

Informed Consent in Mental Health Research at Workplace

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Abstract

Background: Ethical considerations and informed consent are crucial in mental health research within workplace settings. The disclosure of mental health issues, the impact of workplace factors, and the experience of stigma all play significant roles in the ethical management of mental health data and consent processes.

Objective: This review aims to describe ethical issues and challenges related to informed consent in workplace mental health research.

Methods: We have reviewed several publications and journals from the past 5 years by conducting data searches on Google Scholar in May 2024. It is related to ethical issues concerning informed consent in mental health research in the workplace. We utilized keywords such as mental health research, ethical issues, informed consent, and workplace during the search.

Results: The literature review discusses the importance of obtaining informed consent in mental health research in the workplace. It highlights ethical dilemmas faced by employees in disclosing mental health issues, emphasizes the need for cultural sensitivity, and stresses the ethical responsibility of employers to provide mental health support. The review also addresses the significance of ethical issues in designing and assessing mental health interventions and emphasizes the ethical obligation to improve the quality of life for individuals with severe mental illnesses and coexisting somatic conditions in community mental health services.

Conclusion: Obtaining informed consent for mental health research in the workplace presents intricate ethical challenges. These include the need to ensure voluntary participation, maintain confidentiality, promote understanding of the research, and navigate workplace dynamics. Researchers are tasked with developing consent procedures that honor participants' autonomy while also addressing their unique needs and concerns.

Keywords: ethical issues, informed consent, mental health research, workplace

Abstrak

Pendahuluan: Dalam penelitian kesehatan mental di tempat kerja, pertimbangan etis dan informed consent merupakan hal yang sangat krusial. Pengungkapan isu kesehatan mental, pengaruh faktor-faktor di tempat kerja, serta stigma yang dialami, semuanya berperan vital dalam manajemen etis data kesehatan mental dan proses pemberian persetujuan.

Tujuan: Review ini diarahkan untuk menggambarkan isu-isu etika dan tantangan yang berkaitan dengan informed consent dalam konteks penelitian kesehatan mental di tempat kerja.

Metode: Kami telah meninjau berbagai publikasi dan jurnal selama lima tahun terakhir dengan melakukan pencarian data di Google Scholar pada Mei 2024, yang berkaitan dengan isu etika dan informed consent dalam penelitian kesehatan mental di tempat kerja. Kata kunci seperti 'penelitian kesehatan mental', 'masalah etika', 'informed consent', dan 'tempat kerja' digunakan selama proses pencarian.

Hasil: Review literatur ini menyoroti pentingnya memperoleh informed consent dalam penelitian kesehatan mental di tempat kerja, mengungkap dilema etika yang dihadapi oleh pekerja saat mengungkapkan isu kesehatan mental mereka, menekankan perlunya sensitivitas budaya, dan tanggung jawab etis dari pemberi kerja untuk menyediakan dukungan kesehatan mental. Review ini juga menekankan pentingnya pertimbangan etika dalam merancang dan mengevaluasi intervensi kesehatan mental, serta kewajiban etis untuk meningkatkan kualitas hidup bagi individu dengan gangguan mental berat dan kondisi somatik yang bersamaan dalam layanan kesehatan mental komunitas.

Kesimpulan: Proses mendapatkan informed consent untuk penelitian kesehatan mental di tempat kerja merupakan tantangan etika yang kompleks, yang melibatkan kebutuhan untuk memastikan partisipasi yang sukarela, menjaga kerahasiaan, memperkuat pemahaman tentang penelitian, dan mengelola dinamika tempat kerja. Para peneliti memiliki tanggung jawab untuk menciptakan prosedur persetujuan yang menghargai otonomi peserta dan sekaligus menangani keunikan kebutuhan dan kekhawatiran mereka.

