Title
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Journal
American Journal of Geriatric Psychiatry, 24(10)

ISSN
1064-7481

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Publication Date
2016-10-01

DOI
10.1016/j.jagp.2016.07.022

Peer reviewed

HHS Public Access

Author manuscript

Am J Geriatr Psychiatry. Author manuscript; available in PMC 2017 October 01.

Published in final edited form as:

Am J Geriatr Psychiatry. 2016 October ; 24(10): 893–902. doi:10.1016/j.jagp.2016.07.022.

Older adults' perspectives on clinical research: a focus group and survey study

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Abstract

Objectives—Clinical trials can benefit from the patient perspectives to inform their design, such as choice of outcome measures. We engaged older adults in focus groups and surveys to get their

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Financial Disclosure
Dr. Lenze has received research support from NIH, FDA, McKnight Brain Research Foundation, Taylor Family Institute for Innovative Psychiatric Research, Barnes Jewish Foundation, Takeda, and Lundbeck. Dr. Mulsant currently receives research support from Brain Canada, the US National Institute of Health (NIH), the CAMH Foundation, Eli Lilly (medications for a NIH-funded clinical trial), and Pfizer (medications for a NIH-funded clinical trial). Within the past five years he has received research support from the Canadian Institutes of Health Research and Bristol-Myers Squibb (medications for a NIH-funded clinical trial). Within the past five years he has received travel support from Roche. He directly owns stocks of General Electric (less than $5,000). Dr Lavretsky receives grant support from the NIH (NCCIH and NIMH), Forest Research Institute and the Alzheimer's Research and Prevention Foundation. Other authors report no financial conflicts.

perspective regarding needs in clinical research. The goal was to inform the development of a new clinical trial of medication strategies for treatment-resistant depression in older adults.

Methods—Older adults with depression participated in focus groups and a subsequent survey in St. Louis and New York. They were queried regarding research design features including outcomes, clinical management, mobile technology and iPad-administered assessments, the collection of DNA, and the receipt of their personal results.

Results—Patients told us: (1) psychological well-being and symptomatic remission are outcomes that matter to them; (2) it is important to measure not only benefits but risks (such as risk of falling) of medications; (3) for pragmatic trials in clinical settings, the research team should provide support to clinicians to ensure that medications are properly prescribed; (4) technology-based assessments are acceptable but there were concerns about data security and burden; (5) DNA testing is very important if it could improve precision care; (6) they want to receive aggregate findings and their own personal results at the end of the study.

Conclusions—Patients gave useful and wide-ranging guidance regarding clinical and comparative effectiveness research in older adults. We discuss these findings with the goal of making the next generation of geriatric studies more impactful and patient-centered.

Keywords

older adults; antidepressant; treatment-resistant depression; patient perspectives

Introduction

Comparative effectiveness studies in older adults are needed to clarify treatments' benefits and risks

With the aging of the US and world population, more older adults will need medical treatment for acute and chronic illnesses. Often, the relative benefits and risks of these treatments are unknown. For example, for adults aged 60+ with major depressive disorder that fails to remit with standard antidepressant pharmacotherapy, surprisingly little is known about the relative benefits of second-line treatment strategies. [30,31] Medication switch or augmentation is the mainstay, although psychotherapy can also be an effective strategy for treatment resistant depression in older adults.[1,2] We do not know the comparative risk/benefit ratio of second-line antidepressant strategies for older adults, nor which patient is most likely to benefit from (or tolerate) which medication. As a result, providers may be reluctant to prescribe second-line augmentation or switch strategies when their benefits and risks are unknown, thus resulting in a significant number of patients with persistent depression. Also, there are unique safety concerns with medications such as antidepressants in older adults,[345] yet there is a paucity of data to inform clinicians regarding their safe use. For example, serotonin reuptake inhibitors are associated with falls and fall-related injuries,[6] yet it remains unclear whether these medications actually induce falls.[7–11] The lack of data on relative safety means that patients might be exposed to excessive risks.

Well-conducted large pragmatic clinical trials can clarify which medications are most effective and safest in older adults. Such information if disseminated to patients and

providers could vastly improve the quality of life of seniors and save billions of dollars each year in health care costs.[12] Yet, in the example of treatment-resistant depression, no large clinical trials have investigated the comparative risk/benefit ratio of antidepressants in older adults, in contrast with numerous studies in younger adults.[13–17] New comparative effectiveness studies are needed because patients and clinicians want to know the risk/benefit ratio of interventions, and which treatment works best for them individually.

