Cover Page

Protocol (Including Statistical Analysis Plan)

Study Title: Goal Elicitation, Treatment Prioritization, & Electronically-Practiced Discussion – Pilot Study (Aims 2 and 3)

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1.0 Background and Significance

The importance of Shared Decision-Making (SDM) in Mental Health

Community mental health providers frequently struggle to integrate patient-centered,† recovery-oriented care with effective psychiatric medication management for people with severe mental illness (SMI). Indeed, despite long-standing efforts to implement patient-centered care, people with SMI are frequently not active participants in treatment decision-making, particularly with regard to psychiatric treatment decisions[1,2] – this is often due to a mismatch between treatment recommendations and "personal medicines" (individual strategies that people find important for their own recovery).[3] Effective illness management involves complex decision-making and requires a partnership between two experts, the patient and the provider.[4] When SDM takes place, patients and providers share information, express preferences, discuss uncertainties (e.g., pros/cons of options, risks), and ultimately agree on a plan.[5] SDM is vital to patient-centered care – fostering autonomy and efficacy in managing health – because it is ultimately the patients who live with the consequences of treatment.[5-7] Moreover, SDM has been associated with positive outcomes in adults with SMI, including higher quality patient-provider interactions, better coping, and higher treatment adherence.[4,8]

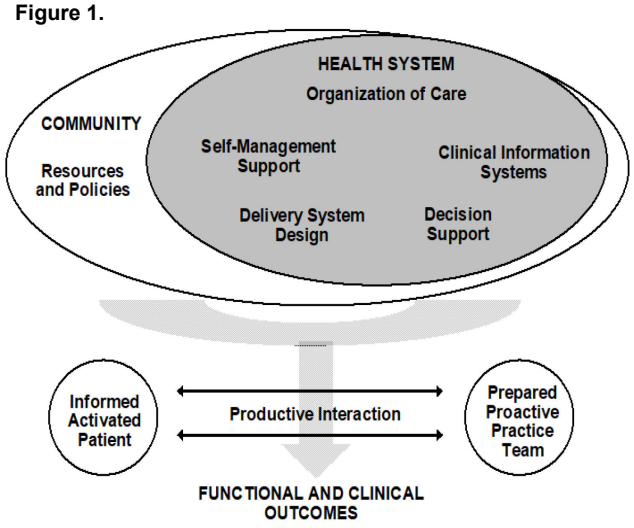
This concept of SDM is now widely recognized as an indicator of high-quality healthcare,[9] with increasing emphasis in mental health settings.[4,6,10,11] Most patients, including those with SMI, desire a role in treatment decisions,[12] and SDM is especially relevant for people who have persistent symptoms, for which preferred treatments vary widely. Unfortunately, SDM is still relatively uncommon in community mental health,[13] and few studies have evaluated approaches specifically designed to increase SDM in these settings. In addition, several barriers have been identified that impede widespread use of SDM for adults with SMI, including provider concerns of time constraints or applicability for some patients, and confusion around roles and responsibilities.[14,15] Patients might not be prepared to interact actively with providers or be aware of multiple options for managing illness. Given these barriers to SDM, approaches are needed to promote active patient involvement and reciprocal exchange of information and preferences that facilitate recovery outcomes.

† We recognize that the mental health field uses a wide variety of terms to refer to people who are using treatment services (e.g., patient, consumer, client, service-user, survivor). Here we use the term "patient" to be consistent with the broader medical field and with the concepts of patient activation and patient-centered care. We use the term "provider" to describe professional health care providers.

Conceptual Framework for Activating Patients for Shared Decision-Making

The Chronic Care Model (CCM) and Self-Regulation Theory provide the theoretical foundation for our intervention: GET PrEPD-Psychiatry. The CCM (Fig 1) emphasizes productive interactions between patients and providers within the larger context of the health system and community.[16,17] Of particular relevance is the model's notion of collaborative management, which takes place when patients and providers have a productive working relationship, well-articulated goals, and shared understanding of their roles.[18] Under a model of collaborative care, patients and providers work together, through sharing information and decisions, to find optimal treatments.[17] This requires an "activated patient," who takes initiative to ask questions and give information to providers that reflect the patient's priorities in seeking care, and who is an equal partner with his/her provider.[17,19,20] The CCM's emphasis on patients' roles in collaborative management is supported by studies showing that patient activation is critical for effective participation in care, including decision-making.[21-23] Self-Regulation Theory[24,25] informs the central focus of GET PrEPD-Psychiatry on goals, because clarifying, prioritizing, and articulating goals are critical for treatment decision-making. According to Self-Regulation Theory, people organize their lives around the pursuit of personally meaningful goals, which are arranged hierarchically, such that specific goals (e.g., reduce voices, improve mood) serve to achieve broader goals (e.g., be a better parent, go back to college). However, goals can conflict with one another, and patients may confuse levels of abstraction, focusing on higher-order goals without first addressing more specific goals.[26,27] GET PrEPD-Psychiatry will help patients organize, understand, prioritize, and ultimately articulate these goals to providers.

Figure 1.



Interventions to Improve Shared Decision-Making in Mental Health

Decision support systems. Few interventions have been designed specifically to address SDM in people with SMI. Perhaps the most comprehensive is CommonGround, which incorporates a variety of strategies, including education and self-management materials, computer technology, decision-aids, peer support and coaching in how to make decisions, and training for service users as well as providers (both prescribing and supporting, e.g., peer providers, case managers).[28,29] Computer kiosks located in a designated decision support center (e.g., room ideally near the meetings with providers) use self-guided discovery modules designed to help individuals learn about recovery and identify strategies to reach recovery goals. Goals take the form of "power statements," succinctly worded to contextualize medication management preferences in line with personal recovery goals. In addition, CommonGround emphasizes "personal medicines,"[3] which are self-identified strategies that provide meaning and help patients stay well, in addition to or instead of prescribed medication. Prior to a psychiatric visit, patients complete a one-page health report that integrates power statements and personal medicines with current symptoms and concerns to share with the prescriber. Trained peers facilitate use of the CommonGround software, and additional recovery tools (e.g., videos, worksheets) are available for patients and providers. Entire treatment teams are trained using the system.

