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Shared decision making for antidepressants in primary care – a clustered randomized trial

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Abstract

Importance—The translation of evidence of comparative effectiveness of antidepressants into practice is suboptimal. This deficit directly affects outcomes and quality of care for patients with depression. To overcome this problem, we developed the Depression Medication Choice (DMC) encounter decision aid, designed to help patients and clinicians consider the available antidepressants and the extent to which they improved depression and other patient important issues.

Trial Registration. Clinicaltrials.gov (NCT01502891) at https://clinicaltrials.gov/ct2/show/NCT01502891

Objective—Estimate the effect of DMC on quality of the decision-making process and depression outcomes.

Design—We conducted a cluster randomized trial by which primary care practices were randomly allocated to treatment of depression with or without use of the DMC decision aid.

Setting—Ten rural, suburban, and urban primary care practices across Minnesota and Wisconsin, U.S.

Participants—Adults with moderate to severe depression considering treatment with an antidepressant and their primary care clinicians.

Intervention—DMC, a series of cards, each highlighting the effect of the available options on an issue of importance to patients for use during face-to-face consultations.

Main outcomes and measures—Decision-making quality as judged by patient knowledge and involvement in decision making, patient and clinician decisional comfort (Decisional Conflict Scale) and satisfaction, and encounter duration, medication adherence and depression symptoms (PHQ-9).

Results—We enrolled 117 clinicians and 301 patients [67% women; mean age=44 (SD=15); mean PHQ-9=15 (SD=4)] into the trial. Compared to usual care (UC), use of DMC significantly improved patients' decisional comfort (DMC=80% vs. UC=75%, p=.02), knowledge (DMC=65% vs.UC=56%, p=.03), satisfaction (RR=1.25, p=.81 to RR= 2.4, p=.002), and involvement (DMC=47% vs. UC=33%, p=<.001). It also improved clinicians' decisional comfort (DMC=80% vs. UC=68%, p<.0001) and satisfaction (RR=1.64, p=.02). There were no differences in encounter duration, medication adherence, or improvement of depression control between arms.

Conclusion and Relevance—The DMC decision aid helped primary care clinicians and patients with moderate to severe depression select antidepressants together, improving the decision-making process without extending the visit. On the other hand, DMC had no discernible effect on medication adherence and depression outcomes. By translating comparative effectiveness into patient-centered care, use of DMC improved the quality of primary care for patients with depression.

BACKGROUND

Depression is a common, debilitating, and costly chronic mental illness affecting 17% of Americans.[1–4] Depression burdens patients, their families, and the healthcare system.[1–4] Fortunately, treatment can effectively mitigate this burden.[5,6] Of the available treatments, pharmacotherapy has become the main modality, particularly for patients with moderate to severe depression.[7,8] Unfortunately, the efficacy of antidepressants is reduced by low patient adherence rates (13–60%) and premature discontinuation (33–42%) that contributes to avoidable disability, increased risk of relapse, and higher healthcare utilization.[9–11] Patients stop taking antidepressants because of unrealistic expectations, lack of treatment efficacy, or unacceptable side effects.[12,13] It would seem critical, therefore, to improve the process by which patients and clinicians select and implement antidepressants.

Choosing the "right" antidepressant is difficult because of limitations in the evidence of their comparative effectiveness.[14,15] More certain are their effects on other important outcomes

(i.e., weight gain) that matter to patients. Clinicians however struggle to present this information to patients in meaningful ways and have a difficult time parting from their preferred antidepressants.[16,17] Clinicians and patients have more to gain by identifying which agent is better given the patient's circumstances and preferences, rather than selecting what might be deemed the "most effective" choice. This shared decision making (SDM) approach forms informed preferences that lead to patient-centered choices. To arrive at informed preferences, patients and clinicians must access and make sense of the best research evidence, which unfortunately has not effectively reached the point of care.[18,19] This suboptimal translation of evidence into practice directly affects outcomes and quality of care for patients with depression.[18–20]

Decision aids are evidence-based interventions designed to engage patients and clinicians in a SDM process and translate research evidence into patient-centered care.[21–24] A body of evidence (115 randomized trials) demonstrates that decision aids increase patients' knowledge, and engagement in and comfort with the decision-making process.[24] Most of this evidence reflects the use of educational tools distributed to patients before making a decision, with the goal to empower patients to participate in decision-making through information.[24] Yet, only a minority of these trials sought to determine if SDM actually took place. An evolving body of evidence, on the other hand, is finding that decision aids can effectively promote SDM when used during the clinical encounter.[25]

In collaboration with patients, clinicians, and stakeholders, we developed an encounter decision aid, Depression Medication Choice, to support pharmacotherapy choices when this approach is being considered in the primary care of patients with moderate to severe depression.[26] We hypothesized that its use would improve patient engagement, the quality of decision-making as perceived by patients and clinicians, and depression outcomes.

METHODS

Study Design

We conducted a cluster randomized trial in which we randomly allocated primary care practices to treat depression with (intervention) or without (control) Depression Medication Choice. Patients and clinicians were surveyed regarding the quality and outcome of the decision-making process, and patient adherence and clinical outcomes were followed for six months after the encounter. Mayo Clinic Institutional Review Board, IRB of record for participating practices, and Hennepin County Medical Center Human Subjects Research Committee approved the study procedures. The trial is registered at Clinicaltrials.gov (NCT01502891) and details of the study procedures are found elsewhere.[26]

Study Setting and Participants

This study took place between December 2011 and November 2013 in 10 rural, suburban, and urban primary care practices across Minnesota and Wisconsin, USA. Primary care practices were eligible for the study if they had at least two clinicians interested in participating, a clinical champion (i.e. outstanding clinician who has earned the respect of their peers and is willing to build support for and actively promote the current project),

eligible patients, and the willingness to have an on-site study coordinator for the duration of the trial.[26] Clinicians were invited to participate if they cared for patients with depression. Eligible adult patients (>18 years) had moderate to severe depression and a Patient Health Questionnaire (PHQ-9)[27] score ≥10, no bipolar disorder, an appointment with a member of their primary care team, and no major barriers to providing informed consent. Eligibility criteria (i.e. severity of depression, PHQ-9) were set so that identified patients, whether on a medication or not, were most likely to engage in antidepressants conversations (i.e. start, increase, or switch).

