewers independently assessed the quality of included studies using the Cochrane Risk of Bias Tool 2 for RCTs and cluster RCT and the ROBINS-I tool for quasi-experimental.²⁰²¹ Conflicts in all assessments were resolved by discussion with a third reviewer.

Data synthesis

We conducted a narrative synthesis for all studies and metaanalyses for the two most common outcomes across RCTs: decisional conflict and patient knowledge. We calculated effect sizes of continuous outcomes as standardised mean difference (SMD). We expressed patient knowledge as a proportion of correct answers and converted it to a percentage and raw value on a scale 0-100. We pooled estimates using random effects meta-analysis with a restricted maximum likelihood estimator; the between-studies variance (T²) was estimated using the methods of moments. I² was used to describe the proportion of variance in observed effects due to variance in true effects.²² For ease of interpretation, we converted estimates of decisional conflict effect sizes from SMD to mean difference in a scale of 0 (no decisional conflict) to 100 (extremely high decisional conflict) (online supplemental file 4). We evaluated the presence of publication bias by using a funnel plot and the Duval and Tweedie trim-and-fill method.¹⁵ Analyses were undertaken with metafor package in R V.4.2.2 (R Project for Statistical Computing in Vienna, Austria).²³

Grading the certainty of evidence

Two reviewers independently used the Grading of Recommendations Assessment, Development and Evaluation approach to





Figure 1 PRISMA flow diagram of included studies. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

rate the certainty of evidence for primary outcomes (ie, decisional conflict and patient knowledge) on each of the following domains: risk of bias, inconsistency, imprecision, indirectness and publication bias.²⁴ We downgraded the certainty of evidence if a serious flaw was present in the domains of risk of bias, inconsistency, imprecision and publication bias. We initially classified certainty of evidence as high then as moderate, low or very low.²⁴

Patient and public involvement

The perspectives of patients with AF informed this study. The results from the present study will be disseminated in lay language.

Results

Search and screening results

The database search(s) retrieved 1482 citations (figure 1). Excluded studies after full-text screen are listed in online supplemental file 5. The kappa statistic measuring intercoder agreement was 0.66 for title and abstract screening, and 0.67 for full-text screening (moderate agreement). 13 articles were included in the systematic review, reporting on 11 studies (table 1).²⁵⁻³⁷

Description of included studies

13 articles reported on 11 studies: 4 RCTs,²⁵⁻³¹ 1 cluster RCT²⁹ and 6 single-group quasi-experimental studies (table 1).³²⁻³⁷ Three articles reported on different outcomes from the same RCT.²⁵⁻²⁷ Studies were published between 2007 and 2022, with most studies conducted in the USA.^{25-28 30 34 36} Follow-up ranged from immediately postintervention to 10 months.^{26 28} Regarding risk of bias for decisional conflict and patient knowledge, one of the four RCTs had low risk,²⁵ two were assessed as high risk^{30 31} and for the remaining trial there were some concerns with bias (figure 2; online supplemental 6).²⁸ One cluster RCT²⁹ had high risk of bias for patient knowledge (online supplemental file 6). Of the six quasi-experimental trials,five had high or unclear risk of bias in six of the seven domains (online supplemental file 7).

Characteristics of study participants

There were 2714 participants across all studies (n=2372 in RCTs), with a mean age of 71 years and 26% were women (table 1; online supplemental 8). Seven studies (n=2508) focused on non-valvular $AF^{25\ 26\ 28-32\ 36}$ (four studies did not report type of AF) and the weighted mean CHAD2DS2-VASc^{25\ 28-31\ 34-37} across studies was 3.2 and HAS-BLED^{25\ 29-31\ 35-37} was 1.9. Of the 5 studies that reported on educational level, 790 of 1275 participants had college or postgraduate studies^{28 30 32 35 36}; 1 study reported on schooling years, with over 26% of the sample having 8 or more years of schooling.³⁷ Five studies did not report on educational level or schooling years, ^{25 29 31 33 34} with one of them reporting instead that 8% of the sample had inadequate health literacy.²⁵ Five studies reported on ethnicity (>80% participants were white) and only one study³² reported on household income (online supplemental file 8).

Characteristics of the digital patient decision-support tools

Out of the 11 tools, 7 were educational decision-support tools^{25,28} ^{29,33} ^{34,36,37} and 4 were patient decision aids (table 1).^{30–32,35} The digital patient decision-support tools were used either previsit (at home^{29,34,35} or in the waiting room^{28,30,33,34,36}) or during the consultation,^{25,31,32,36,37} in primary care,^{30,31} secondary care (eg, cardiology outpatient setting),^{32–34,36,37} or in both primary and secondary care.^{25,28} The tools were delivered using a mobile application,^{29,32,34,37} web-based application,^{25,28,33,35,36} or a desktop (table 2; online supplemental file 9).^{30,38} Only two RCTs reported on the difference in encounter times between intervention and control arm: one RCT reported a longer visit duration with the patient decision-support tool (average increase of 10 min compared with control, no test of significance reported)³¹ and another RCT reported no significant difference in clinical encounter times between the two arms.²⁵

All tools focused on supporting decisions related to anticoagulation treatment for thromboembolic stroke prevention in the

	Primary outcome	 Quality of shared decision- making (composite outcome, measured immediately postvisit): communication quality, knowledge transfer to patient, concordance between clinician and patient's agreed treatment plan, Decisional Conflict Scale. 2. Anticoagulation start and continuation rates 3. Conversations about cost 	Decisional Conflict Scale (1-month post-visit)	Not specified: Patients' knowledge, quality of life, drug adherence and anticoagulation satisfaction	Decisional Conflict Scale (subscales: 'Feeling informed' and 'Having clear values'; immediately post- visit)	Decisional Conflict Scale (measured immediately post-visit)	Not specified: Decisional Conflict Scale, knowledge	Patient-perceived utility in improving patient decision- making	Not specified: app usability; perceived usefulness
	Comparator	Usual care	Usual care	Usual care	Usual care	Usual care	Pre-post	None (post-intervention measures only)	Pre-post
	Type of tool* (treatment decision-support options)	Educational Web application† (Warfarin vs DOAC vs no anticoagulant medication)	Educational Web application‡ (No antithrombotic treatment Warfarin vs DOAC vs aspirin or other antiplatelet)	Educational Mobile application (No antithrombotic treatment vs warfarin vs DOAC)	PtDA§ Computer-based tool (no antithrombotic treatment vs aspirin vs warfarin)	PtDA computer-based tool (warfarin vs no warfarin)	PtDAS Mobile application (Aspirin, warfarin, apixaban, rivaroxaban, dabigatran)	Educational Web application (unspecified medication options, lifestyle modifications)	Educational Mobile application¶ (Unspecified anticoagulation options)
	Setting	Primary and secondary care (in emergency and inpatient hospital departments and outpatient safety-net, primary care and cardiology clinics)	Primary and secondary care Clinicians received training.	Self-utilised by patient at home	Primary care	Primary care	Secondary care (hospital clinics)	Secondary care (cardiology outpatient- waiting room)	Self-utilised at home by patient or at waiting room (cardiology outpatient)
	Population characteristics: mean age; % women	71 years; 20% women	69 years; 40% women	69 years; 44% women	NR (majority over 75 years); 1.5% women;	73.4 years; 44% women	61 years; 10% women	AR	(NR) 46% over 75 years; 38% 65–74 years; 30% women
of included articles	Study design and sample size	 RCT (2 arms) Intervention:463 Control:459 10-month follow-up of Kunneman 2020 RCT (88% of original sample) Secondary analysis²⁵ 	RCT (2 arm) Intervention: 495 Control: 506	Cluster RCT (2 arms) Intervention: 113 Control: 96	RCT (2 arms) Intervention: 69 Control: 66	RCT (2 arms) Intervention: 53 Control: 56	Quasi-experimental (1 arm) Intervention: 67	Quasi- experimental (1 arm) Intervention: 116	Quasi-experimental (1 arm) Intervention: 37
Table 1 Characteristics	Study (authors, year, country)	 Kunneman <i>et al</i>, 2020, USA²⁵ Noseworthy <i>et al</i>, 2022, USA²⁶ Kamath <i>et al</i>, 2021, USA²⁷ 	Wang <i>et al</i> , 2022, USA ²⁸	Guo <i>et al</i> , 2017, China ²⁹	Fraenkel <i>et al,</i> 2012, USA ³⁰	Thomson <i>et al</i> , 2007, England ³¹	de Castro <i>et al</i> , 2021, Philippines ³²	Kovoor <i>et al</i> , 2021, Australia ³³	Kapoor <i>et al</i> , 2021, USA ³⁴

Table 1 Continued						
Study (authors, year, country)	Study design and sample size	Population characteristics: mean age; % women	Setting	Type of tool* (treatment decision-support options)	Comparator	Primary outcome
Loewen <i>et al</i> , 2019, Canada ³⁵	Quasi-experimental (1 arm) Intervention: 37	71 years; 57% women	Self-utilised at home by patient	PtDA§ Web application (No antithrombotic treatment vs aspirin vs Warfarin vs DOAC (ie, (apixaban, dabigatran, edoxaban, rivaroxaban))	Pre-post	Decisional Conflict Scale
Eckman <i>et al</i> , 2018, USA ³⁶	Quasi-experimental (1 arm) Intervention: 65	65.7 years; 35% women	Primary care	Educational Web application** (No antithrombotic therapy vs aspirin vs warfarin vs DOAC: dabigatran, apixaban, rivaroxaban, edoxaban)	Pre-post	Decisional Conflict Scale
Stephan <i>et al</i> , 2018, Brazil ³⁷	Quasi-experimental (1 arm) Intervention: 20	67.7 years; 60% women	Secondary care (cardiology outpatient—waiting room	Educational Mobile application (No antithrombotic therapy vs aspirin+clopidogrel vs warfarin vs DOAC)	Pre-post	AF knowledge ^{tt}
*We classified tools as a tonline free app 'antico: t'Stanford Guide to Afib SStudy states their decis AfAfib 2gether mobile ap **Atrial Fibrillation Share t'tAssessed by AF Knowl AF, atrial fibrillation; app	PtDA if so reported in the article; agulation choice decision aid' (htt Stroke Prevention' (https://afibgi sion aids adhere to International P p, developed by Pfizer (https://pli ed Decision Making web app (http edge Questionnaire (scale from 0 , application; DOAC, direct oral ar	otherwise, the tool was classified as 'e ps://anticoagulationdecisionaid.mayoo Jide.com/). atient Decision Aids Standards. ⁷ ay.google.com/store/apps/details?id= ://chi.uc.edu/afib/1131). to 8; 8 as all correct answers). Researcl ticoagulant; PtDA, Patient Decision Aid	ducational tool'. clinic.org/). com.pfizer.us.AfibTogeth ner-developed questionn 1; RCT, randomised contr	er&hl=en_US≷=US). aire with validation status unclear olled trial.		



