Qualitative Analysis of the Content Validity of the Virtual Reality Functional Capacity Assessment Tool (VRFCAT) in Schizophrenia: A Multi-Stakeholder Perspective

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The US Food and Drug Agency (FDA) requires clinical trials targeting cognitive impairment associated with schizophrenia (CIAS) to demonstrate the functional relevance of cognitive improvements by employing a functional co-primary measure. Although quantitative evidence supports the suitability of the Virtual Reality Functional Capacity Assessment Tool (VRFCAT) for this purpose, FDA guidelines for qualification of clinical outcome assessments require evidence of content validity, defined as qualitative evidence that key stakeholders view the measure as relevant and important. To collect this important qualitative data, semi-structured interviews were conducted with outpatients with schizophrenia ($n = 24$), caregivers ($n = 12$), and professional peer support specialists ($n = 12$) to elicit their views about the definition and importance of functional independence, the importance of the functional domains assessed by the VRFCAT (meal planning, using transportation, handling money, shopping), and the relevance of the VRFCAT tasks to these domains. Qualitative thematic analyses revealed consistent themes across groups in defining functional independence, including performing instrumental self-care, financial, and social tasks; making decisions autonomously; and not depending on others to carry out daily activities. There were, however, notable differences in their views regarding the importance of and barriers to functional independence. All groups viewed the VRFCAT as assessing skill domains that are central to independent functioning and, with some minor differences, the VRFCAT tasks were viewed as relevant and meaningful examples of the domains. These qualitative results provide converging evidence that key stakeholders view the VRFCAT as a content-valid measure.

Key words: clinical outcome assessment/co-primary measure/caregiver/functional independence

Introduction

Cognitive deficits in schizophrenia are profound and functionally disabling,[1,2] limiting patients' ability to perform instrumental activities of daily living, live independently, achieve work and education goals, and develop social networks. Although antipsychotics are effective at controlling acute positive symptoms, they provide minimal cognitive benefit.[2,3] It is widely recognized that cognitive impairment associated with schizophrenia (CIAS) is a critical unmet treatment need.[2]

Recognizing this need, representatives from the Food and Drug Administration (FDA), the National Institute of Mental Health (NIMH), and the pharmaceutical industry, as well as experts in cognition from academia, met as part of the Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) project.[4] The purpose of the MATRICS was to catalyze the development of novel pharmacological treatments for CIAS by establishing standard outcomes assessment methods that would be acceptable to the FDA. FDA and MATRICS representatives concluded that improving cognition alone, as measured by standardized cognitive assessments, is not a sufficient demonstration of drug efficacy. The approval of new treatments for CIAS, therefore, requires evidence that cognitive improvement has a clinically meaningful benefit to the patient's functioning.[4,5]

Since functional gains (eg, obtaining competitive employment) are likely to take longer than a clinical trial

and are dependent upon environmental factors (eg, economic conditions, availability of social resources) the FDA does not mandate *change* on a measure of real-world functioning. Instead, the MATRICS group recommended that clinical meaningfulness could be demonstrated through measurement of changes in the *potential* for real-world functioning. Such tools measure what is termed "functional capacity," which refers to an individual's capacity to perform the tasks required for independent living and functioning. Broader improvements in daily life community functioning, beyond symptom management, is central to recovery-oriented models of schizophrenia.[6–8] These models are grounded in the subjective experience of patients and caregivers, and what they value as important treatment goals and outcomes that would enhance their quality of life.[9–14] Research using qualitative methods in those with lived experience has elucidated several aspects of consumer-defined functional recovery, including living on one's own, handling one's own finances and shopping, developing social connections, working, autonomous decision making, and pursuing personally relevant goals and interests.[10,13,15–20]

Functional capacity assessments require participants to perform tasks that simulate performance of real-world activities that support functional independence, such as finances, preparing meals, shopping, public transportation, or a social interaction, measured in a research setting.[21–23] The field currently offers limited options for reliable measurement of functional capacity. The MATRICS group did not view any existing functional capacity instruments as sufficiently reliable, valid, and

potentially sensitive to treatment effects to be endorsed as the "gold standard."[21,22] Moreover, poor insight and cognitive problems limit the validity of self-assessment. Performance-based measures are an alternative—the original UCSD Performance-Based Skills Assessment (UPSA)[24] was found to be the leading measure based on test-retest reliability, correlation with the MATRICS Consensus Cognitive Battery (MCCB), and tolerability.[22] However, the UPSA has several major limitations: it is prone to ceiling and practice effects; it requires extensive rater training and, with paper-and-pencil administration and real-time scoring, is subject to administration and scoring errors; it requires a large set of physical props; it includes several very outdated items (eg, using directory assistance); norms do not exist; and it is not sensitive to cultural variations. The fact that even the most widely used measure suffers from basic limitations constitutes a major potential impediment for drug developers; without a viable measure, drug developers cannot be certain that there is a clear pathway to regulatory approval.

The Virtual Reality Functional Capacity Assessment Tool (VRFCAT[25]) grew out of the MATRICS process and uses contemporary software and technology to overcome the psychometric and practical problems with older measures for regulatory clinical trials. The VRFCAT presents simulations on a digital device that require participants to complete a series of tasks related to 4 functional domains: meal preparation, using transportation, shopping, and handling money. Patients complete 12 different tasks or "objectives" through a progressive storyboard design (see Figure 1) and the dependent
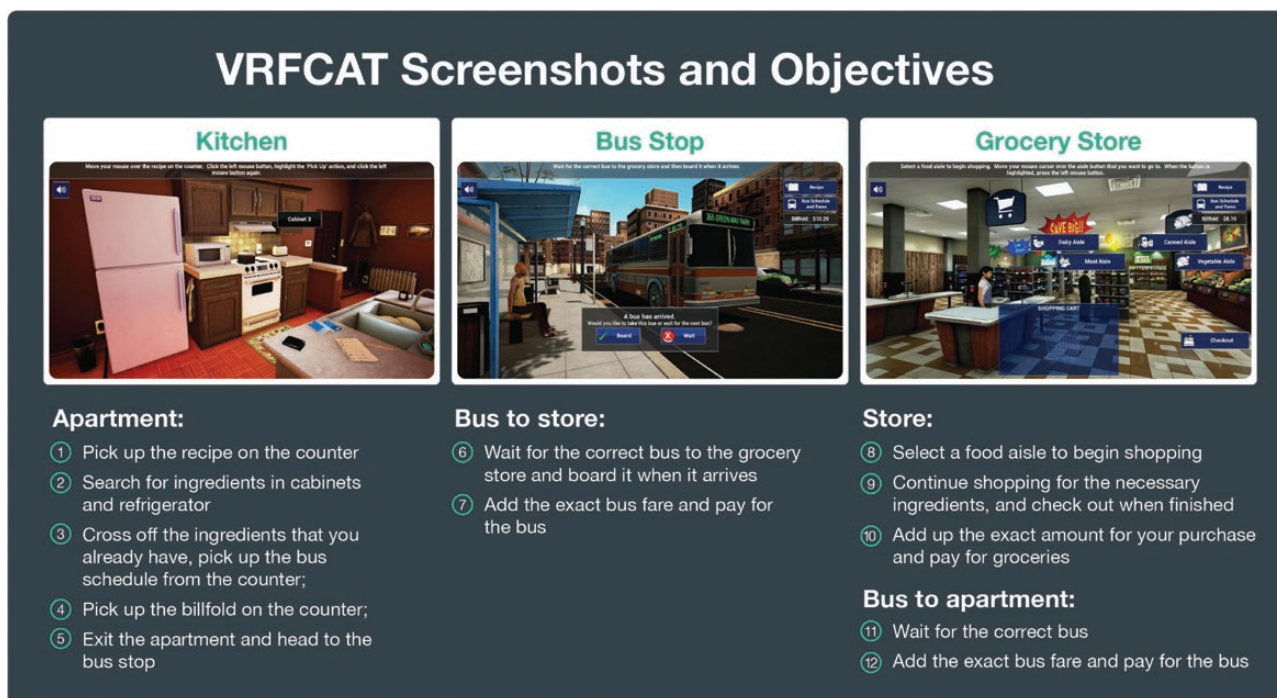

