Final Study Protocol and Analytical Plan

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Protocol Title: Effectiveness of DECIDE in Patient-Provider Communication, Therapeutic Alliance and Care Continuation

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I. Background and Significance

I.A. Historical Background. Most people with mental disorders in the United States are untreated or poorly treated.[1] Numerous researchers, government agencies, and advocates[1-3] call for interventions to enhance treatment initiation and quality. One way to improve quality and retention in mental health care is to implement shared decision making (SDM). When patients and providers engage in SDM, patients' preferences are taken into consideration for their treatment, resulting in more appropriate care, increased satisfaction, and ideally, better health outcomes.[4,5] Examining SDM in behavioral health care among populations in safety net settings is an urgent need given that the Federal Patient Protection and Affordable Care Act (ACA) will make an estimated 32 million uninsured individuals, mostly minorities, eligible for Medicaid coverage.[6] Roughly 20-30% of this population suffers from a behavioral health disorder.[7]

A major obstacle to SDM for patients of color is inadequate provider appreciation of minority patients' preferences for interpersonal relations.[8, 9] Providers rarely receive training in how to motivate minority patients to voice their treatment concerns or preferences. Providers display fewer patient-centered behaviors,[10] are less receptive to question asking, and tend to demonstrate greater verbal dominance[11] with minorities than with white patients. These actions often result in misunderstandings, inadequate services, and failed treatment alliances.[12] Minority patients may infer prejudice or perceive a negative attitude from their provider, thus reducing the likelihood that they perceive receiving quality care.[13] Clinicians face new demands connecting with patients with different customs, values and experiences, and addressing these challenges will likely improve SDM and patient-centered quality care. Language barriers can also be detrimental;[14] patients who do not speak the same language as their providers report worse outcomes[15] and higher dropout rates.[16-18] Tackling these barriers requires new, innovative interventions at the provider and patient level.

I. B. Previous clinical studies leading up to and supporting the proposed research. In this proposal, we test the effectiveness of the DECIDE-PA+PC intervention among non-Latino white, African-American, Latino, and Asian patients in community health centers. Our research team's pilot and randomized trial found that a patient intervention (DECIDE-PA) improved activation and self-management in mental health care.[19-22] However, minority patients expressed concern that becoming 'activated' threatened the relationships they had developed with their providers. This feedback meshed with prior studies showing that providers working under strict time constraints and immediate treatment priorities may be more directive and limit patient-initiated talk.[23] In the DECIDE-PC intervention described in this protocol, we intended to tackle these barriers. We hypothesized that adding a provider component (DECIDE-PC) to the patient component (DECIDE-PA) would enhance providers' receptivity to patients' activation and self-management, improve therapeutic alliance and communication, and improve SDM and perceived quality of care.

The DECIDE-PA intervention (previously called RQP-MH) had its roots in a community-based social action intervention, the Right Question Project (RQP), which was designed to empower participants in social and health situations that required decision making. The DECIDE-PA intervention was a product of the collaboration between the non-profit group which created RQP (Rothstein and Santana), patients, clinicians, and administrators in mental health agencies, and the Disparities Research Unit (DRU), MGH team, which was previously the Center for Multicultural Mental Health Research (CMMHR) at Cambridge Health Alliance. Considerations of cultural, socio-economic, and clinical factors for patients were gleaned from stakeholder groups in the adaption of RQP to DECIDE-PA (see Polo et al. 2012 for details).[12] The continued engagement of patients, clinicians, and administrators in the DECIDE-PA+PC study was vital to ensure that the intervention continued to be relevant and meaningful for patients and to attain sustained improvements in patient care.

The current study was guided by principles of community-based research and was committed to ensure patients, clinicians, and clinic administrators had a purposeful voice in study design and implementation and dissemination of findings. By incorporating the diverse skills, knowledge and expertise of patients, providers and clinic administrators, the research was more likely to be useful and relevant to community members.[24] The research PI and team has an extensive and well-respected history of successful collaboration with patients, clinicians, administrators, and other stakeholders in innovative mental health services studies that aim to improve the lives of multicultural populations. The unique collaborative nature of the research center was evident in the conduct of the DECIDE-PA study. We continued to respect the voice of patients and stakeholders by incorporating extensive input in design, implementation, and dissemination.

I.C. Rationale behind the current research and potential benefits to patients and/or society. Our study is one of the first to test whether changes in patient activation and self-management together with a provider coaching program to increase provider receptivity improves SDM and patient's perception of behavioral health care quality. Although past research suggests that racial/ethnic minority patients take a more passive role in treatment and are less likely to discuss information with a health care provider, the DECIDE-PA study demonstrated that racial/ethnic minority patients' level of activation and self-management can increase. However, the main tenet of SDM is that two active participants, the patient and the provider, are needed.[25]

This study also fills a gap for scientifically rigorous research in clinics that ethnic/racial populations depend on to receive mental health care services.[26] Research shows that minority patients do not have equal access to high quality care.[27, 28] Administrators and providers are eager to implement interventions but first need strong evidence of improved quality or outcomes in resource-constrained safety net environments.[29] The collaborative engagement of patients, clinicians, and administrators helps ensure that DECIDE PA+PC is relevant and meets their needs. Further, the study was designed to triangulate data from multiple perspectives (i.e., patient, clinician, and independent observer) to allow for better measurement of SDM and other outcomes.

STUDY AIMS AND PROCEDURES

We include below the study aims and procedures that reflect our completed protocol.

II. Specific Aims

II.A. Specific Aims: Aim 1: Test the effectiveness of the DECIDE PA+PC intervention and the marginal benefit of DECIDE-PA or PC compared to usual care in improving shared decision making and patient-perceived quality of behavioral health care.
Aim 2: Test whether patient-centered communication and therapeutic alliance mediate the effect of the DECIDE PA+PC intervention on shared-decision making.
Aim 3: Explore whether ethnic/racial or language matching moderates the relationship between the effect of the DECIDE PA+PC intervention on shared decision making, quality of behavioral health care, patient-centered communication and therapeutic alliance.

III. Subject Selection

III.A.1. Provider inclusion criteria: Provider participants in this study consisted of regular paid staff members that provide behavioral health services (i.e., psychotherapy and/or medication) to adult outpatients at each of the participating study clinics. No other criteria were required. Across all study sites, approximately 80 providers were ultimately targeted for recruitment to participate in the study. The final number of participating providers was 79. At each site (a "site" may consist of multiple clinics within one hospital) approximately 4 -10 providers took part in the intervention trial.

III.A.2. Patient inclusion criteria: Enrollment was limited to patients ages 18-80, non-Latino White or Latino, Black,

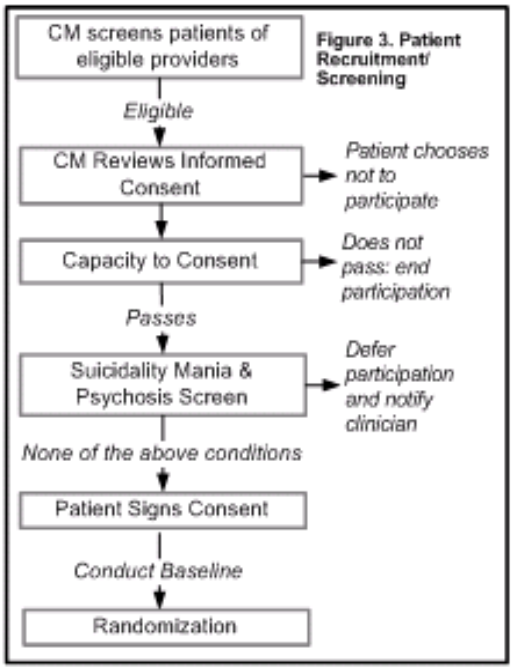


Figure 3. Patient Recruitment/ Screening

or Asian, who were receiving mental health treatment at one of the collaborating clinics, from a participating provider. Non-English speaking patients were included in the study (i.e., patients who speak Spanish or Mandarin).