Figure 2 (A) Forest plot of effect sizes and 95% CIs representing the effects of digital patient decision-support tools on Decisional Conflict Scale. Fraenkel *et al*³⁰ show results for the informed subscale; Kunneman *et al*, Wang *et al* and Thomson *et al* show results for overall scale score.^{25 28 31} Green lines denote studies that have classified tools specifically as a patient decision aid. (B) Forest plot of effect sizes and 95% CI representing the risk difference between the electronic patient decision-support tools and usual care on patient knowledge scored at full marks in respective questionnaires. Green denotes studies that have classified tools as a patient decision aid if reported as such in the article.³⁰

long-term management of AF. None of the included articles focused on symptomatic pharmacotherapy or non-pharmacological interventions, such as ablation. Of the 11 tools, 10^{25} ²⁸⁻³² ³⁴⁻³⁷ could calculate individualised stroke risk at 1 or 5 years (two tools did it automatically using information from the electronic health record),^{29 36} 8 (25, 28, 30–32, 35–37) calculated stroke risk and 8 (25, 29–32, 35–37) also recalculated stroke and bleeding risk for each of the treatment options. One of the three tools not calculating risk of bleeding was sponsored by a drug company.³⁴ Risk was communicated to patients most commonly as a percentage (8 studies).^{25 28 30–32 35–37} or in the form of 100-person pictographs (7 studies).^{25 30–32 36 37}

Out of the four patient decision aid studies, two ^{32 35} adhered to most of the items of the SUNDAE checklist (online supplemental file 10).³⁹ Less reported items of the SUNDAE checklist included: information about the development of the decision aid and on how to identify and access it; fidelity of implementation; and lack of a process evaluation to better understand how or why the tool worked. All four patient decision aids^{30-32 35} adhered to the qualifying criteria for patient decision aids⁷: describing the health condition or problem; explicitly stating the decision in consideration; describing the options available for the index decision; describing both the positive features and negative features of each option and stating consequences of treatment options (eg, out-ofpocket costs, impact on diet) (online supplemental file 11). Other criteria from the IPDAS were mostly met, except for providing more than one way of viewing the probabilities; asking patients to think about which positive and negative features of the options matter most to them; including clinicians in the development process; having an update policy; providing information about the levels of uncertainty around event or outcome probabilities and reporting on readability levels (online supplemental file 11).

Nine of the 11 tools (3 patient decision aids) provided a patient report with additional information and education^{25 28-30 32 34-37} and 4 tools incorporated videos to support patient education.^{28 33 34 37} Five tools (three patient decision aids) included a specific feature to elicit values and/or preferences regarding the treatment decision.^{25 30 35-37} Seven out of 11 tools (3 out of 4 patient decision aids) were co-designed with clinicians^{25 31-35 37} and 9 (4 out of 4 patient decision aids) with patients.^{25 28-32 35-37} Only one article indicated the readability of the materials (below eighth grade).³³ Four tools were publicly available,^{25 28 34 36} and three seemed to have been implemented in clinical practice.^{25 28 33} Most articles reported favourable user feedback regarding the use of the digital patient decision-support tools, such as high perceived usefulness, user-friendliness and overall satisfaction (online supplemental file 12).^{25 28-30 32-36}

Characteristics of control groups

All RCTs described the control groups as some form of usual care, with definitions varying slightly between studies (eg, usual clinical care,^{25 28 29} evidenced-based paper guidelines,³¹ regular scheduled visits³⁰, online supplemental file 13).

Outcomes

Decisional conflict

A meta-analysis of the 4 RCTs using the Decisional Conflict Scale showed digital patient decision-support tools likely reduce decisional conflict in comparison with usual care (4 RCTs (n=2167); SMD –0.19, 95% CI –0.30 to –0.08, p=0.001; I^2 =26.5%, moderate certainty evidence) corresponding to a reduction in 12.4 units on a scale of 0 to 100 (95% CI –19.5 to –5.2) (figure 2; table 3). Of the 4 RCTs, 3 reported overall scores^{25 28 31} (2 RCTs reported on a 0–100 scale and 1 RCT on a 0–5 scale³¹) and 1 RCT³⁰ only reported scores

Table 2 Cha	racteristi	cs of dig	zital patient	t decision	-support	tools (sha	ded rows	are patie	nt decision	aids; non-s	shaded are educ	cational tools)*							
Study	Digital	delivery	mode	Completi of care	on in path	way	Frequen c by patien	y of use (ts 2	Calculation c	of individuali ding risk	ised stroke risk	Risk communi	cation		Addition	al resources		Co-design	
	Mobile app	web app	Computer- based	Waiting room	During consult	Self- utilised at home, pre-visit	Single A	Aultiple 5	stroke risk	Bleeding risk	Recalculates risk with treatment	100-persons pictographs	Score (eg, CHAD2DS2- VASc	Numeric (%, 1 in X chance)	Patient report	Elicits patient values / preferences	Videos	With patients	With clinicians
Kunneman 2020 ^{25–27}		7			7		~	-	Aanual	Manual	7	7		7	7			7	7
Wang 2022 ²⁸		2		7			2		Aanual	No	~	~	7	7	~		~	7	
Guo 2017 ²⁹	7					7	-	1	Automatict	Automatict			7		~			7	
Fraenkel 2012 ³⁰			7	7			7		Aanual	Manual	7	7		7	7	7		7	
Thomson 2007 ³¹			7		7		7		Aanual	Manual	7	7		7	7	7		7	7
De Castro 2021 ³²	7				7		7		Aanual	Manual	2	7	7	7				7	7
Kovoor 2021 ³		~		7			7	-	ło	No							7		7
Kapoor 2021 ³	7			7		7	7		Aanual	No			7		~		7		7
Loewen 2019 ³	5	7				7	7	_	Aanual	Manual	7			Ş	7	7		7	7
Eckman 2018	6	7		7	~		7	1	Automatict	Automatic	7.	7	7	~	7	7		7	
Stephan 2018 ³⁷	7				7		~	-	Aanual	Manual	7	7	7	7	7	7	~	~	7
*Additional inf	ormation i	is availat	le in online	supplemer	ntal file 8.														
tAutomated ri	sk calculat	ion using	g data from t	the electro	nic medica	l record.													
√, characterist	c present.																		

Summary of findings

Table 3 Summary of findings table

, 0						
Patient or population: Patie Setting: Intervention: digital decisio Comparison: usual care	ents with atrial fibrillation on-support tools	n				
	Anticipated absolute e	ffects* (95% CI)				
Outcomes	Risk with usual care	Risk with digital decision-support tools	Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
Decisional Conflict (DCS) assessed with: Decisional Conflict Scale	-	SMD 0.19 SD lower (0.3 lower to 0.08 lower)	-	2167 (4 RCTs)	⊕⊕⊕⊖ Moderate†	The evidence suggests Digital Decision Support Tools reduce Decisional Conflict slightly.
Patient Knowledge (Pt know) assessed with: Patient Knowledge Questionnaire	27 per 100	20 per 100 (19 to 21)	Risk difference 0.72 (0.68 to 0.76)	1057 (2 RCTs)	⊕⊕⊖⊖ Low†‡	Digital Decision Support Tools may result in little to no difference in patient knowledge.

GRADE Working Group grades of evidence high certainty: we are very confident that the true effect lies close to that of the estimate of the effect. Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

*The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). tWe downgraded one level due to issues regarding risk of bias. The majority of studies had some concerns or high risk of bias.

#We downgraded one level due to issues regarding indirectness. We are uncertain of whether the questionnaires in the included studies sufficiently covered patient knowledge of different treatment options

GRADE, Grading of Recommendations Assessment, Development and Evaluation; RCTs, randomised controlled trials; SMD, standardised mean difference

for two subscales ('informed' and 'values clarity' subscales, in a 0-100 scale). A sensitivity analysis including a combined effect size for the two subscales (feeling informed and feeling unclear about values) was also statistically significant with a minimal difference to the overall effect (p=0.01) (online supplemental file 14). The funnel plot and Egger's test suggest signs of publication bias for decisional conflict (online supplemental file 15).

Three quasi-experimental studies also used the Decisional Conflict Scale showing reductions in decisional conflict postintervention (online supplemental file 16).^{32 35 37}

Patient knowledge

All articles evaluated patient knowledge, with varied assessment measures, most showing improvements with the digital decisionsupport tool. Pooled estimates from 2 RCTs^{25 30} showed digital decision-support tools may result in little to no difference in patient knowledge when compared with usual care (2 RCTs (n=1057); RD 0.72, 95% CI 0.68 to 0.76, p<0.001; I²=0%, low certainty evidence; figure 2; table 3). Incomplete data limited the meta-analysis of two other RCTs; one of these RCTs reported an improvement in AF knowledge in the intervention group compared with control; the other RCT reported no difference.^{28 31} One cluster RCT reported an improvement in the percentage of correct responses to 10 of the 11 questions in the questionnaire, compared with two in the control group.²⁹ Four single-arm quasi-experimental studies reported an increase in patient knowledge postintervention (online supplemental file 16).^{32 35-37}

Other outcomes

Other outcomes, including medication-related outcomes, were reported infrequently (online supplemental files 17,18). Four studies (one RCT) measured medication changes,^{26 30 34 36} with a reduction in medication changes in the intervention arm compared with usual care in the RCT.²⁶ Two RCTs reported medication adherence differently,^{26 28} therefore, were not combined in a meta-analysis. One RCT showed an improvement in a number of patients with at least 80% of days covered by a direct oral anticoagulant (DOAC) in the intervention versus control group at the

10 months follow-up,²⁶ whereas the second RCT showed no difference in the number of patient-reported doses of anticoagulant missed in the past week or past month between the two groups.²⁸ One cluster RCT also showed improvements in medication adherence between groups at 1 and 3 months.²⁹ A secondary analysis of one RCT²⁵ showed cost conversations between the patient and the clinician (regarding the price of anticoagulants for treatment of AF) were more likely in the intervention group using the digital patient decision-support tool.27

Discussion

Main results

To our knowledge, this is the first systematic review and metaanalysis focusing on the digital delivery of patient decisionsupport tools for treatment decisions in AF. We found that digital patient decision-support tools likely reduce decisional conflict and may result in little to no difference in patient knowledge, compared with usual care. There were mixed results for medication adherence. Evidence could be strengthened by more standardised measurement. All the tools aimed to support decisions related to anticoagulation treatment for thromboembolic stroke prevention; none focused on symptomatic pharmacotherapy or procedures like ablation. Most tools allowed for personalised risk calculation (stroke and bleeding, with and without treatment), but only two tools did it automatically using data from the electronic health record (all others required manual input). Tools were heterogeneous in features and functions; four tools were patient decision aids. Only 4 of the 11 tools were publicly available and three seemed to have been implemented in healthcare delivery. The readability of content was reported in one study.