Stakeholder Engagement

We developed Depression Medication Choice in close collaboration with two patient advisory groups and with an External Advisory Council comprised of 24 stakeholders (i.e. patients, clinicians, policy makers) from 12 different organizations. We further engaged these groups throughout the set-up and conduct of the trial, seeking insights primarily on eligibility criteria, choice of outcomes, and recruitment strategies (i.e. identifying respectful ways to recruit patients with depression).

Recruitment

We invited practices that were part of the External Advisory Council to participate in the trial, and then extended our reach to Mayo Clinic and Mayo Clinic Health Systems practices. Clinicians were approached for participation during an initial on-site meeting or, afterward, by the study coordinator.[26] On-site study coordinators identified potentially eligible patients from the appointment schedules of clinicians and approached them at the time of appointment. Clinicians and patients both provided written informed consent and neither received financial incentives to participate in the trial.

Allocation Procedure

We initially had set to stratify practices according to their number of clinicians as an indicator of their potential for enrolment but later replaced it with their history of accrual (low vs. high) in past studies, an indicator we deemed more effective in addressing recruitment rate per arm. The lead study statistician therefore stratified practices by their history of accrual and the presence of the DIAMOND program (a practice redesign initiative to improve depression care present in numerous MN practices at the time of the study),[28] and centrally randomized practices within these strata to either care with or without Depression Medication Choice. Study team members, practices, and clinicians were aware of the assigned arms. Patients were kept unaware of the study hypothesis and nature of the intervention.

Intervention and Control

We described the development of Depression Medication Choice elsewhere.[26] The decision aid, laminated 4”x10” cards, presents general considerations about antidepressant efficacy and then side effects in terms that matter to patients: weight change, sleep, libido, discontinuation, and cost (Figure 1). We briefly (<10 min) demonstrated to clinicians how to use the decision aid prior to enrollment of their first patient. A videoclip and storyboard

demonstrating the basic use of the decision aid remained available as well as a leaflet for patients to take home (**eFigures 1–2**).

Clinicians in the intervention group were to use the decision aid during the consultation with their patients, while clinicians in the control arm did not have access to the decision aid (usual care).

Outcomes and Data Collection

The evaluation of the study was guided by the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, Maintenance). This paper focuses on the effectiveness of Depression Medication Choice to improve decision-making and clinical outcomes.

Patient Level Outcomes

Decision-Making Quality Outcomes—Decisional conflict, defined as personal uncertainty about which course of action to take when choice among competing options involves risk or challenge to personal life values, was our primary outcome. Patients completed the Decisional Conflict Scale (DCS) immediately after the clinical encounter.[29] We report results as level of comfort with the decision (0=conflict, 100=comfort). Other measures of decision-making quality were obtained from patients' post encounter: knowledge and acceptability of information sharing (i.e. satisfaction).[30–32]

Clinical Outcomes—Patients self-completed the PHQ-9, a measure of depression symptoms, at entry in the study, 3 months, and 6 months.[27] We extracted PHQ-9 recorded in the medical records of patients during the trial period, to be used as proxy for unreturned ones, if completed with +/− 2 weeks of the 3 and 6 month period.

Adherence—Patients reported on medication usage at time of appointment and after the clinical encounter. We collected pharmacy records and reviewed medical records for the trial period. For patients with pharmacy data, we calculated primary medication adherence as proportion of patients who filled their prescription within 30 days, and secondary adherence as the proportion of patients with a percentage of days covered (PDC) >80%.[33] PDC was defined as the number of days a patient had a supply of each medication divided by the number of days of eligibility for that medication, for each antidepressant prescribed.[33]

Clinician Level and Encounter Level Outcomes

Decision-Making Quality Outcomes—Clinicians completed the DCS (clinician version) and an acceptability of information sharing (i.e., satisfaction) scale following each encounter with a participating patient.[31,32,34] We video-recorded encounters in which both patient and clinician gave us consent to record. From these recordings, we assessed the extent to which clinicians sought to engage patients in the decision-making process using the OPTION scale.[35] We also assessed the extent to which they used the decision aid as intended using a fidelity checklist.[26,36] Study coordinators captured the number of minutes patients remained in the consultation room as a proxy for the impact of using the decision aid on encounter duration and for disruption of clinic flow.

Sample Size

We used a formula for a clustered-adjusted t-test to estimate that the recruitment of 300 patients (30 per practice) would give the study a power of 90% to detect a difference of 9.8 point or greater on the DCS with a 2 sided alpha level of 0.05.[37] Assumptions were based on results from trials of similar design and outcomes: DCS variances are as reported in the Statin Choice Trial (16.9, 14.1), there is a modest correlation of outcomes across practices [intracluster correlation coefficient (ICC) of 0.05], and a 10% average attrition rate.[31,32,38] Assuming a similar ICC and attrition rate for other outcomes, this sample size would have 99% power to detect a 1.0 standard deviation difference in any continuous measure, and 80% power to detect a 30% difference in 6-month adherence rates assuming a control adherence rate of 50%.

Statistical Analysis

All outcomes were analyzed according to the intention-to-treat principle.[37] Because clinicians and patients were randomized in clusters (practices), we used cluster-adjusted t-tests, χ^2 tests, and hierarchical generalized linear models (HGLMs) to compare variables between groups.[39] In particular, HGLMs allowed us to account for the correlation of patient outcomes within clinicians and practices explicitly, by modelling the intercept as a 3-level effect, with random effects at clinician and practice level.[39]

We summarized patient and clinician characteristics by arm, testing for differences using cluster adjusted tests or HGLMs with random effects for practice for patient characteristics and χ^2-tests for clinician characteristics. We summarized outcomes by arm, and then, to assess the effect of the intervention on outcomes, we estimated a series of HGLMs with logit or linear response, with random effects for clinician and practice, and including randomization group as a binary independent variable. We then tested whether there was an intervention effect by testing whether the coefficient of the group indicator was significantly different from null and reported the P-value for this test for all outcomes. Patient prescription, filled status, and adherence outcomes were compared only among those with pharmacy data. Analysis and data management were conducted using SAS 9.2, Stata 13.1, and REDCap Management system.

