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A systematic review and meta-analysis of patient decision aids for disadvantaged populations: update from the International Patient Decision Aid Standards (IDPAS)

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Abstract

Background—The effectiveness of patient decision aids (PtDAs) and other shared decision making (SDM) interventions for socially disadvantaged populations has not been well studied.

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Conflicts of Interest

None for RWY, JS, JE, DMM, SS, JM, LPP, AJO, JKL, OM, TC, AG, AJH, AL, KM.

Purpose—To assess if PtDAs and other SDM interventions improve outcomes or decrease health inequalities among socially disadvantaged populations and determine the critical features of successful interventions.

Data Sources—MEDLINE, CINAHL, Cochrane, PsycINFO and Web of Science from inception to October 2019. Cochrane systematic reviews on PtDAs.

Study Selection—Randomized controlled trials of PtDAs and SDM interventions that included socially disadvantaged populations.

Data Extraction—Independent double data extraction using a standardized form and the Template for Intervention Description and Replication checklist.

Data Synthesis—Twenty-five PtDA and 13 other SDM intervention trials met our inclusion criteria. Compared to usual care, PtDAs improved knowledge (mean difference=13.91, 95% CI 9.01, 18.82 [I^2=96%]) and patient-clinician communication (relative risk=1.62, 95% CI 1.42, 1.84 [I^2=0%]). PtDAs reduced decisional conflict (mean difference=−9.59; 95% CI −18.94, −0.24 [I^2=84%]) and the proportion undecided (standardized mean difference=0.39; 95% CI 0.28, 0.53 [I^2=75%]). PtDAs did not affect anxiety (standardized mean difference=0.02, 95% CI −0.22, 0.26 [I^2=70%]). Only one trial looked at clinical outcomes (hemoglobin A1C). Five out of the twelve PtDA studies that compared outcomes by disadvantaged standing found that outcomes improved more for socially disadvantaged participants. No evidence indicated which intervention characteristics were most effective. Results were similar for SDM intervention trials.

Limitations—Sixteen PtDA studies had overall unclear risk of bias. Heterogeneity was high for most outcomes. Most studies only had short-term follow-up.

Conclusions—PtDAs led to better outcomes among socially disadvantaged populations but did not reduce health inequalities. We could not determine which intervention features were most effective.

Introduction

Clinical equipoise warrants patient involvement in decision making (shared decision making [SDM]).(1) Patient decision aids (PtDAs) and other SDM interventions are often used to facilitate SDM, which has been shown to improve knowledge, risk perception and congruence between informed values and health choices.(2) PtDAs and other SDM interventions come in many forms, including paper-based interventions, computer-based interventions, or health professional training.(2,3) Each type is likely to provide different advantages and disadvantages to patients who are socially disadvantaged with respect to race, ethnicity, literacy, health literacy education, or income when compared to more socially advantaged people.

People from socially disadvantaged groups, and particularly those with lower literacy and/or health literacy, represent a substantial proportion of the population. It is estimated that about 36% of Americans have limited health literacy skills.(4) Australia and European countries report that up to 60% of their citizens have inadequate health literacy.(5,6) This global public health problem affects both high, low, and middle income countries.(7,8) Social

disadvantage, whether due to lower health literacy or other characteristics such as lower education, lower income, or race, has a strong link to health inequalities.(9–12)

We published a systematic review and meta-analysis in 2014 that assessed whether SDM interventions reduced health inequalities.(13) We used a broad definition of social disadvantage in order to determine if people who are socially disadvantaged might benefit differently from PtDAs and other SDM interventions compared to non-disadvantaged people. We found that these interventions improved outcomes for socially disadvantaged groups. A narrative synthesis suggested that socially disadvantaged groups might stand to benefit the most, provided content was tailored to their needs. Most of the studies had been conducted within the prior two years, signaling a growing focus. Therefore we have updated this 2014 review to incorporate more recent evidence and to inform recommendations for the 2.0 update to the International Patient Decision Aid Standards (IPDAS). Our three objectives were:

1. to assess if PtDAs improved outcomes and decreased health inequalities for lower health literacy and socially disadvantaged groups,
2. to assess if other SDM interventions improved outcomes and decreased health inequalities for lower health literacy and socially disadvantaged groups, and
3. to determine the critical features of PtDAs and other SDM interventions that best support SDM for lower health literacy and disadvantaged populations.

Methods

Protocol and registration

We revised and re-registered the protocol for the 2014 review through PROSPERO (CRD42012002200).(13) We planned and reported this review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses and the Cochrane Handbook for Systematic Reviews of Interventions.(14,15) See supplemental file 1.

Inclusion criteria

We included published randomized controlled trials that assessed the effect of PtDAs and other SDM interventions on socially disadvantaged groups and/or health inequalities. We included articles reporting at least 50% of participants from a socially disadvantaged group or if a separate analysis was conducted for this group. We considered multiple criteria for being socially disadvantaged as health literacy is well-correlated with other socially-defined characteristics.(16,17) Using this definition allowed us to broadly examine outcomes among people who might be socially disadvantaged based on one or multiple criteria. We defined a socially disadvantaged group as meeting at least one of the following criteria based on published definitions:(18,19)

1. People who are socially disadvantaged with respect to poverty or lower socioeconomic status
2. People who are socially disadvantaged as a result of their ethnicity or race
3. People who have lower educational attainment (no college degree)

4. People who have lower literacy and/or lower health literacy
5. People who are socially disadvantaged with respect to geographical location (areas described as disadvantaged and/or medically underserved)
6. People who are uninsured or on public health insurance
7. People who have lower numeracy
8. People who are socially disadvantaged as a result of speaking a primary language that differs from the official language(s) of their country of residence

We had no language restrictions. We included all conditions and clinical settings. Interventions were considered PtDAs if they appeared in the 2014, 2017, or upcoming 2021 Cochrane systematic review of PtDAs.(2,20) We defined other SDM interventions as interventions or strategies designed to engage patients in medical decision-making and/or facilitate SDM, patient involvement in medical decision-making, or patient activation.(13) This included professional coaching/training, patient coaching, skills workshops, and patient prompts, provided the aim was to increase patient engagement in decision-making. We included educational or self-management interventions that targeted activation and involvement in medical decision making. We did not prespecify any required outcomes. We allowed multiple definitions of a control group, as long as there was a group not exposed to the tested PtDA or SDM intervention.

Search strategy and study selection

To find PtDAs, we searched the 2014, 2017, and upcoming 2021 Cochrane systematic review of PtDAs.(2) To find other SDM interventions, we adapted our search strategy from the 2014 review, consulted a research librarian, and piloted it in MEDLINE via Ovid (see supplemental file 2, figure 1). We also searched CINAHL, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, PsycINFO, and Web of Science from inception to October 2019. We hand-searched the reference list and performed a “cited by” and “related articles” search through PubMed of all included primary articles. In Google Scholar, one reviewer looked at the first 100 results to check for relevant records not already captured. We included all randomized trials reported in Durand and colleagues’ 2014 review. We independently screened the title and abstract and subsequent full text of retrieved records (two per record: RWY, M-A D, SS, LPP, GE, JE, JS, OM).(21) We resolved disagreements as a team.