Across all study sites, 360 patients were targeted to be randomized into the control and intervention arms of the study, to achieve the target sample size of approximately 300 given expected attrition of 20%. We finalized the study sample with 312 patients. We refer to these patients as RCT patients. We anticipated enrolling approximately 48-72 patients at each site, half of which would go into the control arm and the other half into the intervention arm of the study. Additionally, we planned to recruit approximately 124 patients to consent to having one clinical session audio recorded with their respective consented provider, to use to help train providers enrolled in the intervention arm of the study. These patients were not randomized to the control or intervention arms. We refer to these patients as NRCT. We finalized the study sample with 101 NRCT patients.

III.A.3. Patient exclusion criteria: Patients were excluded for the following: positive screen to a diagnosis of Bipolar Disorder or taking medication for Bipolar Disorder (i.e. Lithium), diagnosis of Schizophrenia; endorsed active suicidal ideation in the last 30 days or pending hospitalization; participation in previous DECIDE trials, failure to pass the mini-cognition assessment for participants 65 years of age or older; or indication by the provider that a patient was too sick to participate in the study. Patients younger than 18 years of age or older than 80 years of age were also excluded. Suicidal patients or patients who were pending hospitalization in the co[illegible]ad the option to be rescreened one month following their initial screening if these previous conditions [illegible]ed. Suicidal patients were referred for immediate help following a study emergency protocol determ[illegible] collaboration with clinic staff.

Figure 1: Patient Recruitment/ Screening

III.A.4. Focus group inclusion criteria: Patients and providers who completed their participation in the study were eligible to participate in focus groups following the clinical trial. Patients and providers who did not participate in the study were also invited to participate, as described further below. A total of 30 patients and 19 providers participated in our focus groups (49 total).

III.B. Source of Subjects and Recruitment Methods: We recruited at selected community health clinics, both those where we had established collaborations, as well as new partnerships that we forged. The clinics were chosen based on criteria including patient and provider volume, demographics in terms of a high percentage of Latino, Black, Asian and non-Latino White patients, previous collaborations, and skilled Site Leaders/Co-Investigators. We recruited providers who are regular staff at each clinic. Only patients of these providers were eligible for randomization**.**

A series of presentations and meetings were held to introduce staff at each of the clinics to the study. We collected informed consent forms from those providers that were interested in participating (as was done in DECIDE-PA). To screen patients, we enlisted the help of providers as well as administrative assistants (AA) at each of the clinics, who had access to provider caseloads, schedules, and patient demographics. To coordinate recruitment, we asked AAs to select those who patients who met basic eligibility criteria: between 18-80 years old, non-Latino White or Latino, Black, or Asian, and not at risk for self-harm if known to the clinic. At selected clinics we had access to EPIC electronic records to help with this process. Patients were assured that accepting or declining to participate would not affect their standard clinical care.

IV. Subject Enrollment

IV. A.1. Methods of enrollment, including procedures for patient registration and/or randomization*:* The DECIDE PA+PC intervention involved a randomized controlled trial of patients within providers participating in the proposed study. The original target was 8-10 providers (always in pairs at participating clinics, half going to the intervention and half to the control condition) every 6 months. Approximately 4-8 patients from each of these providers participated in the study design. In some clinics this number varied depending on patient flow.

At each clinic, participating providers completed a baseline interview, the RA1, after which they were randomized to the control or intervention (DECIDE-PC) arms. All providers audio recorded one clinical session with 1-2 separate patients (called NRCT patients) in order to help train providers enrolled in the intervention arm of the study. Providers in the control arm continued administering usual care. Providers randomized to the intervention arm participated in a 1.5 day training led by coaches as well as 1-6 follow up coaching calls throughout the study period.

Following provider training, consented patients were recruited and randomly assigned to DECIDE-PA or usual care. We implemented a randomized clinical trial, whereby patients were randomized to the DECIDE-PA intervention or usual care within each of the clinics and with each of the randomized consenting providers receiving DECIDE-PC or not. Patients assigned to the intervention received 1-3 training sessions delivered by a Care Manager (CM) over a period of 2-6 months; patients in the control arm received treatment as usual. Patients in the intervention arm elected to complete their trainings either in person (at the participating clinic or in their homes), or over the phone. Providers and participants in the control arm of the study were eligible to receive the DECIDE-PC and DECIDE-PA interventions respectively, once their participation in the study was complete.

Assessment of outcomes: Outcomes were measured by research assistants (RAs) who were not involved in the provider-or patient-level trainings. Patients were assessed at 3 time points during the study, with the RA1 or baseline assessment completed at the time of their enrollment in the study and before treatment exposure. The second assessment, the RA2, occurred 1 to 2 months following the first, and took place within 24 hours of the patient/provider clinical session recording. This was planned to be done after both the provider and patient had treatment exposure. However, in some cases patients in the intervention were given RA2, without having treatment exposure. Patients who lost their health insurance prior to the clinical session being recorded, but who wished to remain in the study, had the opportunity to have one clinical session with their provider paid for by the study. The third and final assessment, the RA3, occurred 3 to 6 months after the baseline assessment and signaled the conclusion of the patient's participation in the study. Patients could elect to complete these assessments either in person (at the participating clinic or in their homes) or over the phone. Providers completed an online assessment, the RA2, ideally within 24 hours of recording a clinical session with their participating patients. Providers randomized to the intervention participated in follow-up calls with coaches, one call for every session recorded, as well as a final wrap-up call. Once all calls were completed, providers completed the final assessment of the study.

We summarize here the three different methods of data collection:

1) *Patient assessments* were collected in face-to-face interviews or by phone at baseline (RA1), 1-2 months (RA2), and 3 to 6 months (RA3). Follow up interviews were conducted with patients even if the patient were no longer receiving care at the clinic or no longer was seeing their study provider.

2) *Provider assessments* were collected in face-to-face interviews or by phone. Providers were asked about their general interactions with patients at baseline and post-intervention, and specifically about their clinical encounter after the clinical visit (RA2).

3) *Coded audio recordings of the clinical visit* (RA2 only). We obtained audio recordings of each clinical visit for the participating patients for both intervention and control providers. These recordings were coded by blinded research staff for SDM, patient-centered communication, therapeutic alliance, provider receptivity, and global interaction rating.

Difficult to reach patients: There were often difficult to reach patients. As the study progressed, we ramped up follow up procedures to assist with patient retention in the study. We offered more flexibility to the patients in terms of when and where the interviews could be completed. We completed interviews after hours, during the weekends, and at times in the patient's home. Our call protocol was increased to 6 daily attempts: 2 in the morning, 2 in the afternoon, and 2 in the evenings. In some cases patients' phones were disconnected, their voicemails were full, or we had outdated information in our records. We worked with clinic administrative staff to obtain updated contact information. For patients who we still could not reach, we sent them a letter informing them that we would visit their homes to check on their well-being and complete the assessments. The research assistants were all trained in safety procedures for home visits. Permission to visit patients in their homes was included in the consent forms.

Focus groups: Towards the end of the study period, two community forums (breakfast meetings) and 7 focus groups were held. These forums and groups were used not only to disseminate preliminary results from the study, but also to enable us to receive feedback and insight from participants in order to inform future research. Patient focus groups took place in English, Spanish, and Mandarin and were audio recorded for quality control and transcription purposes.

