Older Adults' Perspectives on Clinical Research: A Focus Group and Survey Study

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Objectives: *Clinical trials can benefit from patient perspectives to inform trial design, such as choice of outcome measures. We engaged older adults in focus groups and surveys to get their 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) participants 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.* (Am J Geriatr Psychiatry 2016; ■■:■■–■■)

Key Words: older adults, antidepressant, treatment-resistant depression, patient perspectives

With the aging of the U.S. 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+ years with major depressive disorder that fails to remit with standard antidepressant pharmacotherapy, surprisingly little is known about the relative benefits of second-line

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treatment strategies. 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,[3–5] yet there is a paucity of data to inform clinicians regarding their safe use in this patient group. 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 healthcare costs.[12] In the example of treatment-resistant depression, however, no large clinical trials have investigated the comparative risk-benefit ratio of antidepressants in older adults, in contrast with numerous such 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.

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, which funds comparative effectiveness trials in the United States, 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] additionally, 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 these criteria and were scheduled for follow-up in one of the clinics in January 2016. The Institutional Review Board (IRBs) stated that this project did not require separate IRB approval given that 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