Kata Kunci: masalah etika, persetujuan terinformasi, riset kesehatan mental, lingkungan kerja

Background

The inclusion of humans as subjects in health research is governed by several ethical principles that must be maintained to ensure the research is morally sound and legally accountable. The fundamental ethical principles of health research include:¹ Respect for persons, Beneficence and non-maleficence, and Justice. As outlined in the informed consent document, individuals participating as research subjects are required to consent to use their data. Key elements of informed consent encompass disclosure of information, comprehension, and the voluntary nature of participation. Informed consent expresses respect for the subjects, safeguarding their honor and dignity, and ensuring the privacy of all data, materials, and personal identities involved.¹

There are limited circumstances where human research subjects are involved but informed consent is not required for approval. These include: (1) when the subject is a baby, child, or unconscious patient and the family provides consent on their behalf, (2) when the research involves the use of medical records, and (3) when the research is on preserved tissue samples and the subject is unidentifiable.^{1,2}

Informed consent is a fundamental principle in research, ensuring that participants fully understand the nature, benefits, and risks of their involvement. This principle is particularly crucial in mental health research in the workplace, where the sensitive nature of mental health issues intersects with professional dynamics and potential stigma. The complexity of obtaining informed consent in this context requires careful consideration of confidentiality, voluntariness, and the psychological impact of disclosure.¹

Various methods are being explored to improve the informed consent process in mental health research, including using interactive digital tools, emphasizing collaborative decision-making, and managing expectations to ensure full participant understanding and uphold ethical standards.¹¹⁻¹³

The background for research on Mental Health in the Workplace includes:³ (1) Public Awareness: Increased public awareness of employee mental health issues, especially during the COVID-19 pandemic. (2) Organizational Impact: Employee mental health problems can significantly affect organizations. Providing mental health resources can offer a competitive advantage. (3) Role of the Workplace: The workplace

promotes positive mental health, prevents mental illness, intervenes to address employee mental health problems, and accommodates employees with mental health challenges.

Study from Kelloway, Dimoff, and Gilbert (2021) highlighted ethical considerations in workplace mental health research in their publication “Mental Health at the Workplace,” which includes:³ (1) Privacy and Confidentiality: Ensuring the confidentiality of personal information and mental health data of employees, (2) Informed Consent: Securing proper consent from participants while informing them of the research’s purpose and their rights, (3) Stigma and Discrimination: Addressing the potential stigma and discrimination that may result from identifying mental health issues, and (4) Intervention Boundaries: Defining the limits to which researchers can intervene in participants’ mental health without crossing professional boundaries.

As stated in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants by the Indian Council of Medical Research (ICMR 2017), individuals with mental health conditions are considered a vulnerable group that requires special protection in research settings. They are particularly susceptible to the burdens and potential harms of research participation for several reasons: (1) Their conditions may compromise their autonomy and capacity to make decisions, particularly in their own best interests. (2) Their conditions may lead to dependency on caregivers or institutionalization, placing them under additional pressures, whether real or perceived. It is crucial to recognize that mental health research often includes people without mental health conditions, known as “healthy controls.” (3) Due to the stigmatizing nature of mental health conditions, individuals affected by them may face heightened vulnerability to stigma and discrimination if their conditions are disclosed.¹⁰

In workplace mental health research, obtaining informed consent involves addressing complex ethical issues, ensuring confidentiality, combating stigma, and guaranteeing that participation is voluntary. These considerations are crucial for conducting ethical and effective research that can contribute to meaningful improvements in workplace mental health policies and practices.^{3,6}

The focus of this review is to delve into the ethical considerations surrounding informed consent in mental health research within the workplace.

Methods

We have gathered various publications and journals from the past 5 years by conducting data searches on Google Scholar in May 2024. These sources are related to ethical issues concerning informed consent in mental health research within the workplace. We utilized keywords such as mental health research, ethical considerations, informed consent issues, and workplace during the search. When conducting searches using these keywords, we place more emphasis on filtering the title and abstract of the research. Research journals that meet these criteria are included, while various journals that do not meet the criteria are excluded.