IV. A.2. Recruitment and Consent Procedures

Providers: Research staff worked together with Site Leaders at each participating clinic to recruit providers who were regular staff members of the clinic. Dr. Margarita Alegria and the research team then conducted a series of presentations and meetings to introduce the study to providers and clinic staff. Following the presentations, the research staff visited clinics to answer any additional questions and to administer informed consent with providers who expressed interest in participating. Provider Informed Consent forms were explained during the individual and group meetings with providers, including information about the potential risks and benefits of enrollment, the collection of provider data, the need for audio recordings of patient visits, the voluntary nature of their participation, and the option of withdrawal at any point during the course of the study.

Patients: In terms of patient enrollment, study Research Assistants (RAs) collaborated with the participating administrative staff at each clinic in order to obtain the clinical schedule for enrolled providers. The clinical schedules were then used to determine which patients were eligible to approach for participating providers. Patients were approached if they fit the age requirement (age confirmed by administrative staff) and if the patient did not display severe levels of cognitive impairment (judged by the RA or as determined by provider in some rare cases [n=9]). The RAs approached patients that arrived at the clinic well in advance (at least 15 minutes) of their appointment, or as patients were completing their appointments. We also posted flyers in Spanish, English, and Mandarin at participating clinics to increase our equitable recruitment at all clinics. At certain clinics, RAs were granted limited access to electronic scheduling systems (e.g., EPIC), to determine provider schedules or enrolled patients' next appointments. Patient eligibility and consent to participate was then determined during an in person screening visit. All participation in the study was voluntary. Patients were assured that accepting or declining to participate would not affect their clinical care, and their participation in the study was completely voluntary. RAs noted patients who declined participation with a study ID so as not to approach them in the future and for tracking purposes.

Patients were given as much time as they needed to think about participating. Patients who might have been eligible for the study, but who did not have time to speak with an RA in the clinic originally signed a "pre-consent" form giving permission to the study staff to contact them by email or phone. The RA contacted them with more information about the study and to set up a time to administer the screening. Once the research team moved to Massachusetts General Hospital, the hospital's IRB no longer required a "pre-consent" form. In lieu of the "pre-consent" form, RAs provided interested patients a study information sheet that included the research team's contact information. RAs then collected patient information during informed consent and screening, after the patient had contacted the research team.

RAs took patients to a separate, private room in order to review the informed consent form and perform the screener for eligibility. Patients over the age of 65 were further screened for cognitive impairment using a mini-cognition assessment to ensure they were capable of participation. Patients in substance abuse clinics only were asked to demonstrate capacity-to-consent by answering 8 out of 10 questions about the consent form correctly in order to participate in the study, given concern about intoxication or use of substances prior to the consent process. Those who could not complete the capacity to consent measure were considered ineligible, even if their screener indicated eligibility. Patients were informed that the research team would make every effort to ensure that the information they shared during the course of the trainings and assessments was kept confidential and only reported in aggregate form.

English and non-English speaking patients were also included in the study (i.e., patients who spoke Spanish or Mandarin). The study was conducted fully in three languages: English, Spanish, or Mandarin Chinese). To assist with their equitable recruitment, RAs in charge of recruitment were fluent in at least two of the three languages to assist and be able to fully consent non-English speaking patients. Consent forms were professionally translated and available in all three languages.

Focus Groups: Patients and providers who previously participated in the study were contacted by an RA to gauge interest in participating in a focus group. Focus Group Informed Consent was obtained verbally, since no PHI was collected during the course of the groups.

Provider final qualitative data: As we finalized the study, we examined potential challenges and barriers to implement our intervention in real world practice. We collected qualitative data from a portion of the providers (n= 41) on clinical and organizational challenges and facilitators to implementing the DECIDE-PC provider intervention

in a real-world setting. We used a survey questionnaire with 6 questions. Participants answered the survey on RedCap. The entire survey took less than 15 minutes of their time. Participants received a $50 gift card upon completion of the survey.

IV.A.3. Remuneration

Consented patients who were screened for the study, but who did not meet eligibility requirements based on the screener, were not included in the study, but received a $10 gift card.

The 1-2 NRCT patients per provider, who consented to having their clinical session with their provider audio recorded, completed a brief baseline assessment, the RA0, (i.e., the patient is not randomized to the control arm or intervention arm of the study) and received a $20 gift card.

Patient participants in the intervention arm of the study were given a total of $120 worth of gift cards for their participation. This includes compensation for 3 interviews ($25 for each of the first two assessments and $40 for the final assessment) and 3 training sessions ($10 per session to help with transportation and child care expenses to participate in the trainings). At the conclusion of the study, we increased the incentive from $25 to $50 for the clinical recording and the 2nd interview, to facilitate patient completion of study protocol.

Patient participants in the control group received a total compensation of $90 for the 3 interviews ($25 for each of the first two assessments and $40 for the final assessment). At the conclusion of the study, we increased the incentive from $25 to $50 for the clinical recording and the 2nd interview.

Provider participants in the intervention arm of the study received incentives for the DECIDE-PC behavioral health provider trainings ($300 per provider for participating in the training) and received continuing education credits for their respective disciplines (e.g., social work, psychology, psychiatry). Providers received up to 18.5 total continuing education credits (11.5 for the training and up to 1 additional credit for each follow-up coaching call and 1 for the wrap up call.) Providers were paid $50 for each of two research assessments (total $100), conducted by the RAs. We also paid $50 to providers per patient to take part in a self-administered post-appointment assessment (RA2) that helped them evaluate how they were doing with their patients. Therefore, providers in the intervention group (i.e., those that received the DECIDE training) received a total of $700 [($300 for provider training) + ($50 per research assessment *2 assessments [baseline (RA1 and RA3]) + ($50 per patient post-appointment, self-administered assessment RA2 * up to 6 patients)] to participate in the study.

Provider participants in the control group (i.e., did not receive the DECIDE training, but participated in all other aspects of the study) received a total of $400 [($50 per research interview *2 interviews) + ($50 per patient post-appointment, self-administered survey * 6 patients)] to participate in the study.

Patient and Provider participants in the focus groups received a $50 gift card for their participation.

V. Interventions

V.A.1. Provider Intervention: Provider coaching focuses on augmenting patient-centered communication and therapeutic alliance as a possible underlying pathway by which SDM can take place. Provider Coaching targets three areas that were identified in our previous Patient Provider Encounter Study[30-32] as problematic in forming good provider-patient interactions as well as using recommended coaching on patient-centered communication shown to be effective in clinical encounters.[33-39] These are: 1) lack of **perspective taking** or the ability to step outside of one's own experience and accurately identify the emotions and perceptions of others;[40] 2) frequent **attributional errors** that involve dispositional inferences,[41] where one attributes negative behaviors of out-group members (people of different ethnicity/race or language) to innate traits whereas negative behavior of in-group members is attributed to more situational factors as well as inaccurate identification of patient's feelings and emotions; and 3) decreased **receptivity to patient participation and collaboration in decision making**. In addition, we included three additional areas reported in the literature: 4) **patient activation**; 5) **patient engagement**; 6) **global impressions** (i.e. warmth, respect for patient); and 7) **encouraging open communication**.

The training consisted of three parts totaling ~20 hours. The first part included 12 hours of a small group experiential workshop, including two hours of individual feedback on the seven targeted areas of intervention mentioned above. The second part included 6 hours of individual coaching. A third part consisted of a 1 hour wrap-up call to summarize the coaching work.