Data extraction and risk of bias assessment

We conducted independent double data extraction using a pre-designed, piloted form adapted from previous reviews (two per record: RWY, M-A D, JE, SS, LPP, JM, DM, JS, OM, KM, TC, AG, AL, AH).(13,22) We extracted all intervention characteristics using an adapted version of the Template for Intervention Description and Replication (TIDieR) checklist.(23) We used the Cochrane Risk of Bias tool, version 2, to assess risk of bias (two per record: RWY, M-A D, JE, SS, LPP, JM).(24)

Data synthesis and analysis

We used a random-effects model since the included studies did not come from the same population.(25) Using R, we pooled studies in a meta-analysis to calculate a weighted effect and 95% confidence interval (CI) for outcome measures that were reported at least three times across the included studies.(26,27) For studies with more than two arms, we analyzed the arms that were closest to a control and PtDA or SDM intervention. If measures were repeated, we selected the time point that was the most conservative estimate to understand the intervention's effect on the outcome.

For continuous outcome measures, we calculated standardized mean difference (SMD) when the tools or surveys used to measure the outcome varied using Hedges' g method and mean difference (MD) when the outcome measurement tool was the same across studies.[21] For dichotomous outcome measures, we calculated a relative risk (RR). We conducted sensitivity analyses when findings were significant using the Hartung-Knapp method given the varying study sizes and heterogeneity across the included studies.(28–30) We excluded studies from the meta-analysis that only conducted separate analyses by socially disadvantaged status but did not have >50% participants considered socially disadvantaged as these separate analyses were not reported in sufficient detail to be included.

We conducted a narrative synthesis guided by the UK's Economic and Social Research Council (ESRC) Methods Program to assess the PtDA or other SDM intervention's effect on health inequalities by looking at studies that reported the impact of the interventions by socially disadvantaged versus non-socially disadvantaged status. We also used the narrative synthesis to determine the critical features of included interventions, and for all outcomes that could not be included in the meta-analysis.(31) We combined the evidence by looking at the outcomes and heterogeneity of the included studies to compare and contrast the combined results. To look at the critical features of included interventions, we stratified by whether the outcomes tested for that intervention did or did not favor its use.

Dealing with missing data

If outcomes data were not available in the primary paper, we extracted it from Stacey et al.'s review, if applicable.(2) If standard deviation data were not available, we used methods in the Cochrane Handbook to calculate standard deviation by its relationship to p-values, standard errors, or 95% confidence intervals.(32)

Assessment of heterogeneity

We looked for statistical heterogeneity using the I^2 statistic to determine the percentage of variation across included studies for each outcome in the meta-analysis.(15) We assumed an I^2>50% to indicate significant heterogeneity. For studies or outcomes included in the narrative synthesis, we looked at study quality, outcome measurement, and intervention differences to assess heterogeneity.(31)

Assessment of reporting bias

We used funnel plots to visually assess for potential publication bias for each outcome included in the meta-analysis.(15) Publication bias was assessed quantitatively using Egger's

regression test for asymmetry for outcomes reported by at least 10 studies.(33) A p-value of less than 0.05 indicated significant publication bias.

Subgroup and sensitivity analysis

Our primary goal was to look at the effect on outcomes for PtDAs. However, given the sufficient number of SDM interventions not considered a PtDA, we also conducted a secondary meta-analysis of outcomes including all intervention types. All studies reporting decisional conflict used either the original Decisional Conflict Scale or the low literacy Decisional Conflict Scale.(34,35) We therefore conducted a subgroup analysis for decisional conflict based on the type of scale used.

We conducted two sensitivity analyses to determine whether risk of bias in the randomization of participants or deviations from the intended interventions affected the results of all outcomes with at least six studies in the meta-analysis. Finally, we used the Cochrane standard deviation calculator for a proportion of the studies in the knowledge meta-analysis and conducted a sensitivity analysis to see if the results changed when the calculator was used.

Results

Identified studies

We retrieved 300 articles from the Cochrane reviews, 1,724 records from the database searches, and 43 from additional search methods. After removing duplicates, we screened the title and abstract of 1,366 records then reviewed the full text of 78 articles. Twenty-five PtDAs were included in the primary analysis.(36–60) An additional 13 studies of SDM interventions were included in the secondary analysis (figure 1).(61–73)

Study and participant characteristics

The number of participants ranged from 60 to 1,270, representing 9,591 in total, with an average of 384 participants/study (Table 1). Eighteen PtDA studies focused on screening behavior, six examined treatment options for various health conditions, and one focused on referral for early childhood developmental delays. Fifteen had greater than 50% of participants from racial or ethnic minorities. Eleven included participants of lower educational attainment. Six included participants reporting low annual household income. Thirteen of the studies included participants that met more than one criteria of social disadvantage. Characteristics of the other SDM intervention studies are available in supplementary file, table 1.

Description of included decision aids

Across all PtDAs, one was a verbal script with no visual component (Table 2). Five were paper-based. Thirteen were virtual, computer- or web-based interventions. Of these, nine were interactive (e.g., being able to select specific options or alter the path through the intervention) and four were static (e.g., videos only or click-through design). Six combined mediums.(36,37,49,53,55,57) Fifteen studies mentioned including consumers in the development of the PtDA and fourteen reported user-testing among socially

disadvantaged groups. Seven reported readability scores which ranged from second to tenth grade. An in-depth assessment of the readability of included PtDAs is available in our companion manuscript.(74)

Twelve of the PtDAs were delivered before a specific clinic visit, two were delivered after a specific clinic visit, ten were delivered independent of a specific clinic visit, and one was delivered during the clinic visit. The majority (n=21) were used by or delivered to participants only once. One was given to patients to use repeatedly at home.(38) Eighteen had components tailored to the participant. Our companion paper presents more details regarding how PtDAs were tailored for people who are socially disadvantaged.(74) The other SDM interventions had a similar mix of attributes (supplementary file 2, table 2).

Risk of bias in included studies

A large majority of the PtDAs studies had overall unclear risk of bias (16/25) (figure 2). Reasons for unclear risk of bias varied but the largest domain was reporting results (19/25). This typically occurred because information on a protocol or trial registry was limited or missing, or there was disagreement between the published study and published protocol or trial registry. Most studies had low risk of bias due to randomization procedures (16/25). The highest risk of bias domain was due to deviations from the intended interventions (4/25) which was usually related to a lack of blinding. Risk of bias analysis was similar for the other SDM interventions (supplementary file 2, figure 2).

Meta-analysis

Knowledge—Fourteen PtDA studies reported knowledge as an outcome measure.(37,39,41–45,52–56,58,59) The pooled mean difference was 13.91 (95% CI 9.01, 18.82) favoring the intervention with substantial heterogeneity (I^2=96%, p<0.01) (figure 3). Sensitivity analyses did not affect this finding (supplemental file 2, figures 3–6). Among the three studies not included in the meta-analysis due to insufficient information, one reported no significant difference,(58) and two reported differences favoring the intervention.(42,56) When including other SDM intervention studies, results remained significant, favoring the interventions (supplemental file 2, figure 7).(63,65,67,69,71,73)

Decisional conflict—Fourteen PtDA studies reported decisional conflict as an outcome measure.(39,41,43–45,53,55,56,58,59) The pooled standardized mean difference was −0.41 points (95% CI −0.83, 0.02) favoring the intervention but not statistically significant with significant heterogeneity (I^2=85%, p<0.01) (figure 4A). There were no changes to statistical significance in the sensitivity analyses (supplemental file 2, figures 8–9). Among the three studies with insufficient information for inclusion in the meta-analysis, two reported no significant differences between the intervention and control groups.(56,59) One reported that a print-based intervention reduced decisional conflict more than their video-based intervention or usual care.(55)