RESULTS

Participants Flow and Characteristics

Figure 2 describes the flow of participants and completeness of data. A total of 117 clinicians [median(range): 7(4–30) per practice] and 297 patients [median(range): 34(15–40) per practice, 2(1–14) per clinician], from 10 practices (1 rural, 1 suburban, 8 urban) were included in the analysis. There was no difference in the attrition of participants or completeness of the data across arms (Figure 2). Characteristics of participants are summarized in Table 1. Although gender and ethnicity differed moderately, there were no significant differences in participant characteristics across arms.

Patients Decision Making Quality and Clinical Outcomes

After the encounters with their clinicians, patients in the decision aid arm reported significantly higher comfort with the decision [mean difference(95%CI): 5.3 out of 100(1.1, 9.5), p=0.01], and were more knowledgeable [OR(95%CI): 9.5(0.8, 18.2), p=.03] and satisfied [RR: 1.25(p=.81) to 2.40(p=.002)] compared to patients in the control arm (Table 2). There was no observed difference across arms in control of depression symptoms (mean PHQ-9), remission rate (PHQ-9 <5) or responsiveness (>50% PHQ-9 improvement) at 3 and 6 months, or in medication use or adherence (Table 2).

Clinicians Decision Making Quality and Encounter Outcomes

Table 3 shows that clinicians were more comfortable with the decisions made [mean difference(95%CI): 11.4 out of 100(17.1, 5.7), p<0.0001] and more satisfied with the process when they used the decision aid [RR: 1.64 (p=.02)]. In available video-recorded encounters (n=96), clinicians assigned to the use of the decision aid involved patients significantly more in the decision-making process [mean difference(95%CI): 15.8 out of 100(6.5, 25.0), p=0.001] (Table 3). Clinicians in the intervention arm reported actual use of the decision aid in 81% of the encounters, and of those with video-recordings (n=57) reached, on average, 54% of the targeted fidelity items (i.e. used the decision aid as intended). There was no difference in the duration of clinical encounters [mean(SD), 48(27) vs. 44(22) minutes, p=0.47, for control and intervention arm, respectively].

DISCUSSION

Main Findings

In this randomized trial, the use of Depression Medication Choice by primary care clinicians and patients with moderate to severe depression during clinical encounters was feasible, and effectively improved patient knowledge and engagement in the decision-making process, as well as patient and clinician satisfaction with that process. Use of the decision aid, on the other hand, had no discernible effect on encounter duration, depression control, and medication use and adherence.

Limitations

Our study is at risk of bias. Lack of blinding of participants may have affected questionnaire responses, and lack of blinding of analysts, particularly those reviewing videos, may have biased video-based outcomes. There was substantial loss to follow up (∼20%) for our primary endpoint, mainly due to logistical issues at the beginning of the study, where study coordinators were still adapting to the recruitment and follow up process. While these issues may increase the risk of bias in favor of the intervention, other limitations may bias it toward no difference. Because most clinicians used the decision aid with only two patients, it is possible that our trial underestimates the efficacy of the decision aid when used repeatedly and expertly.[36] We did not access the content of patient-clinician interactions outside the index encounter yet, patients had on average 3 or more appointments (range 1–10) during the trial period (data not shown). We did not capture use of or adherence to co-interventions (i.e. psychotherapy).

This trial also yielded imprecise clinical outcome estimates, which limited our ability to detect meaningful differences in these secondary endpoints across arms. This was due to greater than anticipated ICC and loss to follow-up (30%) affecting both PHQ-9 measures and medication adherence data, and higher adherence rates in the trial (>80%) than the initial estimated rate (50%). Hence, estimates of the effect of the decision aid on clinical outcomes and adherence are favorable to the decision aid arm but too imprecise to draw definitive conclusions about their impact.

Comparison with other studies

This trial shares the strengths of our other practical real-world decision aid trials.[31,32,38,40] We used a rigorous trial design with optimal allocation concealment, and high recruitment rates for clinicians and patients. It was conducted in rural, suburban, and urban, academic and non-academic, small and large practices caring for patients of various ethnic and socio-demographic backgrounds.

This trial is the first to assess the effectiveness of an encounter decision aid for antidepressants and one of a few assessing the impact of SDM in mental health.[41] The magnitude of our findings, including impact on clinical outcomes, is consistent with the results of other trials of encounter decision aids in other contexts.[31,32,40] Moreover, this trial is one of a few that can directly link the use of decision aids to improvements in observed decision-making quality.[25] We also assessed the fidelity with which clinicians and patients used the decision aid as intended during clinical encounters, a rare feature in the SDM literature.[24,42] This is also the first study to assess clinicians' comfort with the decision-making process in the context of mental health. Importantly, clinicians were more satisfied with encounters which used the decision aid than those without, and the use of the decision aid did not add to the duration of the encounters, key findings for promoting implementation.

Implications for practice, policy, and research

There is substantial policy support for SDM. Although there are significant investments in generating comparative evidence of treatment for various conditions,[43] including depression, there is limited information about methods for incorporating this evidence meaningfully in routine clinical practice.[18–20] Depression Medication Choice offers one effective patient-centered method. Our results, however, do not support the notion that SDM will improve the efficacy or efficiency of care, an assumption policymakers often make when they advocate for patient involvement.[44,45]

Several practice guidelines call for SDM in the management of depression under the premise that for treatment to be effective, patients need to actively participate and adhere to these treatments despite their side effects, cost, and burden.[10,11] This remains one of their least translated recommendations.[46,47] Depression Medication Choice with its impact on patient decision-making process, efficient design (i.e. user friendly, easy to update evidence), straightforward implementation (minimal training and support), and clinician buy-in could provide a means to meet this recommendation.

Involving patients in fateful healthcare decisions is an integral component of patient-centered care, a necessary feature of high quality healthcare.[48] When confronted with our findings –which are consistent with the systematic review of 115 randomized trials and with our own previous trials – policymakers will have to decide whether the value of decision aids as promoters of patient-centered care and informed patient engagement, as demonstrated in this trial, argues on its own merits, for its priority.