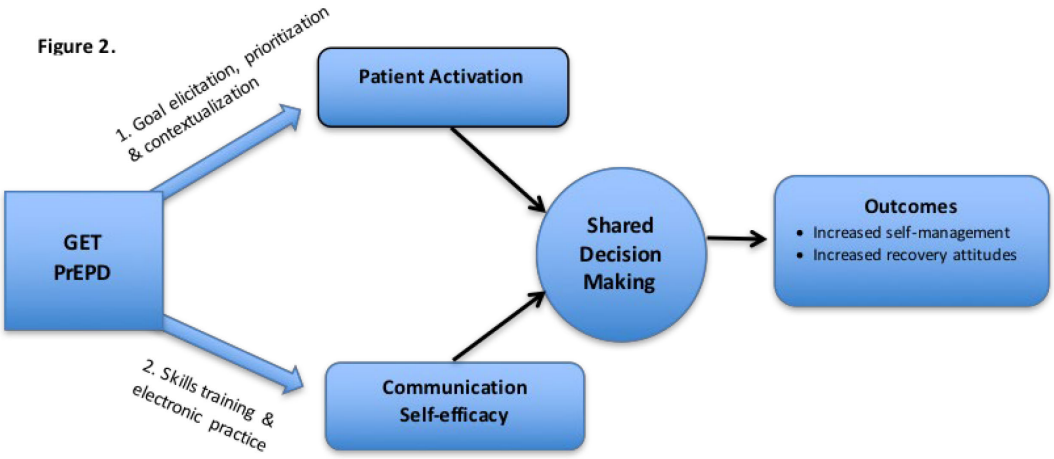
CommonGround has received awards for innovation,[30] and initial pilot work suggested improved communication and a greater emphasis on recovery-oriented goals.[28] Three subsequent evaluations reported varied findings, depending on the outcomes assessed. MacDonald-Wilson and colleagues [31] implemented CommonGround across a large healthcare system and found significantly improved symptoms and functioning and fewer concerns about medication side effects. CommonGround was not associated with changes in medication use.[32] Members of our own research team received NIMH funding (R34MH093563; Salyers PI) to test CommonGround in four community mental health teams. In an uncontrolled, pre-post evaluation, we found improved self-reported symptoms and recovery attitudes, and patients were rated by providers as being more involved over time.[33] However, we encountered a number of barriers in implementation. Few patients used the system consistently. For example, only 22% completed more than three health reports over approximately 18

months,[33] and teams varied greatly in their use of the system, with more frequent use observed among teams that had high investment from the prescribing provider and team leader.[34] Key informants and fidelity reports indicated a number of barriers, including technological difficulties and increased staff burden, as well as contextual barriers, including a poor perceived fit with service structure, inconvenient decision support center location, low staff investment, and high turnover.[34] With taxed resources and strains on providers,[35,36] these types of system requirements can be difficult for organizations to overcome, requiring a high level of leadership commitment, mobilization of resources, and culture change throughout an organization. In fact, although key informants in our study praised qualities of CommonGround, the organization discontinued the program due to significant financial constraints involved with ongoing training and subscription costs. One alternative to CommonGround that also seeks to improve SDM in mental health is to provide more targeted coaching for patients.

Coaching interventions. Early studies in the medical field showed that relatively brief interventions to activate patients, such as a 20-minute coaching session just prior to a medical visit, could have lasting health benefits.[37] Brief, pre-visit interventions have also been applied in the mental health field, but with mixed results. For example, Hamann and colleagues tested "question prompt sheets" for 100 outpatients with depression.[38] Just prior to a visit with the psychiatrist, half the participants were randomly assigned to complete a worksheet describing what they wanted to get out of the session and to identify questions for their provider. Compared to treatment as usual, the prompt sheets were not effective in changing patient behavior during a consultation. In contrast, Alegría and colleagues[40,41] developed a more active coaching intervention for mental health care. The DECIDE approach incorporates three individual coaching sessions with cognitive-behavioral strategies (e.g., role play, homework) to prepare participants for visits with providers and empower them to take a more active role in care. Coaches also discuss cultural issues that might impede taking a more active role. The initial evaluation was promising, showing improved self-reported activation and greater retention and attendance in subsequent services.[40] The intervention was later tested in a more rigorous, multisite RCT with a diverse sample.[41] Compared to patients who received a mental health brochure, those randomized to DECIDE had significantly improved activation and self-management; however, effects were not seen for retention and attendance in services for the 6-month period after the intervention. The trial did not report effects on SDM.

Hamann and colleagues[42] pilot tested a coaching intervention that directly targeted SDM for inpatients with schizophrenia. Their approach involved five, 1-hour group sessions to teach motivational and behavioral aspects of being involved in treatment decisions, including role-playing and encouraging peer support. Compared to controls, patients in the training group reported greater preference for involvement in and responsibility for decisions, after treatment and 6 months later, but no changes in decision self-efficacy. In addition, those in the training group reported less trust in providers, and providers rated relationships with these patients as more difficult. Thus, there may be unintended consequences to the patient-provider relationship with coaching alone. In addition, this intervention did not explicitly report patient goal setting and prioritization as a key element, which are critical pre-cursors to effective SDM.

