REVIEW ARTICLE

ADDRESSING RESEARCH ETHICAL DILEMMAS ON COGNITIVELY IMPAIRED MENTALLY ILL PATIENTS (CIMI): INSIGHTS FROM A PRISMA-GUIDED REVIEW

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ABSTRACT

Participants reserve the right to privacy and confidentiality like other patients to maintain their dignity. This research aims to identify the problems encountered by the researchers and the solutions they proposed while researching cognitively impaired mentally ill patients, to encourage the involvement of this neglected population in terms of research and hence management. The objective of this review was to identify the ethical solutions while researching cognitively impaired mentally ill patients. 21 studies, fulfilling the inclusion criteria from 2003-2024 were selected. This review follows the Cochrane Book of Systematic Review and PRISMA guidelines 2020. Informed consent remained the most inevitable challenge for researchers. There should be the revision of policies for researching such vulnerable populations to find ways to minimize the ailment while keeping in mind the privacy and safety concerns of research participants. Ethical recommendations for research involving cognitively impaired, mentally ill patients include adaptive consent processes using simplified language, involvement of legal guardians, and continuous consent reassessments. Privacy protections and strict data handling protocols are essential, along with minimizing risks and maximizing benefits. Researchers should receive specialized training, and studies should be regularly reviewed by ethics committees to ensure adherence to high ethical standards.

Key words: *Ethics, Cognitive Impairment, Informed Consent, Cognitively Impaired Mentally Ill, Ethical Dilemmas*

INTRODUCTION

The ability of individuals to make a meaningful decision becomes questionable when they are cognitively impaired or mentally ill, so, often neglected as research participants or consent givers.[1] This violates their right to decision-making alongside the potential risk of undertreatment. But why this is happening, remains a question, so we conducted a review that involves challenges faced by researchers while conducting research on such patients and their recommendations. Cognitively impaired mentally ill (CIMI) patients have a mental disability that considerably impairs cognition, or capacity to recall and process information. This includes Alzheimer's disease, schizophrenia, and severe depression.[2,3,4] The prevalence of cognitively impaired mentally ill patients is difficult to estimate, as there is no agreed-upon definition of what constitutes "cognitive impairment." However, multiple studies revealed that 1.7-40% of individuals suffering from common infections report cognitive impairment.[5] The unknown incidence of CIMI patients is due to the underdiagnosed cases or if diagnosed, do not opt for medical treatment.[6] Still, estimates reveal up to 10% of the population may suffer cognitive impairment at some point in their lives.[7,8]

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CIMI presents a unique challenge when it comes to conducting research. The nature of their impairment indicates an inability to give appropriate consent or an inability to understand the information given to them. This can make it difficult to obtain reliable data for research patients.[9] A study involving cognitively

impaired patients needs a special consideration of the benefits-to-risk ratio while proceeding with research. Such types of research can be beneficial for the patients and may enhance evidence-based patient care,[10] but the patient's safety and ability to process or understand the provided information must also be considered as risk factors to avoid any physical, emotional, or mental harm.[11,12]

Studying CIMI patients is tricky, so it's better to work as a team of professionals who are already a part of that community for the selection of an appropriate research design.[9] Choosing an appropriate research design is crucial so as to provide an answer to the research question. For example, if someone wants to determine the efficacy of some treatment, they may select a randomized control trial but as these patients might be unable to give informed consent, it is important to obtain special consent from ethical review boards or policymakers to ensure patient autonomy.[13]

Adhering to ethical principles protects the rights and welfare of the participants along with increasing the researcher's value.[14] Furthermore, researchers must ensure that confidentiality is maintained and that collected data is used in a way that is respectful of participants' rights and dignity.[15,16] The goal of research is to improve the understanding of mental illness and develop new treatments but it is also important to remember that patients may be vulnerable and risks should be minimized as much as possible.[14,9,15]

The aim of this review is to find the difficulties encountered and recommendations while conducting research on cognitively impaired mentally ill patients. This may enhance the recruitment of both healthy volunteers and people with mental illness as they express identical viewpoints.

The rationale of this systematic review is to understand the difficulties encountered during conducting research on cognitively impaired patients and find ethical considerations to counter such challenges while keeping in mind the safety and wellness of research participants.