Part 1*:* Provider receptivity to SDM was introduced in a group workshop. Providers were given an overview of the goals and logistics of the trainings, followed by a brief presentation of the research behind patient activation and our own study findings. We explained how the provider intervention teaches communication skills in listening, eliciting the patient's agenda, encouraging question asking, and illness management education. Videos of two contrasting interviews (responsive and non-responsive providers) were presented and discussed, focusing on *attentiveness* (how patients' concerns and understandings are taken seriously by the provider), *facilitation* (encouraging patients to express concerns in their own words and facilitating self-management and activation) and *collaboration* (supporting patients as partners in the process of mental health care). Techniques demonstrated included "giving the floor" to the patient (attentiveness), focusing on the voice of the patient rather than the voice of medicine (facilitation), and validating the patient as a co-producer/partner of treatment outcomes (collaboration). The training emphasized that allowing patient-initiated topics signals to patients that they are responsible for their treatment. The non-responsive interview exemplified non-specific attention markers (e.g., Um hum), narrow medically-focused questions, ignoring patient distress and confusion, and interrupting the patient. Facilitation was covered by showing how provider utterances can effectively elicit patients' accounts and reinforce question asking. Providers role played both types of providers and reflected on the experience. To increase the effectiveness of the intervention, many of the exercises during the workshop were based on recordings of two audio taped sessions conducted by the provider prior to the training (after securing patient consent). These audio recordings were reviewed by coaches with relevant sections transcribed to provide feedback in the next training session. Reviews of audio-recordings supported the development of attentiveness, facilitation and collaboration in patient encounters. By specifying features of the verbal interaction in the transcription that distinguish between provider "successes" and "challenges" in responsive care, the providers identified how to responsively ask, listen and collaborate. Providers also recognized how patient disclosures lead to exploration of the conditions and circumstances that contribute to mental health problems, activation, and self-management.

As part of the training workshop, providers received up to two hours of individual coaching to reinforce their reactions to the idea that their responsiveness to patients can change clinical practice. These coaching sessions were based on coding of the two recorded sessions from the provider's actual clinical encounters prior to participation in the intervention. Feedback was conducted face to face with the coding coach and was based on written structured feedback that was reviewed with the provider. The goal of the training was to deepen the reflection process and learning through application of skills acquired in real life case material. The emphasis was on giving the provider specific feedback based on an analysis of their SDM, their attributional errors (if they incorrectly assume the patient's age or education as compared to the actual information for the patient) as well as receptivity of patient's activation and self-management. Most of the integration of the trainings was done by providing explicit feedback of how they could conduct the interview differently to promote patient activation and self-management as well as SDM. In a small group format utilizing active learning, providers supported each other, discussing the organizational and clinical barriers that might interfere with institutionalizing attentiveness, facilitation and collaboration in care. The goal of the training was to provide individual learning and application of the knowledge acquired in the workshop as well as to promote reflection to raise awareness on the part of providers.

Part 2: Follow up individual training session (up to a maximum of 6 hours) took place within two to six months of the training workshop (scheduled at the provider's convenience and also depending on the time it took to recruit eligible patients and invite them to be in the study and get an appointment with their provider where we could audiotape their session). The goal of these calls (phone) was to discuss any remaining questions regarding the training, using the additional up to 6 audio taped sessions conducted by the provider following the training. Ideally, each provider had 6 participating patients that were recruited and consented to be in the study (half participating in the DECIDE PA and half in the usual care condition), but due to a limited patient pool, providers typically had fewer than 6 participating patients. The goal of the follow up sessions was to identify more topics from the training to review in some detail. The review was meant to give participants more training in areas that were not mastered during the first two sessions, using examples from the tapes and providing more feedback. Structured individual feedback was provided for each recorded session covering the topics in the workshop and specifying areas of

strength, areas of average functioning and areas in need for improvement. Written feedback was emailed prior to each call to facilitate discussion and practice of skills taught.

Part 3: This consisted of a wrap-up session to summarize and conclude the coaching that providers received.

V.A.2. Implementation of Provider Coaching (PC) Intervention. The PC Intervention began with recruiting providers at the designated clinics. Both Patient and Provider DECIDE Interventions were reviewed and received input from our Community Advisory Board (CAB). This allowed for the first phase of participant recruitment and randomization to occur promptly. Participating providers signed a consent form, agreeing to attend the provider trainings and to complete a process interview for 6 of their participating patients during the following 6 months of the project. In addition, a baseline and 6 month follow-up interview were collected. Once the providers had been trained, the implementation phase of the patient intervention began. Providers could opt out of the coaching intervention at any time.

V.A.3. Patient Activation Intervention (DECIDE-PA). We conducted three trainings with behavioral health patients who were randomized to the intervention. Trainings each lasted 30-45 minutes. *Training 1 (Decisions and Agency)* increased participants' awareness of their role in clinical interactions and encouraged participation and decision making in care. Participants were given an overview of training goals and logistics, and were taught question formulation (Brainstorming) and question-asking strategies. Each participant received a Planner summarizing the intervention sessions. *Training 2 (the Who, How and Why of Decisions)* taught skills for understanding treatment decisions in terms of the roles, processes, and reasons involved. Care Managers reviewed the practice assignment (i.e. asking questions of providers). Because some patients were critical of their 'performance' while others were successful, this was a time where tailoring and addressing barriers was critical. Role-playing and practice assignments helped strengthen learning. *Training 3 (Self-Efficacy and Consolidation)* was a self-efficacy module, in which participants learned different ways to help answer questions about their behavioral health conditions or treatment options, such as consulting information on evidence-based practices. More time was spent reinforcing the skills learned and identifying areas in need of review

VI. Biostatistical Analysis

VI. A. Data and Measures: *The main outcome was SDM*, as measured by the OPTION, a scale based on the blind coded audio recording of the clinical visit at RA2, or what we refer to as the blind coder SDM. OPTION is an observer-rated tool developed from a SDM competencies framework including: problem definition, through exploration and discussion of alternative choices, explanation of options and risk and engagement in the decision making process. The OPTION scale measures overall provider involvement in these competencies and provides an indication of the quality of provider involvement in the SDM process as well as precise areas for improvement. Following Legare and colleagues' recommendation[42] of the need to triangulate SDM measurement from multiple perspectives (patient, provider and independent observer) we also use the SDM-9 to assess patient-reported SDM[43] (which we refer to in the final report as patient's SDM) from the visit and separately the SDM-Q-9 Doc[44] to get the provider-reported SDM for that same visit (which we refer to as provider's SDM). The OPTION (independent observer) is an objective measure of SDM, while the SDM-9 and SDM-Q-9 are subjective measures (i.e. the provider's and patient's perception). Representative items include, "My provider wanted to know exactly how I want to be involved in making the decision" (patient), "I told my patient that there are different options for treating his/her condition" (provider). The SDM-9 (patient and provider forms) measures nine constructs (e.g. preferences for involvement, negotiation) deemed essential to SDM. The nine-items are rated on six point scale from "completely disagree" to "completely agree." A summation of all items results in a raw score of between 0 and 45, transformed by multiplication to result in a range from 0 to 100, where 0 indicates the lowest level and 100 the highest. The analysis of this primary outcome is the focus at RA3.

Our secondary outcome is patient's perception of quality of care, measured with the Perceptions of Care (POC)[45] survey; a patient self-report questionnaire assessing perception of care and interpersonal experience with a provider(s) during an outpatient visit. An 18-item rating system, it measures continuity of care, provider availability, communication, access to provider, and global evaluation of care. It has been utilized to provide precise and detailed feedback about a patient's experience in care. We have adapted the scale and response format by using a 4-item Likert-type scale from "never" to "always" for each of 10-items. Total scores are scaled from 0 to 100, with higher scores representing better patient evaluation of care. Representative items include, "Does the provider give you reassurance and support?"