When we sub-grouped by scale used, the pooled mean difference for PtDA studies using the low literacy scale (n=5) was −9.59 points (−18.94, −0.24) favoring the intervention with significant heterogeneity (I^2=84%, p<0.01) (figure 4B). This lost significance in sensitivity

analysis (supplemental file 2, figure 10). Of the two studies that measured decisional conflict using the original scale, one found lower decisional conflict in the intervention arm; one found no differences.(43,44) These findings were similar when including all SDM interventions (supplemental file 2, figures 11–12).(65,71)

Patient participation in care—Three PtDA studies reported patient participation in care but all three did not report with sufficient detail to perform a meta-analysis. Two found higher patient participation in the intervention arm, (39,58) and one found no differences. (54) When including other SDM interventions, there were six studies to include in the meta-analysis. The pooled standardized mean difference was 0.23 (95% CI 0.05, 0.42) favoring the intervention with low heterogeneity (I^2=35%, p=0.17) (supplemental file 2, figure 13).(39,58,61,66,70,71)

Patient-clinician communication—Four PtDA studies reported patient-clinician communication about the decision being made.(36,37,45,47) The pooled relative risk was 1.62 (95% CI 1.42, 1.84) favoring the intervention with no heterogeneity (I^2=0%, p=0.79) (figure 5). Sensitivity analyses did not affect this outcome (supplemental file 2, figure 14). One study did not distinguish between communication with a clinician versus a family member and was not included in the meta-analysis.(36) These findings were similar when including all SDM interventions (supplemental file 2, figure 15).

Proportion undecided—Four PtDA studies reported whether participants were undecided about their treatment/screening approach after study participation.(37,41,47,48) The pooled relative risk was 0.28 (95% CI 0.20, 0.39) favoring the intervention with reasonably high heterogeneity (I^2=63%, p=0.04) (figure 6). This remained significant in the sensitivity analysis (supplemental file 2, figure 16). When including all SDM intervention studies, results remained significant, favoring the interventions (supplemental file 2, figure 17).(71,73)

Informed choice—Three PtDA studies measured whether participants made an informed choice.(37,53,56) but some did not report with enough detail to conduct a meta-analysis. All three found that more participants made an informed choice in the intervention arm. When including SDM interventions, three studies could be pooled into the meta-analysis where the pooled relative risk was 2.23 (95% CI 1.24, 4.01) favoring the intervention with substantial heterogeneity (I^2=83%, p<0.01) (supplemental file 2, figure 18).(53,56,71) One additional study did not report findings with sufficient detail to be included in the meta-analysis and found no differences.(65)

Screening behavior—Six studies measured screening intent.(37,39,45,52,55,56) The pooled relative risk was 1.02 (95% CI 0.97, 1.07) favoring neither the intervention nor the control with non-significant heterogeneity (I^2=47%, p=0.19) (figure 7a). Sensitivity analysis did not affect this outcome (supplemental file 2, figure 19). Two studies did not report their findings with sufficient detail to be included in the meta-analysis; one found significantly higher intent in the intervention arm,(52) and one found high intent at baseline regardless of arm.(55) These findings remained consistent when including all SDM interventions (supplemental file 2, figure 20).(63) Two additional studies reported outcomes on screening

readiness and screening interest, and reported that the interventions increased screening readiness and interest.(47,60)

Five reported whether screening tests were ordered.(37,39,47,48,52) The pooled relative risk was 1.41 (95% CI 1.02, 1.94) slightly favoring the intervention with high heterogeneity (I^2=89%, p<0.01) (figure 7b). Sensitivity analyses did not affect this result (supplemental file 2, figure 21). These findings held when including all SDM interventions (supplemental file 2, figure 22).(68)

Ten studies measured screening test uptake.(37,39,44,45,47–49,53,55,56,59) The pooled relative risk was 1.31 (95% CI 1.01, 1.71) slightly favoring the intervention with high heterogeneity (I^2=89%, p<0.01) (figure 7c). One study did not report this outcome with sufficient detail; it found no differences between arms.(59) Sensitivity analyses resulted in loss of statistical significance (supplemental file 2, figures 23–25). These findings held when including all SDM interventions (supplemental file 2, figure 26).(65,68,72)

Anxiety—Three PtDA studies measured anxiety, but not all with sufficient detail to perform a meta-analysis. All found no differences.(45,53,56) There were enough studies when including other SDM intervention studies to perform a meta-analysis. The pooled standardized mean difference was 0.02 (−0.22, 0.26) favoring neither the intervention nor the control with significant heterogeneity (I^2=70%, p=0.02) (supplemental file, figure 27). (45,53,65,72) One study that did not report with sufficient detail for the meta-analysis found no difference.(63) One reported their outcome as distress and thus was not pooled in the meta-analysis, it found the intervention reduced distress.(67)

Publication bias

For the two outcomes with at least 10 studies, the Egger's regression indicated there was significant publication bias for knowledge (p=0.03) but not for screening completed (p=0.30). We did not observe publication bias when examining the funnel plots for the remaining outcomes in the meta-analysis (supplemental file, figures 28–34).

Narrative synthesis

Effect on health inequalities—Twelve PtDA studies reported findings that compared the effect of the intervention among who were and were not socially disadvantaged. (38,42,43,46–48,50,51,54,56,58,59) Five found that their interventions were more effective among socially disadvantaged participants based on literacy (n=3), education (n=2), and race (n=1).(38,42,50,56,58) Seven found no differences based on race (n=4), socioeconomic status, income or deprivation (n=4), insurance (n=1), numeracy (n=1), education (n=1), or literacy (n=1).(46–48,50,51,54,59) Two found more improvements in non-disadvantaged populations when stratifying by education, race, or numeracy.(43,50) See supplemental file 2, table 3 for a summary by outcome.

Other outcomes—For all outcomes that could not be pooled into a meta-analysis, the results of the narrative synthesis are available in supplemental file, table 4. Briefly, PtDAs

influenced treatment choice but there were no observed differences in satisfaction, attitudes, or self-efficacy.

Other clinical outcomes—Only one PtDA study measured a clinical outcome not already included in the meta-analysis. It found no differences in hemoglobin A1C improvement by arm.(67) Three additional SDM intervention studies measured clinical outcomes.(62,64,72) Two saw no differences, one found that blood pressure improved more in the intervention arm.(62)

Characteristics of successful interventions—There was limited evidence on which characteristics of the interventions or attributes of the intervention development were more effective at promoting SDM. There were no patterns with respect to intervention length, mode of delivery, time of delivery, involvement of consumers, or user-testing with the socially disadvantaged participants of interest to indicate what might be more likely to improve any of the included outcomes. Tailoring to the individual participants did not differentially affect outcomes.

Across the studies that analyzed their results by socially disadvantaged status, from the five that saw greater benefit for those who are socially disadvantaged, three were computer-based and two were paper-based. Two were independent of a clinic visit, one was delivered before the visit, one was delivered during the visit, and one was delivered after the visit. Three were delivered at a clinic or hospital via a computer, care manager, or physician and two were delivered at home. Four were tailored to the participant and one was not.

Discussion

Summary of main findings

In this meta-analysis, we found that PtDAs tested among socially disadvantaged populations improved knowledge, patient-clinician communication, and ordering or receipt of a screening test. They reduced decisional conflict and the proportion of people undecided. They did not have an effect on anxiety. These findings held when including all SDM interventions. When including the additional SDM studies, interventions also improved informed choice and had a weak effect on patient participation in care. There was limited information on the PtDAs' or other SDM interventions' effects on clinical outcomes. In the narrative synthesis, we found that PtDAs influenced treatment choice. There were no differences in satisfaction, attitudes, or self-efficacy.