METHODOLOGY

The duration of this systematic review was November 2023- March 2024. The data was extracted from November 2005 to January 2024, and out of 5299 matching articles, only 22 discussed the ethical challenges and considerations while researching cognitively impaired patients (Fig 1&2). Keywords used were ethics and research, Informed Consent, Cognitive impairment and ethics, challenges, and cognitive impairment. (Table I)

Data Selection:

Various databases like WOS, PubMed, ScienceDirect,

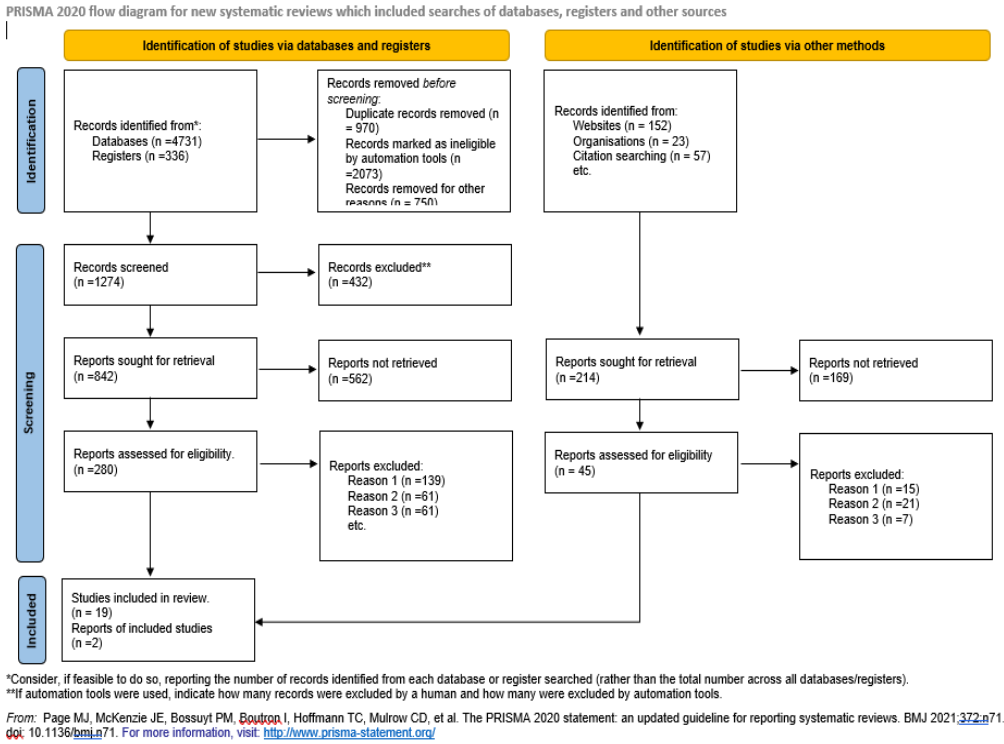

Figure 1: Prisma flow diagram showing a selection of studies for current systematic review.

Willey's, Google Scholar, and registries were searched for the acquisition of data via different automation tools like Segment, Protocols, and Zapier. The last data was searched on January 2024, all authors worked independently for data search and self-reviewed the data after the use of automation tools. Data extraction involved a standardized form where relevant information on ethical challenges was systematically identified. Quality assessment was conducted using a modified risk of bias tool to evaluate the robustness of each study. Automation tools such as Segment, Protocols, and Zapier played a crucial role in retrieving data from diverse databases by filtering relevant studies based on predefined keywords and automating the removal of duplicates. These tools ensured consistency and reduced the risk of bias in study selection. All data was reviewed independently by authors to validate the findings, with counter-reviews conducted to further ensure accuracy. To limit the bias, the received data was counter-reviewed. Quantitative or qualitative studies, particularly clinical trials and epidemiological studies describing ethics and informed consent while conducting research on cognitively impaired patients were included.

Inclusion criteria:

1. Studies on ethical challenges and considerations while researching cognitively impaired patients.

Exclusion criteria:

1. Studies involving patients without significant cognitive impairment.
2. Studies focusing on clinical challenges in mentally ill patients, rather than ethical challenges while conducting research.

Study Protocol

Guidelines from the Cochrane handbook of Systematic Reviews was followed while conducting this systematic review and is reported based on PRISMA 2020 guidelines. The initial draught was produced after careful consideration of these papers. The contributors' levels of clinical and research experience were integrated into the second edition. On a virtual platform, a thorough conversation about the paper's numerous features was done with each author. A position on ethical matters was developed by combining the contributions of all authors.

RESULTS

The final selection of 22 studies was carefully reviewed to address the existing challenges and ethical recommendations associated with conducting research involving vulnerable populations, particularly those with cognitive impairments or severe illnesses. These studies, originating from diverse research backgrounds, emphasize global perspectives on ethical considerations, reflecting various legal, cultural, and institutional challenges in research involving consent and patient autonomy.

