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Rethinking informed consent for ethical research in mental health: Results from a structured consent assessment in catatonia

Z Zingela, MB ChB, MMed (Psych), FC Psych (SA), PhD

Faculty of Health Sciences, Nelson Mandela University, Gqeberha, South Africa

Corresponding author: *Z Zingela (zingelaz@mweb.co.za)*

Background. Catatonia presents distinct challenges for informed consent in psychiatric research, as profound psychomotor disturbance and mutism may obscure preserved decisional capacity. Limited empirical work has explored structured methods to evaluate and uphold autonomy in such contexts.

Objectives. To examine the ethical and operational dimensions of assessing decisional capacity and obtaining informed consent in individuals with catatonia within South African regulatory frameworks.

Methods. Decisional capacity was assessed in 241 consecutively recruited patients with catatonia using a consent assessment tool (CAT) incorporating the iterative approach originally applied in the University of California San Diego Brief Assessment of Capacity to Consent. Proxy and head of health establishment (HHE) consent were used where incapacity was documented and relatives could not be traced. Initial capacity assessment occurred within 24 - 48 hours of admission, with formal reassessment every 72 hours, consistent with the Mental Health Care Act 17 of 2002 observation period.

Results. Of the participants, 67.2% provided self-consent, 25.3% required relative consent, and 7.5% required HHE consent. Higher catatonia severity correlated with lower CAT scores. Structured reassessment enabled ongoing evaluation of capacity, although no participants regained decisional capacity within the first week of admission.

Conclusion. A structured, repeatable capacity-screening process anchored in local legal frameworks can safeguard autonomy while preventing systematic exclusion of vulnerable groups from psychiatric research. The approach exemplifies how empirical assessment, clinical ethics and national law can be integrated to support equitable and defensible consent practices in catatonia.

Keywords: catatonia, informed consent, decisional capacity, research ethics, Mental Health Care Act, South Africa

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Catatonia is a complex neuropsychiatric syndrome characterised by psychomotor disturbance, behavioural withdrawal and, at times, profound mutism or stupor. Its clinical heterogeneity and frequent co-occurrence with psychosis, mood disorders and medical conditions make assessment and management particularly challenging in acute services.[1-8] Previous articles on catatonia at the study site have described the local burden and presentation of catatonia, assessed instruments, reported prevalence and management, and documented the subjective experience in detail.[1-5] Building on this foundation, the present article examines capacity to consent in catatonia using a structured approach and considers the ethical implications for research participation, framed by international and national ethical guidelines.[1,8-15]

Contemporary guidance emphasises early recognition and treatment,[6] but questions about how to assess decisional capacity and obtain ethically defensible, informed consent in catatonia remain under-examined. Challenges with communication during the catatonic state such as mutism, stupor or negativism, may support an impression that patients with catatonia lack decisional capacity. However, emerging evidence suggests that many retain a rich inner experience and varying degrees of awareness and understanding despite limited outward responsiveness.[5] Accordingly, capacity judgements should be task and time specific, revisiting assumptions as patients recover, and should be documented with structured methods.

The University of California San Diego Brief Assessment of Capacity to Consent (UBACC) is a brief, study-specific instrument designed to assess understanding, appreciation and reasoning for research participation.[9] In psychiatric and mixed clinical cohorts, iterative administration has improved comprehension of key study elements and identified individuals needing additional support.[10] Administering the full UBACC typically takes about 15 - 20 minutes in research settings, depending on the complexity of study information and the participant's clinical state.[10] Data collection for the present study was conducted during the COVID-19 pandemic, and decisional capacity was assessed using a set of questions based on the iterative approach of the UBACC. We grouped a set of questions that could be applied in half the time to minimise direct contact time while preserving the iterative intent of the original tool. Situated within a programme of work describing assessment, prevalence, management, and lived experience in this cohort,[1-5] this article examines consent

pathways and capacity assessment in patients with catatonia, and considers how autonomy, beneficence, non-maleficence and justice can be balanced to support ethically robust inclusion in research.[11]

Background

Decisional capacity is task specific and time specific. It requires an ability to communicate choice effectively, demonstration of understanding of information about choices available, and an assessment that ensures that the patient's ability to communicate their understanding and choice is preserved. Use of structured tools to assess decisional capacity may help with reducing inconsistency when assessing decisional capacity and may therefore help to differentiate performance barriers due to catatonia and decisional incapacity. The UBACC was designed as a rapid, study-specific screen of understanding and appreciation for research invitations and recruitment.[9] In psychiatric cohorts and mixed clinical samples, UBACC administration and brief iterative learning have improved participants' grasp of key study elements and flagged those requiring more in-depth assessment or remediation to improve understanding and support decision-making.[10,16] Although structured tools such as the UBACC assess comprehension and appreciation, evidence from African genomic research shows that consent decisions may also be shaped by interpersonal and contextual variables such as recruiter characteristics, regional culture and participant age.[17] These findings underscore that decisional capacity is necessary but not sufficient for genuine voluntariness. The present study applied a specifically designed and short consent assessment tool (CAT) for assessment of decisional capacity, as described in the 'Methods' section below.