Among the twelve PtDA studies that included an analysis of outcomes based on being a member of a socially disadvantaged group relative to those not defined as disadvantaged, less than half found that their interventions were more successful among those who were socially disadvantaged. There was significant heterogeneity regarding key features of the PtDAs and no specific features led to improved outcomes for socially disadvantaged populations. Tailoring the intervention to the user did not disproportionately improve outcomes.

We therefore concluded that while most outcomes of interest were better in PtDA or other SDM intervention arms, there was no evidence of a reduction in health inequalities through the use of these interventions (aims 1 and 2). Additionally, there were no critical features that stood out as exceptionally improving outcomes among socially disadvantaged groups (aim 3).

Strengths and limitations

Strengths and limitations of the included studies—We limited our analysis to randomized controlled trials that represented multiple complex definitions of social disadvantage. A large number of studies had an overall unclear risk of bias. This was often because there was not enough information in the article about study personnel blinding or prespecified outcomes. The range of included interventions and controls could be seen as a limitation because of the heterogeneity this might have introduced. The overwhelming majority of the studies were from the US and all included studies were from wealthy countries.

Strengths and limitations of the review method—We built on and strengthened the meta-analysis conducted in 2014.(13) The 2014 review included seven randomized controlled trials compared to the 38 in this analysis (including PtDAs and SDM interventions). We used the newest version of the Cochrane Risk of Bias tool, strengthening our risk of bias assessment. We included a critical appraisal of the included interventions using the validated TIDieR checklist.(23) We included a primary analysis of PtDAs as well as a secondary analysis of all included SDM interventions, which allowed us to confirm our results within the larger body of SDM literature.

There was substantial heterogeneity for most outcomes so we must take this into account. Using the Hartung-Knapp method was a methodological strength but showed that some results were sensitive to this emerging analysis approach. We captured three studies in our database search that are reported as PtDAs but are not in Stacey and colleagues' updated 2021 Cochrane review so were not included as PtDAs in this analysis.(65,69,71)

Comparison with other studies

Our findings align with the conclusions from the 2014 review regarding knowledge, informed choice, and patient participation.(13) Different from this previous review however, our results showed that PtDAs and other SDM interventions did not reduce health inequalities since there was no differential benefit to socially disadvantaged populations. This could be because of the larger number of studies in the updated review. Our findings align with Stacey and colleagues' 2017 Cochrane, indicating that PtDAs may improve knowledge and informed choice, lower decisional conflict, and but have no association with anxiety.(2) They found significant reductions in people having prostate-specific antigen testing but found no significance for other screening decisions. Stacey and colleagues' 2017 review includes 105 PtDAs, over four times the number of PtDAs included in our more narrowly-focused review. While our analysis is robust with important findings that can inform future work, additional rigorous randomized controlled designs are needed to examine interventions among socially disadvantaged groups. Specifically, there is a lack of

evidence demonstrating the effectiveness of decision-making interventions among people who are socially disadvantaged compared to those who are not disadvantaged.

Implications for research and clinical practice

The differences in how people who are socially disadvantaged receive care have been well documented.(75–79) These differences are compounded by the likelihood that people who are socially disadvantaged are less likely to seek out health information.(80,81) We need additional research on how PtDAs and other decision-making interventions improve longer term outcomes such as clinical indicators and decision satisfaction. Additionally, we need further research on the differential impact these interventions might have on the health care experiences among people from socially disadvantaged groups. For example, PtDAs for common health conditions that have been specifically tested among socially disadvantaged groups.

National policy in recent years has highlighted the need for improvements in patient-centered care with limited discussion on how this shift might affect populations differently depending on their background, literacy, or socioeconomic status.(82–84) The current IPDAS criteria and the SUNDAE (Standards for UNiversal reporting of patient Decision Aid Evaluation) checklist encourage developers to write interventions in plain language. However, in addition to the barrier of lower health literacy other factors can result in poorer care and worse outcomes, including lower education, minority race/ethnicity, lower socioeconomic status, or lower income.(75–79) Only including recommendations for plain language might not fully address the various complex needs of those who are socially disadvantaged.(85,86) Both the IPDAS criteria and the SUNDAE checklist include user-testing or stakeholder involvement, however it could be emphasized that patient involvement and user-testing should include a range of participants the PtDAs are designed for, particularly those who are socially disadvantaged. Future research could delve more into the complexities of PtDAs and other decision-making interventions across the range of patient backgrounds. Redefining how policymakers and researchers think about what it means to be socially disadvantaged in a complex healthcare system will help us create and implement interventions that are appropriately able to change the care these populations receive.

Conclusions

This updated review shows strong evidence that PtDAs and other SDM interventions for socially disadvantaged populations can improve patient-reported outcomes. However, this review did not reveal what PtDA characteristics best support populations who are socially disadvantaged. Despite the evidence presented here, the development of tailored, effective interventions for socially disadvantaged populations is not keeping up with the broader global trajectory focused on the development of SDM interventions. It is critical to keep using interventions proven to be effective, and develop, adapt, and evaluate, interventions that ensure socially disadvantaged groups can benefit the most from their implementation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Glyn Elwyn has edited and published books that provide royalties on sales by the publishers: the books include Shared Decision Making (Oxford University Press) and Groups (Radcliffe Press). Glyn Elwyn's academic interests are focused on shared decision making and coproduction. He owns copyright in measures of shared decision making and care integration, namely **collabo**RATE, **integ**RATE (measure of care integration, **conside**RATE (patient experience of care in serious illness), **coope**RATE (measure of goal setting), **incorpo**RATE (clinician attitude to shared decision making, Observer OPTION-5 and Observer OPTION-12 (observer measures of shared decision making). He has in the past provided consultancy for organizations, including: 1) Emmi Solutions LLC who developed patient decision support tools; 2) National Quality Forum on the certification of decision support tools; 3) Washington State Health Department on the certification of decision support tools. He is the Founder and Director of **&think** LLC which owns the registered trademark for Option GridsTM patient decision aids; Founder and Director of **SHARP**NETWORK LLC, a provider of online training for shared decision making. He has provided advice in the domain of shared decision making and patient decision aids to: 1) Access Community Health Network, Chicago (Adviser to Federally Qualified Medical Centers); 2) EBSCO Health (Consultant); 3) Bind On-Demand Health Insurance (Consultant), 4) abridge AI Inc (Chief Clinical Research Scientist).