All of the variables and measures collected are listed in Table 1. This includes variables for both patients and providers and at which point in time they were collected.

Table 1: Description of Outcome Measures, Mediators, and Control Variables

Type of Measure	Measure Description	Administration (Baseline (T1), Clinical Visit (T2), Post (T3))			Measure Description	Administration (Baseline (T1), Clinical Visit (T2), Post (T3))		
	Patient Assessment	**T1**	**T2**	**T3**	**Provider Assessment**	**T1**	**T2**	**T3**
Primary Outcome Variables								
Self-perceived Shared Decision Making (SDM) Questionnaire: SDM-Q-9[43, 44]	SDM-Q Patient version: 9-item scale rates patient perception of collaboration with provider.	X	X	X	SDM-Q Clinician Version: 9-item measure of perceived SDM; α= .88	X	X	X
Shared Decision Making Coded from Visit: Shared Decision Making OPTION	Observer-rated tool of patient involvement developed from a framework of SDM competencies.		X		Measures quality of provider involvement.		X	
Shared Decision Making (internal measure)	An additional 10-item measure, developed internally, will also be used to assess shared decision making. This measure is more specific to the mental health context and addresses aspects of shared decision making that are targeted by both the patient and provider DECIDE interventions.		X		An additional 10-item measure, developed internally, will also be used to assess shared decision making. This measure is more specific to the mental health context and addresses aspects of shared decision making that are targeted by both the patient and provider DECIDE interventions.		X	
Secondary Outcome Variable								
Perceptions of Care Survey[45]	18-item scale, focused on patients' perception of quality of care.	X	X	X				
Mediators of the Intervention Effect on SDM								
Therapeutic Alliance	Therapeutic alliance goals, tasks, and bond. Internal consistency (α=.98).	X	X	X	Provider assessment of WAI. 12-item version.	X	X	X
Patient-Provider Communication: Sub-scale of Kim Alliance Scale	Sub-scale of KAS (11 items) measures patient-provider communication. Validity and	X	X	X	Provider perception of patient provider communication adapted	X	X	X

(KAS)[46]	reliability (α=0.87).				from KAS.			
Mediators of the Intervention Effect on SDM Operating through the DECIDE-PA Patient Intervention								
Patient Activation Scale[47]	9 item scale. Good internal consistency: (α=0.82 Spanish and α=0.75 English).	X	X	X	Provider perception of patient's activation.		X	
Patient's Perception of Self-Management, Decision Making	Short-form of PEPPI measures patients' perceived efficacy and self-management (α=0.91; 0.85 in Spanish).	X	X	X	Provider perception of patient's self-management and decision making.		X	
Patient's Perception of Provider's Demographic Factors	Accuracy of patient's perception of their provider's ethnicity, education, SES, and social position.	X			Provider's perception of patient's ethnicity, education, SES, position.		X	
Mediators of the Intervention Effect on SDM Operating through the DECIDE-PC Provider Intervention								
	Provider Assessment					**T1**	**T2**	**T3**
Patient-Centered Behavior Coding[48]	Measure of provider's facilitating and inhibiting behaviors.						X	
Active Listening Observation Scale[49]	Captures the provider's effort to unravel patient's reason for the visit.						X	
Global Rating[50, 51]	Three one-minute excerpts rated for tension, interest, warmth, engagement, linking (of the other), and emotional openness.						X	
Four Habits Coding Scheme[52]	Items measured on 5-point scale: Habit 1 (Invest in the Beginning); Habit 2 (Elicit Patient's Perspective): Habit 3 (Demonstrate Empathy): Habit 4 (Invest in the End).						X	
Race/Ethnicity and Language Concordance								
	Patient Assessment	**T1**	**T2**	**T3**	**Provider Assessment**	**T1**	**T2**	**T3**
Race/Ethnicity	Census definition of Race/Ethnicity for patient	X			Census definition - provider	X		
Language Proficiency	Evaluated by single item	X			Evaluated by 1 item	X		
Mental Health Status / Health Status Variables – For Adjustment in Regression Models								
Clinical Global Impression – Improvement (CGI-I)	7-point scale rates patient's change in symptoms relative to baseline state.	X	X	X	Perception of patient's CGI-I.		X	
	Patient Assessment					**T1**	**T2**	**T3**
Depression: Patient Health Questionnaire (PHQ-9)[53]	PHQ-9: 9 criteria for depression screening; Health professional Dx (k = 0.74; overall accuracy, 88%; sensitivity, 87%; specificity, 88%).					X		X
Generalized Anxiety Disorder: (GAD-7)[54, 55]	GAD-7: 7-item measure; good values of sensitivity (86.8%) and specificity (93.4%); AUC statistically significant [AUC = 0.957-0.985; p < 0.001].					X		X
Trauma: Primary Care-Post Traumatic Stress Disorder (PC-PTSD)[56, 57]	PC-PTSD screen: Brief 4-item screener for PTSD with good sensitivity (0.77), specificity (0.85), and efficiency of 0.85.					X		X
Physical Comorbidity: SF-12[58]/ WHODAS 2[59]	SF-12[148] and WHODAS 2[149]: Functional Health Status (SF-12): physical health =.91 and emotional health=.92. WHODAS 2, global measure of disability; 0.89.					X		X

Chronic Conditions	From NLAAS	X		X
Alcohol and Drugs: CAGE – AID[60]	CAGE-AID screener exhibited sensitivity (0.79) / specificity (0.77) for 1+ 'yes' responses. sensitivity (0.70) and specificity (0.85) for 2+ 'yes' responses.	X		X

Other Variables

	Patient Assessment	T1	T2	T3	Provider Assessment	T1	T2	T3
Patient's Demographics and Socio-contextual Factors	Includes gender, education, employment, income insurance, perceived social status, literacy, language, preferences in care.	X			Includes gender, education, income, training, perceived social status, language.	X		
Patient activation Measure	13-item patient scale, measures activation among individuals with mental health.	X	X	X				
In Vivo Scale	13-item scale, patient rates to what extent s/he experienced 13 feelings during visit with provider (ex., nervous, relieved, etc.)		X		14-item scale, provider rates to what extent patient seemed to experience 14 feelings during visit. The extra 14th item is "satisfied, overall."			
Questions Related to Decision Making	Ten questions related to how the patient and his/her provider communicated with each other and made decisions during their most recent visit.	X	X	X	Provider version includes 10 questions related to how provider and patient communicate with each other and make decisions during most recent visit.			
Relationship with Patient	NA				23 items, questions relate to the typical relationship provider has with patients in general.			
Provider Bias	Eight questions related to provider characteristics that may influence dropping out of care.	X		X	NA			
Decision Making-Clarity of Provider	10-item assessment, patient rates perceived communication between him/her and provider. For example, patient assesses how often provider uses clear language, how often provider makes sure s/he understands treatment options.	X			NA			
Reasons for Termination	10 items, asks patient to rate how important each reason was in deciding to terminate treatment.		X	X				
Perceptions of Provider/ Patient-Provider Interaction	"Perceptions of Provider"; 4-item, patients assesses perceived race/ethnicity, education and socioeconomic status of provider.	X	X	X	Provider assesses perceived race/ethnicity, education and socioeconomic status of patient.			
Language Proficiency	4 questions that ask patient how well s/he is able to read, write and speak in English. Language preference for interview is asked.	X			4 questions that ask providers how well s/he is able to read, write and speak in English.			