Involving patients as partners in clinical trials is important

Clinical trials need patient input,[18] not just as participants but as collaborators and partners, to be impactful.[19] For example, the Patient-Centered Outcomes Research Institute (PCORI), which funds comparative effectiveness trials in the US, requires patient input into all aspects of clinical trials, including the study design and the choice of outcome measures.[20] Older adults may offer a unique patient voice in the design of such studies.[21] Aging is associated with decline in multiple aspects of brain function and physical health, resulting in medical illness, frailty, polypharmacy, and cognitive impairment;[22] as well, the latter half of the lifespan brings with it both wisdom[23] and lifelong experience from decades lived with illness and its treatment.[24] For example, a prior study of older adults' perspectives provided valuable insights for psychotherapy research.[25] Methods for patient engagement in research have been proposed,[26,27] and these include the incorporation of patient perspectives into the design and conduct of clinical trials.

Accordingly, we carried out a two-stage project to gather older adults' perspectives on clinical and comparative effectiveness research. Our specific goal was to inform the design of a patient-centered comparative effectiveness trial for antidepressants in treatment-resistant depression. More broadly, we wished to elicit the patient voice in a variety of topics related to how clinical research studies should be conducted throughout the geriatrics field.

Methods

We used an exploratory sequential mixed methods design whereby qualitative focus group data collection informed the subsequent development of a quantitative and qualitative survey.

Participants

Qualitative data collection in the form of a survey and focus group was conducted over a one-month span in the geriatric psychiatry clinics at Washington University in St. Louis and Columbia University in New York. A convenience sample was identified based on participants' age (60 years or older), diagnosis (major depressive disorder), and treatment (with an antidepressant medication either clinically or under the auspices of an ongoing clinical trial). Patients were approached for participation if they met the above criteria and were scheduled for follow-up in one of the clinics in January of 2016. The Institutional Review Board for both institutions provided an exception for patient participation and stated that this project did not require separate IRB approval given that these patients were already part of ongoing IRB approved protocols and the questions/information asked of the patients were deemed programmatic evaluation.

Focus groups

At each site, a trained qualitative interviewer conducted a focus group with participants (n=4 at Columbia by SPR and PJB, n=8 at Washington University by AR). These individuals were asked open-ended questions regarding their current and past depression treatment experiences. Questions included "*Do you feel you have recovered from your depression?*," "*How many treatments have you received? How many did it take to get you better?,*" "*Did you receive treatments from your primary care physician?,*" "*Did you doctor seem confident with each treatment you received?*", and "*What were the obstacles to getting treatment?*" Next, a hypothetical pragmatic trial was discussed with feedback garnered about all elements of this trial including the setting, outcome measures, and treatments themselves. Finally, we prompted participants to identify ways to better engage future participants of pragmatic studies; questions included "*In what ways can we include and engage participants in each phase of the study?*" and "*How can we make sure we are hearing their 'voice' and capturing their concerns in an ongoing way?*" Focus groups lasted approximately 50 minutes. Responses were transcribed, analyzed, and then utilized in the design of the survey.[28]

Survey

On the basis of focus group data and themes, we constructed a survey asking individuals to imagine that they were a participant in a research study on antidepressants. The survey asked nine quantitative questions and 18 open-ended questions. Most of the quantitative questions asked them to judge how important (using a five-point Likert scale ranging from "not important" to "extremely important") were the following: (1) an outcome measure of depressive symptoms (the interview described was a phone-based assessment using the structured interview format of the Montgomery-Asberg Depression Rating Scale [MADRS][29]); (2) an outcome measure of psychological well-being (the measure described was the NIH Toolbox Psychological Well-being measure,[30] iPad version); (3) an assessment of frequency of falling and fall-related injuries; (4) cognitive and mobility testing (the measure described was the NIH Toolbox Cognition and Motor batteries[31], iPad version); (5) collection of DNA in order to personalize treatment based on individual genetic profile; (6) assistance by the researchers to the prescribing doctor to adjust medication dose based on depression severity and side effects ratings performed by the research team; (7) that at the end of the study the participant would receive their own results. Additional quantitative questions were: (8) if experience sampling (i.e., ecological momentary assessment) were used to assess symptoms and side effects (via an iPhone provided by the study team), how many surveys per day would be acceptable?; (9) at the end of the study, how would they like to find out about the overall (aggregate) results?