Further work in this area is necessary. The ideal decision support should probably include non-pharmacological options. A larger and longer trial to study the effect of the decision aid on adherence to therapy in patients selected because of non-adherence may be more informative.[49] Larger studies are needed to identify subgroups (i.e., socioeconomic status)[50] that may benefit more from using the decision aid. Identifying the amount and type of support needed to effectively embed the use of this decision aid in the routines of primary care practices to support its longitudinal use also remains to be determined.

CONCLUSION

Depression Medication Choice is a novel and efficient SDM tool. It effectively helps patients with moderate to severe depression and their primary care clinicians engage in collaborative deliberation by using evidence about the comparative effectiveness of antidepressants. Depression Medication Choice can help patients and their clinicians identify and implement treatment that best fits the patient's values, preferences, and goals, in a timely way; a path to higher quality healthcare.

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AL participated to the conception and design of the study, contributed to the analysis and interpretation of the data, supervised the conduct of the trial, and wrote the first draft of the manuscript. VMM conceived the study, applied for funding, contributed to the interpretation of the data, and provided critical revision to the manuscript. NDS, MDW, and KJY participated to the conception and design of the study, contributed to the interpretation of the data, and provided critical revision of the manuscript. JH participated to the conception and design of the study, led the statistical analysis and interpretation of the data, and provided critical revision of the manuscript. MEB and JWI contributed to the analysis and interpretation of the data, and provided critical revision of the manuscript. SRD and EMH contributed to the acquisition of the data, technical support (i.e., protection of participants' confidentiality), and provided critical revision of the manuscript. ML, DHB, KMDW, and MRM contributed to the acquisition of the data, provided technical support (i.e. clinical champions) and critical revision of the manuscript. KKS led the design of the intervention and provided critical revision of the manuscript. All authors approved the final version of this manuscript. AL, VMM, and JH had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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We certify that this manuscript represent valid work and that neither this manuscript nor one with substantially similar content under our authorship has been publish or is being considered for publication elsewhere.

REFERENCES

1. Kessler RC, Chiu WT, Demler O, Merikangas KR, Walters EE. Prevalence, severity, and comorbidity of 12-month DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry. 2005; 62(6):617–627. [PubMed: 15939839]
2. Moussavi S, Chatterji S, Verdes E, Tandon A, Patel V, Ustun B. Depression, chronic diseases, and decrements in health: results from the World Health Surveys. Lancet. 2007; 370(9590):851–858. [PubMed: 17826170]
3. Burcusa SL, Iacono WG. Risk for recurrence in depression. Clin Psychol Rev. 2007; 27(8):959–985. [PubMed: 17448579]
4. Merikangas KR, Ames M, Cui L, et al. The impact of comorbidity of mental and physical conditions on role disability in the US adult household population. Arch Gen Psychiatry. 2007; 64(10):1180–1188. [PubMed: 17909130]
5. Simon GE. Long-term prognosis of depression in primary care. Bull World Health Organ. 2000; 78(4):439–445. [PubMed: 10885162]
6. Practice guideline for the treatment of patients with major depressive disorder (revision). American Psychiatric Association. Am J Psychiatry. 2000; 157(4 Suppl):1–45.
7. Coulehan JL, Schulberg HC, Block MR, Madonia MJ, Rodriguez E. Treating depressed primary care patients improves their physical, mental, and social functioning. Arch Intern Med. 1997; 157(10):1113–1120. [PubMed: 9164377]
8. Katzelnick D, Simon G, Pearson S, Manning W, Kobak K. Depression management programs. Arch Fam Med. 2000; 9(8):689–670. [PubMed: 10927702]
9. Akincigil A, Bowblis JR, Levin C, Walkup JT, Jan S, Crystal S. Adherence to antidepressant treatment among privately insured patients diagnosed with depression. Med Care. 2007; 45(4):363–369. [PubMed: 17496721]
10. Sheehan DV, Keene MS, Eaddy M, Krulewicz S, Kraus JE, Carpenter DJ. Differences in medication adherence and healthcare resource utilization patterns: older versus newer antidepressant agents in patients with depression and/or anxiety disorders. CNS Drugs. 2008; 22(11):963–973. [PubMed: 18840035]
11. Demyttenaere K, Enzlin P, Dewe W, et al. Compliance with antidepressants in a primary care setting, 1: Beyond lack of efficacy and adverse events. J Clin Psychiatry. 2001; 62(Suppl 22):30–33. [PubMed: 11599645]
12. Wierzbicki M, Pekarik G. A meta-analysis of psychotherapy dropout. Prof Psychol Res Pr. 1993; 24(2)
13. Van Grieken RA, Beune EJ, Kirkenier AC, Koeter MW, van Zwieten MC, Schene AH. Patients perspectives on how treatment can impede their recovery from depression. J Affect Disord. 2014; 167:153–159. [PubMed: 24972363]
14. Gartlehner, G.; Hansen, R.; Morgan, L., et al. Prepared by the RTI International–University of North Carolina Evidence-based Practice Center, Contract No. 290-2007-10056-I. AHRQ Publication No. 12-EHC012-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2011. Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression: An Update of the 2007 Comparative Effectiveness Review. www.effectivehealthcare.ahrq.gov/reports/final.cfm)
15. Cipriani A, Furukawa TA, Salanti G, et al. Comparative efficacy and acceptability of 12 new-generation antidepressants: a multiple-treatments meta-analysis. Lancet. 2009; 373(9665):746–758. [PubMed: 19185342]
16. Gaissmaier W, Anderson BL, Schulkin J. How do physicians provide statistical information about antidepressants to hypothetical patients? Med Decis Making. 2014; 34(2):206–215. [PubMed: 23986033]
17. Davies NM, Gunnell D, Thomas KH, Metcalfe C, Windmeijer F, Martin RM. Physicians' prescribing preferences were a potential instrument for patients' actual prescriptions of antidepressants. J Clin Epidemiol. 2013; 66(12):1386–1396. [PubMed: 24075596]
18. Sox HC. Comparative effectiveness research: a progress report. Ann Intern Med. 2010; 153(7):469–472. [PubMed: 20679544]