Methods

This article presents a secondary analysis of prospectively collected data from an observational study examining the prevalence, assessment and outcomes of catatonia. Ethical approval for the study was obtained from the relevant institutional review board as indicated in the ethics statement below (ref. no. H20-HEA-PSY-002).

Study site

The study was conducted in a mental health unit, a 35-bed acute inpatient facility located in South Africa (SA). The unit forms part of a regional general hospital that also provides psychiatric services and accepts referrals from surrounding clinics, district hospitals and emergency departments. The catchment area includes both urban and peri-urban communities, characterised by high levels of unemployment and associated psychosocial stressors.

Study population

The study population comprised all patients admitted to the mental health unit between September 2020 and August 2021 who were screened for catatonia as part of a broader prevalence and outcomes programme. Most admissions were involuntary under the Mental Health Care Act 17 of 2002,[18] and the ages of those admitted to the unit ranged from adolescence to late adulthood.

Sampling

Sampling was consecutive: every patient admitted to the unit during the 12-month study period was eligible to be recruited. This approach ensured comprehensive inclusion of all inpatients within the defined time frame, providing a representative sample of presentations encountered in an urban SA psychiatric service context during the COVID-19 pandemic.

CAT and process of assessment

Capacity was screened using a CAT comprising a structured set of four scored questions assessing comprehension, retention, and understanding of the right to consent or refuse. This tool was used to ensure a standardised, structured assessment of capacity to consent while reducing direct contact time with participants, as data collection occurred during the COVID-19 pandemic. The CAT included an iterative learning component modelled on a similar process applied in the UBACC. The process undertaken was as follows:

1. Sharing the study information verbally and in writing, inclusive of risks, benefits, implications of consent, and whether there would be remuneration for participating.
2. Providing a written summary of the study information after the initial sharing of full study information and asking the CAT questions with formal scoring out of a maximum of eight. A score of eight was therefore defined *a priori* as indicating full decisional capacity, irrespective of whether it was attained at the first, second or third attempt. However, CAT scores reported in the analysis reflect the initial (index) score obtained prior to the iterative clarification process. This distinction ensures that reported scores represent baseline comprehension, while final classification of retained capacity to consent was based on performance following iteration.
3. For the iterative process, if a participant's understanding or appreciation of the four key questions was incomplete, the researcher briefly re-explained the information once and then re-assessed comprehension using the same items. This iterative step preserved the instrument's intent to support comprehension. This approach avoided inflation of capacity scores through iteration while preserving ethical safeguards for informed participation.

To confirm clarity and scoring feasibility of the CAT in this study, it was initially applied during the validation of the Bush-Francis Catatonia Rating Scale (BFCRS) to assess catatonia in the study population, the results of which were reported in an earlier article.[2] Inter-rater consistency was maintained through calibration between two trained raters using three parallel cases. The feasibility of the tool was also evaluated qualitatively based on the proportional distribution of scores across consent categories, showing similar relative differentiation between self, relative, and head of health establishment (HHE) consent groups.

The HHE was approached in cases where a relative could not be traced, which is permissible under SA law, specifically under the Mental Health Care Act.[18] All proxy and HHE consents were recorded in writing using the same predesigned consent forms developed for the study, ensuring uniform documentation and procedural consistency across consent pathways. The process started with attempts to trace the relatives, and where relatives could not be reached after three documented call attempts within 48 hours, the HHE was approached for consent in line with section 71(2)(c) of

the National Health Act 61 of 2003[14] and section 8(4) of the Mental Health Care Act.[18] Table 1 shows the comparison between the UBACC and the CAT used in the present study.

A copy of the CAT used in this study is provided in Appendix I, allowing comparison with the original UBACC instrument described by Jeste *et al*.[9] In the present study, when individuals showed non-verbal assent (eye contact, nodding, calm co-operation), participation continued; overt behavioural dissent such as agitation, withdrawal, or distress on approach triggered an immediate pause with referral to the managing clinical team, followed by a reassessment of decisional capacity, still within the first 24 - 48 hours of admission. This process ensured continued respect for individuals' rights to refuse participation even when formal capacity had yet to be assessed. Following the initial consent assessment, which occurred within 24 - 48 hours of admission, further formal reassessments of capacity were done every 72 hours.