Comparison with existing literature

We found improvements in decisional conflict and knowledge with digital patient decision-support tools compared with usual care. Decisional conflict is defined as personal uncertainty about which choice to select among competing interests.^{40 41} Reduced decisional conflict scores are associated with higher patient satisfaction with their decisions^{17 42} and may indicate these tools

benefit patients by informing their options and clarifying their personal values, further equipping them in shared decision-making.⁴³ Meta-analyses assessing patient decision aids in other contexts (eg, treatment and screening decisions in cancer) have also found reductions in decisional conflict, for both digital and non-digital tools.^{44 45} Our findings report a reduction in decisional conflict of similar magnitude as a recent meta-analysis which pooled non-digital decision aids in AF treatment,¹¹ including two RCTs.^{46 47} The improvements we found in patient knowledge are in line with previous systematic reviews of decision aids,¹⁰⁻¹³ educa-tional⁴⁸ and self-management⁴⁹ interventions in AF.

Current digital patient decision-support tools for AF treatment have some limitations. Despite most studies reporting codesign with patients, many lacked reporting on health literacy considerations in tool development, with only one study mentioning readability of the content. Socioeconomically disadvantaged groups were poorly represented in the included studies. A systematic review of non-AF patient decision aids showed knowledge improvements were greater in studies reporting strategies to reduce cognitive demand (eg, plain language, visual cues) in the tool development compared with studies that did not.⁵⁰ Co-production with target populations, including low health literacy patients and other disadvantaged groups, is key to ensure their needs and preferences are met.^{39 50-55} In addition, developers of these tools should better leverage available resources to ensure tool quality, such as the IPDAS⁵⁶⁻⁵⁸ and the Patient Education Materials Assessment Tool from the US Agency for Healthcare Research and Quality.⁵⁹

Most studies in our review focused on single use of these tools (typically in the waiting room before a consultation or during the medical appointment) even though the shared decision-making process should ideally allow for enough time for patients to consider the information and deliberate outside of the clinical encounter.⁶⁰ The focus on use in a clinical context could also explain why only a few of these tools seem to have been implemented in the real-world, due to clinician inertia and fear of lengthier consultations.^{54 61 62} We found encounter times in intervention and control arms were rarely compared, with no differences reported. Future studies could leverage the digital capabilities of these tools to enable remote delivery of patient education and decision-support (ideally integrated with the electronic health record for automated risk calculation), providing adequate time for patients to process the information and deliberate, before visiting their clinician.⁵⁴

Strengths and limitations

The strengths of this review include the development and systematic adherence to a registered protocol, piloting of the screening procedures and the moderate agreement between reviewers in title and abstract and full-text screening. Included papers were limited to English language, limited in number and heterogeneous in design and outcomes evaluated. Including studies from 2005 onwards (based on the consensus from the IPDAS Collaboration) allowed for a broader assessment of different tools, with some predating the availability of novel treatment options used in current practice (ie, DOACs). We followed our protocol for assessment of publication bias, yet this analysis is constrained by the limited number of studies available. A subgroup analysis focusing on contemporary tools that reflect current practices in AF treatment was not possible due to the limited number of RCTs. Finally, there are known gaps in measuring AF knowledge, with current validated instruments either being too long, lacking validation in different populations or having low reliability.9 Limitations in knowledge scales may explain the common use of non-validated study-specific questionnaires,⁴³ as we found in this review.

Implications

Digital patient decision-support tools can facilitate shared decision-making in AF stroke prevention, resulting in improvements in decision quality. Recent studies have shown that shared decision-making is not widely implemented in contemporary AF practice.^{2 4 6} A recent study analysing the content of discussions between patients with AF and doctors regarding anticoagulation choice found imbalances in discussion of stroke versus bleeding risk, as well as persuasive communication from doctors to convince patients to accept anticoagulation with a DOAC instead of warfarin, with insufficient discussion of medication costs.⁶³ This suggests some specific treatment decision scenarios may particularly benefit from a patient decision-support tool: (1) DOACs versus no therapy in non-valvular AF patients with a low risk of stroke, (2) DOACs versus warfarin in special populations and in non-valvular AF patients if DOACs are cost-prohibitive and (3) anticoagulation versus none in patients with very high bleeding risk. Outside of these specific situations, patient decisionsupport tools may still be beneficial for all AF patients considering treatment decisions regarding stroke prevention, supporting objective understanding of the benefits, risks and other considerations relevant to patients, for an informed decision regarding long-term anticoagulation treatment.

There is a dearth of evidence regarding the use of digital patient decision-support tools for other treatment decisions in AF, such as rate and rhythm control decisions for symptom management.² ⁶⁴ ⁶⁵ Future research should also analyse the effect of these tools on other outcomes (eg, medication adherence), as well as their impact in disadvantaged groups.⁶⁶ ⁶⁷ In particular, it is important to consider the digital divide and health literacy levels of diverse groups and foster inclusive design strategies⁶⁸ in the development of these tools, to avoid worsening health disparities.

Despite their value, decision aids are not routinely used in clinical practice. The National Health Service (NHS) has attempted to increase the uptake of decision aids by launching a webpage in November 2023 with freely available decision-support tools for multiple health conditions developed according to the National Institute for Health and Care Excellence (NICE) shared decisionmaking support tools framework.^{69 70} Although a useful starting point, this repository of documents provides limited options to personalise information. Another proposed solution is to create a 'universal' electronic decision-support tool where a template using a modular design can enable the incorporation of individualised user profiles (attributes, characteristics and values), and specific disease and treatment modules.⁷¹

The capacity of artificial intelligence (AI) to create more personalised content could improve the adoption and engagement with decision-support tools. Recent studies are starting to incorporate AI to provide tailored information based on patient-reported outcomes (eg, quality of life), for example, in a recent RCT assessing a patient decision aid for patients with knee osteoarthritis.⁷² Another option to allow for individualised and engaging patient interactions with decision-support tools is the application of conversational AI (ie, the use of machine learning and natural language processing allowing computers to have human-like conversations).^{73 74} Future research should evaluate the impact and acceptability of patient decision-support tools that are able to 'chat' with patients and support the decision-making process in a personalised manner.

Conclusions

Moderate certainty evidence suggests digital patient decisionsupport tools reduce decisional conflict, with low certainty evidence of knowledge improvement in the context of stroke prevention in patients with AF and mixed results for medication adherence. Digital capabilities could be further leveraged to optimise personalisation and interaction with the tools. Health literacy considerations and co-production with disadvantaged populations are key for the development of future tools. Additional robust trials and implementation studies are warranted to further evaluate digital features and to understand barriers and enablers to the use of these tools so they can be translated into the real world.

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SUPPLEMENTS

Supplement 1 eMethods 1: PRISMA 2020 Checklist
Supplement 2 eMethods 2: Modification from original PROSPERO Registration
Supplement 3 eMethods 3: Search Strategy
Supplement 4 eMethods 4. Calculating effect sizes as mean difference from standardized difference in means
Supplement 5 eResults 1: List of Excluded Studies after Full-text Screen
Supplement 6 eTable 1: Risk of bias assessment of included randomised trials
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Supplement 1 | eMethods 1: PRISMA 2020 Checklist

PRIS MAT

PRISMA 2020 Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	1
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2
INTRODUCTIO	N		
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	3
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	4
METHODS	-		
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	5,6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	5
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Supplement 3
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	5,6
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	6
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	6
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	6
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	6
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	6
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	6
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data	6

Section and Topic	Item #	Checklist item	Location where item is reported
		conversions.	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	6
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	6
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	-
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	6
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	6
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	-
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	7
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	7, Supplement 4
Study characteristics	17	Cite each included study and present its characteristics.	8
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Supplement 6,7
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Figure 2, Supplement 11-16
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Figure 2, Supplement 15
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Figure 2, Supplement 15
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Supplement 12
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Supplement 12
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Supplement

Section and Topic	Item #	Checklist item	Location where item is reported
			13
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	-
DISCUSSION	-		
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	14
	23b	Discuss any limitations of the evidence included in the review.	15
	23c	Discuss any limitations of the review processes used.	15
	23d	Discuss implications of the results for practice, policy, and future research.	16
OTHER INFORM	MATIO	Ň	
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	5
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	5
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	5, Supplement 2
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	1
Competing interests	26	Declare any competing interests of review authors.	1
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	1

Supplement 2 | eMethods 2: Modification from original PROSPERO Registration

Included interventions as described in original protocol:

Electronic patient decision aids used to facilitate patient decision-making regarding the use of therapy for the management of atrial fibrillation (AF). The included patient decision aids will encompass individualised stroke risk and relevant patient education material. Electronic tools can include, but are not limited to: computerised decision support tool, mobile applications. The intervention may include other components in addition to the decision aid tool. Decision aids for AF therapy can be focused on medication (e.g. anticoagulation medication) or procedures (e.g. AV node ablation).

The protocol was modified to include both digital patient decision aids and digital education tools to support treatment decisions in atrial fibrillation. The population was broadened to include patients with any type of AF.

Supplement 3 | eMethods 3: Search Strategy

Search strategy was formulated with assistance from a clinical librarian.

English studies from 2005 onwards (consensus on the quality appraisal criteria of patient decision aids was established by International Patient Decision Aids Standards Collaboration that year(1)).

(Reference lists of included studies were also screened.)