Fig. 1. VRFCAT screenshots and objectives.

variables are time to completion and accuracy. Aside from addressing outdated content in other measures, the VRFCAT incorporates first-person perspective gaming technology to maximize ecological validity, includes alternate forms to minimize practice effects, eliminates administration and scoring errors through automatic delivery of stimuli and scoring, uses automatic cloud-based data transfer, and is regulatory compliant. It also includes skills that are well understood and performed across many cultural contexts to facilitate translatability for multi-national trials. Extensive data indicate that the VRFCAT has strong test-retest reliability, good distributional properties, minimal practice effects, an interpretable unidimensional structure, and strong convergent validity with cognition and real-world functioning in schizophrenia.[25–35]

It is important to ensure that what we measure with clinical outcome assessments (COAs) in CIAS trials is functionally relevant and important to those who are impacted by schizophrenia. There is evidence that the 4 functional domains assessed by the VRFCAT are relevant to stakeholders since they were originally selected based on input from the multiple stakeholder perspectives represented in the MATRICS process. In addition, their relevance is supported by extensive quantitative research on functional independence and capacity in schizophrenia,[22,23,36–43] as well as a handful of qualitative studies of patients and caregivers on the perceived importance and impact of these challenges.[44–46] However, the functional relevance of the specific domains measured by the VRFCAT has not been directly examined with qualitative methods in those impacted by schizophrenia.

The need to evaluate the functional relevance of the VRFCAT is aligned with the FDA's Patient-Focused Drug Development Initiative, which has delineated criteria to evaluate the fitness of measures for clinical trial use in their COA Qualification Program.[47] This program is intended to qualify drug development tools that can be relied on to have a specific interpretation and application in any drug development program and regulatory review in a specific "context of use." In addition to quantitative evidence attesting to their psychometric properties, structure, and convergent/discriminant validity (among other characteristics), qualification requires evidence that establishes the content validity of a measure in the target clinical indication using qualitative research methods. This definition of content validity refers to whether patients and other stakeholders view the functional domains and tasks assessed as important and relevant for independent functioning. Qualitative evidence of content validity is required for both de novo measure development and established "legacy" measures like the VRFCAT.[48]

Regulatory guidelines for appropriate qualitative methods (eg, concept and item elicitation, item development) and evidentiary standards for content validation are well-established for patient-reported outcome (PRO) measures[49–55] and the FDA has qualified a number of PROs.[56] However, content validation of legacy Performance-based Outcome Assessments (PerfOs), particularly for difficult-to-describe concepts that involve cognition-dependent behavior (eg, functional capacity) or in populations with impaired cognition/insight, has received much less attention[55,57–59] and there are currently no FDA qualified PerfOs. This study was designed to collect requisite qualitative data on the content validity of the VRFCAT in schizophrenia. The over-arching goal of this qualitative study was to gain insight into how people with schizophrenia and their caregivers define functional independence and their views on the relevance of the skill domains measured by the VRFCAT for maintaining or enhancing functional independence.

Semi-structured interviews were conducted with 3 stakeholder groups and were analyzed to address the following questions: (1) What is the definition and importance of functional independence? (2) Are the 4 functional skill domains assessed by the VRFCAT important? (3) Are the tasks used in the VRFCAT meaningful examples of the skills domains?

Methods

Study Overview

The study had 3 primary aims. First, an expert panel iteratively developed a semi-structured interview. Second, we administered the interview to people with schizophrenia and other stakeholders ($N = 48$). Third, thematic analyses of transcripts from recorded interviews were conducted. The project included investigators at VeraSci (project coordination and scientific oversight), the University of Miami (UM; participant recruitment and data collection site), and the University of California, San Diego (qualitative analyses). This study was funded by the FDA (to WPH: FD006872). The study received IRB approval and all participants provided written or verbal informed consent. Data were collected between May 2020 and May 2021.

Interview Development

The interview was developed through a 2-stage process that incorporated feedback from a panel of 8 representatives from academia, industry, and the FDA (see Appendix 1 for a full description). The interview was organized into 4 sections. After a brief introduction, participants were first asked general questions about their daily activities and views regarding functional independence. Second, open-ended questions elicited participants' views about the relevance of the 4 functional domains assessed by the VRFCAT and whether improvements in these areas are needed. Third, participants were shown a series of 4 audio/video segments (2–3 minutes each) of VRFCAT tasks reflecting the 4 functional domains. After

each video, participants completed a series of Likert scale ratings about how relevant and realistic the tasks are and answered open-ended questions. Fourth, open-ended question elicited views about other potentially important areas of functioning. In this manner, the interview was designed like a funnel with broad questions about function, followed by more narrow questions about the functional domains presented in the VRFCAT, and then questions about the relevance and importance of the specific tasks deployed in the VRFCAT. The purpose of arranging the interview in this manner was not to bias responding toward the domains evaluated in the VRFCAT. The interview (with separate versions for each group) is presented in Appendix 2.

Interviewer Training

For interviewer training, we conducted three 2-hour training sessions with 2 experienced Master's level clinical interviewers at UM. The training sessions covered general background on qualitative research, qualitative interviewing skills, the specific content of the semi-structured interview, and role-play interviews with feedback. Drs Depp and Hurst provided weekly supervision to the interviewers throughout data collection.

Data Collection

Participants   Since it can be challenging for some people with schizophrenia to provide introspective reports,[60] we sought to elicit perspectives on functional independence and the VRFCAT from 3 stakeholder groups: outpatients with schizophrenia comparable to those enrolled in CIAS trials ($n = 24$), unaffected family members of people with schizophrenia ($n = 12$), and peer support specialists in recovery from SMI ($n = 12$). The sample size was based on the intended goal of attaining appropriate representation across caregivers and peer providers and was selected in a sample size consistent with prior qualitative research. The perspectives of the patient sample were seen as the most important among the 3 stakeholder groups, and so the sample size for patients was larger. The study capitalized on the racial and ethnic diversity of the greater Miami region to recruit a diverse, English-speaking patient sample. All participants consented to audio recording of study interviews and to have de-identified portions of interview transcripts reported in future scientific publications.