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Highlights

- Systematic review and meta-analysis of patient decision aids and other shared decision making (SDM) interventions for disadvantaged populations
- Patient decision aids and other SDM interventions improve patient-reported outcomes for disadvantaged populations
- There was no evidence on what intervention characteristics best supported disadvantaged populations

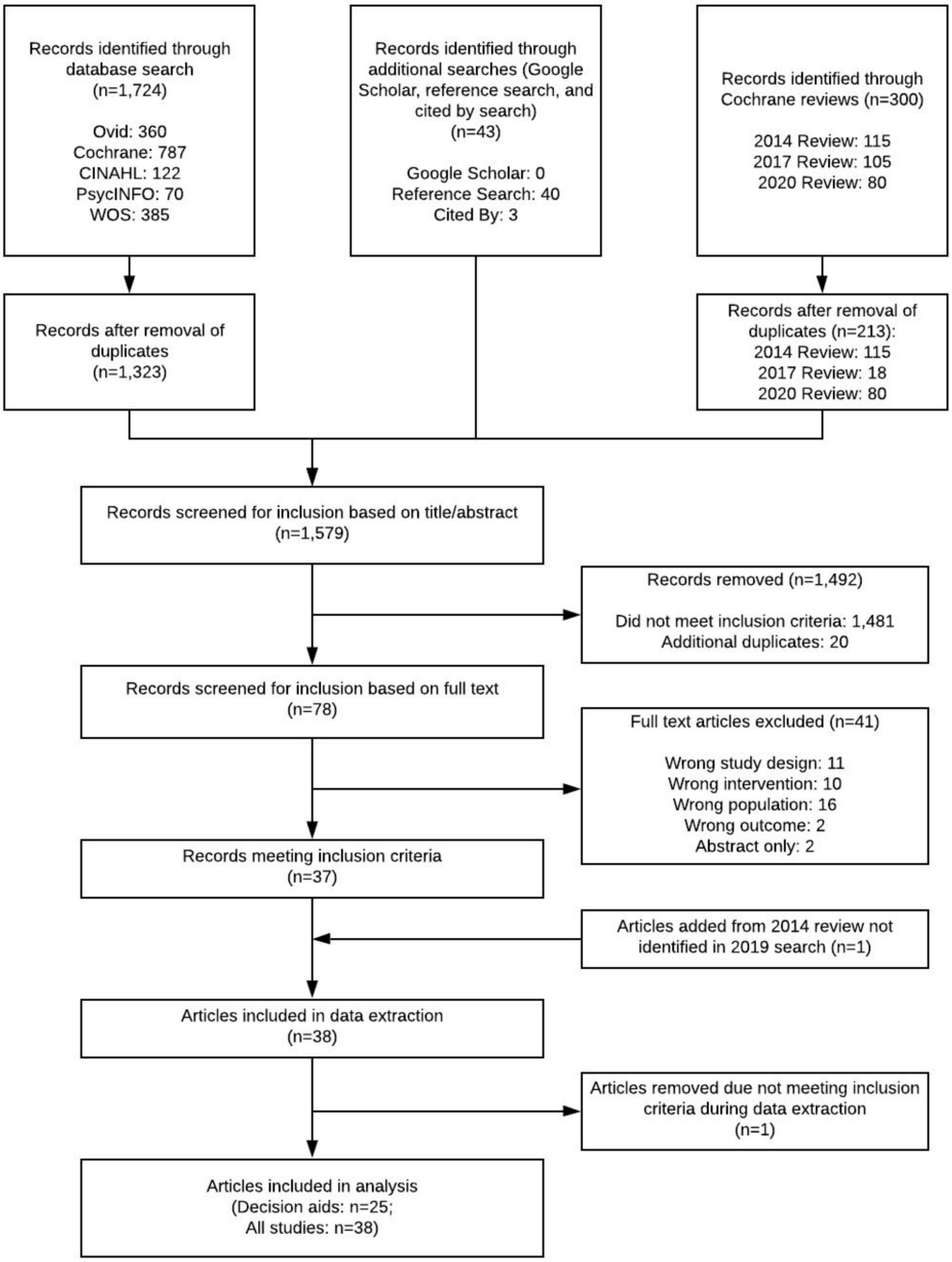

Figure 1. PRISMA flow diagram

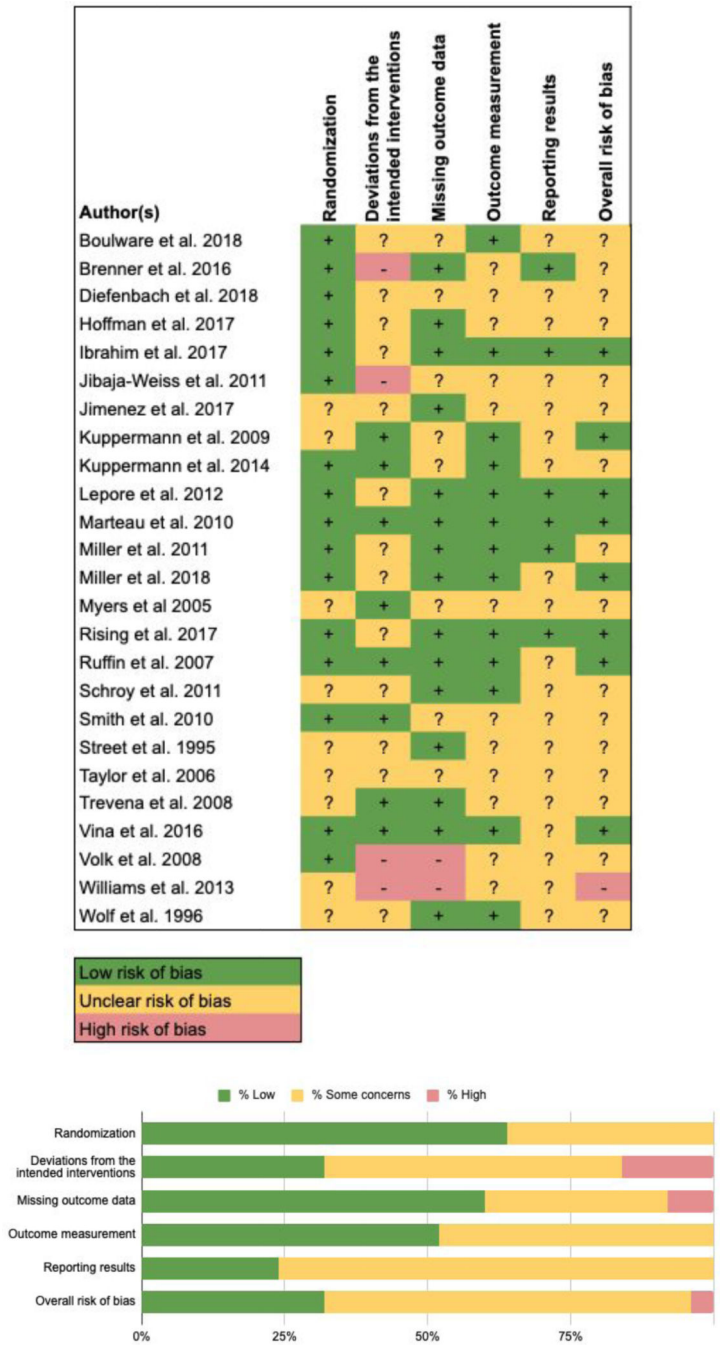