Results

Five articles discuss informed consent issues in the workplace. The study outlined in the first article aims to explore the experiences of workers with mental health issues, focusing on their decisions to disclose their condition to their managers and the consequences of those decisions.⁷

Organizations need to promote supportive leadership practices and reduce stigma to create a safer environment for employees to discuss mental health concerns.¹⁸

The second article aims to assess the impact of workplace factors on the mental health of healthcare workers (HCWs) during the COVID-19 pandemic across 41 countries. It will use depressive symptoms as the primary outcome to assess mental health and identify key workplace factors associated with mental health outcomes. The goal is to provide evidence-based data to inform governments and policymakers of future strategies to safeguard HCWs' mental health during pandemics.⁴ These considerations demonstrate the researchers' dedication to ethical conduct and the protection of participants' rights and data privacy. The study emphasized the significant levels of stress, anxiety, and burnout experienced by healthcare workers. This was due to heavy workloads, lack of personal protective equipment (PPE), and inadequate support. Ensuring informed consent in such high-stress environments is crucial. Participants must be fully aware of the study's purpose and their rights, especially amid ongoing stressors related to their professional duties.

The third study conducted by Subu et al. (2021) in mental health research faces challenges in obtaining informed consent due to the vulnerable nature of the participants. Patients with mental illness may have impaired decision-making capacity, requiring additional measures to ensure their understanding and voluntary participation. The research was conducted at a psychiatric hospital in West Java, Indonesia, with 15 patients and 15 nurses participating. The study aimed to provide a comprehensive understanding of stigma within the Indonesian cultural context to guide effective interventions.⁵

The fourth research conducted by Tsantila et al. focused on creating a detailed framework for assessing complex mental health interventions in the workplace using a Theory of Change (ToC) approach. The framework is designed to delineate the pathways and mechanisms that enable mental health interventions to achieve intended results, taking into account the unique contextual elements and dynamics present in workplace environments. The aim is to offer a systematic approach to the design, execution, and assessment of mental health interventions, with an emphasis on their efficacy and ethical integrity.⁸

1. Informed consent within this study is multifaceted due to the intervention's complexity and the variety of stakeholders involved. The approach to the study underscores several critical aspects of informed consent:⁸
2. Transparency and Comprehensiveness: Participants must grasp the entire extent of the intervention, its various elements, and the anticipated results at different levels (employee, team, leader, organization). This requires transparent communication regarding the study's objectives, methods, potential risks, and benefits.
3. Cultural Sensitivity: With the study's international scope, the informed consent procedures must be culturally tailored to comply with the ethical norms and expectations of each participant's country. This involves the translation of consent documents and their simplification for participants of diverse cultural origins.
4. Confidentiality and Data Protection: Assurance is necessary that participant data will be confidentially managed, particularly as mental health information is exceptionally sensitive.

Table 1. Ethical Consideration: Comparing the First and Second Articles

Article title	Authors	The aims of study	Informed consent	Ethic Approval	Data Privacy	Data Availability
Workers' Decisions to Disclose a Mental Health Issue to Managers and the Consequences. ⁷	Dewa CS, van Weeghel J, Joosen MCW, Gronholm PC, Brouwers EPM	<p>- Disclosure Proportion: Determine what proportion of workers with mental health issues disclosed their condition to their managers.</p> <p>- Disclosure Factors: Identify the factors that influenced workers' decisions to disclose or not disclose their mental health issues.</p> <p>- Disclosure Consequences: Examine the consequences of workers' decisions to disclose their mental health issues.</p>	The study involved human participants who provided informed consent to participate in monthly questionnaires, including the one for this study.	The research protocol was reviewed and approved by the University of California Institutional Review Board (IRB).	The study dataset was de-identified by CentERdata before analysis to protect participants' privacy.	The data supporting the findings are available from CentERdata but are subject to restrictions and not publicly accessible.
Workplace factors associated with mental health of healthcare workers during the COVID-19 pandemic: an international cross-sectional study. ⁴	Khajuria A, Tomaszewski W, Liu Z, Chen J hua, Mehdian R, Fleming S, et al	<p>- Identify Key Correlates: Determine the main factors affecting the mental health of HCWs during the COVID-19 pandemic.</p> <p>- Impact on Mental Health: Assess how workplace conditions influence HCWs' mental health on a global scale.</p> <p>- Inform Policy-Makers: Supply data-driven insights to aid in the formulation of policies and the provision of services that will protect HCWs' mental health during subsequent outbreaks.⁴</p>	Participation in the study was voluntary, and participants had the option to withdraw from the survey at any time. Measures were implemented to ensure confidentiality and privacy in compliance with GDPR, and all responses were kept anonymous.	The study did not require formal ethics approval according to the online decision tool of the NHS Health Research Authority	The study maintained compliance with the General Data Protection Regulation (GDPR) to protect the confidentiality and privacy of the survey participants.	The article is licensed under Creative Commons, allowing its use, sharing, adaptation, distribution, and reproduction in various mediums or formats, provided that proper attribution is given and any modifications are noted