Outpatients between 18 and 65 years old who met DSM-5 criteria for schizophrenia were recruited from a database of individuals who had participated in various types of studies in the UM schizophrenia research program. We enrolled clinically stable, community-dwelling outpatients since CIAS trials focus on this population. Study exclusion criteria were kept to a minimum to enroll a diverse sample; we purposely recruited participants to ensure sufficient sex and race representation. Diagnoses were based on a structured diagnostic interview documented in subjects' research records. If a subject had not received a diagnostic interview in the past 12 months, a diagnosis was established with the Mini-International Neuropsychiatric Interview (MINI).[61] Patients were clinically stable with no hospitalization in a psychiatric or detoxification facility during the prior 2 months and no acute or chronic medical illness that would substantially diminish their ability to participate in an interview study (eg, documented neurological disorder) or interfere with daily functioning.

Family members were recruited through the UM schizophrenia research program's registry of informants from previous studies, as well as from regional NAMI affiliates. We opted to include family members who were not related to patient participants to avoid potential overlap/nonindependence of observations in patient-family member pairs. Family members did not meet the criteria for schizophrenia or schizoaffective disorder based on self-report of no history of psychotic symptoms or treatment for psychosis, were at least 18 years old, and lived currently or previously with a relative diagnosed with schizophrenia or schizoaffective disorder.

Peer support specialists were recruited from staff members of the Peer Support Program at UM. Peer Support Specialists were trained and certified to provide recovery-oriented services to people with psychosis, leveraging their lived experience with the illness as a source of knowledge and inspiration in supporting their clients. Diagnoses were confirmed by a structured clinical research interview documented in their research record or by administration of the MINI (if no record is available within the past 12 months).

Participant Interviews

All participants completed an individual, semi-structured interview that lasted approximately 1 hour. This study was originally designed to conduct in-person assessments at UM. However, the launch of the data collection phase closely coincided with the onset of the COVID-19 pandemic, which substantially disrupted plans. Fortunately, from scientific and feasibility perspectives, the interview procedures for this study were amenable to remote assessment methods. Following consultation with the funding agency, we obtained IRB approval to recruit participants as planned and conduct remote assessments using the UM HIPAA compliant Zoom platform. Based on our prior and ongoing studies using remote assessment methods in schizophrenia, as well as the research literature in this area, we fully expected that a large majority of eligible participants would have appropriate devices. We made iPads and WiFi bricks temporarily available to participants if they did not have access to an appropriate device for videoconferencing.

All interview audio recording files were coded and stored with subject identification numbers only; no personally identifying information was attached to the files. Audio files were professionally transcribed in verbatim fashion and proper nouns, names, places, and other potentially identifying information were redacted. Given that in the original VRFCAT psychometric and validation study,[25] healthy controls ($n = 165$) and schizophrenia patients ($n = 158$) self-reported (using Likert scales) that the VRFCAT is easy to understand, realistic, and enjoyable to complete (see Appendix 3), participants were not administered the VRFCAT in this study. The sole focus of this study was on content validation.

Data Processing and Analyses

Coding Framework

Using a guiding framework known as qualitative thematic analysis,[62] the process began with the 2 main coders (SH, CD) becoming immersed in randomly selected interviews from each of the stakeholder groups through repeated reading and active discussion of all aspects of the data.[63] During this immersion phase, general patient insights were explored regarding the definition and importance of functional independence, as well as insights from participant reflections on various skill domains covered in the video vignettes. Initial findings were expanded to develop a preliminary coding schema for all interviews that highlighted both *a priori* (ie, responses to questions in the interview guide) and explanatory descriptive excerpts about participant beliefs and experiences. The preliminary coding schema was provided to the full research team for debriefing. Any disagreements in code assignments, descriptions of codes, or construct relevance were resolved through discussions until a final coding framework was confirmed by the entire team. We attained saturation among the definitions of functional independence in each of the 3 groups.

The final coding manual included detailed definitions and exemplar text that was applied systematically in a retroactive review of the data corpus, giving full and equal attention to each data item. Individual extracts of data were coded in as many different themes as they fit and as many times as deemed relevant. To facilitate the entire analysis process, a standardized web-based qualitative analysis program known as Dedoose (Version 9.0.46) was used to structure and organize all data processing and enable more efficient human analytic reflection.

General Approach to Qualitative Coding and Thematic Analysis

Each transcript was reviewed using the developed coding matrix, and guided by an iterative, consensus method that incorporated 2 main coders (CD, SH) to achieve inter-rater consistency in organizing and interpreting the qualitative data collected.[64] The team-based technique provides multidisciplinary reflection of the data that is built on mutual discussion and intersubjective agreement about contextualized accounts of participants' daily experiences. The practice of team-based coding preserves the contextual and subject nature of the data, which results in a more consistent and transparent application of the coding framework to the final thematic concepts.

Post-coding analysis concluded with an integration of coded excerpts into more inclusive hierarchical concepts that explored the association between *a priori* and emergent ideas and newly identified or previously unrecognized conceptual views. The number of times that codes and concepts cooccurred, either in duplicate assignments to the same text or paired within the same discussion, were tagged as subjectively important and highlighted in the final thematic findings. This method enabled organization of the most salient of the interview excerpts into essential concepts and constructs for comparison. Finally, through the process of constantly comparing these concepts, the different constructs were condensed into thematic categories for the stakeholder groups and the entire sample.

Specific Analyses for Content Validation and Consensus

Specific analyses to address content validity included evaluation of "fit" of the VRFCAT from the open-ended questions about the 4 functional domains and the tasks within those domains. Each of these themes were evaluated for consensus within and across the stakeholder categories. The content validation analyses were organized around the 3 research questions described above.

The study team conducted an analysis of complementarity of themes across the stakeholder groups, anticipating some discrepancies. When discrepancies did arise, the team evaluated the coding framework to evaluate the influence of researcher interpretation and considered a coding revision if needed. The primary coders also selected the text segments that most exemplify discrepancies for discussion with the research team to gain additional perspectives on the source and significance of discrepant views. This approach was aimed at systematically evaluating the meaningfulness and source of diversity in perspectives across stakeholder groups in relevance of the VRFCAT.

Results

Participant Characteristics

Demographic characteristics of the 3 groups are summarized in Table 1. The groups were diverse in terms of sex and race. Patient participants had an average age in the low 40s, an average of 13 years of education, and a relatively high proportion of African Americans, which is consistent with CIAS trials. Caregivers were

significantly older and more likely to be female than patients and peer specialists, who did not differ from each other on these variables. Caregivers were significantly more likely to be married than peer specialists, who were significantly more likely to be married than patients. Consistent with expectations for schizophrenia, the patient group had lower educational attainment than the other groups. The groups did not significantly differ in racial composition.

What is the Definition and Importance of Functional Independence?

Regarding the definition of functional independence, the themes were consistent across the 3 groups. Content analyses revealed several areas of convergence when defining functional independence, including:

1. Instrumental self-sufficiency, in particular within financial, social, and self-care activities
2. Ability to make decisions that affect their life on a daily basis
3. Not being dependent on other people to carry out daily activities

Regarding views on the importance of functional independence, there was uniform agreement across groups that achieving functional independence is important.