The 18 open-ended questions were mostly follow-up questions that asked individuals to elaborate on why they selected their answer and what concerns they had. One question also asked individuals what other aspects of depression or antidepressant treatment should be included in a clinical trial. Although open-ended survey questions alone are generally not a sufficient form of qualitative data, the open-ended questions were the most appropriate and efficient way to expand on the closed-ended survey responses. Participants often appreciate this opportunity to explain or expand on their quantitative responses [32]. Combining these

responses with our focus group data provided greater depth of understanding for many of these questions, ensuring overall comprehensiveness of qualitative responses.

Data analysis consisted of mixed methods analysis to integrate qualitative and quantitative data at two stages. First, focus group discussions were transcribed, summarized, and coded by a trained qualitative researcher. The focus groups were analyzed using directed content analysis, where an initial set of codes were pre-determined based on documented patient experiences in depression care more broadly, and new codes were added as necessary during data analysis.[33] While prior research informed a very general *a priori* template of predefined codes, several new codes were assigned to emergent response categories during coding of the transcript. This was an iterative process that incorporated both inductive and deductive approaches[28]. Through frequent research team meetings, this coding scheme was refined and finalized. Subsequently, codes were grouped into larger categories, representing themes reported herein. Response themes were then utilized to design the survey questions. Survey responses were tabulated and representative quotes were extracted. Second, we compared the two datasets to systematically integrate, or merge, both forms of data. Specifically, we report the qualitative themes and quotes followed by the quantitative results, highlighting ways in which they confirm the qualitative findings.[28]

Results

Focus groups

The focus groups consisted of 12 patients (four in New York, eight in St. Louis); mean age was 70 (range 66–74), 8/12 were female and all were Caucasian; all were clinical trial participants. Table 1 summarizes the primary themes and sub-themes and presents some representative quotes from the groups. Four key themes emerged; first, patients indicated dissatisfaction with their antidepressant medications, both in terms of their tendency to lose benefits over time, and the side effects. Second, antidepressant side effects were some of the most salient experiences with treatment, including sweating, trouble sleeping, and unsettling dreams. Third, patients felt their primary care physicians did not have enough expertise with antidepressant medications to feel confident when prescribing them. Participants felt it was “to be expected” that primary care physicians were less confident with prescribing antidepressants because it was not their specialty. They believed (1) that this lack of confidence also led to a tendency to prescribe more conservatively (i.e., lower dose) and (2) that primary care physicians were more likely to treat depression as a relatively short-term, situational condition rather than a long-term disorder. Approximately half of the participants echoed this sentiment. If treatment were to be provided by their primary care physician, the addition of a case manager would be both necessary and appreciated to counteract what they perceived as a “quantity over quality” approach in contemporary primary care settings. Fourth, and lastly, patients wanted to be engaged in the research process; they indicated their preferences for ongoing communication by telephone, to be a collaborative partner during treatment, and to have access to both their personal and the aggregate results from the study.

Survey

Twenty participants completed the survey; mean age was 72 (range 65–88), they were evenly split between male and female, and 17/20 were Caucasian (3/20 African-American). Fifteen (75%) were participants in a recent clinical trial, with the rest being patients in a geropsychiatry clinic. Findings are summarized below in terms of themes and representative quotes. The full results of the nine quantitative questions are provided in Figure 1.

Theme 1: Important outcomes and how to measure them

a. Patients agreed that psychological well-being and symptomatic remission are outcomes that matter to them, with 85% and 100%, respectively, describing them as important, very important, or extremely important. Regarding psychological well-being, patients told us, for example:

> "As I age I wonder if I will have the same sense of purpose I had in my career…depression exacerbates that sense;" *and* "Life isn't worth much without a certain level of satisfaction."

Regarding assessment of depressive symptoms, representative quotes are:

> "It really hits on personal experience with depression;" *and* "I just want to stop feeling sad when my life at this point should be peaceful and enjoyed."

However, some participants also expressed concerns regarding the nature of a depression symptom assessment:

> "Usually the questions as presented are too simplistic and don't address the nuances of individual conditions;" *and* "some of the areas [symptom domains] are important to me and others are not."

b. Tablet-based assessments using the NIH Toolbox can measure important dimensions of late-life depression treatment.