Ethical principles and framework

The study was conducted in accordance with international bioethics frameworks and SA regulations governing research with vulnerable populations.[12-14,19-22] These include observing the principles of bioethics guided by the Declaration of Helsinki,[13] the National Health Act,[14] and assessing decisional capacity guided by the Mental Health Care Act.[18] Key ethical principles that were actively considered and weighed at each stage of assessment are listed below.

Autonomy. Wherever possible, patients were re-assessed for decisional capacity, with the intention of restoring self-consent if clinical improvement occurred. Use of the CAT allowed for structured, task-specific assessment of retained comprehension about the study and autonomy, avoiding assumptions of incapacity based on presentation alone.

Beneficence and non-maleficence. Participation in the current research carried potential benefits in terms of advancing understanding and improving care for catatonia, consistent with beneficence.[12] At the same time, safeguards were put in place to avoid harm through coercion, misrepresentation, or enrolment without genuine understanding. Proxy or HHE consent was used cautiously, and only where incapacity was documented, and relatives could not be traced.

Confidentiality. Patients with catatonia may be unable to assert or defend their own privacy interests at the time of enrolment. They may also not be able to communicate clearly who they want personal or private information shared with while in the catatonic state. Protecting confidentiality was therefore treated as paramount, with anonymisation and secure data handling practices implemented in accordance with Research and Ethics Committee approval.[13,19,20]

Justice. Inclusion of patients with impaired capacity was balanced against the ethical imperative to ensure that there was no systematic exclusion of vulnerable populations from research that stands to benefit them.[12,13] The use of structured, repeatable capacity assessments allowed for more equitable participation, ensuring that autonomy was respected without denying access.

These principles guided both the methodological design and the consent process, forming the basis for ethical decision-making in line with existing research and the Declaration of Helsinki, the National Health Act, the South African Medical Research Council research ethics guidelines, and National Health Research Ethics Council standards and recommendations.[13,14,19-22]

Data collected were de-identified through the assignment of a unique numerical code without personal identifiers and stored as hard copies in a securely locked cupboard in the departmental archive. The electronic data that were collated from those records were then stored securely on the principal investigator's password-protected and firewall-restricted computer. These data will be retained for a minimum of 5 years, in compliance with the Protection of Personal Information Act 4 of 2013 (POPIA).[23] Access has only been provided to the principal investigator and data analyst.

Results

A total of 321 patients were approached for recruitment. Of these, 241 (75.1%) agreed to participate, while 80 (24.9%) declined. Agreement to participate included both self-consent and behavioural assent in cases where decisional capacity was impaired.

Table 1. Conceptual comparison of the UBACC and the CAT

UBACC constructs represented	CAT domain	CAT assessment question	Iteration process
Items 1 - 2 • Purpose of the study • Eligibility to participate	Comprehension	What is the study that I explained to you about?	All admissions received the full participant information leaflet (Appendix 1). A written and verbal summary of the study was then provided (Appendix 2). Four CAT assessment questions were administered. Where required, the summary and four CAT questions were repeated for up to three iterations until a maximum score of 8 was achieved.
Items 3 - 4 • Study procedures • Benefits of participation	Retention of study information	I can remember all the information you gave me about the study.	Same iterative process
Items 5 - 6 • Voluntary participation • Withdrawal and confidentiality	Understanding of autonomy	I can choose whether I want to take part in this study or not.	Same iterative process
Items 7 - 8 • Refusal • Reimbursement	Understanding of the right to refuse	If I refuse to take part in this study, will that interfere with the treatment I am going to receive?	Same iterative process
UBACC constructs	**Ideal CAT score: 8**	**Maximum CAT score: 8**	

UBACC = University of California San Diego Brief Assessment of Capacity to Consent; CAT = Consent Assessment Tool.

In these cases, formal consent was obtained through relatives or the HHE. Among the 241 participants, 162 (67.2%) were assessed as having retained capacity and provided self-consent, while 79 (32.8%) had incapacity to consent but showed behavioural assent. For 61 (25.3% of the total) of the 79 participants with decisional incapacity and behavioural assent, relative consent was sought, while in 18 (7.5% of the total), HHE consent was obtained when relatives could not be traced (Fig. 1). This breakdown reflects the differential capacity profiles in the cohort and provides a more complete picture of consent pathways. Although a structured reassessment was undertaken every 72 hours for participants with impaired capacity, none of the participants who required proxy or HHE consent regained decisional capacity within the first week of admission, which was the main period of data collection.