GET PrEPD (Goal Elicitation, Treatment Prioritization, & Electronically-Practiced Discussion)
GET PrEPD incorporates several strengths of the above SDM interventions and is designed to increase *patient activation* and *communication self-efficacy* (See Fig 2). As detailed below, this is accomplished by working with patients to (1) elicit and discuss their goals, priorities, and preferences; (2) develop skills, particularly agenda setting and question asking, to communicate these goals, priorities, and preferences with providers; and (3) practice these skills in an interactive format with Virtual Providers. The intervention was initially developed for use in chronic pain patients (see Section C1 below). Given similar needs for helping patients with SMI be more active and develop skills to effectively participate in SDM, we believe GET PrEPD can also be applied to this population. However, we needed to modify the content of the coaching sessions to be specific to people with SMI and program the Virtual Provider to be specific to areas of concern expressed in psychiatric visits. Based



on the Chronic Care Model (CCM) and Self-Regulation Theory described above, we have identified specific targets through which the modified intervention ("GET PrEPD-Psychiatry") can lead to better outcomes. In the following sub-sections (and Table 1), we describe the two targets and how GET PrEPD-Psychiatry addresses them. We also detail the unique features of GET PrEPD-Psychiatry, contrast it with other SDM approaches, and describe how these unique features increase GET PrEPD-Psychiatry's likely effectiveness on a broad scale.

Target I: Patient Activation. Patient activation refers to having the knowledge, skills, and confidence to manage one's health, and is an important precursor to SDM.[43-45] GET PrEPD-Psychiatry will increase patient activation by (1) eliciting and helping patients to prioritize their treatment goals, (2) eliciting patients' treatment preferences and rationale for those preferences, (3) connecting treatment goals to patients' life goals and values, and (4) connecting treatment goals to other important people in patients' lives. The coach begins by eliciting and discussing patients' treatment goals, priorities, and preferences. This exploration is akin to identifying personal medicines in CommonGround and allows patients to actively consider which goals are most important to them, which treatments they prefer in pursuing those goals, and their reasons for these priorities and preferences. This self-awareness is a critical first step toward patient activation, as this helps to increase patient knowledge of their condition, which is essential for SDM.[21,23,46] During the next session, the coach helps patients elaborate and clarify treatment goals, priorities, and preferences by asking how psychiatric treatment fits into patients' broader life contexts, particularly personal values and connections to family and friends. That is, GET PrEPD-Psychiatry will help patients clarify *why* their goals and preferences matter, thereby fostering motivation and engagement in actively managing their condition. **Importantly, through goal clarification, GET PrEPD-Psychiatry is sensitive to individual differences, which is critical for people with SMI who may have similar needs as a population, yet are individuals who should not be treated as a homogenous group. This helps ensure personalized treatment.**

Table 1. Targets of Goal Elicitation, Treatment Prioritization, & Electronically-Practiced Discussion (GET PrEPD-Psychiatry) Intervention

Target 1: Patient Activation	Target 2: Communication Self-Efficacy
Elicit Patient Treatment Goals	Agenda Setting
Prioritize Treatment Goals	Stating Treatment Goals & Preferences
Elicit Patient Treatment Preferences	Handling Interruptions
Discuss Rationale for Preferences	Asking Specific Questions
Connect Treatment Goals to Patient Life Goals & Values	Communicating Goal Context to Provider
Connect Treatment Goals to Important People in Patient's Life	Discussing Pros & Cons of Treatment Options with Provider

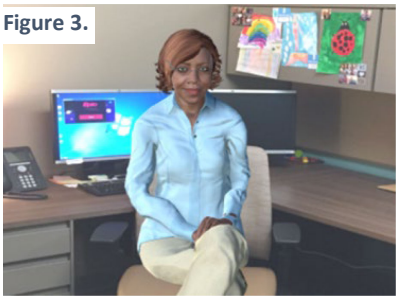
GET PrEPD-Psychiatry will help patients formulate and practice asking questions. This will increase patient activation by ensuring the unique information needs of patients are met during the visit. Indeed, information seeking is a fundamental skill in effective patient-provider communication.[47] As described above, similar goal setting and coaching takes place in Alegría's DECIDE intervention, which was shown to increase patient activation in people with mental illness.[41] GET PrEPD-Psychiatry will re-assess patient goals, priorities, and preferences across sessions in recognition of the dynamic nature of patients' lived experiences and mental health treatment. This will enhance patient activation by giving them the opportunity to re-evaluate how a decided-upon treatment approach is working.

Target II: Communication Self-Efficacy. Communication self-efficacy refers to patients' confidence interacting with providers and is critical for participation in SDM, as patients must be able to communicate goals and preferences to providers to reach a mutually agreeable decision.[5,48] GET PrEPD-Psychiatry will increase communication self-efficacy by allowing patients to practice newly learned skills with a Virtual Provider in a non-threatening, individualized format, thereby facilitating increased confidence as practice progresses. During each session, the coach introduces patients to specific skills necessary for effective communication with providers (e.g., agenda setting). The coach then models and role-plays the skills with patients. Finally, patients are encouraged to practice the skills with the Virtual Provider program, allowing for multiple, tailored practice sessions. The practice with the Virtual Provider program is a key element of GET PrEPD-Psychiatry and unique from other interventions.