1. Search strategy for MEDLINE (via PubMED interface)

	Search String
#1	(("atrial fibrillation"[MeSH Terms] OR ("atrial"[All Fields] AND "fibrillation"[All Fields])) OR "atrial fibrillation"[All Fields] OR "AF"[All Fields])
#2	("decision support techniques"[MeSH Terms] OR (("decision"[All Fields] AND "support"[All Fields]) AND "techniques"[All Fields]) OR "decision support
	techniques"[All Fields] OR ("decision"[All Fields] AND "aid"[All Fields]) OR "decision aid"[All Fields] OR "decision making, shared"[MeSH Terms] OR
	("decision"[All Fields] AND "making"[All Fields] AND "shared"[All Fields]) OR "shared decision making"[All Fields] OR ("shared"[All Fields] AND "decision"[All
	Fields] AND "making"[All Fields]) OR ("decision making"[MeSH Terms] OR ("decision"[All Fields] AND "making"[All Fields]) OR "decision making"[All Fields])
	OR "patient participation" [MeSH Terms] OR ("patient" [All Fields] AND "participation" [All Fields]) OR "patient preference" [MeSH Terms] OR ("patient" [All Fields]]
	AND "preference"[All Fields]))
#3	(("digital"[All Fields] AND "health"[All Fields]) OR "digital health"[All Fields] OR "ehealth"[All Fields] OR ("mobile"[All Fields] AND "health"[All Fields]) OR
	"mobile health"[All Fields] OR "smartphone"[MeSH Terms] OR "smartphone"[All Fields] OR "smartphones"[All Fields] OR "smartphone's"[All Fields] OR "mobile
	applications"[MeSH Terms] OR ("mobile"[All Fields] AND "applications"[All Fields]) OR "mobile applications"[All Fields] OR "computers, handheld"[MeSH
	Terms] OR ("computers"[All Fields] AND "handheld"[All Fields]) OR "handheld computers"[All Fields] OR ("tablet"[All Fields] AND "computer"[All Fields]) OR
	"tablet computer"[All Fields] OR "web-based"[All Fields] "internet"[MeSH Terms] OR "internet"[All Fields] OR "internet-based"[All Fields] OR "website"[All
	Fields] OR "technology"[MeSH Terms] OR "technology"[All Fields] OR "technologies"[All Fields] OR "medical informatics"[MeSH Terms] OR ("medical"[All
	Fields] AND "informatics"[All Fields]) OR "medical informatics"[All Fields] OR ("health"[All Fields] AND "information"[All Fields] AND "technology"[All
	Fields]) OR "health information technology"[All Fields] OR "computerised" [All Fields] OR "computerized" [All Fields])
#4	#1 AND #2 AND #3

2. Search strategy for EMBASE (Ovid platform)

	Search String
#1	("atrial fibrillation" or "AF").af.
#2	("decision support techniques" or "decision aid" or "shared decision making" or "decision making, shared" or "decision making" or "patient participation" or
	"patient preference").af.
#3	("Digital health" or "ehealth" or "mobile health" or "smartphone" or "smartphones" or "smartphone's" or "mobile applications" or "computers, handheld" or
	"handheld computers" or "tablet computer" or "web-based" or "internet" or "internet-based" or "website" or "technology" or "technologies" or "medical
	informatics" or "medical information technology" or "computerised" or "computerized").af.
#4	#1 AND #2 AND #3

3. Search strategy for Scopus (Elsevier platform)

	Search String
#1	TITLE-ABS-KEY ("atrial fibrillation" OR "AF")
#2	TITLE-ABS-KEY ("decision support techniques" OR "decision aid" OR "shared decision making" OR "decision making, shared" OR "decision making" OR "patient participation" OR "patient preference")
#3	TITLE-ABS-KEY ("Digital health" OR "ehealth" OR "mobile health" OR "smartphone" OR "smartphones" OR "smartphone's" OR "mobile applications" OR "computers, handheld" OR "handheld computers" OR "tablet computer" OR "web-based" OR "internet" OR "internet-based" OR "website" OR "technology" OR "technologies" OR "medical informatics" OR "medical information technology" OR "computerised" OR "computerized")
#4	#1 AND #2 AND #3

Supplement 4 | eMethods 4. Calculating effect sizes as mean difference from standardized difference in means

1) Conducting a meta-analysis including only the 3 studies that reported decisional conflict on a scale of 0-100, in order to obtain the standard error of the effect size (SE)

```
Random-Effects Model (k = 3; tau^2 estimator: REML)
tau^2 (estimated amount of total heterogeneity): 17.3615 (SE = 25.1448)
tau (square root of estimated tau^2 value):
                                                4.1667
I^2 (total heterogeneity / total variability):
                                                74.68%
H^2 (total variability / sampling variability): 3.95
Test for Heterogeneity:
Q(df = 2) = 8.0066, p-val = 0.0183
Model Results:
estimate
                                     ci.lb ci.ub
             se
                    zval
                            pval
 -5.5274 2.8682 -1.9271 0.0540 -11.1490 0.0942
Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
SE: 2.8682
```

2) Using the standard error of the difference in means (SE) to calculate the standard deviation (SD) of the effect size of the 3 studies that reported on decisional conflict on the scale of 0-100.

Estimated SD Calculation:

 $SD = \frac{SE}{\sqrt{\frac{1}{Total sample size in interventions groups} + \frac{1}{total sample size in control groups}}}$

Total sample size in intervention groups = 1027 Total sample size in control groups = 1031 SD= 65.058

Table 1: Sample size in interventions and	l control groups for the 3 studies	that reported decisiona	l conflict on scale of 0 to 100
		· · · · · · · · · · · · · · · · · · ·	

First author, year	Sample size (intervention)	Sample size (control)
Kunneman 2020(2)	463	459
Wang 2022(3)	495	506

Fraenkel 2012(4)	69	66
Total sample size	1027	1031

 Using the SD to extrapolate the difference in means in the 4 studies from the standardized difference in means Standardized difference in means = Difference in means/SD

Difference in means= Standardized difference in means*SD

= -0.19*65.058

= -12.36102

= -12.36

4) 95% CI Confidence intervals :

Upper limit: upper limit (of the SMD) x SD

 $= -0.08 \ge 65.058$

= -5.20

Lower limit = lower limit (of the SMD) x SD

 $= -0.30 \times 65.058$

= -19.5174

Supplement 5 | eResults 1: List of Excluded Studies after Full-text Screen

List of articles excluded after full-text review for not meeting inclusion criteria regarding the population, intervention or outcome

Population:

1. Abedin Z, Hoerner R, Habboushe J, Lu Y, Kawamoto K, Warner PB, et al. Implementation of a Fast Healthcare Interoperability Resources-Based Clinical Decision Support Tool for Calculating CHA(2)DS(2)-VASc Scores. Circ Cardiovasc Qual Outcomes. 2020;13(2):e006286.

2. Arts DL, Abu-Hanna A, Buller HR, Peters RJG, Eslami S, van Weert HCPM. Improving stroke prevention in patients with atrial fibrillation. Trials. 2013;14(1).

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4. Bajorek B, Magin P, Hilmer S, Krass I. Therapeutic outcomes postapplication of a computerised antithrombotic risk assessment tool (carat) for therapeutic decisionmaking in a cohort of australian patients with atrial fibrillation. European Stroke Journal. 2017;2 (1 Supplement 1):344-5.

5. Heaven B, Murtagh M, Rapley T, May C, Graham R, Kaner E, et al. Patients or research subjects? A qualitative study of participation in a randomised controlled trial of a complex intervention. Patient Educ Couns. 2006;62(2):260-70.

6. Holbrook A, Labiris R, Goldsmith CH, Ota K, Harb S, Sebaldt RJ. Influence of decision aids on patient preferences for anticoagulant therapy: a randomized trial. Cmaj. 2007;176(11):1583-7.

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10. Zhang C, Pan MM, Wang N, Wang WW, Li Z, Gu ZC, Lin HW. Feasibility and usability of a mobile health tool on anticoagulation management for patients with atrial fibrillation: a pilot study. European Journal of Clinical Pharmacology. 2022 Feb 1:1-2.

Intervention:

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7. Fatima S, Holbrook A, Schulman S, Park S, Troyan S, Curnew G. Development and validation of a decision aid for choosing among antithrombotic agents for atrial fibrillation. Thromb Res. 2016;145:143-8.

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9. Ferguson C, Hendriks J. Partnering with patients in shared decision-making for stroke prevention in atrial fibrillation. Eur J Cardiovasc Nurs. 2017;16(3):178-80.

10. Gordon S, Rowse V, Everington T, Meehan D, Duggan C. Supporting initiation of anticoagulation with 'jack', a video counselling tool. Europace. 2017;19 (Supplement 1):i47.

11. Guo Y, Lip GYH. Mobile health for cardiovascular disease: The new frontier for AF management: Observations from the huawei heart study and mAFA-II randomised trial. Arrhythmia and Electrophysiology Review. 2020;9(1):5-7.

12. Gussoni G, Di Pasquale G, Vescovo G, Gulizia M, Mathieu G, Scherillo M, et al. Decision making for oral anticoagulants in atrial fibrillation: the ATA-AF study. Eur J Intern Med. 2013;24(4):324-32.

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16. Hirsch O, Keller H, Krones T, Donner-Banzhoff N. Arriba-lib: association of an evidence-based electronic library of decision aids with communication and decision-making in patients and primary care physicians. Int J Evid Based Healthc. 2012;10(1):68-76.

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23. Kesselheim AS, Gagne JJ, Franklin JM, Eddings W, Fulchino LA, Campbell EG. Do patients trust the FDA?: a survey assessing how patients view the generic drug approval process. Pharmacoepidemiology and Drug Safety. 2017;26(6):694-701.

24. Kirchhof P, Schroeder S. NOACs in atrial fibrillation. European Heart Journal. 2017;38(31):2382-91.

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26. Kovoor J, McIntyre D, Chik W, Chow C, Thiagalingam A. Prospective Evaluation of a Cardiologist-Narrated Audio-Visual Educational Module in Facilitating Shared Decision-Making during Cardiology Outpatient Consultation for Atrial Fibrillation. Heart Lung and Circulation. 2019;28 (Supplement 4):S226.

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6. Fox KAA, Lucas JE, Pieper KS, Bassand JP, Camm AJ, Fitzmaurice DA, et al. Improved risk stratification of patients with atrial fibrillation: An integrated GARFIELD-AF tool for the prediction of mortality, stroke and bleed in patients with and without anticoagulation. BMJ Open. 2017;7(12).

7. Fraenkel L, Street RL, Jr., Fried TR. Development of a tool to improve the quality of decision making in atrial fibrillation. BMC Med Inform Decis Mak. 2011;11:59.