However, there was notable divergence among the groups about why functional independence was important and perceived barriers to achieving independence Table 2. Patients emphasized being self-directed, more efficient, and not depending on people, and focused on practical barriers such as having insufficient money or unstable housing. Caregivers emphasized the importance of self-reliance because a caregiver may not always be available, and focused on barriers related to psychiatric symptoms and stigma. Finally, peer specialists emphasized the ability to be self-directed in choosing activities that further independence, and focused on barriers related to deficient functional skills. Representative quotes depicting these divergent views are presented in Table 3.

Are the Domains Assessed by the VRFCAT Important for Functional Independence?

Content analyses revealed similar themes across groups regarding how the domains of meal preparation, using transportation, shopping, and handling money supported independence. The themes included links to sustaining good physical health (eg, using transportation to get to appointments; shopping so as to avoid unhealthy eating), social networks, self-sufficiency, and either progressing toward higher levels of independence or sustaining current independence. For example, independent use of transportation was uniformly viewed as important for minimizing social isolation and taking care of health-related needs, as well as accessing work and opportunities for recreation and growth. Shopping independently was viewed as important for being able to take care of one's own daily needs, to learning and practicing healthy eating habits, being less dependent on others, and expressing one's own identity by choosing items in line with personal preferences The core themes for each domain, along with illustrative quotes, are summarized Table 4.

Table 1. Demographic Characteristics of the 3 groups

	Age Mean (SD)	Sex (% female)	Education Mean (SD)	Marital status (% married)	Race (% AA, white, other)		
Patients (n = 24)	41.8 (9.6)	54	13.2 (1.8)	8	46	46	4
Caregivers (n = 12)	64.0 (8.1)	83	15.2 (2.3)	92	25	75	
Peer specialists (n = 12)	44.9 (10.7)	50	15.8 (2.3)	58	33	67	

Table 2. Definition of and Perceived Barriers to Functional Independence

	Importance of Functional Independence	Barriers to Functional Independence
Patients emphasized	• Being self-directed, more efficient, and not depending on other people	• Practical barriers such as not having sufficient money or unstable housing
Caregivers emphasized	• Importance of self-reliance because the caregiver may not be available	• Psychiatric symptoms and stigma
Peer specialists emphasized	• Ability to be self-directed in choosing activities that further independence	• Emphasized lack of functional skills

Are the Specific Tasks in the VRFCAT Meaningful Examples of the Functional Domains?

Ratings of the tasks used to assess the 4 functional domains in the VRFCAT (as depicted in audiovisual segments) indicated a generally high level of perceived relevance. As shown in Table 5, the groups reported similarly high ratings (greater than 5 on a 7-point scale) for meal planning and preparation, using transportation, and shopping; family members reported a slightly lower average rating of 4.8 (and larger standard deviation) for

Table 3. Illustrative Quotes on the Definition and Importance of Functional Independence

Group	Independence Quotes
Patients	• *So being independent means—to me, it means living on your own, paying your bills, basically managing what your responsibilities, what you need to do* • *Being able to support yourself by being able to provide for yourself financially and do the basic daily living activities for yourself without being told or reminded what to do.* • *Independent means to me having my own apartment, being trusted to have the responsibilities of cleaning on my own, taking care of my plants, taking public transportation freely as I do*
Caregivers	• *Being able to get through life on your own steam and being able to ask for help when you need it.* • *Being able to take care of myself physically, emotionally, financially by myself, either with or without assistance*
Peer specialists	• *I would define being independent as being able to function with as little assistance as possible or, you know, function independently, you know, take care of their activities of daily living.* • *I would defer to the client, to establish the basic framework of what independent means to him, and in the context of goals that I can help him achieve.*

Table 4. Core Themes and Illustrative Quotes on the Importance of the 4 Functional Domains

Functional Domain	Core Theme Across Groups	Importance of Domains to Independence Quotes
Mean planning and preparation	• A way to become more confident in general to master the task • To manage weight and weight gain • Social health and preparing food for children and others	• *If I'm able to learn how to cook things, I'm able to function on my own (Patient).* • *Absolutely. I think it would foster independence, in the sense that they would– they could be able to rely less on fast food or rely less on other people providing food for them (Peer)* • *You need to know how to prepare it for yourself. And you can't always depend on somebody else to do all of that for you (Caregiver)*
Using transportation	• Important for socializing and not being socially isolated • To access medical care and managing health • Necessary typically for accessing work or other social/occupational endeavors	• *It's really important, because you can't be stuck at home all day. You have to venture the world, get out a little bit for your health. Your mind has to explore a little bit to be healthy (Patient)* • *I think it's really important for them to be able to travel independently and if they have appointments out in the community, to be able to get there on their own (Peer)* • *It keeps you from being stuck in one place, I might say, keep you from isolating yourself if you're able to function and get around, especially on the bus, and it's not easy on the bus (Caregiver)*
Shopping	• For being able to live independently • Learn healthy food habits, shop well, and express your identity by choosing items and having preferences • Rely less on other people	• *It's a very good idea to learn how to shop. If you eat the right things, you have a more longer-living capacity (Patient).* • *If you have no one around to take you there or if you don't have a ride or you don't have transportation it's very crucial, because sometimes you have to be the one that has to go to the store and look for the items (Peer)* • *Now that I think is important because again, unless you have a caretaker that's going to do it for you it's going to be tough and then you can't-- eating out all the time, sometimes that itself can be an impediment to your body (Caregiver)*
Handling money	• Mismanaging finances can lead directly to loss of independent living, especially on a fixed budget • Managing money well helps you acquire belongings that are symbols of your independence	• *If you can't keep your money-- if you can't keep your money in your wallet, even though people may be able to steal it and not know where it goes (Patient)* • *Because a person a lot of the time wouldn't pay attention to how much they got back or prices and how much they're paying for it or giving money, and one thing that people do in this situation is to give money away easily and lose a lot of money (Peer)* • *You know it's not just handling the money, it's connecting the availability of the money to what they're doing, to their lifestyle, to earning money, you know it's the whole package (Caregiver)*

using transportation. For handling money, patients reported significantly higher ratings than caregivers and peer support specialists, who did not significantly differ from each other.

Content analyses revealed consistent themes across groups regarding the skills and scenes within the 4 VFRCAT functional skill areas. For example, participants indicated that the meal planning task depicted relevant skills such as using a recipe, searching around a kitchen to determine items that are missing/needed, and organizing money and transportation to go to a grocery store. Similarly, the shopping scene depictions of navigating the aisles of a grocery store, selecting items based on aisle and product labels, checking off items on a shopping list, and considering the prices of items were seen as particularly relevant. Core themes related to why the functional skills depicted were viewed as relevant and realistic examples of skills needed for functional independence are summarized in Table 6, and representative quotes are presented in Appendix 4.

Stakeholders were also queried about features of the VRFCAT that were considered limitations or areas for further method development. Core themes and quotes are presented in Appendix 4. Their responses generally suggested inclusion of more complex skills, such as cooking skills, using more complex bus schedules or getting around through other means, budgeting, and managing finances in order to support purchases, considering nutritional information, using alternate payment methods, and including social interactions/distractions during these tasks.