	If second language spoken, they are asked about that as well.				Language preference for interview is asked. If second language is spoken, they are asked about that as well.			
Services	6-item assessment of service use, used to assess the patient's use of mental health services, such as therapy or psychological counseling, reasons for the services use, and frequency of services use.	X			NA			
Health Literacy	18-item assessment. Patient sees a card with one word on top and two words on bottom. Patient is asked to read the top word and to indicate which of bottom two words is associated.	X			NA			
Cultural Training	NA				One item, Provider is asked if s/he has received cultural training before and how much.			
Provider's Perception	NA				5 items, asks provider to rate different statements regarding perceived patient's confidence in addressing concerns during visit.			
Barriers to Treatment	15 items, assesses whether low perceived need, attitudinal problems and structural barriers have prevented patient from getting help in the last year.			X	NA			
Questions about Stigma	2 items, asks patient whether s/he has been affected by stereotypes and if s/he has been mistreated due to her/his identity etc.			X	NA			
Everyday Discrimination	2-items taken from the 9-item Everyday Discrimination Scale. Patient is asked how often s/he is treated with less respect than others and if so, to specify the reason.			X	NA			
Preference for Receiving Patient Intervention	8 questions, asks patient about participation in trainings, to comment on skills they learned and to comment on anything they would want.			X	NA			
Questions about Shared Decision Making	2 questions that ask the patient if s/he has heard of the term "Shared Decision Making" before and to elaborate on what s/he thinks the term means.			X	2 questions that ask if provider has heard of the term "Shared Decision Making" before and to elaborate on what s/he thinks the term means.			

VI. B. Study Endpoints. The study was designed to last 3 years. Data collection concluded in September 2016.

VI.C.1. Statistical Methods: Mental Health Status and Health Status Covariates and Other Potential Control Variables: The effect of patient-centered communication has been found to be dependent on patient's baseline mental health status and illness severity.[61] While randomization is likely to provide balance on both unobserved and observed covariates, there is the possibility that one or more of the four study groups may be unbalanced on certain clinical characteristics. As such, in patient- and provider-interviews, we collected additional information at each time period related to mental health status and health status, and we collected demographics at RA1. We compared patients' demographics across the study groups and found that only personal income differs across groups. The current preliminary analysis does not include covariates except for baseline outcome measures. However in future work, we will run a sensitivity analysis including more covariates.

VI.C.2. Analytic Methods: Overview*:* Table 2 depicts four groups that are analyzed: patients randomized to the DECIDE-PA intervention or usual care were seen by providers who were randomized to DECIDE-PC or no intervention. We describe our analytical approach for each specific aim below. Before formal analyses, we carried out thorough descriptive data analyses to assure that data were free of coding and data entry errors, and to describe the marginal distributions of the key variables. We also described the missing variable patterns and determined whether the patterns varied by design, clinical or demographic features of the participants. To account for missing data, we used multiple imputations which created multiple datasets with missing values replaced by the generated imputed values. Our imputation was done via chained equations which generates predictions based on each conditional density of a variable given other variables.[62] Aim 1 and 3 were conducted using imputed data and the non-imputed original data was used for preliminary analysis of Aim 2. We describe the reason for choosing imputed vs. non-imputed data in detail below.

Table 2. Randomization Design

	Provider Training (PC)	
Patient Training(PA)	NO	YES
NO	**A** /Usual Care	**B** / Only PC
YES	**C** / Only PA	**D** / PA+PC

VI.C.3. Analysis, Specific Aim 1 (The Effect of DECIDE PA+PC on Shared Decision Making, Patient Activation, Patient's Perception of Care, Patient Activation): The first aim was to test whether the intervention (DECIDE-PC or DECIDE-PA) had an impact on three outcomes at RA2 and RA3: shared decision making, patient activation, and patient's perception of quality of their care. We first estimated a multilevel mixed-effects model that allows for random effects at the provider level. Thus, the hierarchical nature of the models accounted for the non-independence of patients seeing the same provider.[63] For example, let Y_{ij} denotes the RA2 blind coder SDM score for the j^{th} patient who was seen by the i^{th} provider. We estimated the model:

(1) $Y_{ij} = \beta_{0i} + \beta_1(\text{DECIDE-PA})_{ij} + \beta_2(\text{DECIDE-PC})_{ij} + \beta_3(\text{DECIDE-PA+PC})_{ij} + \beta_4 X_{ij\ k} + \varepsilon_{ij}$

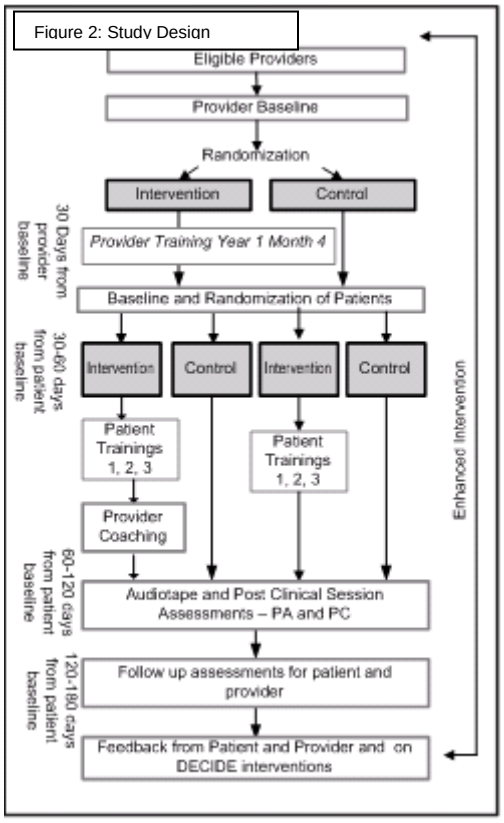
(2) The provider-specific random intercept can be written as: $\beta_{0i} = \alpha_{00} + \omega^*_{0i}$

where DECIDE-PA was assigned effect codes (-.5, +.5) with -.5 being assigned to patients in the control arm (Category A and B in Table 3) and +.5 being assigned to patients in the treatment arm (Category C and D in Table 3). Similarly, DECIDE-PC was effect coded as well where -.5 was assigned to providers in the control groups (Category A and C) and +.5 was assigned to providers in the intervention groups (Category B and D). DECIDE-PA+PC denotes the interaction term of the DECIDE-PA and DECIDE-PC. X_{ij} included baseline outcome measures to adjust for imbalance despite random assignment. The term ω^* denotes provider random effects and ε_{ij} is the individual error term. We ran sensitivity analyses allowing for random effects at the clinic level, but they suggested that random effects at clinic level are minimal, i.e., estimated to be close to zero.

Estimations of the model in (1) render the main effects of DECIDE-PA and PC intervention interpretable in the context of interactions. Effect-coded regressions allow us to estimate how much the intervention changed the outcomes across all patients that were affected by the intervention, i.e., the marginal effect of the DECIDE-PA intervention (β_1), and to estimate how much the intervention changed the outcomes across all provides that received the intervention, i.e., the marginal effect of the DECIDE-PC intervention(β_2). An interaction term (β_3) significantly different from zero would suggest additional synergy or anti synergy from the combined DECIDE PA+PC treatment over and above the patient-level intervention DECIDE-PA. We also run estimations of the model in (1) with the

intervention indicators coded as 0 and 1 (instead of -0.5 and 0.5) but we only report the results of the benchmark regressions as recommended by our consultants.