GET PrEPD-Psychiatry focuses on 4 communication skills: (1) agenda setting, (2) asking questions, (3) communicating goal context, and (4) discussing pros/cons of treatment options. Agenda setting skills help patients ensure their central goals, priorities, and preferences are discussed in the visit.[49,50] Helping patients to formulate effective questions and engage providers in instructive dialogue about their concerns enables them to obtain tailored information and creates an atmosphere conducive to SDM.[51] For example, by developing skills to communicate how treatment goals fit into their broader life context, patients are better equipped to elicit understanding and empathy from providers. Developing discussion skills (e.g., pros/cons) prepares patients to "hold their own" when negotiating treatment with providers and, ultimately, to make an informed, collaborative decision.[52]

Skills Practice. Although interventions to enhance patient activation and communication exist in mental health,[41,42] GET PrEPD-Psychiatry is innovative by allowing individualized, repeated practice of skills using the Virtual Human system. Patients practice these skills by interacting with 3D animated Virtual Providers who display gestural and facial expressions that are triggered by patients' questions/statements (see Fig 3 for sample). To personalize the practice sessions, patients can select the gender and race of the Virtual Provider. Patients interact with Virtual Providers by selecting questions/statements from a menu (with the option of using a typed interface only in the "Questions about my treatment" category). Providing pre-populated choices is easier for users, especially patients with lower health literacy and who are less technologically-savvy, particularly during early stages of skill acquisition. Provider responses are transmitted with on-screen text, pre-recorded audio, and animations (non-verbal behavior). The system maintains a log of practice frequency/duration, which topics were selected and in what order for each patient (using assigned Research IDs), which allows for monitoring of progress (and subsequent troubleshooting during individual coaching sessions) and examining the relationship between amount of skills practice and our outcome measures. The system will also maintain a log of which Virtual Provider was chosen, if the Welcome Video was viewed, and the number of times the Help and Go Back to Main Page buttons were selected.

Figure 3.



Impact on Science, Practice, and the Field

This R34 is the next logical step in a program of research to help activate people with SMI to be more involved in treatment decisions as a critical part of self-management and recovery. The GET PrEPD-Psychiatry intervention builds on strengths of prior promising SDM interventions, while aiming to overcome key barriers of those approaches. The proposed project will result in a technologically advanced, ecologically-valid, and highly scalable approach to activating patients and enhancing their communication skills for participation in SDM. This project will also increase scientific knowledge by establishing feasibility and acceptability of this approach in community mental health settings. Importantly, we will also be examining proximal targets for the intervention – patient activation and communication self-efficacy – that can lead to better SDM, and ultimately to better recovery outcomes. These are critical steps before GET PrEPD-Psychiatry can be rigorously tested in a large, multi-site clinical trial. Ultimately, successful completion of our work will yield an innovative and scalable approach to addressing a critical issue for mental health services.

We have created a Virtual Provider program (described above in *Skills Practice*) to be specific to psychiatric decision-making. The interactive practice sessions will consist of real-time, dynamic communication with a Virtual Provider, with a particular emphasis on practicing skills in agenda-setting and question-asking, and articulating goals, priorities, and treatment preferences. This innovative program allows us to create practice scenarios consistent with effective learning principles, thus maximizing participants' mastery of skills. Prior patient-focused SDM interventions included minimal skills practice – typically simple role-playing with a coach during training sessions.[41,42] By contrast, learning research and theory indicate that to master new skills, practice must be (a) frequent and (b) tailored to the individual's learning needs/preferences, and (c) the practice environment must approximate the context in which the skills will be employed.[67-70,73] As detailed above, our intervention allows patients to access the online platform to practice as often as they like, separate from coaching sessions; and, will use high-fidelity computer simulations based on conversations from real psychiatry visits to better approximate an actual clinical context. Moreover, the intervention is efficient, targeting patients with 4 coaching sessions and online, self-directed practice. Our system is innovative, consistent with best learning practices, and allows for widespread dissemination if GET PrEPD-Psychiatry is effective.

Preliminary Studies

Our team has an extensive history of grant-funded, published research that directly informs this proposal. The investigators bring complementary expertise: patient activation and SDM for people with SMI (Salyers) and Virtual Human Technology and developing GET PrEPD for people with chronic pain (Hirsh). Other investigators bring additional expertise in communication self-efficacy, SDM, Virtual Providers, and goal-setting.

Patient Activation, Communication Self-Efficacy, and Shared Decision-Making. Dr. Salyers has a long history of research focused on helping people with SMI better manage illness and achieve personal recovery goals. Her early work focused on Illness Management and Recovery (IMR), a curriculum based program incorporating evidence-based practices to help patients learn self-management skills.[74] She has completed several studies of IMR, including a VA-funded RCT[75] and federally-funded implementation studies.[74,76-78] The VA-funded RCT included a sister study, also funded by VA (*Mechanisms of Patient Activation and Self-Management in Schizophrenia, VA HSR&D: IIR 08-324-1*), where she partnered with Dr. Matthias to better understand the concept and correlates of patient activation in people with SMI through narratives of recovery from illness.[79,80] Drs. Salyers and Matthias also collaborated in observing how patients might be active in discussions with their treatment providers.[81] Through her work in self-management training, Dr. Salyers recognized that although the IMR program helped patients identify recovery goals and learn important self-management skills, IMR did not directly address how to work with treatment providers more effectively. This led to her work in SDM, first to better understand how to measure it, and then implementing programs to improve SDM for people with SMI. Drs. Salyers, Matthias, and Fukui adapted a coding system to measure observed SDM in psychiatric visits,[23,45,80,82,83] which we will be using in the proposed study to determine the impact of GET PrEPD-Psychiatry on actual decision-making in sessions with providers. As described above, Dr. Salyers recently led a team, including Dr. Fukui, to implement and evaluate CommonGround.[33,34] We successfully recruited and followed 167 patients (and their providers) at Eskenazi (formerly) Midtown Community Mental Health Center (now, Sandra Eskenazi Mental Health Center), our partner agency in the proposed GET PrEPD-Psychiatry study. In addition, we audio recorded visits between participants and their prescribing providers at baseline and at 12- and 18-month follow-ups. We used the transcripts from these observations to adapt the Virtual Providers in Aim 1, and attempted to use the same procedures of audio recording sessions to gather data for Aim 3. Ultimately, the challenges we experienced in implementing CommonGround led us to conclude that the unique aspects of GET PrEPD-Psychiatry are necessary for effective change in patients' participation in SDM. That is, we aim to build on some of the strengths of CommonGround (i.e., goal setting and prioritization, coaching), while finding an effective and less resource-intensive way to engage patients more actively with treatment providers. GET PrEPD-Psychiatry holds the promise of fulfilling these aims.