Figure 2. Risk of bias for included patient decision aid studies

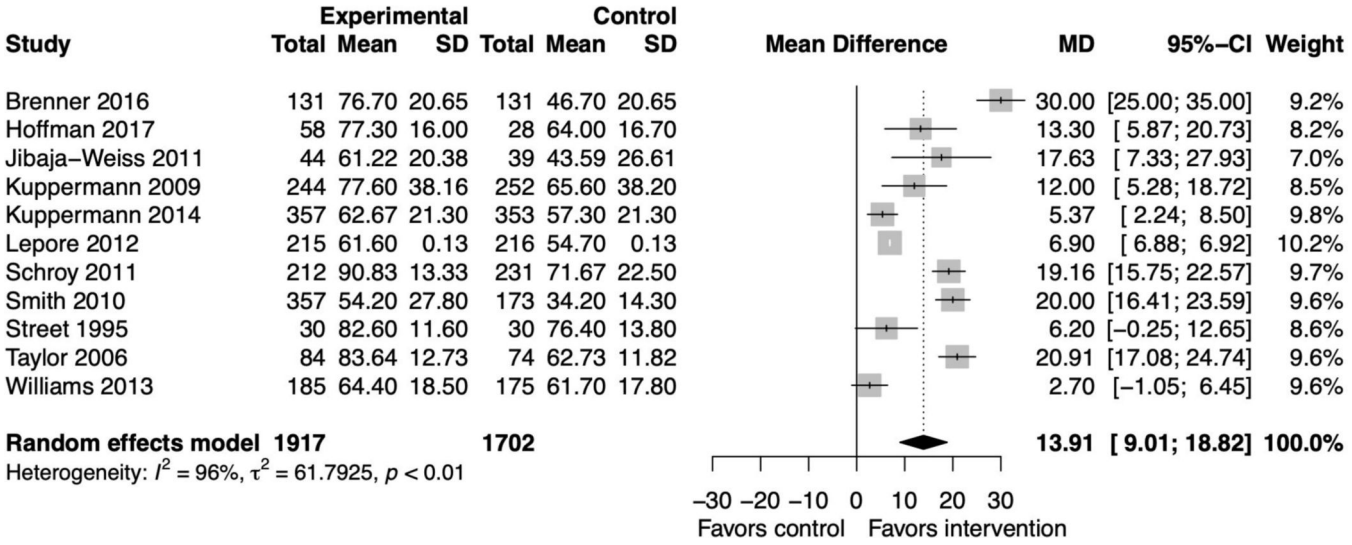

Figure 3. Forest plot for decision aid studies reporting knowledge

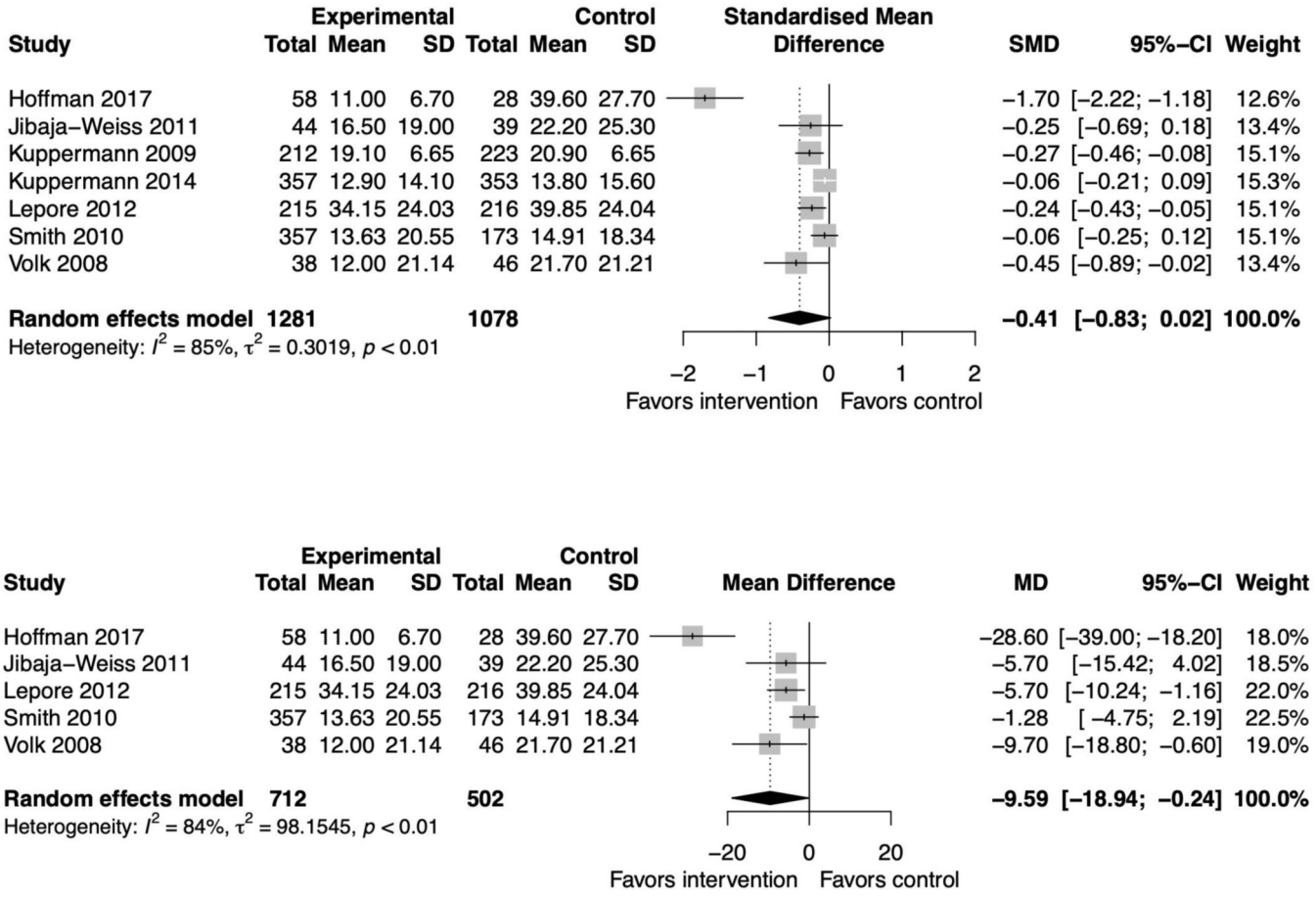

Figure 4. Primary forest plots for decisional conflict

Figure 4A. Forest plot for all decision aids studies reporting decisional conflict

Figure 4B: Forest plot for studies using the low literacy Decisional Conflict Scale

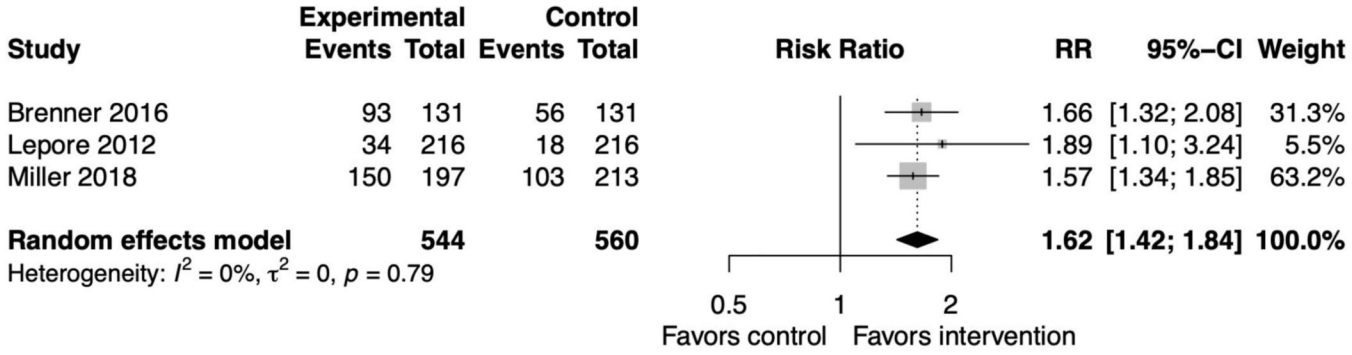

Figure 5. Forest plot for decision aid studies reporting patient-clinician communication