The study must detail the protection and usage of data, with participants agreeing to these conditions.

5. Voluntariness: Essential to the study is the complete voluntariness of participation, with the option for participants to withdraw anytime without repercussions. This element of informed consent ensures participants do not feel compelled or pressured to join due to workplace dynamics or other influences.

Ongoing Consent: Informed consent is a continuous dialogue, not a singular occurrence. Participants ought to receive consistent updates on the study's development and any intervention modifications that may impact them, thus permitting them to renew their consent as necessary.

The last study from Martens, et.al (2021) aims to systematically review and synthesize existing research on the organization of community mental health services for individuals with severe mental illness (SMI) and comorbid somatic conditions. The main goal is to evaluate the impact of these services on somatic health outcomes and overall health-related quality of life (HRQoL). This comprehensive review seeks to identify effective organizational strategies that improve the physical health and quality of life of this vulnerable population.⁹

Informed consent is a vital ethical element in treating individuals with severe mental illness (SMI), especially when they also suffer from somatic conditions. These patients might not fully understand the consequences of their treatment choices. Therefore, healthcare providers should implement enhanced consent procedures, including simplified explanations, visual aids, and ongoing discussions, to ensure comprehension and voluntary agreement. Research has pointed out the challenges in securing informed consent from individuals with SMI.⁹

Discussion

Participating in workplace mental health research can be a dilemma for some individuals, leading to a lack of willingness to take part. The research findings highlight various ethical concerns, especially regarding informed consent in mental health research within the workplace.

Informed Consent and Disclosure

Dewa et al. (2021) emphasize the complexities that workers face when deciding whether to disclose mental health issues to their managers.⁷ The study underscores the importance of ensuring employees fully comprehend the implications and potential outcomes of such disclosures, both positive and negative. Transparent communication and voluntary disclosure, free from coercion, are essential.⁷

There are ethical concerns when employees feel compelled to disclose mental health conditions due to fear of stigma or discrimination. True informed consent requires clear communication regarding the use of the disclosed information, access to it, and the safeguards for confidentiality.

Impact of Workplace Factors on Mental Health

Swetha et al (2023) and Khajuria et al. (2021) : This study examines workplace factors that affect the mental health of healthcare workers during the COVID-19 pandemic. The ethical challenge here involves obtaining informed consent in a high-stress environment and ensuring participants are aware of their rights to withdraw from the study without any repercussions.^{5,14}

Ethical considerations from this study: The pandemic context adds another layer of complexity, as healthcare workers might be more vulnerable and feel obligated to participate. Researchers must emphasize voluntary participation and provide adequate support to participants experiencing distress during the study.

Stigma and Its Impact on Consent

Subu et al. (2021): This qualitative content analysis explores the types of stigma experienced by patients with mental illness and mental health nurses in Indonesia. The study underlines the importance of understanding cultural and contextual factors that influence informed consent.⁴

This research has encountered an ethical issue. Informed consent processes should address the fear of stigma, which might discourage individuals from participating in research. Researchers must build trust and ensure confidentiality to alleviate these concerns.