The primary analysis used intent-to-treat principles and assigned all subjects to their randomly determined category, regardless of whether or not they actually received treatment. For patients who didn't complete RA2 or RA3 assessment, we used imputation to project their RA2 and/or RA3 outcomes and accessed them according to the initial random assignment. Therefore, the intent-to-treat analysis used the imputed datasets to fit model in (1).



We ran a similar analysis using treatment dosage as the independent variable, where treatment dosage is defined as the number of coaching sessions that patients and/or providers received relative to the intended treatment (up to 3 for patients and up to 6 for providers). While this analysis no longer relies on random assignment, it may still serve as additional confirmation of the results of the intent-to-treat analysis and also provide us with further estimates of the magnitude of the effects.

As our primary SDM analysis, we assessed the effect of the intervention on SDM as measured by the blind coder (OPTION scale), a continuous-valued variable standardized to a scale between 0 and 100. As a secondary SDM analysis, we assessed patient- and provider-perceived SDM (SDM-Q-9) scores at RA2 and RA3 using the same model as in (1), controlling for the outcomes at RA1. Two separate models were estimated, one for patient SDM and one for provider SDM. We also adapted the model as in (1) to measure our additional primary outcome variables, patient perceived quality of health care (five continuous variables measured at RA2 and RA3). Further, we ran the same analyses for our secondary outcomes of patient activation (assessed by patient at RA2 and RA3; and by provider only at RA2) as well.

VI. C.4. Analysis, Specific Aim 2 (Understanding the Mechanisms by which Enhanced DECIDE Impacts Shared Decision Making and/or Patient Perceived Quality of Care): Aim 2 assessed the mediators for the intervention effects identified in Aim 1. To address not only whether an intervention works but also how it works, we examine as potential mediators: 1) patient-centered communication (KAS) using both audio recordings and patient interview data; 2) therapeutic alliance (WAI) (i.e. the degree to which the patient and provider were "engaged in collaborative, purposive work");[64] and 3) DECIDE-PA outcomes, i.e., patient activation (PAS) and self-engagement; perceived efficacy in patient-physician interactions (PEPPI).

VI.C.5. Mediation Analysis: The mediation analysis plan built on the analysis described for Aim 1 with the addition of the mediator of interest as a key independent variable. We assessed the impact of the DECIDE-PA and PC intervention on the hypothesized mediators, and then estimated the direct effect of the intervention after adjusting for the mediators. These two analyses allowed the indirect path to be estimated and tested using bootstrap methods or the Sobel test.[65, 66] Our bootstrap methods allow for clustering at the provider level and the clinic level. We implemented two different types of models: either a so-called 1-1-1 multi-level mediation model, in which the dependent variable, the independent variable, and the mediator are all at the patient level (level 1); and a 2-1-1 multi-level mediation model in which the independent variable is at the provider level (level 2). We used the non-imputed data for the preliminary analysis of Aim 2 to circumvent computational constraints imposed by the compound simulation of bootstrap samples and imputed samples. Moreover, we used a preliminary analysis of the a-path, i.e., the relationship between the intervention and the mediator, to screen possible mediators. In other words, only mediators affected by interventions can mediate intervention effects, thus, this analysis helps us to narrow the set of potential mediators. Finally, we tested for mediation effect only for candidates suggested by A-path analysis on the intervention effect identified in Aim 1.

In a causal mediation framework, the identification of mediators is predicated on an unambiguous ordering of the treatment, mediator and outcome variables.[67] Having three time periods allowed for an appropriate ordering for the patient- and provider-perceived SDM-Q-9 measure (i.e., randomization→RA2 communication→ RA3 perceived SDM). We used assessments of the mediator variables at either RA2 or RA3, depending on the timing of the assessment of the outcome variable. If the outcome variable was assessed at RA 2, we only use concurrent mediator variables, i.e., those assessed at RA 2. If the outcome variable was instead assessed at RA 3, we use both concurrent mediators, i.e., those assessed at RA3, and past mediators, i.e., those assessed at RA 2.

We recognize the potential bias of concurrent measurement of the mediator and outcome. A possible prospective analysis would minimize this bias using adjustment methods proposed by Shrout et al.[68] that account for the information already available in the *baseline* association between the mediator (i.e., communication) and outcome (perceived SDM). Considering the baseline mediator (measured at RA1) to be an instrumental variable that has an impact on SDM only through its connection with the RA2 mediator, we could identify a residual correlation between the mediator and the outcome variable. Furthermore, we could incorporate the association between the DECIDE intervention and the mechanisms of interest (communication, therapeutic alliance, perceived self-efficacy in patient-provider interactions, etc.) as well as the association between the mechanism and the outcomes, conditional on other covariates. This test of mediation improves upon tests typically conducted[69] in that it uses models with a full set of covariates, so models are not prone to omitted variable bias.[70]

VI.C.6. Analyses, Specific Aim 3 (Understanding the Moderating Effects of Racial/Ethnic and Linguistic Discordance on the Impact of DECIDE on Shared Decision Making and/or Patient Perceived Quality of Care): In Aim 3, we explored whether patient/provider racial/ethnic or linguistic discordance moderated the effect of the DECIDE PA and/or PC intervention. We hypothesized that the intervention effect would be greater among discordant dyads because there would be more potential to break down communication and decision-making barriers. Built upon the model described in Aim 1, regression models of Aim 3 included the main effects of patient and provider racial/ethnic groups (and in separate analyses, language groups) and additional interaction terms: (Discordant × DECIDE-PA), (Discordant × DECIDE-PC), (Discordant × DECIDE-PA × DECIDE-PC). The DECIDE PA and PC effect as well as racial/ethnic (and linguistic) discordant indicators were assigned effect codes (-.5, +.5) to render their main effects interpretable in the context of interactions. We acknowledged major differences existed across sub-ethnicity, language, and culture within the broad ethnic/racial categories of Latino, Black, Asian, and non-Latino White. However, the relatively small sample of the DECIDE PA and DECIDE-PC only allowed us to assess the differences in racial/ethnic groups or language groups rather than more specific differences.

The outcome variables of interest are likely to have a non-linear relationship with the independent variables in regression models. In the case of non-linear models, interaction coefficients do not represent the marginal effect of the interaction term.[69] Thus, a possible sensitivity analysis would use a predictive margins approach which applies the model coefficients from the model to subsequent *counterfactual* populations (i.e., DECIDE-PA with concordant dyads, DECIDE-PA with discordant dyads, DECIDE-PC with concordant dyads, DECIDE-PC with discordant dyads, etc.). This technique, named *standardized predictions*[62, 70] or *predictive margins*,[71] has been used in previous health services studies[72-74] and would allow us to compare the effect of the intervention among discordant and concordant dyads, after standardization of all other variables.

VII. Risks and Discomforts

VII.A.1. Complications of Procedures: We did not foresee any potential complications to occur with this intervention.

VII. A.2. Psychosocial (non-medical) Risks to Providers: There were no expected serious risks to the provider participants. Minimal risks included potential loss of confidentiality as in all research. We did everything we could to keep all data we collected confidential. We told provider participants that they may experience some discomfort from having sessions be audio recorded and from receiving feedback of their audio recordings or from receiving feedback in emotion recognition exercises. All provider participants were reminded that their participation was always voluntary and that they could decline continued participation at any time.