19. Timbie JW, Fox DS, Van Busum K, Schneider EC. Five Reasons That Many Comparative Effectiveness Studies Fail To Change Patient Care And Clinical Practice. Health Affairs. 2012; 31(10):2168–2175. 2012. [PubMed: 23048092]
20. Morrato EH, Concannon TW, Meissner P, Shah ND, Turner BJ. Dissemination and implementation of comparative effectiveness evidence: key informant interviews with Clinical and Translational Science Award institutions. J Comp Eff Res. 2013; 2(2):185–194. [PubMed: 24236560]
21. Stiggelbout AM, Van der Weijden T, De Wit MP, et al. Shared decision making: really putting patients at the centre of healthcare. BMJ. 2012; 344:e256. [PubMed: 22286508]
22. Shah N, Mullan R, Breslin MA, Yawn BP, Ting H, Montori VM. Translating comparative effectiveness into practice. The case of diabetes medications. Med Care. 2010; 48(6 suppl):S153–S158. [PubMed: 20473211]
23. Joosten EA, DeFuentes-Merillas L, de Weert GH, Sensky T, van der Staak CP, de Jong CA. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. Psychother Psychosom. 2008; 77(4):219–226. [PubMed: 18418028]
24. Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014; 1:CD001431. [PubMed: 24470076]
25. Agoritsas T, Heen AF, Brandt L, et al. Decision aids that really promote shared decision making: the pace quickens. BMJ. 2015; 350:g7624. [PubMed: 25670178]
26. LeBlanc A, Bodde AE, Branda ME, et al. Translating comparative effectiveness of depression medications into practice by comparing the depression medication choice ision aid to usual care: study protocol for a randomized controlled trial. Trials. 2013; 14:127. [PubMed: 23782672]
27. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001; 16(9):606–613. [PubMed: 11556941]
28. A new direction in depression treatment in Minnesota: DIAMOND program, Institute for Clinical Systems Improvement, Bloomington, Minnesota. Psychiatr Serv. 2010; 61(10):1042–1044. [PubMed: 20889647]
29. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995; 15(1):25–30. [PubMed: 7898294]
30. O'Connor, A. User Manual _ Knowledge [Document on the Internet]. 2000. http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Knowledge.pdf
31. Branda ME, LeBlanc A, Shah ND, et al. Shared decision making for patients with type 2 diabetes: a randomized trial in primary care. BMC Health Serv Res. 2013; 13:301. [PubMed: 23927490]
32. Mullan RJ, Montori VM, Shah ND, et al. The diabetes mellitus medication choice decision aid: a randomized trial. Arch Intern Med. 2009; 169(17):1560–1568. [PubMed: 19786674]
33. Hess LM, Raebel MA, Conner DA, Malone DC. Measurement of adherence in pharmacy administrative databases: a proposal for standard definitions and preferred measures. Ann Pharmacother. 2006; 40(7-8):1280–1288. [PubMed: 16868217]
34. LeBlanc A, Kenny DA, O'Connor AM, Légaré F. Decisional Conflict in Patients and Their Physicians: A Dyadic Approach to Shared Decision Making. Med Decis Making. 2009; 29(1):61–68. [PubMed: 19196706]
35. Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. Health Expect. 2005; 8(1):34–42. [PubMed: 15713169]
36. Wyatt KD, Branda ME, Anderson RT, et al. Peering into the black box: a meta-analysis of how clinicians use decision aids during clinical encounters. Implement Sci. 2014; 9:26. [PubMed: 24559190]
37. Donner, A.; Klar, NS. Design and Analysis of Cluster Randomisation Trials in Health Research. London: Hodder Arnold; 2000.
38. Weymiller AJ, Montori VM, Jones LA, et al. Helping patients with type 2 diabetes mellitus make treatment decisions: statin choice randomized trial. Arch Intern Med. 2007; 167(10):1076–1082. [PubMed: 17533211]
39. Snijders, T.; Bosker, Rj. Multileve analysis: An introduction to basic and advanced multilevel modeling. London: Sage; 2004.

40. Montori VM, Shah ND, Pencille LJ, et al. Use of a decision aid to improve treatment decisions in osteoporosis: the osteoporosis choice randomized trial. Am J Med. 2011; 124(6):549–556. [PubMed: 21605732]
41. Duncan E, Best C, Hagen S. Shared decision making interventions for people with mental health conditions. Cochrane Database Syst Rev. 2010; (1):CD007297. [PubMed: 20091628]
42. Couet N, Desroches S, Robitaille H, et al. Assessments of the extent to which healthcare providers involve patients in decision making: a systematic review of studies using the OPTION instrument. Health Expect. 2013 [Epub ahead of print].
43. McKinney M. 'Time is of the essence'. PCORI moves to implement comparative effectiveness research, funding. Modern healthcare. 2012; 42(5):12–13.
44. Katz SJ, Hawley S. The value of sharing treatment decision making with patients: expecting too much? JAMA. 2013; 310(15):1559–1560. [PubMed: 24061082]
45. Oshima Lee E, Emanuel EJ. Shared decision making to improve care and reduce costs. NEJM. 2013; 368(1):6–8. [PubMed: 23281971]
46. Gilbody SM, Whitty PM, Grimshaw JM, Thomas RE. Improving the detection and management of depression in primary care. Qual Saf Health Care. 2003; 12(2):149–155. [PubMed: 12679514]
47. Harter M, Bermejo I, Ollenschlager G, et al. Improving quality of care for depression: the German Action Programme for the implementation of evidence-based guidelines. Int J Qual Health Care. 2006; 18(2):113–119. [PubMed: 16260456]
48. Institute of Medicine. Crossing the Quality Chasm. A new health system for the 21st century. Washington, DC: National Academy Press; 2001.
49. Nieuwlaat R, Wilczynski N, Navarro T, et al. Interventions for enhancing medication adherence. Cochrane Database Syst Rev. 2014; 11:CD000011. [PubMed: 25412402]
50. Coylewright M, Branda M, Inselman JW, et al. Impact of sociodemographic patient characteristics on the efficacy of decision AIDS: a patient-level meta-analysis of 7 randomized trials. Circ Cardiovasc Qual Outcomes. 2014; 7(3):360–367. [PubMed: 24823953]