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Supplement 6 | eTable 1: Risk of bias assessment of included randomised trials

Rationale for judgement: Available as additional Supplement

eTable 1.a | Risk of bias assessment (RoB 2) of included randomised trials (Decisional Conflict Scale)

Authors, year of publication	D1	D2	D3	D4	D5	Overall
Kunneman et al, 2020(2)	+	+	+	+	+	+
Wang et al 2022(3)	+	+	+	?	+	?
Fraenkel et al, 2012(4)	?	?	+	?	-	-
Thomson et al, 2007(5)	+	?	-	-	?	-

Outcome-related domains were assessed considering the outcomes mentioned in Table 2. +, Low risk of bias; -, high risk of bias; ?, some concerns of bias. D1: Risk of bias arising from the randomization process; D2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention); D3: Missing outcome data; D4: Risk of bias in measurement of the outcome; D5: Risk of bias in selection of the reported result

eTable 1.b | Risk of bias assessment (RoB 2) of included cluster- randomised trials (Decisional Conflict Scale)

Authors, year of publication	D1a	D1b	D2	D3	D4	D5	Overall
Guo et al, 2017(6)	NA	NA	NA	NA	NA	NA	NA

NA: Not applicable (because the outcome was not reported); Outcome-related domains were assessed considering the outcomes mentioned in Table 2. +, Low risk of bias; -, high risk of bias; ?, some concerns of bias. D1a: Risk of bias arising from the randomization process; D1b: Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial; D2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention); D3: Risk of bias due to Missing outcome data; D4: Risk of bias in measurement of the outcome; D5: Risk of bias in selection of the reported result

Authors, year of publication	<u>D1</u>	<u>D2</u>	<u>D3</u>	<u>D4</u>	<u>D5</u>	<u>Overall</u>
Kunneman et al, 2020(2)	+	-	+	+	+	+
Wang et al 2022(3)	+	+	+	?	?	?
Fraenkel et al, 2012(4)	?	-	?	?	?	-
Thomson et	+	?	-	-	?	-

al, 2007(5)

Outcome-related domains were assessed considering the outcomes mentioned in Table 2. +, Low risk of bias; -, high risk of bias; ?, some concerns of bias. D1: Risk of bias arising from the randomization process; D2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention); D3: Missing outcome data; D4: Risk of bias in measurement of the outcome; D5: Risk of bias in selection of the reported result.

eTable 1.d | Risk of bias assessment (RoB 2) of included cluster- randomised trials (patient knowledge)

Authors, year of publication	D1a	D1b	D2	D3	D4	D5	Overall
Guo et al, 2017(6)	?	+	-	-	-	?	-

Outcome-related domains were assessed considering the outcomes mentioned in Table 2. +, Low risk of bias; -, high risk of bias; ?, some concerns of bias. D1a: Risk of bias arising from the randomization process; D1b: Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial; D2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention); D3: Risk of bias due to Missing outcome data; D4: Risk of bias in measurement of the outcome; D5: Risk of bias in selection of the reported result;

eTable 1.e Ri	sk of bias (RoB 2) assessment of included	randomised trials	(other outcomes-	medication related outcome)
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Authors, year of publication	<u>D1</u>	<u>D2</u>	<u>D3</u>	<u>D4</u>	<u>D5</u>	<u>Overall</u>
Noseworthy et al. 2022(7)	+	-	?	?	?	?

Outcome-related domains were assessed considering the outcomes mentioned in Table 2. +, Low risk of bias; -, high risk of bias; ?, some concerns of bias. D1: Risk of bias arising from the randomization process; D2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention); D3: Missing outcome data; D4: Risk of bias in measurement of the outcome; D5: Risk of bias in selection of the reported result.

eTable 1.f | Risk of bias (RoB 2) assessment of included cluster randomised trials (other outcomes- medication related outcome)

Authors, year of publication	D1a	D1b	D2	D3	D4	D5	Overall
Guo et al, 2017(6)	?	+	-	+	+	?	-

Outcome-related domains were assessed considering the outcomes mentioned in Table 2. +, Low risk of bias; -, high risk of bias; ?, some concerns of bias. D1a: Risk of bias arising from the randomization process; D1b: Risk of bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial; D2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention); D3: Risk of bias due to Missing outcome data; D4: Risk of bias in measurement of the outcome; D5: Risk of bias in selection of the reported result;

Supplement 7 | eTable 2: Risk of bias assessment of included non-randomised trials

	Pre-intervent	ion		At intervention	Post-inter	rvention	
Authors, year of publication	Bias due to confounding	Bias in selection of participants into the study	Bias in classificatio n of intervention s	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
De Castro et al, 2021(8)	+	-	?	?	-	?	-
Kovoor et al, 2021 (9)	+	-	?	?	-	?	-
Kapoor et al, 2021(10)	+	-	?	?	_	?	-
Loewen et al, 2019(11)	+	-	?	?	_	?	-
Eckman et al, 2018(12)	+	-	?	?	-	?	-
Stephan et al, 2018(13)	+	-	?	?	-	?	+

eTable 2 Risk of bias assessment and quality rating of included non-randomised controlled trials (ROBINS-I)

Outcome-related domains were assessed considering the outcomes mentioned in Table 2. +, Low risk of bias; -, high risk of bias; ?, some concerns of bias.

Supplement 8 | eTable 3: Population characteristics

	Population Characteristics					
Study (Authors, year, study design)	Mean CHAD2DS2- VASc ^a ; HAS- BLED ^b / HEMORR ₂ HAGE S ^c	Type of atrial fibrillation	Socioeconomic status	Educational level		
Kunneman et al., 2020(2) RCT	3.5; 2.1	Non valvular	White: 767/906 Black: 102/906 Asian: 10/906 American Indian or Alaskan native: 5/906 Multiple races: 18/906 Other: 4/906 Hispanic: 7/893	Inadequate health literacy ⁱ 73/883		
Wang et al, 2022(3) RCT	3.4; NR	Non valvular	Race and ethnicity Non-Hispanic White: 734/1001 Hispanic or Latino: 45/1001 Asian: 36/1001 Black or African American: 169/1001 American Indian or Alaskan Native: 1/ 1001 Native Hawaiian or other Pacific Islander: 3/1001 Other or multiple: 13/1001	Highest level of education No college: 328/1001 College: 461/1001 Postgraduate: 181/1001 Decline to state: 31/1001		
Guo et al, 2017(6) Cluster RCT	2.6; 1.5	Non valvular ^d	NR	NR		
Fraenkel et al, 2012(4) RCT	2.1; 1.3	Non valvular ^e	Hispanic: 5/135 Non-white: 8/135 Lives alone: 35/135 Married: 81/135	Highest education level <9 th grade: 5/135 9-12 th grade: 60/135 >High School: 70/135		

				Health literacy <9 th
				28/ 135
Thomson et al, 2007(5) RCT	2.2; 1.6	Non valvular ^f	NR	NR
De Castro et al, 2021 (8) Quasi- experimental (1 arm)	NR	Non valvular	Annual household income (Philippine peso) < 80,000: 35/37 80,000-160,000: 1/37 320,000- 400,00: 1/37	Highest education level Elementary: 12/37 High School: 13/37 College: 4/37 Vocational: 3/37 Postgraduate: 5/37
Kovoor et al, 2021 (9) Quasi- experimental (1 arm)	NR	NR	Demographically diverse population	NR
Kapoor et al, 2021(10) Quasi- experimental (1 arm)	3.64; NRº	NR	Non white:1/37 White: 36/37 Hispanic: 1/37 Non-Hispanic: 1/37	NR
Loewen et al, 2019(11) Quasi- experimental (1 arm)	2.4, 2.2	NR ^g	NR	Highest education level Elementary/high school: 6/37 Vocational/ technical school: 4/37 College/University: 8/37 Undergraduate: 6/37 Graduate: 4/37 Rather not say: 8/37
Eckman et al, 2018(12) Quasi- experimental (1 arm)	3.0; 1.9	Non valvular ^h	White/Caucasian: 55/65 Black or African American: 9/65 Marital status: Single: 6 /65 Married: 44 /65 Divorced: 8 /65 Widowed: 7 /65	Highest education level 8 th grade through high school graduate: 14/65 Some college or 2- year degree: 16/65 4-year college: 11/65 More than 4-year college: 24/65
Stephan et al, 2018(13) Quasi- experimental (1 arm)	3; 2	NR	(n=20) White (%) : 83.3	Schooling years 0-4 years (%): 33.3 5-8 years (%): 40 > 8 years (%): 26.7

	Who patients live	
	with	
	Alone (%) : 16.7	
	Companion (%) :26.7	
	Family (%): 53.3	
	Institutionalized (%):	
	3.3	
	Family income	
	4-10 minimum wages	
	(%): 26.7	
	2-4 minimum wages	
	$(\%) \cdot 20$	
	< 2 minimum wages	
	(0_{2}) · 53 3	
	(10) . 55.5	

^aCHA2DS2-VASc score(14): congestive heart failure, hypertension, age \geq 75 years, diabetes, previous stroke or transient ischemic attack or thromboembolism, vascular disease, age 65-74 years, and sex category; score range 0-9, with higher scores indicating higher risk (a CHA2DS2-VASc score of 1 or more for men and 2 or more for women indicates high risk); ^bHAS-BLED score(15): hypertension, abnormal kidney or liver function, stroke, bleeding, labile international normalized ratio, elderly age (>65years), and drug or alcohol use (score range, 0-9, with higher scores indicating higher risk); ^cHEMORR₂HAGES score(16): Hepatic or renal disease, Ethanol abuse, Malignancy, Older age, Reduced platelet count or function, Rebleeding risk, Hypertension, Anemia, Genetic factors, Excessive fall risk, Stroke. The weighted mean CHAD2DS2-VASc across studies was 3.2. The weighted mean HAS-BLED score across studies was 1.9. ^dexcluded valvular atrial fibrillation ^e paroxysmal atrial fibrillation were included if participants had at least two episodes of atrial fibrillation, with the most-recent episode documented in the previous 12 months or were receiving therapy with aspirin or warfarin. ^f paroxysmal atrial fibrillation was included. ^gand at risk of AF (defined as being >50 years without atrial fibrillation and with at least 1 atrial fibrillation stroke risk factor). ^h or atrial flutter ⁱ Self reported categories of being "not at all" or "a little bit" confident in filling medical forms without assistance