Discussion

This study used qualitative research methods to understand how people directly impacted by schizophrenia define functional independence and to elicit their views on the extent to which the particular skill areas measured by the VRFCAT are relevant to functional independence. All 3 stakeholder groups viewed the VRFCAT as assessing 4 functional skill domains that are important for independent functioning. Further, the tasks used in the VRFCAT were uniformly viewed as relevant and meaningful examples of the 4 functional skill domains. Together, these qualitative results provide evidence that the VRFCAT measures content that patients and caregivers regard as meaningfully linked to functional independence and support its suitability as a coprimary measure of functionally relevant changes in CIAS clinical trials. The study may provide a useful approach for other groups evaluating the content validity of legacy PerfO measures, particularly in neuropsychiatric populations characterized by impaired cognition, insight, and/or speech.

Patients, caregivers, and peer support specialists expressed consistent themes in defining functional independence. Their shared definition focused on 3 themes: instrumental self-sufficiency, particularly within

Table 5. Subjective Ratings of the Relevance of Tasks in the Functional Domains

Functional Domain	Patients	Caregivers	Peer Specialists	ANOVA
Mean planning and preparation	5.9(1.1)	6.0(1.2)	5.7 (0.9)	$F(2,45) = .006$, $P = .99$
Using transportation	6.0(1.2)	4.8(2.0)	5.9 (1.6)	$F(2,45) = 2.71$, $P = 1.00$
Shopping	6.2(0.8)	5.6(1.8)	5.7 (0.8)	$F(2,45) = .82$, $P = .45$
Handling money	6.6 (0.6)[a]	5.2 (2.0)[b]	5.3 (1.0)[b]	$F(2,45) = 5.22$, $P = .009$

Note: For handling money, groups with different superscripts significantly differ from each other.

Table 6. Core Themes and Illustrative Examples for Task Relevance

Themes	Relevant and Realistic Features of the VRFCAT
Mean planning and preparation	• Depicted steps involved in preparing a meal with a recipe • Depicted searching cabinet and refrigerator to determine which items are needed/missing • Depicted wallet to bring to the store and bus schedule to get there
Using transportation	• Depicted choosing the proper bus to select based on the number • Depicting choosing the proper bus on the scheduled time • Waiting for the bus and not accidentally taking the wrong bus
Shopping	• Depicted moving up and down aisles in a grocery store • Depicted choosing items within each aisle labeled according to the product (eg, veggie, dairy) • Depicted checking items off the list as they were placed in cart • Depicted prices of items
Handling money	• Easy to understand how to manage exact change • Good breakdown of the cost of items and available funds • Good depiction of counting out exact change by denomination

financial, social, and self-care tasks; the ability to make decisions autonomously; and not being dependent on others to carry out daily activities. Although functional independence was uniformly viewed as important, the groups differed in their views about why it is important and in perceived barriers to independence. While patients focused on the importance of self-directedness and practical barriers, family members focused on concerns about how their affected family member would be able to function if they were not unavailable to provide support and the impact of symptoms and social stigma. These findings converge with a small number of prior qualitative studies indicating that patients and relatives describe schizophrenia as being accompanied by a substantial reduction in the ability to independently complete activities of daily living, work and earn an income, and engage with other people,[65,66] all of which are associated with caregiver burden.[67] Along these lines, qualitative research on the concept of recovery indicates that patients and relatives identify restoration of cognition and daily life functioning as central to the goals of recovery and enhanced quality of life.[20,45,68–72] Peer support specialists, who had relatively advanced functional recoveries, focused on the importance of being able to make choices that align with personal values and emphasized barriers stemming from skills deficits in domains needed to plan and execute the steps required for more complex goals.

The complementary perspectives across the groups in this study shed light on how challenges with functional independence affect those who are impacted by schizophrenia in different ways (patient vs. family member) and at different stages of recovery (patients vs. peer support providers). The number and divergence of perceived barriers also highlight the complexity of challenges those with serious mental illness face in their efforts to become more functionally independent. These differing perceptions may be important to consider in the context of recovery-based treatments. For example, misaligned priorities and emphases between patients and family members could contribute to stressful interactions and miscommunication that impede progress toward the underlying common goal of enhancing independence.

The 4 particular functional domains measured by the VRFCAT were uniformly viewed as important across stakeholders. Their views about the importance of the skills were also consistent and focused on how these domains contributed to independence: sustaining/enhancing physical well-being, enhancing social connections, and decreasing isolation; maximizing financial well-being; and maximizing autonomy and self-confidence. The perceived importance of these 4 domains is supported by many studies documenting real-world impairments in these areas (and associated caregiver burden) using standard clinical-interview-based measures with patients and informants[36–41] and skill deficits in these areas on older functional capacity measures,[22,23,42,43]

as well as a few qualitative studies indicating that patents describe substantial cognitive and skill challenges related to performing tasks in these domains.[44–46]

Analyses of the specific tasks used to assess the 4 functional domains in the VRFCAT were based on Likert-scale ratings and open-ended follow-up questions about why participants selected their ratings. Participants rated generally high levels of perceived relevance for the tasks in all 4 domains, with minor differences across groups. In particular, patients reported even higher relevance ratings for the task that involves handling money. Since it is fairly common for patients to receive fixed allocations of money from disability insurance, family members, or other sources, one might speculate that patients regard paying for things themselves as a particularly salient exercise of autonomy in their lives. In line with the generally high overall ratings, there was strong convergence across groups about task features that were seen as relevant and realistic examples of skills required in the 4 domains. Thus, the current results provide direct confirmatory evidence for the relevance of the 4 domains, and corresponding exemplar tasks. Notably, participants described ways in which the tasks could potentially incorporate more complex skills, more precisely fit their personal circumstances or preferences, or be expanded to include other functional domains. These descriptions provide useful directions to consider in future functional capacity task development activities, although a moderate level of difficulty capturing minimally required levels of competence on widely applicable tasks (eg, across cultural contexts) may be best for a functional capacity measure that could be deployed in very diverse samples of participants with schizophrenia (ie, ranging from first episode to older/chronic/treatment refractory).

Some limitations of this study should be acknowledged. This study was designed to examine content validity in stable community-dwelling outpatients, which is the type of patient eligible for CIAS trials.[4,73] However, the results may not generalize other patient samples, such as those in prodromal or recent-onset periods. Another limitation is that the groups were too small to evaluate within-group variation by characteristics such as gender or race/ethnicity.

In conclusion, achieving functional improvements is a major goal of contemporary drug development efforts that target CIAS. The current qualitative findings reinforce the notion that those directly impacted by schizophrenia strongly value functional independence as a key component of treatment and recovery. They also provide evidence that stakeholders view skills related to meal planning, using transportation, handling money, and shopping as important contributors to maintaining and enhancing functional independence. In conjunction with considerable quantitative psychometric, construct validity, and usability/tolerability evidence, these qualitative findings support the VRFCAT as a fit-for-purpose measure to detect

functionally relevant changes in the context of CIAS trials. The current study might also serve as a model for collecting confirmatory, stakeholder-based content validity evidence for other legacy PerfO measures, which could help advance efforts to qualify existing performance-based drug development tools for other contexts of use.