While assessing the results of each study we found some important challenges which were common in most of the studies and created significant impact. These included informed consent, patient patient-centric environment, social stigma, and obtaining ethical approval from concerned departments. Table I, Figure 2

The current study also proposed certain ethical recommendations based on the results. These include developing simplified and accessible consent materials alongside cognitive assessment tools tailored to capacity levels that may ensure that even individuals with limited cognitive function can participate meaningfully. It also

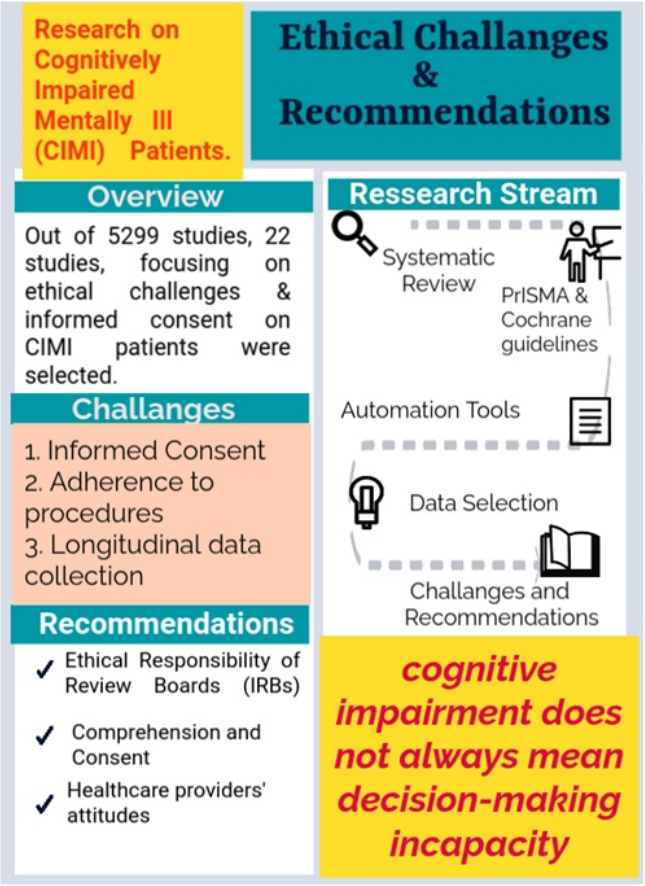

Figure 2: An overview for visualization of the main crux of the study.

suggests supportive decision-making while respecting participants' right to assent or dissent, even with cognitive limitations. Researchers should strive to

maintain autonomy and safeguard human rights throughout the study. The current study also presented solutions for following national and international ethical guidelines, including principles like autonomy, beneficence, and justice, that may protect against coercion and ensure participants' well-being. We also propose employing validated, easy-to-use assessment tools tailored to older or cognitively impaired participants to improve the feasibility of assessing consent capacity without imposing significant time constraints.

Table I: Ethical challenges faced by the researchers and the best-proposed solutions for research on Cognitively Impaired Mentally Ill patients.

Sr. No.	Author	Challenges	Ethical recommendations
1.	Laing (2024)[17]	Consent and lack of emotional and social support to the consent givers.	Attention should be paid to the laws and policies involving consent from mentally ill patients or their assigned relatives.
2.	Lange MM (2013)[18]	Informed Consent.	The importance of autonomy also requires that, even if a surrogate is chosen, participants should be told about the potential research before agreeing or disagreeing to participate.
3.	Witham G (2015)[19]	Lack of Patient patient-friendly environment.	Health practitioners can start to develop more flexible ways to care through interaction with the larger environment by allowing the circumstances to develop where different choices are acceptable.
4.	Warner J (2008)[20]	The Mini-Mental State Examination alone was insufficient to predict the ability of informed consent after controlling for confounding factors.	To determine the eligibility of giving consent, cognitive testing alone is insufficient. Researchers and practitioners should be aware of the difficult procedures involved in assessing capacity.
5.	Monroe(2012)[21]	Social stigma and barriers	When studying people with cognitive impairment, researchers must be careful to take several precautions to protect all participants. Researchers should not be discouraged from adding people with dementia to their studies by the need to take the time to implement additional protections.
6.	Duke(2010)[22]	Numerous issues are raised by the literature on palliative care while conducting research on such patients.	Concerning the morality of studying patients with life - threatening illnesses, specifically if such is morally acceptable, the researcher must conduct the study.
7.	Casarett (2003)[23]	Unawareness/lack of following the guidelines for taking informed consent.	Guidelines for the prudent application of processes for evaluating decision-making competence must be followed.
8.	Williams et al (2006) [24]	Bias	Patients in healthcare as well as the people who are caring for them want to take part in studies. Younger hospice patients had a higher likelihood of being enthusiastic about taking part. The desire to participate was the same for older patients in the hospital and older non -hospital patients. So, such patients should be included, and the researcher should not be biased.

