

Ethical issues arising in research with people with mental health conditions

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Case study: Setting exclusion criteria: implications for upholding the ethical principle of justice in conducting research in low income setting

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Research project summary

The research project that I am working on involves the detection of co-morbid mental disorders in adult people with epilepsy and their impacts of comorbid mental disorders in the quality of life, functional disability and seizure control. We did a prospective cohort of people with active convulsive seizures who were identified from the community and recruited from primary health clinic in rural southern, Ethiopia. The prevalence and the rate of detection of co-morbid mental disorders were evaluated at baseline and their impacts upon the important outcomes were measured after six months of follow up. We also did a qualitative interview to explore the experience of co-morbid mental disorder in the context of epilepsy. Some of the result of this project is published (1, 2).

Background

Epilepsy is a chronic neuropsychiatric disorder and is commonly associated with comorbid intellectual disability and mental disorders (depression and anxiety disorders) (3, 4). The prevalence of the most commonly occurring mental disorders in people with epilepsy (depression, anxiety disorders, psychosis, suicidality) ranges from 5-23.1% (4). The prevalence of intellectual disability is estimated to be 22.2% which is much higher than the general population (3).

Ethiopia is one of the low income countries with scarce mental health services and professionals and has been working on scaling up of mental health services integrated in primary health care (5).

Ethical issues during the conduct of this research project

Informed consent and witnessed verbal consent (for the illiterate participants) was sought after adequate information was given about the study. Those people who had substantial cognitive deficits and who lacked the capacity to consent were excluded from the study after appropriate assessment was carried out by psychiatric nurses. In this research project we have tried to keep all the principles of research ethics with especial emphasis on the equitable selection of participants. Those who lacked the capacity to analyse the research questions or the benefits or the risk of being part of the research were excluded in order to avoid any undue burden on these vulnerable groups of people. The reality of the challenge in conducting research in low income setting like Ethiopia comes when facing a number of adult people with developmental disorders (DD) and epilepsy who are living in the society. Our research question was also applicable to those people with DD and epilepsy, and perhaps even more so given that DD is a risk factor for mental health conditions in high-income country settings, but the questionnaires and the information sheet prepared was in line with those who have typically developed intellectual capacity.

The ethical principle of justice denotes the equal distribution of benefits, risks and cost of the research to participants (6, 7). This principle also includes the equal selection of participants with a clear justification of the eligibility criteria. Inclusion or exclusion of vulnerable group of people like individuals with DD without adequate reason would violate the ethical principle of justice. It is not only sharing the risks but also the equal distribution of benefits of the research and compensation of the participants who are harmed by the research is part of this ethical principle (6).

Involvement of people with developmental disorders in health care research has a lot of advantages in acquiring comprehensive evidence and in reduction of economic, health and social disparities but has been shown to be challenging (8). Some of the reasons for excluding these group of participants were challenges in communication, vulnerability to coercion, inexperience in decision making, excessive concerns for these people to be over-researched, difficulty to recruit into a study at multiple levels (8). The lengthy process of getting ethical approval or the ethical committees not being familiar with such kinds of research might also make researchers reluctant to include those people with DD.

Despite the efforts to protect these people from abuse and coercion, exclusion of them from researches will provide incomplete evidence. In addition this can also result in exclusion of people with DD from packages of care or service delivery. The availability of this information has paramount importance for policy makers who design implementation strategies and make decisions on service delivery. Inclusion of people with DD also has implications on training packages and improvement of curriculum for mental health professionals.

In a low income setting, conducting a mental health research project with the inclusion of people with DD needs assessment instruments designed specifically for this group. It requires more expertise and more time than is expected for participants who do not have developmental disorders. The cost for development, adaptation and validation of instruments for assessment of intellectual functioning or for the evaluation of common emotional problems in people with DD will be high. There is also a scarcity of trained human resources with the requisite competence to support inclusion of people with DD in these kinds of setting.

Conclusion and recommendations

In conclusion involvement of people with developmental disorders in health care research has a lot of advantages in acquiring comprehensive evidence designing packages of care or service delivery but has been challenging especially in low income setting. The ethical principle of justice is accorded when there is equitable distribution of research benefits and equal opportunities for contributions regardless of the research setting.

There are a number of strategies suggested by scholars to promote the participation of people with DD. Some of them includes: - creating a collaborative relationship between the researcher and the participant (use compassionate and respectful ways which promote ability to consent and protect against the violation of confidentiality), researchers should recognise and support the different levels of support needed, use of visual research methods. Researchers should also assist in making decisions to participate in research through minimal coercion by recognizing that adults with DD may experience power imbalance and establishing a clear relationship and promoting understanding (presenting information in relationship to familiar situations and experiences and using simple, jargon free symbols, concrete visual aids and multi-format practical demonstrations, repeated information, providing information in person verbally with nonverbal communication signals and allowing participants increased time to make decisions. The presence of strong, independent and knowledgeable ethical review committee can help to address coercion and vulnerability. Involvement of active researchers, participants with developmental disorder or those individuals knowledgeable about DD was suggested by some scholars. Researchers work collaboratively with the ethics committee and even evaluate the performance of the committee to help them change understanding and create effective practices that ensures protection and participation. Some authors suggested that

policies must match the ethical principles, standards of the cultural group or the country where the research take place (8).

References

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In 2021 GFBR hosted a series of five online seminars on the broad theme ‘Ethical issues arising in research with people with mental health conditions’. This case study was prepared for the seminar ‘The ethics of neurodevelopmental disorders research’. Recordings of the seminar series are available at www.gfbr.global.