				11	
	Functionalities		Features		
Study	Delivery (Format, administered by, mode of delivery)	Usage (frequency; duration)	Personalisation to the patient	Risk communication	Additional education resources
Kunneman et al., 2020(2) Noseworth y et al, 2022(7)	Web app ^a . Utilised with clinicians <u>during</u> consultation	 Single use by patient Clinicians used tool with high fidelity^b Average encounter duration: 32 mins 	 Individualised (1 year or 5 year, with and without anticoagulant treatment) stroke risk calculated with CHAD₂DS₂-VASc score^c and bleeding risk with HAS-BLED2 score^d after <u>manual selection of risk factors</u> Section to enter own notes of decision 	- Natural frequency expressions (e.g., "out of 100 people like you") - 100-persons pictographs	- Creates patient report - Explains how to use the medications, estimated out-of-pocket costs, and association of lifestyle or medical factors with the risk of bleeding
Wang et al, 2022(3)	Web app via tablet (and can function offline) Patient utilised <u>prior</u> to consultation with minimal assistance. Clinicians had separate clinical tool.	Single use by patient Encounter duration: 11-20 mins	 Individualised risk score to determine stroke risk (with and without anticoagulant treatment) with CHAD2DS2-VASc score^c after manual selection of risk factors 	- Natural frequency expressions (e.g., "out of 100 people like you") - 100-persons pictographs	 Creates patient report Provides online guide to anticoagulation for AF stroke prevention, video, quiz to check patient understanding Worksheet for patients to record questions for the clinician visit English & Spanish available; catered to wide range of health literacy
Guo et al, 2017(6)	Mobile app ^e with separate versions for patients and clinicians. Self-utilised by patient at home	Multiple use by patient (continual monitoring of heart rate and blood pressure and completion of patient educational program)	 <u>Automatically calculates</u> <u>individualised</u> stroke risk with CHAD2DS2-VASc^c score and bleeding risk with HAS-BLED^d score after upload of patient's personal health record. 	-High versus low	- Educational and self-management resources, e.g., blood pressure self- monitoring - Includes personal health record

Supplement 9 | eTable 4: Extended Table of Function and Features of Electronic decision-support tools

Fraenkel et al, 2012(4)	Computer software tool. Utilised <u>prior</u> to consultation (after it is administered by research nurse), followed by discussion with clinician	Single use Time to administer tool: 20-35 minutes to administer.	 Calculates individualised stroke risk with CHADS2^f score and bleeding risk on Warfarin with HEMORR2HAGES^g score after manual selection of risk factors by research nurse Estimates stroke risks on aspirin and warfarin and provides baseline bleeding risk and bleeding risk with aspirin (based on systematic reviews and meta-analyses). Elicits patient preferred option and reasons. 	- Natural frequency expressions (e.g., "out of 100 people like you") - 100-person pictographs	 Creates patient report
Thomson et al, 2007(5)	Computer software tool. Utilised with clinicians <u>prior</u> to consultation	Single use for patients Encounter (median) duration: 31 minutes (10 min longer compared to control)	 Calculates individualised (1 or 5 year) stroke risk with Framingham equation⁵² after manual selection of risk factors. Estimates stroke risk on warfarin and bleeding risk on warfarin (based on systematic review data). 	- 100-person pictographs - Percentage	No
De Castro et al, 2021 (8)	Mobile application Utilised with clinicians <u>during</u> consultation	Single use of patients Encounter (median) duration: 15 (SD 6) minutes	 Calculates individualised stroke risk with CHAD2DS2-VAScc score and bleeding risk with HAS- BLEDd score after <u>manual</u> <u>insertion of risk factors</u> (with and without treatment) 	 Natural frequency expressions (e.g., "out of 100 people like you") 100-person pictographs 	Medication dosing and diet advice
Kovoor et al, 2021(9)	Web-based Audio-visual modules Utilised <u>during</u> waiting time	 Single use for patients. Encounter (median) duration: 14 min and 46 sec; maximum of 20 min to complete 	No	N/A	4 educational videos (What is AF, AF management, stroke risk and anticoagulants, lifestyle modifications) -The module was recorded in English with language and readability aimed below an eighth grade level.
Kapoor et al, 2021(10)	 Mobile app^h with versions for patients and clinicians. Self-utilised at home by 	Single use for patients Encounter (approximate)	Calculates individualised stroke risk with CHAD2DS2-VASc1 score ^c after manual insertion of risk factors	CHAD2DS2-VASc score	 Creates patient report Selection of commonly asked questions for clinicians to review and answer Links, Videos

	patient <u>prior</u> to visit with	duration: 2-3 minutes			
Loewen et al, 2019(11)	Cardiologist Online app in a web browser ⁱ Self-utilised at home by patient	Single use for patients Encounter duration: 27 min.	 Calculates individualised stroke risk with CHAD2DS2-VASc^c score and bleeding risk with HAS- BLED^d score, with and without medication, after <u>manual insertion</u> <u>of risk factors</u>. Ranks the strength of their values on the 9 most important attributes of AF stroke prevention therapy (i.e., dietary and alcohol restrictions, number of daily doses, requirement for international normalized ratio blood tests, risk of stroke, risk of major bleeding, risk of intracranial haemorrhage, participation in occupational or recreational activities with a risk of traumatic injury, availability of an antidote, and cost). 	 Risk communication through % and "1 in X chance of" format. Tool shows a "best match" % score for each therapy option along with corresponding patient values and preferences. 	- Creates patient report - Standardized educational materials developed and used by Canadian province of British Columbia
Eckman et al, 2018(12)	Online web application ^j Utilised <u>prior</u> and during to consultation with cardiologist	Single use for patients Encounter duration: approximately 20 min.	 Calculates individualised stroke risk with CHAD2DS2-VASc^c score and bleeding risk with HAS- BLED^d score, <u>automatically from</u> <u>EHR data</u> Elicits patient values and preferences (e.g., stroke with either mild or severe long-term neurological sequelae, major gastrointestinal haemorrhage, taking a pill each day, having blood tests done on average once or twice a month) 	100-person pictographs; scale with colours denoting risk; graphics of medication cards Risk communication: <i>through a</i> <i>"gambler" tool with a "poison pill"</i> <i>analogy</i> (the patient chooses a pill with varying probabilities that the pill leads to death versus the certainty of one of the above situations). ^k treatment recommendation based on projections for quality-adjusted life years	 Medication info Creates patient report
Stephan et al, 2018(13)	Mobile app (clinician tablet). Utilised with Cardiologist <u>during</u> consultation	Single use for patients	 Calculates individualised stroke risk with CHAD2DS2-VASc^c score and bleeding risk with HAS- BLED^d score, <u>manually entered</u>. Estimates stroke risk and bleeding risk for each treatment option. Elicits patient's preference 	100-person pictographs; graphics and colour code for risk information Risk communication: literacy targeted to low-income patients with low educational attainment Practical considerations	 Creates patient report (via SMS) Medication info Videos

Abbreviations: %: percentage; AF: atrial fibrillation; app: application; NR: not reported; SMS: Short Message Service;

^aFreely available online conversation aid 'Anticoagulation choice decision aid' (<u>https://anticoagulationdecisionaid.mayoclinic.org</u>/),^bRecorded interviews were reviewed by study coordinators using an ad hoc scale (total score of 7) points). Clinician(s) had a mean [SD] score, 5.6 [1.4] points of 7.0.; ^cCHA2DS2-VASc score(38): congestive heart failure, hypertension, age ≥75 years, diabetes, previous stroke or transient ischemic attack or thromboembolism, vascular disease, age 65-74 years, and sex category; score range 0-9, with higher scores indicating higher risk (a CHA2DS2-VASc score of 1 or more for men and 2 or more for women indicates high risk); ^dHAS-BLED score(39): hypertension, abnormal kidney or liver function, stroke, bleeding, labile international normalized ratio, elderly age (>65years), and drug or alcohol use (score range, 0-9, with higher scores indicating higher risk); ^emAF app available in China for Android and Apple Operating Systems; ^fCHADS2 algorithm(44): Congestive heart failure history, Hypertension history, Aged ≥75, Diabetes mellitus history, Stroke symptoms previously or transient ischemic attack; ^gHEMORR₂HAGES score(40): Hepatic or renal disease, Ethanol abuse, Malignancy, Older age, Reduced platelet count or function, Rebleeding risk, Hypertension, Anemia, Genetic factors, Excessive fall risk, Stroke; ^hAFib 2gether mobile app, developed by Pfizer (<u>https://play.google.com/store/apps/details?id=com.pfizer.us.AfibTogether&hl=n_US&gl=US</u>); ⁱ The underlying software system, Dynamic Computer Interactive Decision Application (DCIDA; <u>http://www</u>, dcida.ubc.ca); ^jAtrial Fibrillation Shared Decision Making AFSDM web app; ^kGafni A. The standard gamble method: what is being measured and how it is interpreted. Health Serv Res 1994:29:207-24.:

Supplement 10 | eTable 5: SUNDAE Checklist

Section	SUNDAE Checklist for evaluation studies of patient decision aids	Studies that evaluated patient decision aids
Title/abstract		1=Fraenkel et al. 2012(4) 2=Thomson et al. 2007(5) 3=Loewen et al. 2019(11) 4= de Castro et al. 2021(8)
1.	Use the term patient decision aid in the abstract to identify the intervention evaluated and, if possible, in the title.	2,3,4
2.	In the abstract, identify the main outcomes used to evaluate the patient decision aid.	2,3,4
Introduction	As part of standard introduction (the problem, gaps, purpose):	
3.	Describe the decision that is the focus of the patient decision aid.	1,2,3,4
4.	Describe the intended user(s) of the patient decision aid.	1,2,3,4
5.	Summarise the need for the patient decision aid under evaluation.	1,2,3,4
6.	Describe the purpose of the evaluation study with respect to the patient decision aid.	1,2,3,4
Methods	Studies with a comparator should also address items $7-13$ for the comparator, if possible	
7.	 Briefly describe the development process for the patient decision aid (and any comparator), or cite other documents that describe the process. At a minimum include the following: participation of stakeholders in its development the process for gathering, selecting and appraising evidence to inform its content any testing that was done. 	3,4
8.	Identify the patient decision aid evaluated in the study (and any comparator) by including:	3,4

	 name or information that enables it to be identified date and/or version number how it can be accessed, if available. 	
9.	Describe the format(s) of the patient decision aid (and any comparator) (eg, paper, online, video).	1,2,3,4
10.	List the options presented in the patient decision aid (and any comparator).	1,2,3,4
11.	 Indicate the components in the patient decision aid (and any comparator) including: explicit description of the decision* description of health problem* information on options and their benefits, harms and consequences* values clarification (implicit or explicit)* numerical probabilities tailoring of information or probabilities guidance in deliberation guidance in communication personal stories reading level or other strategies to help understanding other components. 	1,3,4
12.	Briefly describe the components from item 11 that are included in the patient decision aid (and any comparator) or cite other documents that describe the components.	1,3,4
13.	 Describe the delivery of the patient decision aid (and any comparator) including: how it was delivered (eg, by whom and/or by what method) to whom it was delivered where it was used when it was used in the pathway of care any training to support delivery setting characteristics and system factors influencing its delivery. 	1,2,3,4
14.	Describe any methods used to assess the degree to which the patient decision aid was delivered and used as intended (also known as fidelity).	3,4