VII.A.3. Psychosocial (non-medical) Risks to Patient Participants: Minimal risks included potential loss of confidentiality as in all research. The DECIDE intervention has been tested in pilot and multi-site randomized

controlled settings with no adverse patient reactions. There was some possibility of patient participant discomfort when discussing behavioral health problems and treatments in the course of the assessments and trainings. Patient participants enrolled in the control and intervention arm of the study were asked to disclose information about their appointments and their interaction with their providers, which may have made them uncomfortable or anxious. The informed consent form explicitly stated that patient participation was voluntary and that patients could skip or refuse to answer any items in the assessments. They could stop participation in the study at any point.

VII.A.4. Psychosocial (non-medical) Risks to Community Forum and Focus Group Participants: Minimal risks included potential loss of confidentiality as in all research.

VIII. Potential Benefits

VIII.A.1. Potential Benefits for Providers: The DECIDE PC was designed to help providers improve therapeutic alliance, patient-provider communication, continuance in care, and satisfaction with services for patients in concordant and discordant ethnic/racial dyads in order to improve SDM. The DECIDE PC training for providers consisted of 1.5 days of training which focused on augmenting patient-centered communication and therapeutic alliance as a possible underlying pathway by which SDM could take place. The training also addressed 1) lack of perspective taking; 2) frequent attributional errors that providers make; and 3) decreased receptivity to patient participation and collaboration in decision making. The training included provider coaching totaling 15-20 hours. Providers learned about their own clinical skills and how to enhance them.

VIII.A.2 Potential Benefits for Patients: Patients who received the DECIDE-PA may have received a better quality of care from their mental health providers. Patients may have found it useful to learn new ways to talk with their health provider about their treatment and that may have improved their overall care. Patients who did not receive the DECIDE-PA intervention might have benefitted from improved communication or involvement with their provider, if the provider was part of the DECIDE-PC intervention.

VIII.B. Potential benefits to society: This study also filled a gap for scientifically rigorous research in clinics that ethnic/racial populations depend on to receive mental health care services.[75] Research shows that minority patients do not have equal access to high quality care.[16, 17] Administrators and providers are often eager to implement interventions but first need strong evidence of improved quality or outcomes in resource-constrained safety net environments.[18] The collaborative engagement of patients, clinicians, and administrators helped ensure that DECIDE PA+PC were relevant and met their needs. Further, the study was designed to triangulate data from multiple perspectives (i.e., patient, clinician, and independent observer) to allow for better measurement of SDM and other outcomes.

Ensuring quality in behavioral health treatments is a critically important goal, especially so for racial/ethnic minorities given that they receive less behavioral health care[76] and experience more severe consequences from behavioral health disorders than non-Latino Whites.[77-80] Yet, quality behavioral health care is contingent upon effective communication and strong therapeutic alliance.[81, 82] The DECIDE intervention had the potential to impact quality given the centrality of tailoring behavioral provider practices to respond to patient preferences and concerns[83] and its strong correlation with perceived quality of care.[84] By improving patient-centered communication and forming a strong therapeutic bond, DECIDE could have helped overcome cultural and social differences across patients and providers allowing for quality care that reduces disparities in service delivery.[10, 85, 86]

IX. Monitoring and Quality Assurance

IX.A. Data Collection: To improve the security of data collection, we used Dimagi software's secure server to collect data via CommCare HQ technology. This was installed in a series of secure tablets through which research assessments were collected. Dimagi utilizes a HIPAA compliant, secure, encrypted server that allows for host intrusion and intrusion monitoring system. All technology can only be accessed through secure and password servers. The CommCareHQ application was installed on tablets and these tablets were made available to research assistants serving as interviewers on the PCORI study. Our research assistants had already undergone training by Dimagi. All data transfers to and from the Dimagi server were conducted over industry standard transmission encryption (HTTPS). All access to the cloud infrastructure was protected behind a firewall and required unique VPN access permissions. All data was transferred through channels that are monitored by intrusion monitoring system.

IX.B.1. Safety Monitoring: Privacy and Confidentiality: All documents that include PHI were coded so that identifiers (i.e., names, addresses, and telephone numbers) were removed and separated from the research assessments and completed training materials. Research data and notes from participant observations were stored by research staff in a locked file at each of the study sites and the study data was coded. All materials were securely transported from study sites to the central DRU site at MGH, where they continued to be kept under lock and key. Notes and data were uploaded from project laptops to a secure, password protected network maintained by MGH, for transcription and analysis. In addition to paper forms, assessment data was also collected via Dimagi CommCare HQ. All audio-recorded in-depth interviews were also uploaded immediately to the same secure, password protected server maintained at the MGH. No reports were made public using any names or identifying information. Our coded dataset was stored on a secure central server. Only authorized research staff approved by the site Institutional Review Boards had access to the data.

PHI will be destroyed according to standard protocols, 7 years after the completion of the study. Patients were told they could withdraw from the study at any point. Information that had been collected up to that point continued to be used unless specified by the patient.

Consent forms were kept at each of the recruitment sites under lock and key as was approved.

IX.B.2. Safety Monitoring, Ensuring the Safety of Subjects

Provider participants: Provider participation was voluntary and information they provided to study staff throughout the course of the study remains confidential. Providers were assured that none of their study data was reported to the Site PI or their supervisor. They could have elected to withdraw from the study at any time.

Patient participants: Patients were informed in advance that their responses to a suicidality screener may have required contact with a provider to maintain their safety. This situation was taken very seriously and followed the emergency protocol developed. Patients were also given contact information for the PI and project coordinator to whom they could directly report any concerns or questions about their study participation.

Community Forum and Focus Group participants: There were no serious risks to the participants as a result of these forums and groups. There was always at least some risk of loss of confidentiality associated with participating in a community forum or focus group. To help mitigate this risk, we set out as a ground rule of participation that participants kept confidential the views expressed by their fellow participants and that they did not disclose any information to anyone outside of the focus group

IX.B.3. Monitoring Plans for Quality Assurance

All research team members followed the procedures of confidentiality adhered to by collaborating institutions. Further, all research staff who worked on this project were required to complete training in data confidentiality and security issues and sign a confidentiality agreement prior to working with patients or handling identifying information. The Community Advisory Board (CAB) of this study and all of the Site PIs worked with the DRU's research team to ensure that the study was monitored from a scientific and ethical standpoint and we held yearly meetings to assess data collection and management.

We provided required research materials, documents and technology, such as audio recorders, to facilitate this work. The CMs and RAs were granted remote access to the MGH server, to be able to upload recordings, tracking materials and other information. This information was monitored through quality control checks by the MGH team. Study staff provided regular supervision and oversight to CMs and RAs. Focus groups were also recorded for quality assurance and transcription purposes.

IX.C. Outcomes Monitoring

The study staff at DRU worked closely with the Site PI, Care Manager (CM) and Research Assistant (RA) at each participating clinic in the set up and ongoing implementation of the study. We provided required research materials, documents and technology, such as audio recorders, to facilitate this work. The CM and RA were granted remote access to the MGH server, to be able to upload recordings, tracking materials and other information. This

information was monitored through quality control checks by the MGH team. Study staff provided regular supervision and oversight to CMs and RAs.

Fidelity checks were performed on at least 20% of all DECIDE-PA sessions to ensure interventions were delivered accurately and fully. These were also rated in a series of markers for each intervention. We worked to make sure each CM was delivering the intervention at the highest standards. These checks were performed by adherence checkers who were familiar with the intervention and who had adequate clinical background to provide feedback to CMs.

Quality control checks were performed on 15% of all assessments to ensure that the assessments were conducted fully and that the data had been entered correctly. Each paper assessment performed was individually checked to ensure it was entered correctly. Each questionnaire performed using the Dimagi technology was also hand-verified. Each RA was also required to do weekly checks to ensure all consent forms and patient data was saved securely.

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