Supplementary Material

Supplementary data are available at *Schizophrenia Bulletin Open* online.

Appendix 1 Interview Development

The investigators began by developing a beta version of a semi-structured interview. The purpose was to elicit views from key stakeholders about the definition and importance of functional independence, the 4 functional capacity domains assessed by the VRFCAT, and the specific tasks used to assess these domains in the VRFCAT. The interview was designed to be individually administered, conducted by a specially trained clinical interviewer, and to last no more than 1 hour. The content of the interview was the same across the groups though the questions were adjusted for each group (eg, self vs. affected relative).

The interview was organized into 4 sections. After a brief introduction, participants were first asked general questions about their daily activities and views regarding functional independence. Second, open-ended questions elicited participants' views about the relevance of the 4 functional domains assessed by the VRFCAT and whether improvements in these areas are needed. Third, participants were shown a series of 4 audio/video segments (2–3 minutes each) of VRFCAT tasks reflecting the 4 functional domains. After each video, participants completed a series of Likert scale ratings about how relevant and realistic the tasks are and answered open ended questions. Fourth, open ended question elicited views about other potentially important areas of functioning. In this manner, the interview was designed like a funnel with broad questions about function, followed by more narrow questions about the functional domains presented in the VRFCAT, and then questions about the relevance and importance of the specific tasks deployed in the VRFCAT. The purpose of arranging the interview in this manner was not to bias responding toward the domains evaluated in the VRFCAT.

To obtain external feedback, we engaged a panel of 8 experts in an iterative, 2-stage interview development process. The panel included representatives from academia, industry, and the FDA:

- Academia: Michael Green, University of California, Los Angeles; Dawn Velligan, University of Texas Health Sciences Center at San Antonio; Amy Pinkham, University of Texas, Dallas
- Industry: Michael Sand, Boehringer Ingelheim; Estibaliz Arce, Biogen
- FDA: Bernie Fischer, Mike Davis, Elektra Popadopoulos

Panelists logged into a web-based portal to access all materials (a summary of the purpose of the study and interview, and electronic copy of the interview that incorporated questions for the panelists and accompanying note fields throughout to enter their responses/feedback, video clips, and Likert scales). The goals were to obtain feedback on whether the questions captured key information about participants' perspective on functioning and VRFCAT content, were easily understood, were biased or leading, or were missing relevant issues. A series of meetings reviewed and integrated comments, and the interview was revised accordingly. Most of the changes focused on simplifying the language and streamlining the interview. In addition, a single Likert scale was retained for ratings of perceived task relevance.

For stage 2, a revised version of the interview was distributed to each expert reviewer by email. Each reviewer

also received a copy of their original comments. Both general (eg, overall approach) and specific (eg, terminology, phrasing of questions) feedback was encouraged. A final series of meetings was held to make consensus-based refinements to the interview. We also conducted pilot interviews with a few subjects in Miami to ensure that the interview was well-structured, comprehensible, and not overly long. This led to the final interview (with separate versions for each group), which is presented in .

Appendix 2 Functional Capacity and VRFCAT Interview: [Patient/Caregiver/Peer] Version

Section 1: General Introduction

- Description: Introduction to the interview followed by general questions about activities perceived as important for independent living

Section 2: Skills and Abilities Required for Daily Functioning

- description: Transitions to skills or abilities perceived as important for completing activities related to maintaining independence

Section 3: The 4 Content Domains in the VRFCAT

1. PLANNING AND PREPARING MEALS

   1a. QUESTIONS ABOUT PLANNING AND PREPARING MEALS IN GENERAL

   1b. QUESTIONS ABOUT VRFCAT PLANNING AND PREPARING MEALS VIDEO

2. GETTING PLACES

   2a. QUESTIONS ABOUT GETTING PLACES IN GENERAL

   2b. QUESTIONS ABOUT VRFCAT GETTING PLACES VIDEO

3. SHOPPING

   3a. QUESTIONS ABOUT SHOPPING IN GENERAL

   3b. QUESTIONS ABOUT VRFCAT SHOPPING VIDEO

4. HANDLING MONEY

   4a. QUESTIONS ABOUT HANDLING MONEY IN GENERAL

   4b. QUESTIONS ABOUT VRFCAT HANDLING MONEY VIDEO

Functional Capacity and VRFCAT Interview:

Patient Version

Section 1: General Introduction

In our interview today, we will be talking about everyday activities in the community where you live. We would like to learn about the types of activities, skills, and abilities you view as important for living independently and being productive in the community. These could involve a range of activities related to living on one's own, including activities inside or outside your home, or engaging in activities with others. Some of these activities you may currently do or you might not currently do on your own, but we would like to hear your opinions either way.

1. *What sorts of activities do you currently do to maintain your current level of independence?*
   a. If difficulty with 1: *Think about from when you get up in the morning until the end of the day, what are the things you do to keep your independence?*
2. *Of all of tasks you mentioned, which are the most important tasks you do to keep your independence?*
   a. *Why are those activities you just mentioned the most important?*
   b. *Does anything get in the way of completing those tasks as well as you would like to?*
3. Can you describe activities you are no longer able to do or you need help with?a.   If yes: *Why do you think that is?*
4. Can you describe activities you wish you could do more independently these days?

Section 2: Skills and Abilities Required for Daily Functioning

The activities you engage in may depend on where you live and what kind of help you have. Also, it may depend on how much you are interested in or motivated to do those activities. The next questions are about common skills or abilities involved in completing tasks related to maintaining independence, even if you don't currently do those tasks at all.

1. *Thinking about the most important activities you mentioned, we are interested in skills or abilities that are needed to complete those activities effectively. For example, a person might say that having social relationships is important to them, and so using a telephone may be an important skill for them. You mentioned several activities (*REMIND PARTICIPANTS WHAT THEY SAID IN SECTION 1*) - what skills or abilities do you feel are important in completing those activities as well as you can?*
2. *If you were offered a treatment (like a medication or a therapy) that could improve skills or abilities required for independent functioning, which abilities would you most want to improve?*

3. *If your skills or abilities did improve, how would you know?*
4. *How would it change your life? In what way would it make it better?*

Section 3: The 4 Content Domains in the VRFCAT

1. PLANNING AND PREPARING MEALS

1a. QUESTIONS ABOUT PLANNING AND PREPARING MEALS IN GENERAL

1. *Now we want to ask about some specific skill areas. We would like to start with planning and preparing meals—when is the last time you did this?*
2. *In general, what tasks do you do (or did you do) to plan and prepare meals?*
   a. IF currently does this:
      i. *What challenges might you run into when planning and preparing meals in general?*
      ii. *Does anyone help you with meal planning and preparation and how do they help?*
   b. IF used to do this but stopped:
      i. *What changed so you stopped doing this?*
      ii. *What would get in the way of you planning and preparing meals in the future?*
      iii. *Does anyone help you with meal planning and preparation? If so, how do they help?*
   c. IF never did this:
      i. *Putting aside for a second whether you want to, do you think you would you be able to prepare a meal?*
      ii. *What might get in the way of you doing this?*
      iii. *Does anyone help you with meal planning and preparation? If so, how do they help?*
3. How important is it to you to be able to plan and prepare a meal as an activity for independent living?
4. If a treatment were offered to you that could improve your ability to independently plan and prepare a meal, how important would that be to you?
5. How would improving your ability in this area affect your life?