A significant negative correlation was observed between the CAT scores and BFCRS total scores (r=–0.46, 95% confidence interval –0.55 - –0.35, p<0.001), indicating that higher catatonia severity was associated with lower decisional capacity. One-way analysis of variance showed significant differences in mean (standard deviation) CAT scores across consent pathways (F(2, 238) = 19.3, p<0.001): self-consent = 6.9 (1.1), relative consent = 4.7 (1.3), and HHE consent = 3.2 (1.0). Post-hoc Tukey tests confirmed that all groups differed significantly. A linear regression model controlling for age, diagnosis, psychotropic medication use, and recruitment period (early v. mid-COVID) confirmed that the BFCRS remained an independent predictor of the CAT score (β=–0.42, p<0.001).

Although a score of eight was required to classify decisional capacity, reported CAT scores reflect initial (index) performance prior to iteration, accounting for mean scores below the threshold in the self-consent group (6.9).

Discussion

The inverse association between BFCRS severity and CAT suggests that behavioural and motor features of catatonia may obscure, rather than fully determine, underlying decisional capacity. This distinction is clinically important, as it challenges the assumption that reduced responsiveness equates to incapacity and supports the use of structured tools to differentiate performance limitations from true decisional impairment.

The present study, by embedding the iterative aspect of the UBACC in the CAT, demonstrates that it is possible to conduct structured capacity screening in patients with catatonia as part of the consent process. Use of the CAT in this cohort strengthened the process of obtaining consent in an ethical manner and enhanced transparency in documenting decisional capacity. It also supported a clearer and well-documented alternative pathway to consent when a relative or HHE was required to provide proxy consent, while preserving a route to restore autonomy in cases where improvement could potentially result in regained decisional capacity. The process therefore demonstrates the feasibility of structured, ethically robust inclusion of individuals with impaired but potentially recoverable capacity.

The finding that 67.2% of participants were able to provide self-consent highlights that decisional capacity is frequently retained even in acute presentations of catatonia. However, this figure also implies that a substantial proportion (32.8% in the present study) of patients may lack capacity at the point of recruitment. Excluding these individuals would systematically bias research towards less severe presentations and limit the clinical applicability of findings. The structured consent process applied in this study therefore represents a pragmatic ethical approach that balances respect for autonomy with the principle of justice, ensuring that