Most (85%) felt that the NIH Toolbox Cognitive and Motor batteries, assessed before and after treatment as predictors and outcomes, were important. The open-ended responses indicated a desire to measure both benefits (e.g., for cognitive function) and risks (e.g., impaired balance) of medications. Representative quotes include:

> "Any change in physical abilities could affect the research or be a negative side effect of the medication;" *and* "Cognition and mobility are very important to me."

Participants indicated minimal concerns with this technology-based assessment, other than one stating it was "too intrusive" and one wondering, "Would this stress me or cause negative feelings?" Similarly, the tablet format for assessing self-reported psychological well-being was felt to be largely acceptable, although one individual commented, "The

iPad may feel unsatisfying for someone who is being asked such intimate questions about the meaning of their life."

c. Falls and fall-related injuries are important outcomes in an antidepressant study.

Fifteen (75%) of the 20 participants felt that the assessment of falls and fall-related injuries as outcomes in antidepressant studies was important. Representative quotes were "Risk of falling and falling are major threats to quality of life!" and "I have osteoporosis…falling is dangerous."

d. Measuring outcomes via mobile technology was seen as acceptable but there were concerns about data security and burden.

In response to a series of questions about use of mobile phone assessments, most (90%) found frequent at-home assessments of their symptoms and side effects to be acceptable; 55% felt that 2 or more assessments daily were acceptable although 35% would accept only 1 assessment daily. Most indicated that around 6–8 questions per survey was acceptable. However, two concerns were raised: first, regarding burden, representative quotes were: "Keep it less intrusive, as unobtrusive as possible;" "Time, time, and more time…"; and "I have to make time to answer the daily questions." Second, several participants reported privacy concerns; a representative quote was: "How secure is the information that you are giving over the phone?"

Theme 2: In pragmatic trials, the research team should provide support to the clinical prescriber—The provision of decision support, whereby the research team carries out systematic follow-up assessments of patients' target symptoms and side effects and then provides the information to the treatment provider with suggestions for how to adjust the medication, was seen by participants as "very" or "extremely" important. Examples of responses included:

> "Drugs do have side effects and sometimes it's confusing as to what is going on;" "It's critical for the physician to know how and when to make adjustments in treatment;" "This helps me; this helps your study;" and "My medication would then be tailored to my needs."

Theme 3: DNA testing was very important to improve precision care— Participants were strongly in favor of this aspect of research, with 95% describing it as important. Representative quotes were:

> "That's so people don't have to try several anti-depressants and can zero in;" and "If DNA would help in relieving my depression, I am in favor of it."

Participants had minimal concerns, and two individuals indicated a desire to know their genetic results.

Theme 4: Receipt of results is important—Participants told us how they would like to hear aggregate results from a study they participated in, and the modal answer was they prefer a phone call from a researcher in the study (65% of participants). With regard to their personal results from the study, all 20 participants described this as "very [or] extremely important." Representative quotes:

> "I would want it, but I also would like to know up front if I can expect this or not. If it isn't available to participants, would it be available to [my] physician?" and "It would help me to become more knowledgeable about my depression."

Discussion

We used focus groups and surveys to query older adults with depression about their perspectives for clinical research. The themes that emerged pertain to clinical trials of treatment-resistant depression; as well, some of the themes below are applicable to geriatric clinical trials generally.

Theme 1: Measure outcomes that matter to patients

With respect to benefits, patients agreed that both symptomatic remission and psychological well-being were important outcomes to measure. Remission of depressive symptoms can be measured with scales such as the Montgomery-Asberg Depression Rating Scale. This standard scale can be supplemented by patient-reported outcomes, including psychological well-being. Mobile technology in clinical research is increasingly feasible and acceptable to older adults;[34] it can carry out more accurate assessments[35] or even fully mobile clinical trials,[36] but researchers need to be cognizant of security concerns and perceived burden of answering assessments. For any technology-based assessment, Computer Adaptive Testing can reduce the amount of items needed, which reduces burden on participants and potentially individualizes the measure to their specific concerns. This movement towards more patient-centered outcomes has seen progress in other areas of mental health and the rest of medicine. For instance, a computer-mediated intervention was developed for patients with psychosis/schizophrenia that makes the assessment of change centered on life domains and issues that patient rate as important to their well-being[37]. Patients randomized to this program report better subjective quality of life and objective social outcomes out to one year compared to those who were randomized to an active control condition.