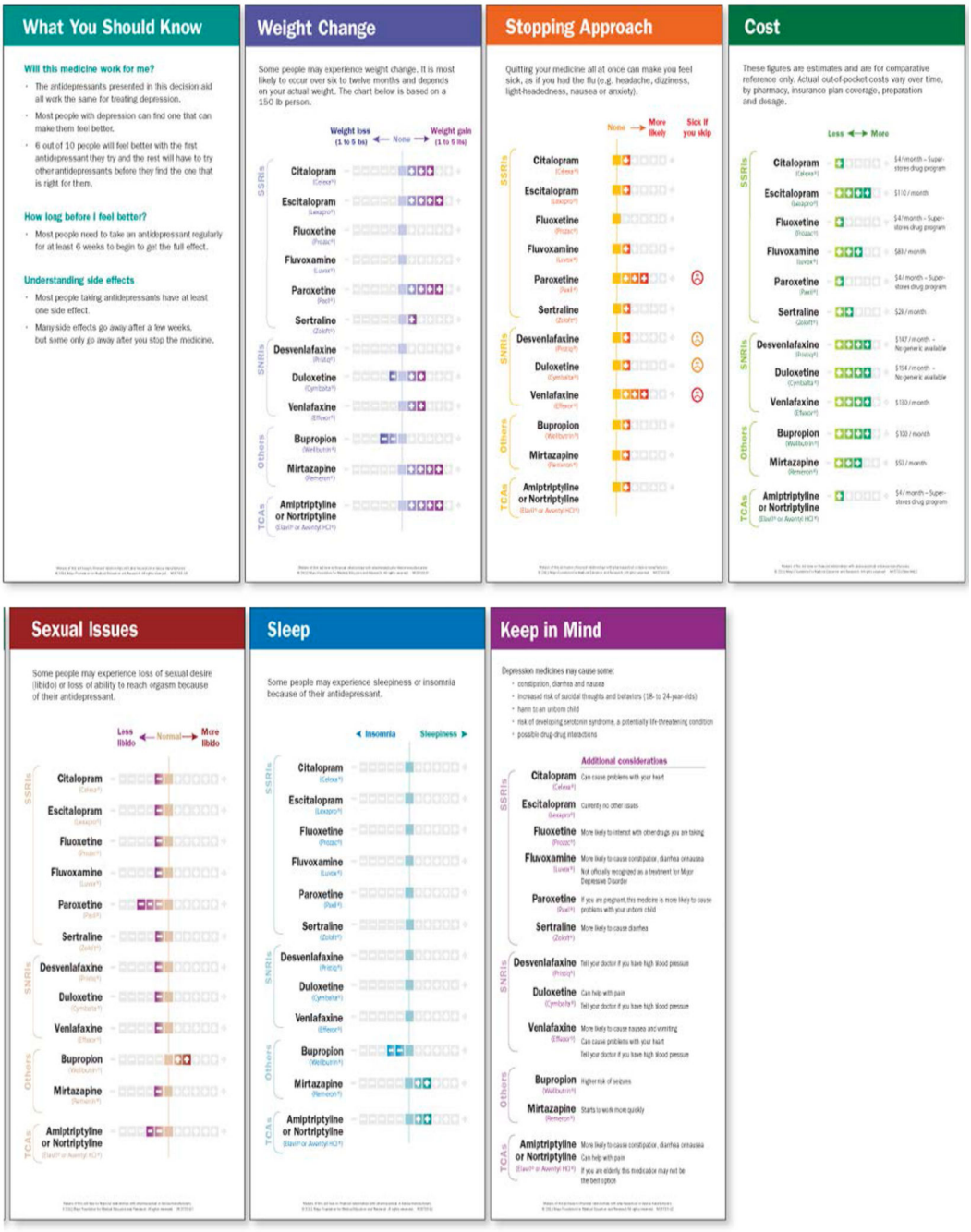

Figure 1.

This decision aid presents itself in form of 4”x10” laminated cards The Depression Medication Choice Encounter Decision Aid