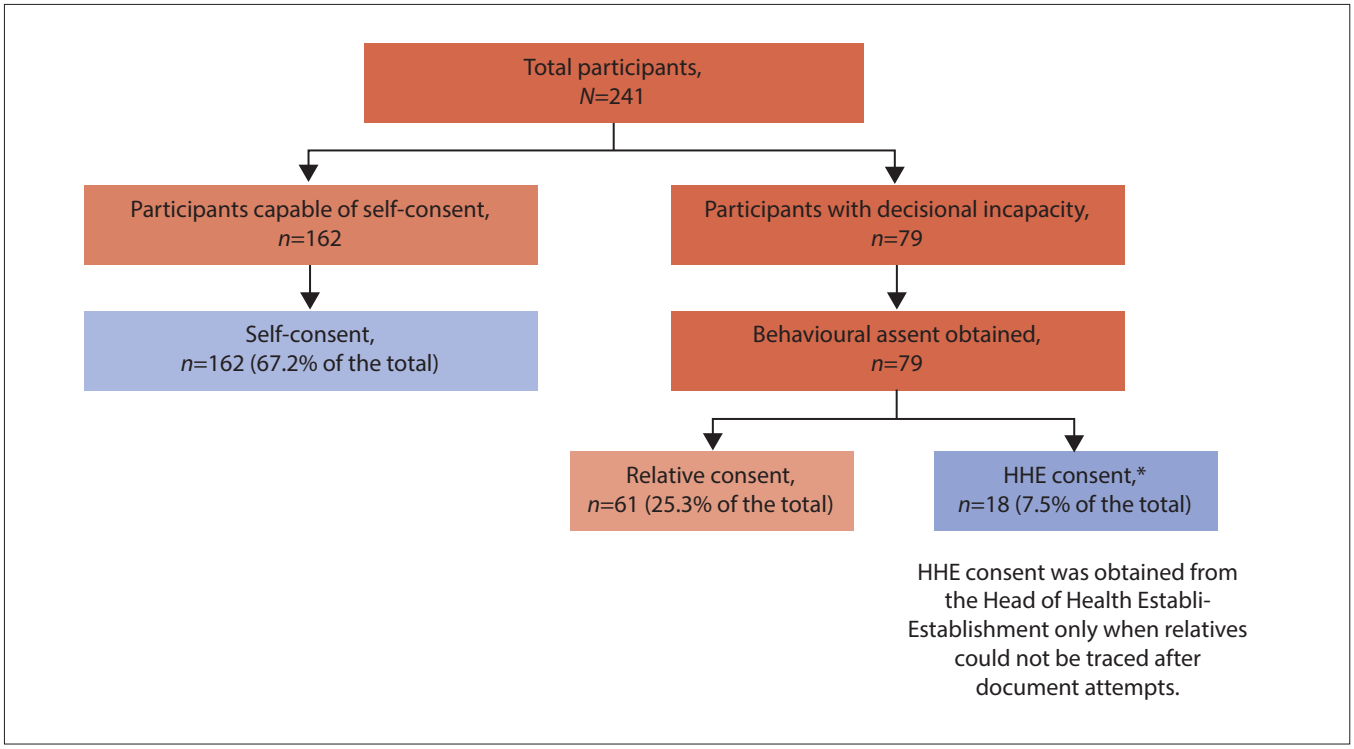

Fig. 1. Recruitment pathway for study participants.

vulnerable populations are not excluded from research that directly concerns them.

Taken together, the integration of empirical and ethical data illustrates how research inclusion can be balanced with protection. The framework applied here demonstrates a realistic approach to conducting ethically sound research with individuals who may temporarily lack decisional capacity, without defaulting to exclusion. The process for assessment of capacity to consent in the present study aligns with the ethical commitment to equity in research participation and the moral responsibility to advance understanding of catatonia.

Clinical implications

The inverse association between BFCRS severity and the CAT underscores the importance of early treatment and proactive capacity reassessment in line with contemporary catatonia recommendations.[6] Embedding a brief, repeatable capacity-screening process within routine care can normalise re-invitation to self-consent and improve documentation quality when proxy or HHE consent is used. The approach described in this study may be applicable beyond catatonia to other acute neuropsychiatric conditions characterised by fluctuating or impaired decisional capacity. By combining structured capacity assessment, iterative clarification and legally grounded proxy pathways, the model provides a scalable framework for ethically robust research participation in vulnerable populations. This approach to capacity assessment has particular relevance in low- and middle-income settings, where exclusion of individuals with impaired capacity may further limit the development of locally relevant evidence.

Study strengths and limitations

This was a relatively large cohort with use of standardised measures for assessment of participants. Integration of ethical analysis with operational data enabled in-depth evaluation. The study maintained continuity with previous cohort studies conducted in this population, thereby providing a holistic and comprehensive account of catatonia, inclusive of the assessment of decisional capacity presented in this article.[1-5]

The cross-sectional design could not capture within-person fluctuation over time. The CAT recorded a maximum of eight points, differing from the 10-item version. It was also not formally validated against the original 10-item tool, although the score distributions showed similar discriminatory patterns. Analysis was constrained by incomplete coding within the HHE consent subgroup, which limited direct pathway comparisons.

Recommendations

This study suggests a realistic approach to assessment of capacity to consent even in cases where intuitive reasoning suggests that such capacity may be impaired. Adopting a structured, iterative consent assessment process as described in this study enables a consent process to be integrated with routine assessments for data collection and re-assessment. It is important for researchers always to document the consent process effectively to ensure explicit recording of the pathways to informed consent, which may include self-consent, consent from an appropriate relative, or consent from the institutional manager of the health establishment.

Future directions

Prospective, longitudinal designs should examine trajectories of scores demonstrating change driven by iteration in the consent process alongside symptom resolution. There is also a need to evaluate research consent processes focused on reducing assumption-based exclusions. These should be combined with quantitative capacity metrics and post-recovery interviews to triangulate understanding and appreciation of research consent in cases where there may be decisional impairment due to mental illness.[5,10] Future longitudinal work should include formal psychometric validation, trajectory analyses of decisional recovery, and post-recovery patient perspectives, which have been shown to be informative in catatonia research.[5]

Conclusion

The findings of the present study indicate that the presence of catatonia should not be assumed to indicate decisional incapacity. Undertaking a structured assessment of capacity to consent provides a practical and ethically defensible means of distinguishing impaired performance from impaired decision-making. By combining iterative clarification, documented proxy pathways where necessary, and reassessment as clinical status evolves, the framework described here offers a practical approach to supporting equitable inclusion in mental health research while maintaining respect for autonomy and compliance with SA legal and ethical standards.

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Conflicts of interest. None.

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