15.	Describe any methods used to understand how and why the patient decision aid works (also known as process evaluation) or cite other documents that describe the methods.	1,2,3,4
16.	Identify theories, models or frameworks used to guide the design of the evaluation and selection of study measures.	3,4
17.	 For all study measures used to assess the impact of the patient decision aid on patients, health professionals, organisation, and health system: identify the measures indicate the timing of administration in relation to exposure to the patient decision aid and healthcare interventions. 	2,3,4
18.	 For any instruments used: name the instrument and the version (if applicable) briefly describe the psychometric properties, or cite other documents. 	3,4
Results	In addition to standard reporting of results:	
19.	Describe the characteristics of the patient, family and carer population(s) (eg, health literacy, numeracy, prior experience with treatment options) that may affect patient decision aid outcomes.	1,2,3,4
20.	Describe any characteristics of the participating health professionals (eg, relevant training, usual care vs study professional, role in decision-making) that may affect decision aid outcomes.	3,4
21.	 Report any results on the use of the patient decision aid: how much and which components were used degree to which it was delivered and used as intended (also known as fidelity). 	2,3,4
22.	Report relevant results of any analyses conducted to understand how and why the patient decision aid works (also known as process evaluation).	2,3
23.	Report any unanticipated positive or negative consequences of the patient decision aid.	3

Discussion	As part of the standard discussion section (summary of key findings, interpretation, limitations and conclusion):	
24.	Discuss whether the patient decision aid worked as intended and interpret the results taking into account the specific context of the study including any process evaluation.	2,3,4
25.	Discuss any implications of the results for patient decision aid development, research, implementation, and theory, frameworks or models.	1,2,3,4
Conflict of interest	est	
26.	All study authors should disclose if they have an interest (professional, financial or intellectual) in any of the options included in the patient decision aid or a financial interest in the decision aid itself.	1,2,3,4

*These components are needed to meet the definition of a patient decision aid.

Abbreviations: SUNDAE, Standards for Universal reporting of patient Decision Aid Evaluations.

Supplement 11 | eTable 6: Adherence to International Patient Decision Aids Standards

eTable 6.a: Qualifying criteria for Patient decision aids (PtDAs)

			Q	Qualifying criteria for P	PtDAs ^a	
Study	Tool	The patient decision aid describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required	The patient decision aid explicitly states the decision that needs to be considered (index decision).	The patient decision aid describes the options available for the index decision.	The patient decision aid describes the positive features (benefits or advantages) and negative features (harms, side effects, or disadvantages) of each option.	The patient decision aid describes what it is like to experience the consequences of the options (e.g., physical, psychological, social).
Fraenkel et al, 2012(4)	Patient	A	A	A		s.
Cluster RCT	Decision Aid	•	•	•	•	~
Thomson et al, 2007(5)	Patient					
RCT	Decision Aid	×	V	V	V	×
De Castro et al, 2021 (8)	Patient					
Quasi- experimental (1	Decision Aid	✓	✓	✓	✓	✓
arm)						
Loewen et al, 2019(11)	Patient					
Quasi- experimental (1	Decision Aid	✓	×	×	<	✓
arm)						

^a Adapted from IPDAS(17)

eTable.6b: Additional criteria for Patient decision aids (PtDAs): certification and quality criteria

		Fraenkel	Thomson	De	Loewen
		et al,	et al,	Castro et	et al,
		2012	2007	al.	2019
Information	The patient decision aid shows the negative and positive features of options with equal detail (e.g.,		~	♦	~
mormation	using similar roots, sequence, presentation of statistical monitation)	•			
	The patient decision aid describes the natural course of the health condition of problem, if no action is		~	~	~
	taken (when appropriate).	~	•	•	•
	The patient decision aid makes it possible to compare the positive and negative features of the				
	available options.	✓	•	•	•
	The patient decision aid provides information about outcome probabilities associated with the options				
Probabilities	(i.e., the likely consequences of decisions).	~	*	*	~
	The patient decision aid specifies the defined group (reference class) of patients for whom the outcome				
	probabilities apply.	×	V	V	~
	The patient decision aid specifies the event rates for the outcome probabilities	 Image: A start of the start of	V	~	<

	The patient decision aid allows the user to compare outcome probabilities across options using the same time period (when feasible).	~	~	~	~
	The patient decision aid allows the user to compare outcome probabilities across options using the	v			. 4
	same denominator (when feasible).	<	×	×	~
	The patient decision aid provides more than 1 way of viewing the probabilities (e.g., words, numbers,				v
	and diagrams).		•	•	х
	The patient decision aid asks patients to think about which positive and negative features of the options			v	
Values	matter most to them (implicitly or explicitly).	✓	•	Λ	•
Guidance	The patient decision aid provides a step-by-step way to make a decision.	✓	 ✓ 	 ✓ 	\checkmark
	The patient decision aid includes tools like worksheets or lists of questions to use when discussing			v	~
	options with a practitioner.	✓	•	•	•
Developmen t	The development process included a needs assessment with clients or patients.	~	~	~	>
	The development process included a needs assessment with health professionals.	Х	~	 ✓ 	\checkmark
	The development process included review by clients/patients not involved in producing the decision				
	support intervention.	 Image: A start of the start of	•	·	
	The development process included review by professionals not involved in producing the decision		~	~	\sim
	support intervention.	X		•	
	The patient decision aid was field tested with patients who were facing the decision.	✓	✓	✓	
	The patient decision aid was field tested with practitioners who counsel patients who face the decision.	X	 ✓ 	 ✓ 	
Evidence	The patient decision aid (or associated documentation) provides citations to the evidence selected.		 ✓ 	 ✓ 	\checkmark
	The patient decision aid (or associated documentation) provides a production or publication date.	✓	 ✓ 	 ✓ 	~
	The patient decision aid (or associated documentation) provides information about the update policy.	X	X	X	X
	The patient decision aid provides information about the levels of uncertainty around event or outcome		v	v	~
	probabilities (e.g., by giving a range or by using phases such as "our best estimate is ").	X	A	Λ	•
	The patient decision aid (or associated documentation) describes how research evidence was selected			~	
	or synthesized.	✓	•	~	•
	The patient decision aid (or associated documentation) describes the quality of the research evidence		~	~	\checkmark
	used.	\checkmark	•	•	•
	The patient decision aid (or associated documentation) provides information about the funding source		~	~	~
Disclosure	used for development.	<u> </u>	· ·	· ·	
	The patient decision aid includes authors'/developers' credentials or qualifications.	\checkmark	 ✓ 	 ✓ 	 ✓
Plain	The patient decision aid (or associated documentation) reports readability levels (using 1 or more of	x	x	x	х
language	the available scales).				
	There is evidence that the patient decision aid improves the match between the preferences of the	Х	х	X	х
Evaluation	informed patient and the option that is chosen.				
	I here is evidence that the patient decision and helps patients improve their knowledge about options'	. ^	~	~	<
	reatures.	~			

Study	Perceived patient satisfaction +/-engagement
Kunneman et al., 2020(2)	Quality of Communication: NS ^{a,b}
RCT	Preference in communication style ^c : ↔ between arms (aRR 1.0; 95%CI, 0.97 to 1.1)
Noseworthy et al, 2022(7)	NR
RCT	
Wang et al, 2022(3)	Quality of communication: (did the clinician listen carefully)
RCT	↑ between arms ^d
Guo et al, 2017(6)	> 90% of patients agreed <i>intervention</i> was easy, user-friendly, and helpful
Cluster RCT	
Fraenkel et al, 2012(4)	Engagement ^c : ↑ between arms (for risk of stroke and major bleeding discussion)
Cluster RCT	
Thomson et al, 2007(5)	NR
RCT	
De Castro et al, 2021 (8)	100% of patients agreed the patient decision aid was useful and had sufficient information for decision making
Kovoor et al, 2021 (9)	
Quasi- experimental (1 arm)	82 out of 100 VAS Score ^e (IQR 70-90) for the clinician's narration adding benefit to the patient experience
Kapoor et al, 2021(10)	48% of participants demonstrated audio evidence of patient's involvement in the clinician-patient discussion of treatment options
Quasi- experimental (1 arm)	High satisfaction with intervention (Median patient scored: 4.51 out 5 ^f , with 5 as complete satisfaction of intervention on scale)
	62% of national scale)
	Medium usability: 54% of narticinants agreed with "The app helped me decide whether to go on
	anticoagulation".
Loewen et al, 2019(11)	Medium usability: The overall mean usability ^g score was $61/100$ (SD = 15.2),
Quasi- experimental (1 arm)	
Eckman et al, 2018(12)	Patient satisfaction with Decision Scale:
Quasi- experimental (1 arm)	
Stephan et al, 2018(13)	NR
Quasi- experimental (1 arm)	

Supplement 12 | eTable 7: Acceptability and satisfaction with digital patient decision-support tools

Abbreviations: aRR: adjusted risk ratio; CI: confidence interval; IQR: interquartile range; NR: not reported; NS: not statistically significant effect as per p-values (p>0.05) reported in the study; RCT: Randomised Control Trial; SD: standard deviation; VAS: Visual Analogue Scale; \leftrightarrow : no difference; P-values reported between intervention and control arm in RCTs, and pre- vs post-intervention in quasi-experimental studies.; >: more than.; \uparrow : increased;

^aPrimary outcome; ^bQuality of communication measured with the validated Consumer Assessment of Healthcare Providers and Systems (<u>https://www.ahrq.gov/cahps/surveysguidance/survey-methods-research/index.html</u>); ^c Calculated by proportion in intervention over proportion in control; ^dAt one month follow up; ^e100 on the VAS Score indicating complete agreement with the statement.; ^fMobile App Rating Scale (MARS) validated questionnaire; ^gSystem Usability Scale; ^hResearcher-developed questionnaire with validation status unclear

Supplement 13 | eTable 8. Control group / Usual Care Definition

	Control group / Usual Care Definition		
Study (Authors, year, study design)			
Kunneman et al., 2020(2) RCT	"In the standard care arm, clinical encounters were conducted according to the clinicians' usual approach."		
Noseworthy et al, 2022(7) RCT	Same as above		
Wang et al, 2022(3) RCT	"In the control arm (UC), the participants and the clinicians were not provided with the digital SDM tool and, therefore, followed usual clinical practice."		
Guo et al, 2017(6) Cluster RCT	"usual care"		
Fraenkel et al, 2012(4) RCT	"Baseline data were collected in a face-to-face interview before participants' regularly scheduled visits with their primary care provider; for participants in the intervention group, this was followed by administration of the tool."		
Thomson et al, 2007(5) RCT	"Participants were randomised to either: (a) computerised decision aid (intervention) or (b) evidence-based paper guidelines (control) () In the evidence-based paper guidelines group, the clinic treatment recommendation was provided by applying decision analysis derived guidelines according to the participants' risk factor profile and the recommendation made directly to the participant by the clinic doctor. All treatment decisions were conveyed to the participants' own GP for ongoing care."		