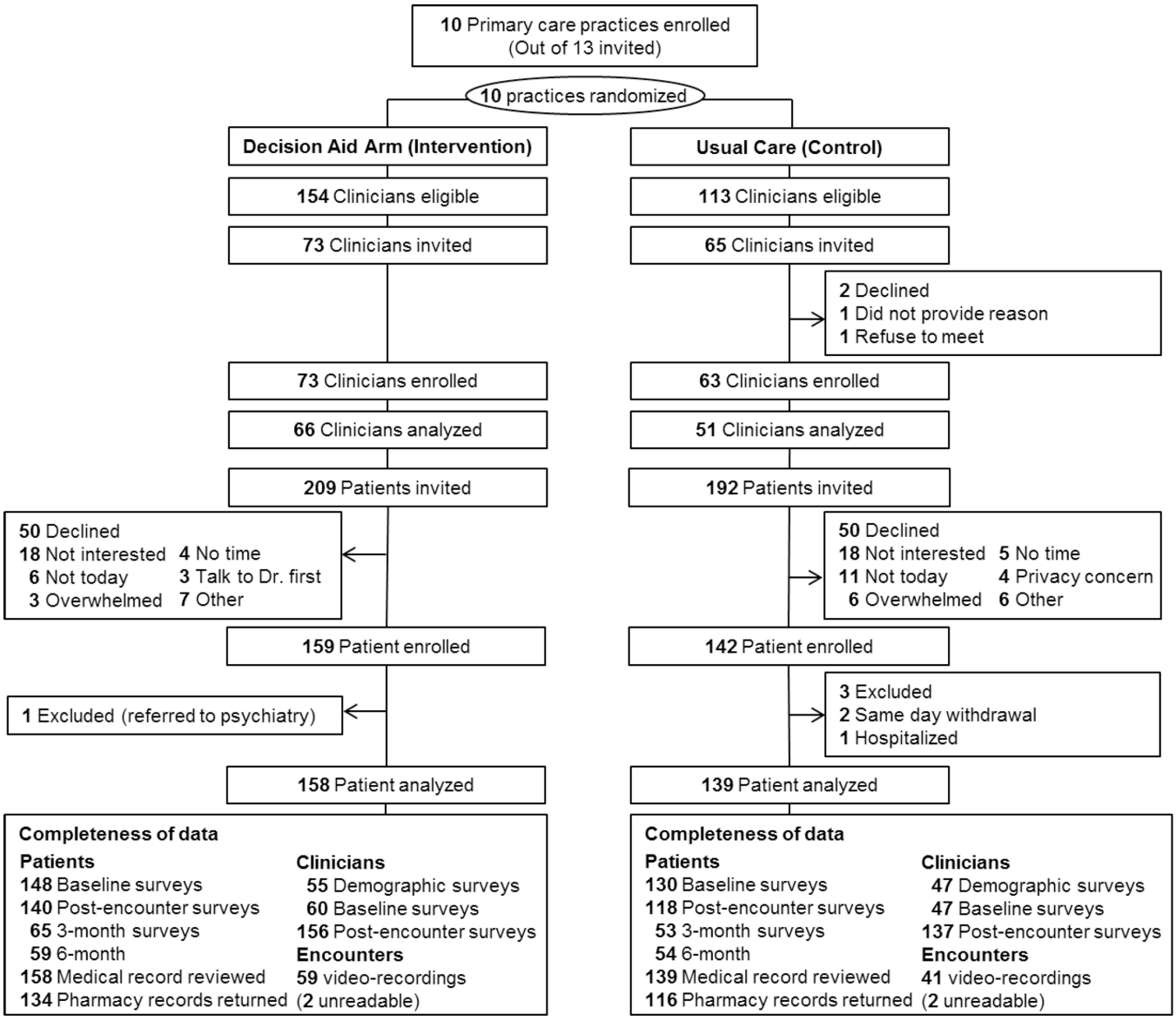

Figure 2.
Flow of Participants

Table 1

Sociodemographic Characteristics of Study Participants

Characteristics	Usual Care	Decision Aid
Patients	N=139	N=158
Female, n (%)	86 (61.9)	114 (72.2)
Age, mean (SD), y	43.9 (15.1)	43.2 (15.6)
> 40 y, n (%)	80 (57.6)	87 (55.1)
Ethnicity, Caucasian, n (%)	92 (66.2)	118 (74.7)
Missing	22 (15.8)	18 (11.4)
Marital status, n (%)		
Married/ Living with someone	50 (36.0)	61 (38.6)
Separated/ divorced/ widowed	24 (20.4)	36 (22.8)
Never married	40 (28.8)	38 (24.1)
Missing	25 (18.0)	23 (14.6)
Education, n (%)		
High school degree or less	36 (25.9)	44 (27.9)
College (with or without degree)	68 (58.3)	78 (49.3)
Graduate or professional	6 (4.3)	10 (6.3)
Other	4 (2.9)	3 (1.9)
Missing	25 (18.0)	23 (14.6)
Income, n (%)		
Less than $30,000	59 (32.5)	51 (32.3)
$30,000 to $59,999	17 (12.2)	26 (16.5)
$60,000 to $99,999	22 (15.8)	39 (24.7)
$100,000 or more	11 (7.9)	15 (9.5)
Missing/ did not want to disclose	25 (18.0)	26 (16.5)
Preference in decision-making style, n (%)		
Make decision alone	3 (2.2)	4 (2.5)
Make decision after considering clinician	20 (14.4)	29 (18.4)
Share the decision	68 (48.9)	76 (48.1)
Clinician makes decision after considering me	21 (15.1)	23 (14.6)
Leave decision to clinician	4 (2.9)	5 (3.2)
Missing	23 (16.5)	21 (13.3)
Literacy and numeracy, n (%)		
Less than adequate literacy	48 (34.5)	38 (24.1)
Missing	9 (6.5)	11 (7.0)
Less than adequate numeracy	66 (47.5)	67 (42.4)

Characteristics	**Usual Care**	**Decision Aid**
Missing	14 (10.1)	12 (7.6)
PHQ-9, mean (SD)	15 (4)	15 (4)
Clinicians	**N=51**	**N=66**
Female, n (%)	30 (58.8)	37 (56.1)
Age, mean (SD), y	41 (12)	40 (12)
Resident, n (%)	19 (37.3)	22 (33.3)
Years in practice, >10y, n (%)	15 (29.4)	16 (24.2)
Missing	4 (7.8)	11 (16.7)
Direct patient care, >50% of time, n (%)	26 (60.0)	47 (71.2)
Missing	22 (43.1)	15 (22.7)
Preference in decision-making style		
Make decision alone	1 (2.0)	1 (1.5)
Make decision after considering patient	0 (0.0)	3 (4.5)
Share the decisions	42 (84.0)	48 (71.6)
Patient makes decision after considering me	4 (8.0)	8 (11.9)
Leave decision to patient	0 (0.0)	0 (0.0)
Missing	3 (6.0)	7 (10.4)