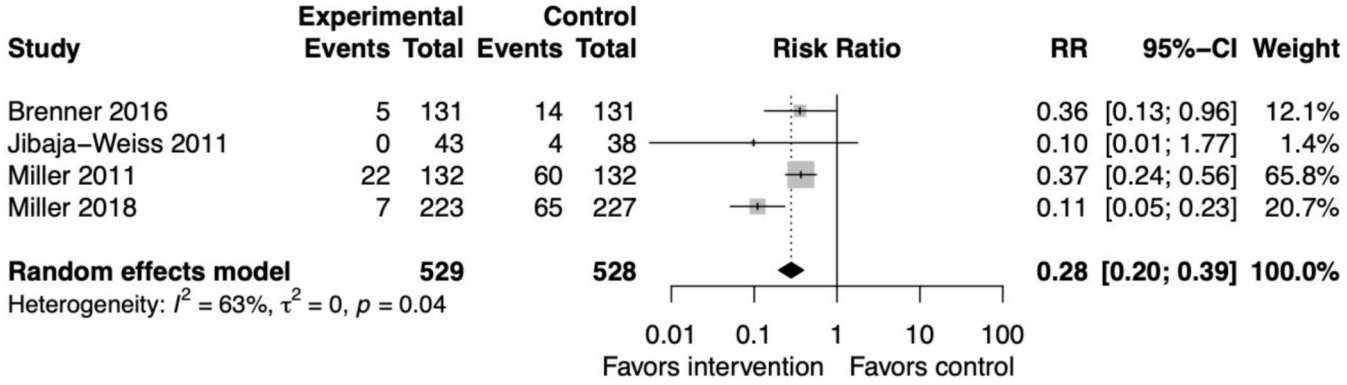

Figure 6. Forest plot for decision aid studies reporting proportion undecided

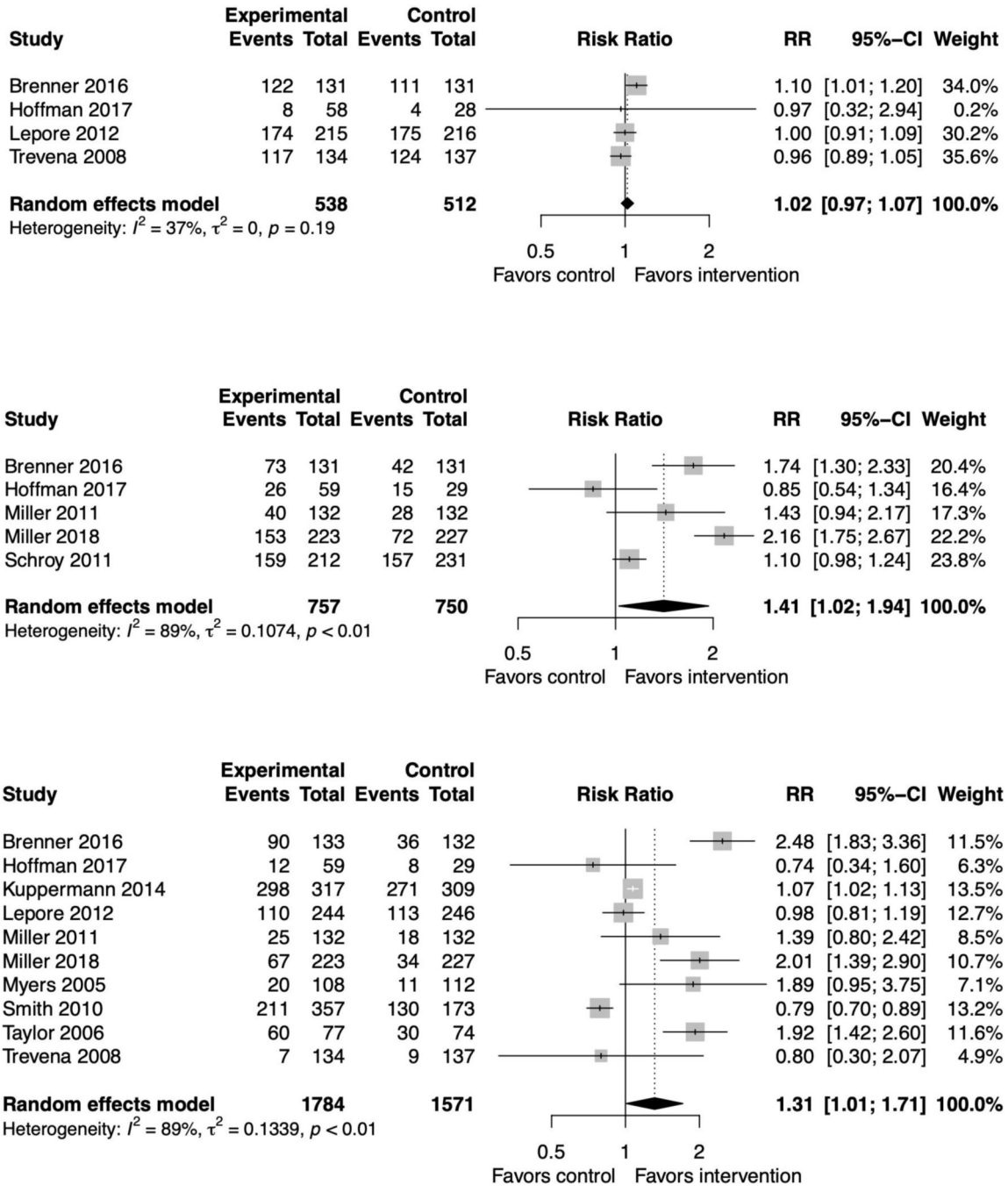

Figure 7. Forest plots for decision aid studies reporting screening behavior

Figure 7A. Intent to be screened

Figure 7B. Screening test ordered

Figure 7C. Screening test done

Table 1.

Study characteristics of included patient decision aid trials

Author and Year	Country	Baseline N (intervention | control)	Poverty, income, or SES	Race/ ethnicity	Education	Low (health) literacy	Geographical location	Underinsured	Lower numeracy	Different language	Separate analysis	Medical Area/ Decision
Boulware et al. 2018[§](31)	United States	61 | 31	59% with income of <$20,000/ year	100% Black	73% high school degree or less			45% on low-income insurance (Medicaid)				Live kidney transplants for patients on hemodialysis
Brenner et al. 2016(32)	United States	131 | 131		61% Latinx, 17% Black				29% on low-income insurance (Medicaid)		71% of Latinx participants (61% of total) preferred Spanish		Colorectal cancer screening
Diefenbach et al. 2018(33)	United States	181 | 168									Race, education	Prostate cancer
Hoffman et al. 2017(34)	United States	59 | 29		100% Black								Colorectal cancer screening
Ibrahim et al. 2017(35)	United States	168 | 168[^]	50.2% household income <$15,000/ year	100% Black								Total knee replacement
Jibaja-Weiss et al. 2011(36)	United States	40 | 36		53% Hispanic/ Latina, 32% Black		Majority lower health literacy (exact % unknown)		100% no insurance				Breast cancer surgery
Jimenez et al. 2017(37)	United States	31 | 33		88% Black (parents)							Health literacy	Early intervention for developmental concerns
Kuppermann et al. 2009(38)	United States	244 | 252		15.7% Black, 18.0% Latina, 13.5% Asian, 5.7% Other							Education	Prenatal genetic testing