9.	M.Ruiz(2014)[25]	Informed consent and Ethical committee barriers.	The study demonstrates that subjects with dementia can still contribute significantly to the treatment or handling of fellow patients.
10.	*Doyle, C* (2013)[26]	Informed consent	The review's findings were analyzed considering national guidelines, and it was determined how capacity should be assessed, what constitutes best interests, how to ascertain and respect the assent and dissent of a person with dementia, and whether such individuals should be involved in high-risk research.
11.	*I.Hellstrom*[27](2012)	Informed consent. Ethical review barriers.	Institutional policies vary widely, researchers must collaborate closely with individual review boards to guarantee safety and scientific rigor.
12.	G.Hougham (2003)[28]	Lack of IRB approval and informed consent.	Policies must be made to protect the human rights of giving informed consent or not and must be followed.
13.	U.Oruche (2009)[15]	Informed consent.	Additional ethical issues arise when using subjects with cognitive impairment in research because they may be more susceptible to coercion. Because of this, nurse researchers not only need to comprehend the common rule's additional precautions for protecti ng participants with cognitive impairments in research but also the principles of informed consent (autonomy, beneficence, nonmaleficence, and justice). These protections include acquiescence, legal representation, and prior informed consent.
14.	N.Ries (2020)[29]	Informed consent by the subjects.	Researchers revealed inconsistent methods for determining whether potential volunteers could give informed consent to their experiments. For this, a variety of instruments are utilized, ranging from more broad cognitive function screens to research -specific tests (such as the MacArthur Competence Assessment Tool for Clinical Research) (e.g., Mini Mental State Exam).
15.	L.Dunn (2015)[30]	Noncollaboration of research results to research participants.	Researchers have different ethical responsibilities when "returning results" to study participants than clinicians, who must follow the beneficence and non -maleficence principles and return results as part of the entire therapy strategy.
16.	T.Gilbert (2017)[13]	Time constraints and informed consent. Subjects' lack of interest.	The best-validated questionnaire now is the MacCAT -CR. But it seems time-consuming and tough to use. Because of its simplicity, relevance, and applicability to older patients, a more modern test called the University of California Brief Assessment must be used.
17.	M.Chandra (2021) [11]	Informed consent	The logistics of including senior citizens in research, improving caregiver assistance, and promoting supportive decision-making must be considered by research policies. Along with enhanced care planning that will guarantee the well-being of study participants, it will also need to address the development of capacity assessment tools.
18.	L.Fields (2015)[31]	Informed consent.	Patients' comprehension of treatment alternatives may be hampered by cognitive limitations. Best practices should be followed when assessing a patient's ability to comprehend treatment alternatives if they have cognitive impairment.

19.	O.Silva (2020)[32]	Participants autonomy.	It is essential to design and carry out ethical studies to protect participants' rights, autonomy, and general well - being. An ethics board evaluation does not signal the start or end of ethical research. In a broader examination of morality, the "person -oriented research ethics" paradigm (American Anthropological Association 2012; Cascio and Racine 2018) offers benchmarks for comprehending the relational and experiential facets of research ethics.
20.	Van Rookhuijzen (2014) [33]	nil	These older subjects were able to develop supported justifications for taking part in a clinical trial despite their (moderate) cognitive impairment. Therefore, it is conceivable that they were able to decide this for themselves, as confirmed by their fami ly. Future clinical research on older adults with minor cognitive impairment must consider the desire to give selflessly to projects that may help others.
21.	H. Taylor (2015) [34]	Patient access for consent	In addition to the substituted informed consent by authorized individuals, vulnerable research participants should be given the ability to at least consent to the research procedure.
22.	L. Roberts (2014) [35]	Ethical concerns for vulnerable participants	Studies involving sick persons are viewed as morally acceptable by clinical research volunteers and healthy clinical research "nave" subjects, but their replies reveal concern about research involving vulnerable subpopulations and research that imposes sig nificant burdens and dangers. Research participants who are physically ill may be more eager to undergo difficult and dangerous research.