Supplement 14 | eFigure 1: Sensitivity analysis for combined effect size for two subscales

		Int	erventi	on		Control				1945	Standardized
Author, Year	Outcome	Mean	SD	Total	Mean	SD	Total		v	Veights Me	ean Difference,IV, Random, [95% CI]
Kunneman 202	0 DCS total score	16.4	14.4	463	17.9	14.9	459			35.16%	-0.10 [-0.23, 0.03]
Wang 2022	DCS total score	9.4	40.97	495	16.4	40.97	506			35.71%	-0.17 [-0.29, -0.05]
Fraenkel 2012	Combined*	9.7	25.56	69	22.9	25.56	66	·		15.74%	-0.51 [-0.86, -0.17]
Thomson 2007	DCS total score	20	8.36	51	23.6	8.36	54			13.39%	-0.43 [-0.81, -0.04]
Test for overall effe RE Model Te	ect: Z=-2.72, P=0.01 st for heterogeneity:(Q = 6.60	. df = 3, p	= 0.09; I ²	= 64.4%)					100.00%	-0.24 [-0.40, -0.07]
							Ē	1	1		
							-1	-0.5 0	0.5	1	
							1	Favours intervention	Favours co	ntrol	

eFigure 1 | Forest plot of effect sizes and 95% CIs representing sensitivity analysis for combined effect size for two subscales (informed and values subscales) of Decisional Conflict Scale

Green denotes studies that adhere to IPDAS definition of decision aids. Data not available in Guo et al.

Supplement 15 | eResults 2: Publication bias analysis



eFigure 2 | Funnel plot of standard error by standardised difference in means (Duval and Tweedie trim- and fill- method) for Decisional Conflict scale. The funnel plot indicates publication bias, with small studies showing a bigger effect in reducing decisional conflict.



eFigure 3 | Funnel plot of standard error by standardised difference in means (Duval and Tweedie trim- and fill- method) for patient knowledge

Egger's regression test for Decisional conflict scale

Regression Test for Funnel Plot Asymmetry

Model: mixed-effects meta-regression model Predictor: standard error

Test for Funnel Plot Asymmetry: z = -2.03727, p = 0.04162 Limit Estimate (as sei -> 0): b = 0.01245 (CI: -0.18165, 0.20655)

Egger's regression test for patient knowledge

```
Regression Test for Funnel Plot Asymmetry
Model: mixed-effects meta-regression model
Predictor: standard error
Test for Funnel Plot Asymmetry: z = 0.57055, p = 0.56830
```

```
Limit Estimate (as sei -> 0): b = 0.04921 (CI: -0.36327, 0.46170)
```

Supplement 16 | eTable 9: Outcomes of included quasi-experimental studies

Study	Decisional conflict	Patient knowledge
de Castro et al,	\downarrow Pre-post ^b	↑ pre-post ^c
2021(8)		
Kovoor et al,	Baseline data not available	NR
2021(18)	90 out of 100 VAS Score ^a (IQR 82.5-	
Cross-sectional	97) for improving patient decision-	
Quasi- experimental	making	
(1 arm)		
Kapoor et al,	NR	40% of patients agreed that the app improved their knowledge of anticoagulation
2021(10)		
Quasi- experimental		
(1 arm)		
	h	
Loewen et al,	\downarrow Pre-post ^b	↑ pre-post ^c
2019(11)		
Quasi- experimental		
(1 arm)	. L	• •
Eckman et al,	↓ pre-post ^b	↑ pre-post ^c
2018(12)		
Quasi- experimental		
(1 arm)		· · ·
Stephan et al,	Data not available ^b	↑ pre-post ^c
2018(19)		
Quasi- experimental		
(1 arm)		

Abbreviations: AC: anticoagulation; IQR: Interquartile Range; NR: not reported; VAS: Visual analogue scale; \uparrow : Increase; \downarrow : decrease; a 100 on the VAS Score indicating complete agreement with the statement; bDecisional Conflict Scale is a validated 16-item scale that evaluates an individual's degree of uncertainty about the choice (score range, 0-100, with higher scores indicating greater decisional conflict; 5 subscales: informed; values; support; uncertainty; effective decision-making)⁽²⁰⁾; cResearcher-developed questionnaire with validation status unclear;

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Supplement 17 | eTable 10: Medication-related outcomes

Study	Medication Outcomes (Change in adherence, preference in treatment/therapy or patient-clinician concordance of		
K 1 2020(2)	treatment outcome)		
Kunneman et al., $2020(2)$	Patient-clinician decision concordance about treatment selection": NS		
RCT			
Noseworthy et al, 2022(21)	Medication change: ↓ in intervention arm (Intervention 72/463; Control: 86/459; aOR: 0.79 (0.55-1.14)) ^{a,b}		
(10-month follow up of	Adherence: NS percentage of days covered ; ↑ intervention vs control on percentage of days covered higher than 80%		
Kunneman 2020 RCT)	(DOAC: aOR 1.42 (0.96 to 2.22); Warfarin: NR) ^{a,b}		
Wang et al, 2022(22) RCT	Medication adherence (self-reported at 1 and 6 months): NS ^c		
Guo et al, 2017(6)	Medication adherence (self-reported at 1 month and 3 months): ↑ between groups ^d		
Cluster RCT			
Fraenkel et al, 2012(4)	Medication change: NS		
RCT			
Thomson et al, 2007(5)	Change in medication preference: Participants in the intervention group not already on warfarin were less likely to start		
RCT	warfarin than those in the control arm (4/16, 25% compared to the guidelines group 15/16, 93.8%, RR 0.27, 95% CI 0.11 to 0.63).		
de Castro et al, 2021(8)	NR		
Quasi- experimental (1 arm			
Kovoor et al, 2021(18)	Data not available		
Quasi- experimental (1 arm)	90 out of 100 VAS Score (IQR 81-97) ^e for improving potential treatment adherence		
Kapoor et al, 2021(10)	Medication change: 12/37 (32%) patients started anticoagulation following their appointment		
Quasi- experimental (1 arm)	Change in Medication preference: 23/37 (62%) patient agreed with statement "the app clarified my AC preferences to my provider)		
Loewen et al, 2019(11)	Change in Medication preference: 22/37 (59%) participants indicated a change in preference to different drug class after		
Quasi- experimental (1 arm)	using the tool		
Eckman et al, 2018(12)	Medication change: 12 out of 65 participants made recommended treatment decision		
Quasi- experimental (1 arm)	Medication Adherence: pre-post (mean difference [95% CI]): 0.5(0.3,0.7) p value <.001		
Stephan et al, 2018(19) Quasi- experimental (1 arm)	NR		

Abbreviations: aOR: adjusted Odds Ratio; aRR: adjusted risk ratio; CI: confidence interval; DOAC: direct oral anticoagulant; NS: not statistically significant effect as per p-values (p>0.05) reported in the study; NR: not reported; RCT: Randomised Control Trial; \downarrow : lower; \uparrow : higher; P-values reported between intervention and control arm in RCTs, and pre- vs post-intervention in quasi-experimental studies. ^a Calculated by proportion in intervention over proportion in control; ^b Adherence assessed by percentage days covered of the direct oral anticoagulant. ^c based on participant self-reported missed doses and

collected for post-adhoc analysis; ^d measured by Pharmacy Quality Alliance 3-item adherence measures: Low risk = 0, moderate risk = 2-7 and high risk = score 8-36; ^e 100 on the VAS Score indicating complete agreement with the statement; ^fMeasured after second visit when shared decision-making recommendation offered, and one month later by telephone survey to assess adherence to decision made at the second with Morisky Medication Adherence Scale

Supplement 18 | eTable 11: Health outcomes in included studies

	Health outcomes			
Study	Perceived risk of stroke +/- bleeding	Anxiety		
Kunneman et al., 2020(2) RCT	NR	NR		
Noseworthy et al, 2022(7) RCT	NR	NR		
Wang et al, 2022(3) RCT	NR	NR		
Guo et al, 2017(6) Cluster RCT	NR	↓ between arms ^a (favouring intervention)		
Fraenkel et al, 2012(4) RCT	↓ between arms (favouring intervention)	NS ^b		
Thomson et al, 2007(5) RCT	NR	NS ^b		
De Castro et al, 2021 (8)	NR	NR		
Kovoor et al, 2021 (9) Quasi- experimental (1 arm)	NR	No data available 89 out of 100 VAS Score ^c (IQR 81-95) for improving consultation anxiety		
Kapoor et al, 2021(10) Quasi- experimental (1 arm)	NR	NR		
Loewen et al, 2019(11) Quasi- experimental (1 arm)	NR	NR		
Eckman et al, 2018(12) Quasi- experimental (1 arm)	NR	NR		
Stephan et al, 2018(13) Quasi- experimental (1 arm)	NS ^d	NR		

Abbreviations: aRR: adjusted risk ratio; CI: confidence interval; IQR: interquartile range; NR: not reported; NS: not statistically significant effect as per p-values (p>0.05) reported in the study; RCT: Randomised Control Trial; SD: standard deviation; VAS: Visual Analogue Scale; \leftrightarrow : no difference; P-values reported between intervention and control arm in RCTs, and pre- vs post-intervention in quasiexperimental studies.; >: more than.; \uparrow : increased;

^aComponent of the EQ-5D-Y questionnaire; ^bSpielberger State Anxiety Index (validated)(46); ^c100 on the VAS Score indicating complete agreement with the statement.; ^dRated as low, moderate, or high risk of stroke and bleeding

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