Author and Year	Country	Baseline N ‘ (intervention | control)	Poverty, income, or SES	Race/ ethnicity	Education	Low (health) literacy	Geographical location	Underinsured	Lower numeracy	Different language	Separate analysis	Medical Area/ Decision
Kuppermann et al. 2014(39)	United States	357 | 353	48% earning ≤$25,000/ year	45% Hispanic/ Latina, 16% Black, 9% Asian/ Pacific Islander	46% high school degree or less				45% Lower numeracy			Prenatal genetic testing
Lepore et al. 2012(40)	United States	244 | 246		100% Black	63% high school degree or less							Prostate cancer screening
Marteau et al. 2010(41)	United Kingdom	633 | 639									Socioeconomic status	Diabetes screening
Miller et al. 2011(42)	United States	132 | 132	70% earning <$20,000/ year	73% Black	77% high school degree or less	56% limited health literacy					Health literacy	Colorectal cancer screening
Miller et al. 2018(43)	United States	223 | 227	53% earning <$20,000/ year		53% high school degree or lesss						Income, health literacy, race	Colorectal cancer screening
Myers et al. 2005(44)	United States	121 | 121		100% Black	62% high school education or less							Prostate cancer screening
Rising et al. 2017(45)	United States	451 | 457				62% lower health literacy					Race, income, insurance, education, health literacy and numeracy	Chest pain testing
Ruffin et al. 2007(46)	United States	87 | 87		47% Black							Insurance, education, and race	Colorectal cancer screening
Schroy et al. 2011(47)	United States	212 | 231		63% Black, 6% Hispanic/ Latinx				66% Medicaid, Medicare, free care, or none				Colorectal cancer screening
Smith et al. 2010[§](48)	Australia	384 | 188	Recruited in low-income communities		58% Lower educational attainment							Colorectal cancer screening

Author and Year	Country	Baseline N ‘ (intervention | control)	Poverty, income, or SES	Race/ ethnicity	Education	Low (health) literacy	Geographical location	Underinsured	Lower numeracy	Different language	Separate analysis	Medical Area/ Decision
					(0–10 years)							
Street et al. 1995(49)	United States	30 | 30			73% Less than college education						Education	Breast cancer surgery
Taylor et al. 2006(50)	United States	164 | 74		100% Black	71% Less than a college degree							Prostate cancer screening
Trevena et al. 2008(51)	Australia	157 | 157			78% Completed secondary (High school) education or less						Education	Colorectal cancer screening
Vina et al. 2016(52)	United States	240 | 253	52% household income < $15,000	100% Black								Knee replacement
Volk et al. 2008(53)	United States	224 | 226		Low-literacy site: 72% Black, 9% Hispanic/ Latinx	Low-literacy site: 77% High school education or less						Literacy	Prostate cancer screening
Williams et al. 2013[§](54)	United States	272 | 271	46% earning less than $50,000/ year	61% Black	51% Less than a college degree						Race	Prostate cancer screening
Wolf et al. 1996(55)	United States	103 | 102	65% household income <$15,000		69% Less than high school education			59.3% Public insurance				Prostate cancer screening

[*] Almost met the threshold or met the threshold at one site

[‘] Patient participants only

[^] Intention-to-treat analyses

[§] Included multiple intervention groups

¶included a clinician intervention however in order to isolate the effect of the patient-facing intervention, we only reported data from the arms that focused on patient interventions.

Table 2.

cision aid interventions*

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
: 45 tes : 162	Visual digital Paper	Before appointment	Clinic	NA - online/ computer program	Once	No	Booklet: 4th grade	✓			✓	✓	✓		✓
o: 14 tes hure: eported	Visual digital - interactive Paper	Before appointment	Clinic	Video: Online/ computer program Brochure: Research staff	Once	Yes	Not reported				✓	✓	✓	✓	
ge of 3 per	Visual digital - interactive	Independent of a clinic visit	Home	NA - online/ computer program	Daily to 1–2x/ week	Yes	7th grade	✓		✓	✓				✓

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
inutes	Visual digital - static	Before appointment	Clinic	NA - online/ computer program	Once	Yes	Not reported		✓	✓	✓				
inutes	Visual digital - static	Before appointment	Clinic	NA - online/ computer program	Once	No	Not reported			✓	✓				

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
eported	Visual digital - interactive	After appointment	Clinic	NA - online/ computer program	Once	Yes	Not reported		✓	✓	✓		✓	✓	
utes	Visual digital - static	After appointment	Clinic	NA - online/ computer program	Once	No	Not applicable		✓		✓	✓			
0 tes	Visual digital - interactive	Before appointment	Research facility	NA - online/ computer program	Not reported	Yes	Not reported				✓	✓		✓	✓

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
0 tes	Visual digital - interactive	Independent of a clinic visit	Not reported	NA - online/ computer program	Once	Yes	Not reported				✓	✓		✓	✓

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
let: Not ted e call: mean of inutes, d, mean ninutes	Paper Over the phone	Independent of a clinic visit	Home	Trained interventionists	Three times	Yes	Flesch-Kincaid: 2.7	✓			✓	✓	✓		
es	Paper	Independent of a clinic visit	Home	NA - mailed to participants	Once	No	Age 11, Flesch-Kincaid 5.76	✓		✓		✓			

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th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
inutes	Visual digital - interactive	Before appointment	Clinic	NA - online/ computer program	Once	Yes	Not reported				✓	✓	✓		
inutes	Visual digital - static	Before appointment	Clinic	NA - online/ computer program	Once	Yes	Not reported				✓	✓	✓		

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
eported	Paper Over the phone	Independent of a clinic visit	Home	Trained health educator	Once	Yes	Not reported		✓	✓		✓	✓		✓

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
e	Paper	During meeting with clinician	Hospital	Clinician	Once	Yes	Not reported		✓	✓		✓	✓		
eported	Visual digital - interactive	Independent of a clinic visit	Research facility	NA - online/ computer program	Once	Yes	Not reported				✓	✓	✓		

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th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
eported	Visual digital - interactive	Before appointment	Clinic	NA - online/ computer program	Once	Yes	Not reported				✓	✓			
ges +	Paper Visual digital - interactive	Independent of a clinic visit	Home	NA - mailed to participants	Not reported	Yes	7th grade	✓	✓	✓	✓	✓	✓		✓

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th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
5 tes	Visual digital - interactive	Before appointment	Clinic	NA - online/ computer program	Once	Yes	Not reported			✓	✓				
let: 16 : 25 tes	Paper Visual digital - static	Independent of a clinic visit	Home	NA - mailed to participants NA - online/ computer program	Once	No	Not reported		✓		✓	✓	✓		✓

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th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
ges	Paper	Independent of a clinic visit	Home	NA - mailed to participants	Once	Yes	10th grade	✓		✓					
: 40 tes view: 30 tes	Video: Visual digital - static Interview: Person to person	Independent of a clinic visit	Not reported	Video: NA - online/ computer program Interview: Trained interventionist	Once	Yes	Not reported				✓				
3 tes	Visual digital - interactive	Before appointment	Clinic	NA - online/ computer program	Once	Yes	Not reported		✓	✓	✓		✓		

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...th of ...vention/ ... to Use ...vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts
...inutes to ...(24 ...)	Paper	Before appointment	Clinic Home	Researcher or mailed to participants	Once	No	8th grade	✓					✓		✓
...eported	Person to person	Before appointment	Clinic	Trained research assistant	Once	No	Not applicable						✓		

th of vention/ to Use vention	How Delivered	When Delivered	Where Delivered	Who Delivered	How Many Times	Tailored to the individual	Readability	Acceptable reading age	Strategies to reduce cognitive demand	Use of pictures or graphs (including icon arrays)	Use of audiovisual	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/ literacy experts

published protocol or other publications on the tool.(38–45)

order to isolate the effect of the patient-facing intervention, we only reported data from the arms that focused on patient interventions.

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