Participants also indicated that cognitive and mobility tests, and falls and fall-related injuries, were important outcome assessments in antidepressant studies. Cognitive and mobility factors are predictors of persistent depression and antidepressant response,[38–40] and they are important outcomes as they are highly associated with disability and mortality.[41,42] Antidepressants could improve cognitive function and mobility, either indirectly by reducing depression, or by more direct pharmacological effects.[43,44] Conversely, antidepressants can also worsen cognitive function (if they have anticholinergic or sedative effects)[45,46] and there is concern that they cause balance problems, resulting in increased risk for falls and fall-related injuries.[47] At present, the question of whether antidepressants cause balance issues, falls, and fall-related injuries remains unanswered,[8,9] and comparative effectiveness research studies are needed to answer this question.[48]

Theme 2: Include case management in pragmatic trials

In pragmatic trials the clinical care is carried out in non-research settings, and both the treatments and the clinical management provided in the clinical trial should reflect what is actually done in the real world, and to the degree that the research team assists in the management of patients, this reduces the external validity of the study.[49] Nevertheless, patients indicated that they had concerns about their primary care providers' confidence and expertise with prescribing antidepressants, and that it was important that the research team provide support to their clinical care. This decision support or case management includes frequent measurement of patients' symptoms and side effects during treatment and providing that information along with dosing adjustment recommendations to their provider. Such support is similar to the duties of a care manager in collaborative care,[50] and it has been a component of past pragmatic trials in geriatric depression such as the PROSPECT and IMPACT studies.[51,52] This theme therefore speaks not only to the need for decision support in clinical trials, but to the overall value of both collaborative care provision and shared decision-making in late-life depression treatment.[53]

Theme 3: Genetic testing for precision medicine: the time is now

The level of enthusiasm for DNA collection in clinical trials was extremely high: most patients indicated it was "extremely important," which was the highest possible response in the survey. This high level of enthusiasm is not surprising: this age group has the most experience (positive and negative) with medications, and they are at once the most likely to be taking multiple medications and to have difficulties with medication side effects and risks. Increasing antidepressants' benefits and reducing their risks through more precision approaches may help improve the dissatisfaction with these medications that was a major theme of the focus groups. Whether genetic testing will lead to more precise antidepressant prescription and dosing and whether this would reduce polypharmacy in older adults remain empirical questions, but patients clearly want the research community to focus on these important issues.

Theme 4: Patients who participate in clinical trials want to know their results

Patients told us that they wanted to hear both the aggregate results of the study and their own results. Regarding overall study results, participants preferred finding out via a personal phone call from the researchers, which is likely to be a new experience for most researchers. Many Americans never answer their phone under any circumstances. Regarding receipt of their own results, participants were extremely positive, indicating that the current movement toward providing research participants with their own findings[54] is applicable to older adults. Receipt of results is an emerging topic of interest, facing issues of autonomy and beneficence against unintended consequences such as worsened distress. Dementia researchers have studied the effects of receipt of results such as diagnostic data and found largely benign reactions by patients and their families,[55] although one study suggested that risk factor results provided to patients could induce a worsening of their cognitive function.[56] Geriatric researchers should systematically incorporate dissemination of results (both aggregate and patient-level) directly to the research participants, using strategies to do so in a positive way that minimizes the risk of psychological distress.[57] The larger point is

that older adults want to be more actively engaged as collaborators throughout the research process, with ongoing two-way communication.

Study limitations include the small sample of convenience and the one-time nature of the surveys. The current results should be considered preliminary. Our group was recently awarded a contract from the Patient-Centered Outcomes Research Institute to study treatment-resistant depression in older adults, and the more extensive qualitative studies in this new study will provide a more comprehensive patient perspective. Additionally, large, nationally representative studies of older adults' perspectives could be technology-based, but doing so may be challenging given that older adults may be underrepresented in current patient-centered communities (such as PatientsLikeMe).[58] In conclusion, older adults with depression provided us with perspectives that can make the next generation of clinical trials more patient-centered and, ultimately, more impactful.