Virtual Human Technology. A key innovation of GET PrEPD-Psychiatry – that will maximize its effectiveness and scalability – is the practice of skills with a Virtual Provider program. Dr. Hirsh at IUPUI and Dr. Lok at the

University of Florida have been leaders in research on Virtual Human technology and pain. They have leveraged this methodology for its enhanced experimental control (allowing rigorous hypothesis testing) and realism (approximating real-world situations) to improve pain care for vulnerable populations, including low-income and Black patients. Their grant-funded work has soundly established the reliability, validity, and feasibility of using Virtual Human technology to study decision-making, patient-provider communication, and disparities in pain care.[53-63,65,66,84-86] Of particular relevance to GET PrEPD-Psychiatry, Dr. Hirsh's current NIMHD-funded R01 uses the Virtual Human platform to facilitate real-time, dynamic communication between physician subjects and virtual patients with pain. This physician-virtual patient interaction is part of an RCT testing an intervention to enhance physician perspective-taking and reduce treatment disparities for low-income minority patients. Over 80 physicians have completed the intervention arm of the trial (>85% completion rate) using the Virtual Human interaction system, and the results provide strong evidence of the system's success in terms of conversational accuracy and subject engagement. Our team has also created Virtual Providers for communication training. In an NSF-funded project, we used Virtual Providers to train operating room staff on best communication practices for drug administration and patient safety.[87] Our other studies have found that people resolve conflicts similarly with Virtual Providers as with human providers[88] and that Virtual Providers can influence participants to use evidence-based teamwork protocols for patient safety.[89,90] Moreover, participants described the Virtual Provider interactions as highly realistic and stated that the learning opportunities were valuable. The empirical work highlighted above is supported by earlier studies demonstrating high correlations between Virtual Human communication and communication with real humans.[91,92]

Goal Setting and Prioritization. Complementing our expertise in activation, communication, and SDM, our team has conducted research related to patients' symptom priorities and treatment goals for people with a variety of chronic conditions. As noted above, Dr. Salyers' work with IMR incorporates goal setting as an important part of self-management. Drs. Hirsh, Matthias, and Rand collaborated on grant-funded (Walther Cancer Foundation, Indiana University), mixed-methods studies examining symptom and treatment priorities of cancer patients. They observed large individual differences in patient perspectives on the symptoms that are most important to prioritize, the criteria by which patients judge treatment effectiveness, and how symptom and treatment priorities are related to their broader values and goals[93,94] – these results underscore the need for patient-centered interventions tailored to individual goals and priorities. This work complements a recent pilot study conducted by Drs. Hirsh and Rand (funded by Indiana University) using a similar goal elicitation and clarification method in chronic pain patients receiving care at Eskenazi Health, as well as earlier studies by Dr. Hirsh on chronic pain patients' symptom and treatment priorities, treatment engagement, and satisfaction with care.[95-98] Based on this and other grant-funded (American Cancer Society) work by Dr. Rand,[99-101] our team has developed a reliable method for eliciting patients' treatment goals, clarifying these goals in the broader context of patients' lives, and determining the subjective importance of the treatment goals to patients. This method serves as the basis for GET PrEPD-Psychiatry.

2.0 Research Design Overview

GET PrEPD-Psychiatry is a mixed-methods, developmental study to adapt an SDM intervention to be specific for psychiatry decisions (Aim 1, IRB #1807699331), evaluate its feasibility and acceptability (Aim 2), and examine potential mechanisms of change and preliminary outcomes (Aim 3) of this innovative intervention to increase SDM and self-management for adults with SMI. In line with NIMH priorities, we are examining whether GET PrEPD-Psychiatry engages the target mechanisms that putatively underlie the intervention (i.e., patient activation and communication self-efficacy; Aim 3). For Aim 1, we used approximately 200 transcripts from our prior study of SDM in psychiatry to cull language used in decision-making. These conversations were used to program the Virtual Provider to represent common interactions and decisions in psychiatric visits. We iteratively tested the use of the Virtual Provider program with patients and obtained feedback from our psychiatry consultants to refine the program. For Aim 2, we will recruit up to 40 patients to participate in GET PrEPD-Psychiatry (4 approximately weekly goal setting/coaching sessions, coupled with Virtual Provider program training and practice). We will assess participant satisfaction and utility ratings, as well as track their use (frequency and time-on-task) of the Virtual Provider program. For Aim 3, we will follow enrolled patient participants to interview them. **We hypothesize that participants will have significantly 1) improved**

mechanisms of change, demonstrated by increases in self-reported activation and communication self-efficacy, 2) improved SDM, and 3) improved self-management and recovery attitudes.