Table 2

Patient Decision-Making Quality & Clinical Outcomes

	Usual Care (N=139)	Decision Aid (N=158)	Mean Diff (95%CI)[a]	P-Value
Decision-Making Quality Outcomes				
Continuous outcomes, mean (95%CI)[a]				
Decisional Conflict(0=conflict, 100=comfort)[b]				
Informed subscale	72.1 (68.5, 75.7)	79.6 (76.4, 82.7)	7.8 (1.9, 13.6)	0.009
Clarity subscale	73.3 (69.6, 76.9)	81.3 (78.2, 84.4)	8.4 (3.3, 13.5)	0.001
Support subscale	79.3 (75.6, 83.0)	83.4 (80.3, 86.4)	4.5 (−1.4, 10.4)	0.13
Uncertainty subscale	71.7 (67.5, 75.9)	74.6 (71.0, 78.1)	2.9 (−2.5, 8.3)	0.30
Effectiveness subscale	75.8 (72.3, 79.3)	79.1 (76.3, 81.9)	3.3 (−1.1, 7.7)	0.14
Overall	74.5 (71.4, 77.6)	79.7 (77.0, 82.5)	5.3 (1.1, 9.5)	0.01
Missing,[c] n (%)	25 (22.7)	20 (14.9)		
Knowledge(0=no correct, 100= all correct)			**OR[d] (95%CI)[a]**	
Tailored to information in the decision aid	46.6 (42.6, 50.5)	58.1 (53.6, 62.6)	13.2 (6.4, 19.9)	0.0001
Generic (i.e. depression in general)	72.4 (67.3, 77.5)	72.5 (68.0, 77.0)	2.8 (−9.3, 14.8)	0.65
Overall (i.e. both tailored and generic)	56.3 (52.9, 59.6)	63.5 (59.9, 67.1)	9.5 (0.8, 18.2)	0.03
Missing, n (%)	23 (20.9)	21 (15.7)		
Categorical Outcomes, N (%)			**OR[d](95%CI)[a]**	
Satisfaction[e]				
Right amount of Information given	102 (91.9)	124 (92.5)	1.25 (0.21, 7.52)	0.81
Information given was extremely clear	64 (58.7)	92 (68.7)	1.17	0.09
Information given was extremely helpful	57 (52.8)	92 (69.2)	1.77 (0.92, 3.38)	0.01
Strongly desire to receive Information this way for other treatment decisions	55 (50.5)	90 (68.2)	2.01 (1.18, 3.40)	0.005
Strongly recommend the way information was shared to others	65 (59.1)	104 (77.6)	2.40 (1.38, 4.19)	0.002
Missing[c]	30 (27.5)	26 (19.7)		
Clinical Outcomes				
Continuous outcomes, mean (95%CI)[a]			**Mean Diff (95%CI)**	
Depression symptoms				
PHQ-9, 3 month[f]	9.0 (7.7, 10.2)	9.2 (8.0, 10.3)	0.4 (−2.5, 3.4)	0.78
Missing	38 (34.5)	44 (32.8)		
PHQ-9, 6 month[g]	9.3 (8.2, 10.5)	8.9 (7.8, 10.0)	− 0.2 (−2.9, 2.6)	0.91
Missing	38 (34.5)	49 (36.6)		

	Usual Care (N=139)	Decision Aid (N=158)	Mean Diff (95%CI)[a]	P-Value
Categorical outcomes, n (%)				
Depression symptoms				
Remission, 3 month	26 (18.7)	31 (19.6)	-	0.85
Response, 3 month	43 (30.9)	53 (33.5)	-	0.77
Missing	38 (34.5)	44(32.8)		
Remission, 6 month	20 (14.4)	34 (21.5)	-	0.18
Response, 6 month	38 (27.3)	55 (34.8)	-	0.15
Missing	38 (34.5)	49 (36.6)		
Adherence to medication			**OR (95%CI)**	
On medication at time of encounter	90 (64.7)	93 (58.9)	-	0.93
On medication after the encounter	110 (79.1)	142 (89.9)	-	0.15
Pharmacy record available	93 (66.9)	113 (71.5)		
Primary adherence (filled prescription)[h]	82 (93.2)	94 (86.2)	-	0.19
Missing	5 (5.7)	4(3.7)		
Secondary adherence[i]				
%PDC >80% (of filled prescription)[j]	85 (97.7)	96 (98.0)	-	0.25
%PDC >80% (of all patients)	91 (97.8)	107 (94.7)		0.67

[a] 95% confidence intervals;

[b] Reported variance σ^2(site)=5.7; σ^2(clinician)=0.00; σ^2(patient)=254.1;

[c] Reported as the highest proportion of missing across items;

[d] Odd Ratios;

[e] Relative Risk;

[f] 7 point-likert scale, reporting proportion of agree/strongly agree;

[g] Reported variance σ^2(site)=0.0; σ^2(clinician)=3.5; σ^2(patient)=35.2;

[h] Reported variance σ^2(site)=0.0; σ^2(site)=3.0 ; σ^2(patient)=31.7;

[i] Calculated out of available pharmacy records;

[j] PDC: Proportion of days covered

Table 3

Clinicians Decision-Making Quality Outcomes

	Usual Care (N=139)[a]	Decision Aid (N=158)[a]	Mean Difference (95%CI)[b]	P-Value
Continuous outcomes, mean (95%CI)[b]				
Decisional Conflict(0=conflict, 100=comfort)				
Informed subscale	65.3 (61.5, 69.1)	79.1 (76.8, 81.5)	14.4 (7.1, 21.6)	<0.0001
Clarity subscale	66.8 (62.2,69.4)	85.3 (83.0, 87.6)	19.9 (11.9, 27.9)	<0.0001
Support subscale	72.1 (69.1, 75.1)	79.2 (76.7, 81.7)	6.6 (1.8, 11.4))	0.007
Uncertainty subscale	64.4 (60.6, 68.3)	74.1 (71.2, 77.1)	9.2 (3.4, 15.0)	0.002
Effectiveness subscale	71.8 (68.9, 74.8)	81.2 (78.9, 83.5)	9.1 (3.9, 14.2)	0.001
Overall	68.3 (65.4, 71.2)	79.7 (77.6, 81.8)	11.4 (5.7, 17.1)	<0.0001
Missing,[c] n (%)	18 (13.1)	17 (10.9)		
Involvement of patients in the decision-making process[d]	32.5 (28.5, 36.6)	46.6 (42.3, 50.8)	15.8 (6.5, 25.9)	0.001
Missing, n (%)	100 (71.9)	101 (63.9)		
Categorical Outcomes, n (%)			**RR (95%CI)[e]**	
Satisfaction,[f] satisfied extremely satisfied	74 (54.0)	119 (76.3)	1.64 (1.25, 2.16)	0.02
Missing	22 (16.1)	19 (12.2)		

[a] N=number of encounters (i.e. multiple entries per clinician);

[b] 95% confidence intervals;

[c] Reported as the highest proportion of missing across items;

[d] OPTION scores (12 items, 0–100 scale, 0= no involvement), inter-rater agreement calculated as Shrout & Fleiss' ICC=0.96;

[e] Relative Risk;

[f] 1 item, 5-point likert scale, reporting proportion of satisfied /extremely satisfied.