Acknowledgments

This study was supported primarily by the National Institute of Mental Health (R01 MH083660 and P30 MH90333 to University of Pittsburgh, R01 MH083648 to Washington University, R01 MH083643 to University of Toronto, and K23 MH099097 and T32 MH20004 to Columbia University and New York State Psychiatric Institute,). Additional funding was provided by the UPMC Endowment in Geriatric Psychiatry, the Taylor Family Institute for Innovative Psychiatric Research (at Washington University), the Washington University Institute of Clinical and Translational Sciences grant UL1 TR000448 from the National Center for Advancing Translational Sciences (NCATS), and the Campbell Family Mental Health Research Institute at the Centre for Addiction and Mental Health, Toronto. These funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

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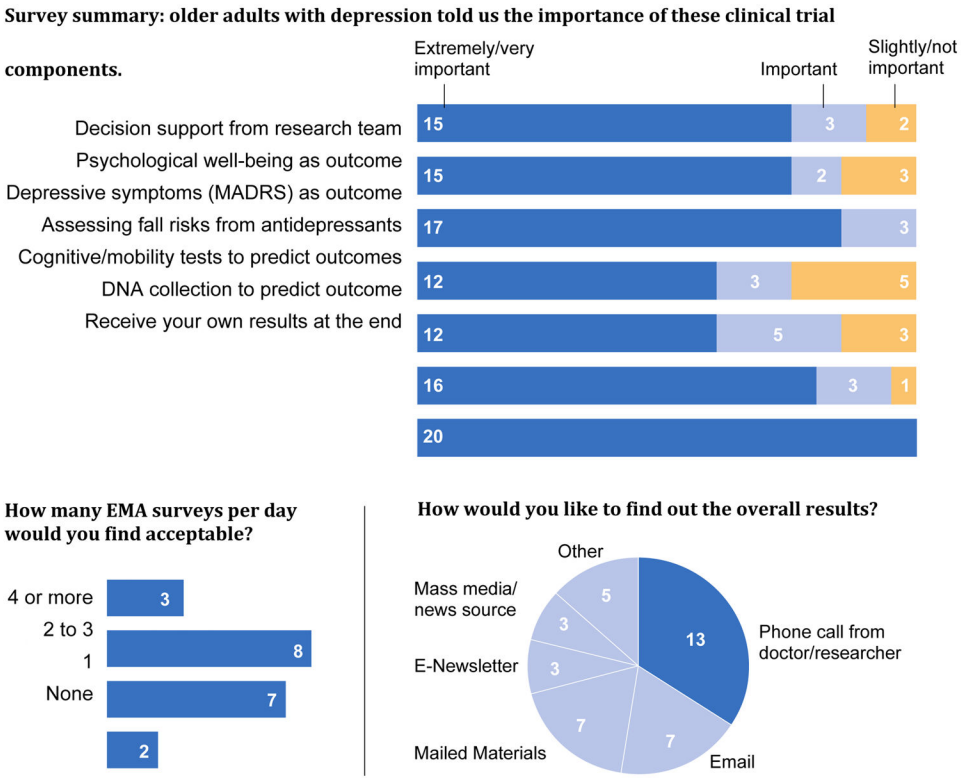

Figure 1. Patient responses to survey questions

Note: numbers in figure show numbers of older adults indicating each response (total N=20). EMA=ecological momentary assessment; MADRS: Montgomery Asberg Depression Rating Scale

Table 1

Focus Group Thematic Coding Summary

Broad Theme	Key Sub-Themes		Representative Quotes
Experience with Treatments	**1**	Patients have received a wide variety of treatments with mostly dissatisfying results	"Nothing works, and I feel like a guinea pig with trying all these drugs; it's very stressful and I finally just gave up on it."
	2	Treatment plans do not seem systematic or targeted	
Outcomes of Importance	**1**	Side effects are central to patient experiences	"Can I give you something negative? Crazy dreams. I have some very weird dreams at night that make no sense at all. Excessive sweating is another thing. All I can think of are the negatives, and these are really big negatives to me."
	2	Most common described side effects include sweating, crying, trouble sleeping, unsettling dreams, and sleepwalking	
Relationship with Physician	**1**	Patients lack confidence in primary care physicians prescribing antidepressant medications	"The last [primary care] doctor…the one that wasn't listening, it's like look, 'This isn't working; it's making me crazy.' She just kept switching me to different drugs."
	2	Shared decision making was relatively rare in primary care settings	
	3	Case managers are needed to serve as the point person in primary care	
Participation in Study	**1**	Patients are willing to be highly engaged	"One study…the woman would call me and talk about my progress. I felt like they cared about me...even though it was part of the study, it gave me a warm fuzzy...I felt accountable and felt like they were really concerned and supporting me. Phone calls work."
	2	Ongoing participation should be made convenient through phone calls	
	3	Patients want access to results and a role in decision making	