1b. QUESTIONS ABOUT VRFCAT PLANNING AND PREPARING MEALS VIDEO
Now, please view the following clip of a research participant completing one segment of a computerized assessment measure. After viewing the clip, you will be asked some questions.
   [SHOW VIDEO CLIP NOW]
   The video you just watched included the following 5 tasks:

- *Pick up the recipe on the counter*
- *Search for ingredients in cabinets and refrigerator*
- *Cross off the ingredients that you already have, and pick up the bus schedule from the counter*
- *Pick up the wallet on the counter*
- *Exit the apartment and head to the bus stop*

1. *Using the following scale from 1 to 7* (hand participant rating scale and *explain anchors*), *please rate how relevant the tasks in the video are for planning and preparing a meal independently:*

Very Irrelevant	Irrelevant	Somewhat Irrelevant	Neutral	Somewhat Relevant	Relevant	Very Relevant
1	2	3	4	5	6	7

2. You gave a score of X out of 7; could you say what things made you chose that score?
3. Were there things that made the tasks in the video more relevant? Things that seemed less relevant? Are there tasks that are missing?
4. Do you think that if you were able to improve on these tasks that you might be able to prepare a meal more effectively in real life? Would that be important to you?
5. How would you know if you performed these meal planning and preparation tasks well?
6. How would you know if you didn't perform these meal planning and preparation tasks well?

2. GETTING PLACES

2a. QUESTIONS ABOUT GETTING PLACES IN GENERAL

1. *Now we want to ask about some questions about getting around to places outside your home that you need or want to go – when is the last time you did this?*
2. *In general, how do you get around? What kinds of things do you do (or did you do) to get around to places on your own?*
   a. IF currently does this:
      i. *What challenges might you run into when getting places in general*
      ii. *Does anyone help you with getting places and how do they help?*
   b. IF used to do this but stopped:
      i. *What changed so you stopped doing this?*
      ii. *What would get in the way of you getting places in the future?*
      iii. *Does anyone help you with getting places? If so, how do they help?*
   c. IF never did this:
      i. *Putting aside for a second whether you want to, do you think you would be able to get places on your own?*
      ii. *What might get in the way of you doing this?*
      iii. *Does anyone help you with getting places? If so, how do they help?*
6. IF not discussed: Do you (or did you) ever use public transportation? When is the last time you did this? What challenges might you run into when using public transportation?
7. How important is it to you to be to able get around to places for independent living?

8. If a treatment were offered to you that could improve your ability to independently get around to places, how important would that be to you?
9. How would improving your ability in this area affect your life?

2b. QUESTIONS ABOUT VRFCAT GETTING PLACES VIDEO

Now, please view the following clip of a research participant completing one segment of a computerized assessment measure. After viewing the clip, you will be asked some questions.

   [SHOW VIDEO CLIP NOW]
   The video you just watched included the following tasks:

• *Wait for the correct bus to the grocery store*
• *Board the correct bus when it arrives*

1. *Using the following scale from 1 to 7* (hand participant rating scale and *explain anchors), please rate how relevant the tasks in the video are for getting places independently:*

Very Irrelevant	Irrelevant	Somewhat Irrelevant	Neutral	Somewhat Relevant	Relevant	Very Relevant
1	2	3	4	5	6	7

2. You gave a score of X out of 7; could you say what things made you choose that score?
3. Were there things that made the tasks in the video more relevant? Things that seemed less relevant? Are there tasks that are missing?
4. Do you think that if you were able to improve on these tasks you might be able to get around to places more effectively in real life? Would that be important to you?
5. How would you know if you performed these tasks related to getting around well?
6. How would you know if you didn't perform these tasks well?

3. SHOPPING

3a. QUESTIONS ABOUT SHOPPING IN GENERAL

1. *Now we want to ask some questions about shopping – when is the last time you did this?*
2. *In general, what tasks do you do (or did you do) for shopping?*
   a. IF currently does this:
      i. *What challenges might you run into when shopping in general*
      ii. *Does anyone help you with shopping and how do they help?*
   b. IF used to do this but stopped:
      i. *What changed so you stopped doing this?*
      ii. *What would get in the way of your shopping in the future?*
      iii. *Does anyone help you with shopping? If so, how do they help?*

   c. IF never did this:
      i. *Putting aside for a second whether you want to, do you think you would be able to go shopping on your own?*
      ii. *What might get in the way of you doing this?*
      iii. *Does anyone help you with shopping? If so, how do they help?*
3. How important is it to you to be able to go shopping for independent living?
4. If a treatment were offered to you that could improve your ability to independently go shopping, how important would that be to you?
5. How would improving your ability in this area affect your life?

3b. QUESTIONS ABOUT VRFCAT SHOPPING VIDEO

Now, please view the following clip of a research participant completing one segment of a computerized assessment measure. After viewing the clip, you will be asked some questions.

   [SHOW VIDEO CLIP NOW]
   The video you just watched included the following tasks:

• *Select a food aisle to begin shopping*
• *Continue shopping for the necessary ingredients*
• *Check out when finished shopping*

1. *Using the following scale from 1 to 7* (hand participant rating scale and *explain anchors), please rate how relevant the tasks in the video are for shopping independently:*

Very Irrelevant	Irrelevant	Somewhat Irrelevant	Neutral	Somewhat Relevant	Relevant	Very Relevant
1	2	3	4	5	6	7

2. You gave a score of X out of 7; could you say what things made you choose that score?
3. Were there things that made the tasks in the video more relevant? Things that seemed less relevant? Are there tasks that are missing?
4. Do you think that if you were able to improve on these tasks you might be able to shop more effectively in real life? Would that be important to you?
5. How would you know if you performed these tasks related to shopping well?
6. How would you know if you didn't perform these tasks well?

4. HANDLING MONEY

4a. QUESTIONS ABOUT HANDLING MONEY IN GENERAL

1. *Now we want to ask some questions about handling money—when is the last time you did this?*

2. *In general, what tasks do you do (or did you do) for handling money?*
    a. IF currently does this
        i. *What challenges might you run into when handling money in general*
        ii. *Does anyone help you with handling money and how do they help?*
    b. IF used to do this but stopped:
        i. *What changed so you stopped doing this?*
        ii. *What would get in the way of you handling money in the future?*
        iii. *Does anyone help you with handling money? If so, how do they help?*
    c. IF never did this:
        i. *Putting aside for a second whether you want to, do you think you would be able to handle money on your own?*
        ii. *What might get in the way of you doing this?*
        iii. *Does anyone help you with handling money? If so, how do they help?*
3. How important is it to you to be able to handle money for independent living?
4. If a treatment were offered to you that could improve your ability to independently handle money, how important would that be to you?
5. How would improving your ability in this area affect your life?

4b. QUESTIONS ABOUT VRFCAT HANDLING MONEY VIDEO

Now, please view the following clip of a research participant completing one segment of a computerized assessment measure. After viewing the clip, you will be asked some questions.