DISCUSSION

The current review included 22 research studies from 5299 studies selected from different databases, registrars, and websites from the period 2005-2024. The present study suggests exclusion of individuals with cognitive impairment from trials due to their inability to consent, follow procedure, and give longitudinal data is a significant barrier to this type of research. However, depending on the risk-benefit profile, numerous studies among older persons show a strong willingness to participate in research if they become disabled and unable to give consent. Instead of excluding people with dementia from studies, one institutional review board (IRB) recommended that researchers screen for decisional capacity, conduct more thorough and detailed capacity assessments for studies involving higher levels of risk, and ask for an IRB-appointed proxy for those who are unable to consent.

Most patients with a serious mental disease may make logical decisions about their medical care and can participate in decisions about treatments despite temporal deficits, according to authors of several research. As a result, the degree of impairment that may be a component of the mental disease rarely equates to decision-making incapacity. The results also show that, in routine clinical practice, people with psychotic disorders or other serious mental illnesses can make sophisticated risk-reward judgments. Small variations from ideal performance may be caused by limitations in the capacity to completely comprehend the worth of various possibilities for responses and choices. [33-35]

The current study emphasizes the responsibility of ethical review boards to particularly focus on studies in CIMI patients and maintain follow-up till completion of such studies. This highlights the role of the Ethical Committee in previous studies, which oversees not only approving the start of studies but also continuously ensuring that the approved study complies with the ethical standards.[36] According to a study, certain individuals may be more susceptible to engaging in misconduct, highlighting an essential consideration for all involved in research ethics. Ethical guidelines in

research recognize that vulnerability is an intrinsic aspect of the human experience. This analysis centers on developing a typology of vulnerability sources and demonstrating how these different sources create specific obligations for researchers. A key principle is that researchers must avoid actions that increase the vulnerability of study participants. To illustrate this approach, we examine two cases: an international research study involving a vulnerable population and a domestic study of individuals with impairments.[18]

The current study highlighted challenges in gatekeeping individuals with intellectual disabilities and mental health issues. Beyond the oversight of ethics committees and governance, identifying and recruiting vulnerable participants often proves difficult due to healthcare providers' perceptions and judgments on whether to "permit" access to certain patient groups. These perceptions and conclusions appear to be closely tied to ingrained attitudes toward mental illness. Similarly, William's clinical trial encouraged the inclusion of this demographic in research since they have shown that many in-patients were interested in participating in research and could explain the benefits and barriers.[24,22,23,26]

The study emphasizes that researchers must recognize and mitigate vulnerabilities in participants, ensuring their responsibilities do not exacerbate these vulnerabilities, particularly in marginalized populations. In contrast, few authors declared that patients' comprehension of treatment alternatives may be hampered by cognitive limitations. Similarly, others report that when assessing a patient's ability to comprehend treatment alternatives if they have cognitive impairment. This is necessary for proper informed consent. Therefore, it is crucial to correctly identify patients whose capacity is in doubt, assess their capacity, determine their competence, and rely on suitable alternative consent procedures.[31,32,30]

CONCLUSION

The significance of the inclusion of cognitively impaired individuals as research participants is beyond doubt. Neglecting such a population may lead to greater suffering in already vulnerable populations owing to a lack of appropriate data to support best clinical practices.

CIMI patients are unable to decide consent and hence are at risk of being exploited, so it is a huge responsibility for a researcher and team to be ethically imperative and take necessary steps while conducting research on this vulnerable population. Ethical considerations that need to be addressed include obtaining informed consent from the research participant or the nearest of kin/guardian if the participant doesn't hold the capability to understand the information provided. Researchers should maintain confidentiality and not let the integrity of participants hurt. If proper precautions are followed, then research may include such vulnerable populations in their study. Researchers may include such individuals by offering alternative exclusion until a fundamental shift in the viewpoint of funders of ethical boards takes place. Additionally, a transdisciplinary approach may provide a deeper comprehension of how this issue impacts individual disciplines and might aid in working as a unit to mishandle such a population.

List of Abbreviations:

Cognitively Impaired Mentally Ill (CIMI)

Institutional Review Board (IRB)

Limitations of study

Non-availability of open-access articles is the major limitation of this study.

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Authors' contributions:

Aqsa Saleem, Iqra Saleem, Duaa Younus, Nimra Khalid, Seher Naeem, Sampana Fatima: Conception of study / Designing / Planning, Analysis / Interpretation / Discussion, Critical Review, Manuscript Writing

Delima Maria: Analysis / Interpretation / Discussion, Critical Review, Manuscript Writing

Rafia Yasmin Khan: Analysis / Interpretation / Discussion, Manuscript Writing

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