While we hypothesize that this intervention will increase self-reported activation and communication self-efficacy, improve SDM, and improve self-management and recovery attitudes, there is no evidence to suggest that the intervention may cause worsening of these. There is the possibility that there will be no change. In Dr. Matthias' COOPERATE study in which Drs. Salyers, Hirsh, and Rand are co-investigators (IRB #1712397218), a similar coaching intervention is used; 76 subjects have completed the intervention so far. There have been no risks identified to suggest the intervention is associated with negative outcomes for subjects. Potential risks of the study include feeling uncomfortable, nervous, or anxious, as well as the risk of loss of confidentiality.

3.0 Setting, Recruitment, and Enrollment

We will recruit up to 40 patients at the Sandra Eskenazi Mental Health Center (SEMHC, formerly Midtown Mental Health Center) who are being seen in outpatient services for adults with SMI. In our prior study with these teams, over half of participating consumers were male (56.9%) and African American (54.8%). Most participants were diagnosed with schizophrenia (67.6%); other frequent diagnoses included bipolar disorder and major depression. Following procedures established in our CommonGround study [33] and our earlier pilot study on patient activation,[81] we will recruit patients in the clinic, as they check in for a visit. The receptionist or other clinic staff will notify patients of an opportunity to learn more about the study and may distribute brief information about the study (recruitment flyer). Recruitment flyers may also be posted or distributed to potential subjects. If interested, patients will be referred to the RA or to call the phone number on the recruitment flyer with any questions or to find out more information. RAs will be stationed in the waiting area on specific, pre-determined days and be available to describe the study, complete informed consent, complete a baseline interview, and attempt to audio-record the visit with prescribers who have already given consent to participate. There may be times audio-recording the prescriber visit is not feasible (e.g., subject eligibility not complete prior to appointment time with prescriber or the prescriber has not provided consent). Following the initial visit, we will complete the first session of the intervention or, if needed, arrange a time for this session to be completed within approximately 10 days. Because the treatment teams serve people with SMI who may have more difficulties in patient activation and SDM skills, we will be able to test feasibility and acceptability with people who experience a range of difficulties. The follow-up measures can occur any time after coaching session 4, within about 3 months of baseline. Audio-recording of the psychiatry visit with consented prescribers will take place approximately 3 months after baseline – based on clinic flow, we expect this will be the next available clinic visit after completion of the intervention, but this could vary somewhat for individual patients. Participants will be paid $25 for each research assessment visit completed (baseline and 3 months), for a total of $50 per participant.

Although GET PrEPD-Psychiatry is a patient-focused intervention, psychiatric providers (e.g., psychiatrists, nurse practitioners providing psychiatric care) will also be recruited (from SEMHC) because we will attempt to audio-record clinic visits for enrolled patients. To minimize burden, provider involvement is limited to allowing up to two psychiatric care visits *per patient* to be recorded (one at baseline and one again approximately 3 months later after patients have completed the intervention). While patients will be aware that they are learning skills to be more active and effective communicators and more involved in decision-making about their psychiatric care, providers will be told more generally that patients are learning communication skills, so as not to prime providers to place a greater emphasis on SDM. Potentially eligible providers will be individually invited to participate by a research team member by email, phone/video call, or in person interaction and informed consent will be obtained. Patients who receive mental health care at the SEMHC may be eligible for the study even if their prescriber has not provided consent (e.g., prescriber declined participation, prescriber is at a different location). In those cases, no attempt to audio-record prescriber appointments will take place. As of January 2022, 4 prescribers consented to participate; however, recording appointments has proven to not be particularly feasible and it will not be possible to analyze pre-post changes as initially proposed. No further attempts will be made to audio-record prescriber appointments.

4.0 Eligibility Criteria

Providers:
Must be a prescribing provider (e.g., psychiatrist, nurse practitioner providing psychiatric care) at SEMHC who provides care to adult outpatients

Patients:

Inclusion Criteria

- At least 18 years of age
- Current outpatient receiving mental health care at SEMHC
- English speaking
- Willing to participate in 4 approximately weekly coaching sessions, engage in practice with the Virtual Provider Program, allow prescriber appointments (if prescriber has provided consent) and coaching sessions to be audio recorded*

Exclusion Criteria

- No reasonable access to the internet on a computer
- Inability or unwillingness to use a computer (necessary for Virtual Provider Program practice)
- Never or rarely uses a computer or similar device (based on self-report)
- Very or somewhat uncomfortable using a computer or similar device (based on self-report)

*Research assistants will always ask permission prior to beginning audio recording and subject can refuse individual audio recording events and continue participation in the study.

4.0 Outcome Measures, Training, Fidelity

We will measure each component of our model, with the exception of observed SDM, (Figure 2 and Table 2) in addition to demographics and chart-reported diagnoses. We chose brief validated measures for low participant burden. Aside from Feasibility (Aim 2) and SDM ratings (Aim 3), the remaining measures are self-report. Acceptability (Aim 2) is only measured after the intervention, and all others are administered at both baseline and 3 months. From each enrolled subject's medical record, we will collect recent primary and secondary mental health diagnoses made by a prescriber (or other mental health provider if prescriber diagnoses are not available) in relation to the baseline visit date.

Feasibility Assessment (Aim 2). Feasibility will be assessed by (1) tracking the number of participants who sign up for the intervention, and recording the number of people we invited in order to meet sample size goals and the reasons for declining; (2) tracking the number of enrolled participants who attend and complete the coaching sessions; and (3) tracking use of the online Virtual Provider program (which is accessible from any computer) via time-stamp data showing how frequently each participant accessed the online program and how much time they spent – during individual sessions and in total – using the program. In terms of benchmarks, the percentage of people who agree to enroll will inform the planning for our next study – a full-scale clinical trial – by allowing us to estimate the number of participants we need to engage in order to meet sample size goals for a fully powered trial.