The study conducted in Ireland centers on the mental distress experienced by transgender individuals. It underscores the effects of stigma, the deficiencies in

mental health services, the crucial role of education on transgender identities, the value of peer support, and the pursuit of self-acceptance and societal inclusion. The research stressed the importance of informed consent, particularly for participants below the age of 18, and ensured confidentiality through the use of anonymous surveys and the anonymization of quotes.¹⁷

Frameworks for Mental Health Interventions

Tsantila et al. emphasized the importance of developing a Theory of Change for complex workplace mental health interventions. This involves evaluating the effectiveness and impact of these interventions.⁸

One ethical issue to consider is ensuring that participants are fully informed about the nature of the interventions, the expected outcomes, and any potential risks involved. Ethical considerations require researchers to ensure that the informed consent process includes a thorough explanation of the intervention framework, expected benefits, and any potential risks. This allows

participants to make an informed decision about their involvement.

Community Mental Health Services

Martens et al. conducted a review of mental health services for individuals with severe mental illness and comorbid somatic conditions. The ethical discussion should address challenges in obtaining informed consent from individuals with impaired decision-making capacity.⁹

In studies involving vulnerable populations, informed consent is handled with meticulous care to ensure ethical standards and respect for the participants’ autonomy and privacy.^{9,15,16} Interviews are conducted in private settings, and there have been no reports of discomfort or embarrassment regarding the content or format of the interviews, indicating that confidentiality has been maintained.¹⁵ The consent process may involve the use of simplified language, visual aids, or the participation of caregivers.⁹

Table 2. Article selected overview

Article title	Study design	Population	Result
Workers’ Decisions to Disclose a Mental Health Issue to Managers and the Consequences	Mixed-methods research design, a combination of quantitative and qualitative data collection and analysis methods	The data comes from the February 2018 Longitudinal Internet Studies for the Social Sciences (LISS) panel, consisting of 5,000 households and 7,357 panel members over the age of 18 who were employed or seeking employment.	<p>Disclosure Decisions: About 73% of workers with mental health issues disclosed them to their managers.</p> <p>Factors Influencing Disclosure: Decisions were influenced by both intrinsic factors (like responsibility and manager relationship) and extrinsic factors (such as organizational policies).</p> <p>Consequences of Disclosure: The majority had positive experiences, mainly due to managerial support, while a minority faced negative consequences, including job loss.</p> <p>Workplace Stigma: The study highlights the complexity of workplace stigma and suggests that interventions should be tailored to individual workplace contexts.</p>

Article title	Study design	Population	Result
Workplace factors associated with mental health of healthcare workers during the COVID-19 pandemic: an international cross-sectional study	Descriptive statistics by using Cross-sectional studies. Inferential statistics by using regression analysis	Healthcare workers from multiple countries, provide a diverse and global perspective on the issue.	A total of 2527 responses were received from 41 countries, and respondents from China reached 48% of the total samples. 1343 (57.1%) were aged 26 to 40 years, and 2021 (80.0%) were female; 874 (34.6%) were doctors, and 1367 (54.1%) were nurses. Factors associated with an increased likelihood of depressive symptoms were: working in the UK and USA; being female; being a nurse and caring for a COVID-19-positive patient who subsequently died. Workplace factors associated with depressive symptoms were: redeployment to the Intensive Care Unit (ICU); redeployment with perceived unsatisfactory training, not being issued with appropriate personal protective equipment (PPE), perceived poor workplace support within the area/specialty, and perceived poor mental health support
Types of stigma experienced by patients with mental illness and mental health nurses in Indonesia: a qualitative content analysis	Qualitative research method based on directed content analysis. Data collected through semi-structured interviews, memos, field notes, and document reviews	It was conducted at the largest of Indonesia's 33 psychiatric hospitals in West Java, with participants from various ethnicities and urban and rural areas.	Five themes emerged. Four themes were patient-related: personal/patient stigma, public/social stigma, family stigma, and employment stigma. The fifth theme related to stigma toward healthcare professionals working with patients with mental illnesses, which we categorized as professional stigma
Developing a framework for evaluation: a Theory of Change for complex workplace mental health interventions	The study uses a participatory approach to develop the ToC, involving a large project team with diverse academic backgrounds. MENTUPP Project as a research context, aims to improve mental health in occupational settings, particularly in SMEs. Systematic Reviews and Surveys: The ToC is informed by six systematic reviews and survey results from practitioners and experts in the field of mental health in SMEs.	The study's population is diverse, encompassing employees from various industries and roles, as well as stakeholders involved in mental health intervention strategies	The ToC revealed four long-term outcomes that we assume MENTUPP can achieve in the workplace: <ol style="list-style-type: none"> 1) improved mental well-being and reduced burnout 2) reduced mental illness, 3) reduced mental illness-related stigma 4) reduced productivity losses. They are assumed to be reached through six proximate and four intermediate outcomes according to a specific chronological order. The intervention consists of 23 components that were chosen based on specific rationales to achieve change on four levels (employee, team, leader, and organization).