[SHOW VIDEO CLIP NOW]

The video you just watched included the following 5 tasks:

- Add up the exact amount for your purchase
- Pay for your groceries

1. *Using the following scale from 1 to 7* (hand participant rating scale and *explain anchors), please rate how relevant the tasks in the video are for handling money independently:*

Very Irrelevant	Irrelevant	Somewhat Irrelevant	Neutral	Somewhat Relevant	Relevant	Very Relevant
1	2	3	4	5	6	7

2. You gave a score of X out of 7; could you say what things made you choose that score?
3. Were there things that made the tasks in the video more relevant? Things that seemed less relevant? Are there tasks that are missing?

4. Do you think that if you were able to improve on these tasks you might be able to handle money more effectively in real life? Would that be important to you?
5. How would you know if you performed these tasks related to handling money well?
6. How would you know if you didn't perform these tasks well?

Appendix 3

The original VRFCAT Psychometric and Validation Study[25] collected data on participants' ratings of subjective usability and practicality of the VRFCAT for clinical trials, as patients must be willing to engage in the VRFCAT at repeated visits without feeling as though the task is either too burdensome or too stressful. After completing the VRFCAT, healthy control (*n* = 165) and schizophrenia (*n* = 158) participants were administered a qualitative survey about their experiences and perceptions of the VRFCAT. Participants were asked to rate the pleasantness, ease of use, clarity of instructions, and realism of the VRFCAT virtual environment on 7-point Likert scale:

- *How pleasant or unpleasant was the experience of using this tool? (1=very unpleasant; 7=very pleasant)*
- *How difficult or easy was it to use the controls? (1=very difficult; 7=very easy)*
- *How difficult or easy was it to follow the instructions? (1=very difficult; 7=very easy)*
- *How unrealistic or realistic did you find the environment? (1=very unrealistic; 7=very realistic)*

As shown in the Table below, participants reported high average ratings for the VRFCAT in being pleasant to take, easy to use, easy to understand the instructions, and realistic. Notably, although all subjects rated the task highly with respect to ease of use and understandability of instructions, these ratings were significantly higher for healthy controls. As a result, the task instructions were revised and simplified in order to improve the clarity of test instruction and ease of use for schizophrenia patients.

Table: Subjective Experience Ratings for Completing the VRFCAT

	HC (N=165)	SZ (N=158)
Pleasantness, Mean (SD)	5.9 (1.37)	5.5 (1.70)
Ease of Use, Mean (SD)	6.5 (1.01)	5.7 (1.54)
Instructions, Mean (SD)*	6.5 (1.01)	5.3 (1.81)
Realistic, Mean (SD)*	6.1 (1.24)	(1.60)

* = Significant between-group difference.
Note: 1–7 scale.

Appendix 4 Representative quotes for good examples and core themes/representative quotes for task limitations and directions for development

	Good Examples – Representative Quotes	Limitations and features to consider in future development activities	Poor or Missing Examples – Representative Quotes
Mean planning & preparation	• *A good example was looking at the recipe and seeing the items that you needed to get (Patient).* • *Well, starting with the list and then going through a recipe and then the ingredients, checking the fridge and the cabinets and stuff like that, and then checking the bus schedule and remembering to remember the address, and grabbing your wallet and heading out the door, so I think those were all good examples. (Peer)* • *Taking stock of inventory, looking at the bus schedule, and doing steps in order (Caregiver)*	• Not inclusive of other methods acquiring meals (e.g. take out, home delivery) • Cooking skills and equipment were not included • Unclear how much money is available to purchase food	• *(Videos) were missing instructions on how to prepare the meal and basically what type of meal are you preparing. And how many friends are coming over (Patient).* • *There are other ones, there are other ones like cleaning up after, no there's no dishwashing detergent, you know, there's no sponge (Peer)* • *I think it could go farther to getting the pan and the what type of utensils you would use, people don't always know that, how to operate different you know, the stove or whatever, step by step (Caregiver)*
Using transportation	• *I think it's a good representation of taking the bus (Patient).* • *I like the fact that it tells you which bus you need to look for and that I'm so glad that the first bus that pulled up was not the right one, but it gives you the option. Should I choose this one or not. Also, it gets them accustomed to "You've got to wait," and just because the first bus pulls off, it's not the right one, but that doesn't mean that the next one coming may not be the correct bus. (Peer)* • *The good example is you always have to know what bus to catch and what time the bus is coming and what's the number of the bus (Caregiver)*	• The bus was labeled "grocery store" which is not evident in real life • The bus schedule was less complex than in real life • The payment aspect of bus fare was not depicted (bus passes) • Unclear where the bus stop is in relation to the home of the actor	• *So, this bus schedule was a lot easier than the actual real bus schedule that we have nowadays (Patient).* • *I guess my mind went to, "Okay, the grocery store, but there should be a bus number for the grocery store." And I completely missed it. (Peer)* • *…depending on where you live and what the technology is, if it's a card or whether you have to pay cash or exact change or (Caregiver)*
Shopping	• *Well, it gave you the prices, so you knew how much you were paying for, so you could actually check out and have enough money (Patient)* • *So, the way that there were multiple items to select from, where it wasn't just arriving at an aisle, and there's one item there. They had to kind of look at it. I found all those things to represent... somewhat be a reflection of what real life is like (Peer)* • *I think that there was enough challenge in terms of selecting the right thing because you could have selected things that you didn't need, like that. I thought the supermarket looked realistic, and I think it tested their ability to remember what they were there for and not be distracted by other things (Caregiver).*	• If only 2 items needed, not clear why go through the whole store • Other people in the store were minimal (eg., store personnel, other customers) • Nutrition comparison was unavailable • Not clear what the "budget" the individual has and whether sufficient funds were available to return home on the bus	• *I didn't see a lot of people in the store, so maybe, I mean, that could be improved on (Patient).* • *(Also) there's other like physical activities that are involved in going to the grocery store, like bagging your groceries. Something missing might be like interacting with someone, asking them (for help) (Peer)* • *It didn't show like any like human beings, really. I don't think I saw anybody in the picture, which is something you would definitely see if you went to a grocery store (Caregiver)*

	Good Examples – Representative Quotes	Limitations and features to consider in future development activities	Poor or Missing Examples – Representative Quotes
Handling money	• *I like being able to open up the wallet and pick the right denominations and that. I think it's a good representation (Patient).* • *It demonstrated it well by showing them how to have the exact change, exact amount they need to pay (Peer)* • *Because they priced everything and he had the correct change for it and that is good, he has the correct change for everything he wanted to buy (Caregiver).*	• Alternative payment methods were not included (eg, card, food stamps) • Not clear why cashier only accepted exact change • No cashier social interaction, receipt, or bagging of groceries was depicted	• *You also have to think there are people that pay with debit cards and credit cards (Patient).* • *and most things are automated nowadays, so they don't have to really worry about providing exact change, but knowing how much you have at the end is good, because you still got to take the bus home (Peer)* • *I would say that, you know, there's a lot of other ways that are much more likely to be paid, you know? In fact, I think counting out exact change would be almost unlikely, you know? Like using a debit card or being sure you get the correct change (Caregiver)*

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