Table 2. Measures

Aim	Construct	Measure	Items
2	Acceptability*	Narrative Evaluation of Intervention Interview (NEII)	16
3	Patient Activation	Patient Activation Measure for Mental Health (PAM-MH)	13
3	Patient Activation	Altarum Consumer Engagement (ACE) Measure	12
3	Communication Self-Efficacy	Perceived Efficacy in Patient-Provider Interactions (PEPPI-5)	5

Acceptability Assessment (Aim 2). In this open trial, we will assess participants' satisfaction with the training by asking them to complete the Narrative Evaluation of Intervention Interview[105] that we have used in other interventions with people with SMI.[106,107] These questions will focus on participant feedback on the whole intervention as well as specific components that were most and least helpful to them (e.g., goal setting, coaching sessions, Virtual Provider).

3	Observed SDM**	SDM Scale, rated from audiotaped patient-provider visit	9
3	Self-management	Illness Management and Recovery Scale	15
3	Recovery attitudes	Recovery Assessment Scale (brief version)	20

*With the exception of acceptability completed at the follow-up visit, all measures will be given at baseline and 3-month follow-up.
**Audio recordings of prescriber appointments have not been feasible; therefore, changes in observed SDM will not be analyzed. (updated 1/21/2022)

Target Mechanisms (Aim 3). Patient activation will be measured with the 13-item Patient Activation Measure Short Form-Mental Health (PAM-MH),[108] which assesses patient knowledge, skill, and confidence for self-managing one's chronic health condition. The PAM-MH has shown good reliability (α = .87-.88) and validity in many studies, including our own.[81,108-111]

Communication self-efficacy will be measured with the Perceived Efficacy in Patient-Physician Interactions Scale (PEPPI-5), a 5-item scale that measures patients' self-efficacy in obtaining medical information and getting their most important health concern discussed in a clinic visit. The PEPPI-5 has demonstrated responsivity to interventions to activate adults with SMI.[41,112] We will also use the Altarum Consumer Engagement (ACE) Measure that assesses commitment, informed choice, and navigation. Utilizing both of these measures of patient activation for this pilot test will inform our research to determine which may be the most viable measure for a larger controlled trial in the future.

Primary Outcome: SDM (Aim 3)*.* To ascertain effects of GET PrEPD-Psychiatry on SDM, we attempted to audio-record each patient's baseline visit (prior to intervention) and the first visit available after the fourth and final coaching session for those who are patients of prescribers who provided consent; however, recording has proven to not be feasible for various reasons. Given this is a feasibility study and we have learned that collecting recordings this way is not feasible, we have still learned something important from the work we have done. We will no longer attempt to record these appointments.

Secondary Outcomes: Self-Management and Recovery (Aim 3)*.* ***Illness self-management*** will be assessed with the consumer-rated Illness Management and Recovery Scale.[114] Items are rated on a 5-point behaviorally anchored scale; the mean across all 15 items forms an overall score of illness management, with higher scores indicating better self-management. The IMR Scales have shown internal consistency, stability, sensitivity to change over time, and correlations with indices of functioning, symptoms, and recovery.[115-117]

Recovery attitudes will be assessed using the total score of the Brief version of the Recovery Assessment Scale.[118,119] Respondents endorse 20 items (e.g., "I have a desire to succeed.") on a scale from 1 ("strongly disagree") to 5 ("strongly agree"). RAS total score has shown good test-retest reliability, internal consistency, and correlates with measures of self-esteem, empowerment, and quality of life.[118]

Training for Coaches. Clinical psychology doctoral students and/or staff with community mental health experience will serve as coaches. Dr. Rand will oversee training, which will consist of didactics, demonstrations, and role-plays developed by the research team based on prior experience. Intervention sessions will be audio-recorded; however, participants may, at times, decline audio recording an intervention session. A random subset of session recordings will be reviewed for fidelity and quality control. On those selected sessions, Dr. Rand will complete a coach adherence checklist to help guide feedback during weekly group supervision. Role-play will be used to reinforce and correct deviations from study procedures.

Treatment Fidelity. We will use treatment fidelity strategies consistent with the NIH Behavior Change Consortium recommendations.[104] Strategies will include: (1) using standardized intervention protocols and training; (2) monitoring audio-recorded intervention sessions; (3) using coach adherence checklists to track

protocol deviations; (4) using coach notes to document uptake of intervention; and (5) holding weekly study administration meetings to address problems or concerns.

5.0 Study Calendar

	Screening	Baseline	Weekly Coaching Sessions 1-4	3-Month Follow-up^
Informed Consent and Authorization	X			
Eligibility Checklist	X			
Demographics, Contact Information	X			
PAM-MH		X		X
ACE Measure		X		X
PEPPI-5		X		X
IMR Scale		X		X
RAS		X		X
NEII				X
Intervention**			X	

^Activities can occur any time after coaching session 4, within approximately 3 months of Baseline.
*After completion of coaching intervention, ideally the first prescriber appointment that follows the intervention (time frame could vary).
**Practice with Virtual Provider Program will be encouraged through the end of the study.

We anticipate each subject's participation to last approximately 3-4 months; however, this is dependent on when their first prescriber appointment following the intervention takes place.

The goal is to complete 4 weekly coaching sessions with each subject and the first session taking place within approximately 10 days of baseline data collection. We recognize the need to be flexible with the remaining sessions and will allow coaching sessions 2-4 to take place up to approximately 14 days after the previous session barring extenuating circumstances.