Article title	Study design	Population	Result
Organization of Community Mental Health Services for Persons with a Severe Mental Illness and Comorbid Somatic Conditions: A Systematic Review on Somatic Outcomes and Health-related Quality of Life	<p>Systematic Review:</p> <ul style="list-style-type: none"> - Literature Search: Researchers performed an extensive search across various databases to find pertinent studies, which probably encompassed PubMed, Cochrane Library, and PsycINFO, among others. - Inclusion and Exclusion Criteria Determination - Data Extraction - Quality Assessment: Standardized tools were employed to evaluate the quality of the studies included, confirming the systematic review's findings' reliability and validity. Data Analysis: <ul style="list-style-type: none"> - Descriptive Analysis - Comparative Analysis - Thematic Synthesis 	<p>1. Persons with Severe Mental Illness (SMI): Individuals diagnosed with severe mental health conditions, which may include disorders such as schizophrenia, bipolar disorder, severe depression, and other serious psychiatric illnesses.</p> <p>2. Individuals with Comorbid Somatic Conditions: These are patients who, in addition to having a severe mental illness, also suffer from one or more significant physical health conditions (somatic comorbidities). These conditions can range from chronic diseases such as diabetes and cardiovascular diseases to other significant health issues impacting their overall quality of life.</p>	<p>Regular health checkups and adopting a healthy lifestyle can aid in the early detection and management of health issues, thereby reducing the burden of chronic diseases.</p> <p>Enhanced Quality of Life: Individuals who availed themselves of integrated Community Mental Health Services (CMHS) reported an improved overall quality of life. This was attributed to better physical health, increased support from their social network, and improved caregiving.</p> <p>Enhanced Functional Capability: Participants also experienced improved functional capability, enabling them to engage in daily activities and social interactions more effectively.</p> <p>Enhanced Mental Well-being: While the primary focus was on physical health, the integrated approach also positively impacted mental well-being, leading to a reduction in symptoms of severe mental illness and an overall improvement in mental health.</p> <p>Key Organizational Aspects:</p> <ul style="list-style-type: none"> - Diverse Teams: The presence of diverse teams within Community Mental Health Services (CMHS), comprising psychiatrists, general practitioners, nurses, and social workers, proved crucial in providing comprehensive care for both mental and physical health. - Care Coordination: Effective coordination of care was vital for ensuring seamless continuity of care and managing co-occurring conditions. - Patient-Centric Approach: Prioritizing the individualized needs and preferences of each person was essential in fostering greater engagement in their care and adherence to treatment plans.

Conclusions

Ethical issues in obtaining informed consent for mental health research at the workplace are complex and involve voluntary participation, confidentiality, understanding of the research, and workplace dynamics. Researchers must establish sensitive consent processes that respect participants' autonomy and address their specific needs and concerns.

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