6.0 Data Management and Analysis Plan

Data Management and Quality Control. The Project Manager and RAs will create and maintain all databases. To ensure quality, data will be entered by one team member and checked by another. For qualitative data, transcribed interviews and coaching sessions will be checked for accuracy, de-identified, and entered in Atlas.ti or other appropriate qualitative data analysis program. The Project Manager and RAs, supervised by Dr. Salyers, will be responsible for data management. Each patient will be assigned an ID number, and all data will be entered into a database stored behind the University firewall on a secure, HIPAA-compliant server with limited access to appropriate IU research team members.

Data Analysis. Because inspection of the variable distributions is important for multivariate statistics, univariate and multivariate outliers, histograms, probability plots, and residual plots will be examined. We will also check the homogeneity of variances/covariances assumption by determining whether the correlations of the outcome measures with the covariates and their intercorrelations are approximately the same over time. Once we confirm the required assumptions for multivariate statistics, paired Hotelling's T-square test will be used to examine the mean differences of outcomes between baseline and post-intervention. Paired Hotelling's T-square test is used to account for the effect of correlations when there is more than one outcome variable. If the omnibus test rejects the null hypothesis, post-hoc tests will be conducted using the "partial" Bonferroni correction for potential family-wise type I error rates, which incorporates the mean correlation among dependent variables, because the traditional Bonferroni would be too conservative in our correlated data.[120]

Power and sample size. This is a pilot study to test the feasibility and acceptability of GET PrEPD-Psychiatry. The primary purpose is not to conduct inferential statistical testing based on p-values.[121] Nonetheless, we conducted a power analysis given the sample size we plan to obtain in order to facilitate our interpretation of the study findings. We are recruiting up to 40 subjects, and we expect minimal attrition based on our prior experience working with patients in this clinical setting – thus, our primary power analysis was based on a sample size of 40. Nevertheless, we also calculated power for a conservative estimate of 30 participants to account for potential loss to follow-up. Basing power on our two target mechanisms (patient activation and communication self-efficacy), G*Power 3.0.10 indicated that our study will have .64 to .78 power for the paired Hotelling's T-square test with a sample size of 30 to 40 (.05 alpha, D^2=.5 [medium effect size], two measures).

Missing data analysis. We anticipate some missing data, including study dropouts. We will compare patient demographic characteristics as well as baseline outcomes between those who withdraw and those who are retained to identify characteristics that discriminate dropouts. Further, we will carefully track study participation and try to understand reasons for dropout (and missing data) wherever possible. Identifying potential dropout (and missing data) mechanisms in this pilot study will allow us to incorporate those factors as auxiliary variables for multiple imputation as well as full information maximum likelihood estimation method assuming Missing At Random in our future full trial.

7.0 Reportable Events, Suicidality Assessment

Adverse events will not be systematically collected from subjects. If a research team member becomes aware of any adverse events possibly related to study procedures, they will be reported to the Indiana University (IU) IRB according to the IU Standard Operating Procedures for Research Involving Human Subjects. Any unanticipated problems involving risk to participants or others will also be reported according to the IU Standard Operating Procedures for Research Involving Human Subjects.

Because this is a study to develop a shared decision-making intervention, and we are not targeting depression or suicide (or assessing either as a study outcome), we will not directly assess suicidal thoughts. However, we recognize that the topic of suicide may come up during a coaching session or during a data collection interview. If a participant describes having current thoughts of suicide, hopelessness, or feeling as though they would be better off dead during a research activity (either a coaching session or a data collection event), the research assistant will proceed to a scripted brief interview (Patient Suicidality Form) to assess risk. If a participant is considered high risk (patient answers "yes" to questions 1 and/or 2 on the form), procedures are immediately employed by connecting the participant with a qualified mental health professional at SEMHC during an in-person visit. SEMHC is a mental health facility that employs psychiatrists, clinical psychologists, nurses, and social workers who are qualified and capable of assessing and treating suicidality. In our other studies with Eskenazi Health, we have established a similar referral protocol so that participants who express suicidal ideation are connected with a clinician during the visit, while onsite. If a patient is assessed to be high risk for suicidality during a phone or video call (using the Patient Suicidality Form), the research assistant will connect the patient with the Sandra Eskenazi Mental Health Center crisis line and/or other appropriate community resource (e.g., emergency department, national suicide hotline). The research assistant will also inform appropriate treatment team staff at SEMHC as soon as possible. In addition, the research assistant will inform either Dr. Hirsh, Dr. Salyers, or Dr. Rand (all are Clinical Psychologists) as well as the project manager immediately following the visit so that it can be ensured that effective safety procedures were followed and appropriate reporting is completed.

8.0 Summary

This project addresses the **significant** public health issues of providing patient-centered care to enhance self-management and recovery outcomes for people with SMI. As a developmental R34, we are taking the critical first step in assessing feasibility and acceptability of an innovative and scalable approach that has the potential to efficiently and substantially shift care. GET PrEPD-Psychiatry is characterized by key **innovations**. Our intervention explicitly focuses on patient-level target mechanisms that facilitate self-management and

collaborative care. Moreover, the innovative practice sessions with Virtual Providers are tailored to the learning needs/preferences of individual patients and allow for frequent skills practice, leading to skills mastery and patient self-efficacy. Our **approach**, informed by our extensive prior work, is scientifically rigorous and pragmatic. GET PrEPD-Psychiatry will yield new and important knowledge about collaborative care for people with SMI and will be ready for wide dissemination in a variety of clinical settings. The **investigators'** expertise, track record, and history of collaborating on funded and published research provide strong evidence of our ability to complete this project. The **scientific and clinical environments** are optimal, and there is considerable institutional support for the study team. In summary, **successful completion of this project** will result in a new, highly scalable intervention that can be implemented across a range of settings to reach a large number of patients, thus having a positive and sustained impact on mental health research and care.

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