Ethical issues arising in research with people with mental health conditions

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Case study
Ethical issues of involving people with mental health conditions who lacked capacity to consent in the TaSCS trial

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Background

Task sharing mental health care through integration of mental health into primary health care is advocated globally as a means to narrow the high treatment gap for people with mental health conditions in low-income countries. This task-sharing model of mental health care is at the centre of the Ethiopian National Mental Health Strategy which is being scaled up in Ethiopia. The expectation is that task-shared care would be more affordable and accessible to most people with severe mental health conditions (MHC), including psychotic disorders and bipolar disorder, compared to existing centralized models of mental health care. However, the effectiveness and safety of this approach had not been evaluated using a randomized controlled trial in a low-income country. In the TaSCS study[1], a randomized, controlled non inferiority trial was conducted to investigate whether mental health care for people with severe MHCs integrated within primary health care using task-sharing was non-inferior to a less accessible, but more specialist, existing model of psychiatric nurse-led care. In the trial, a range of outcomes were evaluated, including clinical indicators, functioning, stigma and the quality and safety of care. The study was conducted in Meskan and Mareko districts, Gurage Zone, and Silti Zone, Southern Nations, Nationalities and People's Region, Ethiopia.

Ethical issues of involving people with mental health conditions who lacked capacity to consent

In the TaSCS trial, we included people with severe MHCs who lacked decisional capacity to consent to participation in the study. Psychiatric nurses, who were trained to assess decisional capacity for the purpose of the trial, assessed the participants' decisional capacity using a semi-structured form. Severe MHCs can affect the capacity for autonomous control over important aspects of an individual's life and people with such illness may periodically lose the ability to protect themselves. Our rationale for including people with severe MHCs who lacked decisional capacity was based on the ethical principle of equity. It was felt to be crucial to include people who lacked capacity as we were testing a task-shared service intervention which was already going to be scaled up by the Ministry of Health and would inevitably be delivered to people with MHCs who lacked capacity in real world settings. Therefore, the evidence from the trial needed to be applicable to the target group for this intervention, particularly in relation to safety concerns. Balanced against this was a concern for the wellbeing of the person with a MHC. We sought to establish procedures that would safeguard a person who lacked capacity from harms arising from involvement in the study. These are discussed below alongside potential limitations of these approaches.

(1) A mental health professional was involved in assessment of decisional capacity to consent to participate in the study. For feasibility, the mental health professionals were psychiatric nurses who were trained by experienced psychiatrists. However, the concept of decisional capacity is unfamiliar to most mental health practitioners in Ethiopia and may have limited the quality of assessment.

(2) When a person was unable to consent because of lack of capacity, and as long as they were not communicating unwillingness to participate, we sought permission from their caregiver.

Information about the trial was explained to both the person with a MHC and the caregiver during the consent process. The legal concept of 'guardian' is not widely used in Ethiopia, and so we decided on the more practical option of involving caregivers. We sought permission from one of three caregivers documented during a home visit by project outreach workers when they went to invite participants for screening. Caregivers play a vital role in facilitating access to care for people with MHCs in Ethiopia and many low-income country settings.[2] However, previous studies from Ethiopia have also indicated that the treatment priorities of people with MHCs and caregivers sometimes diverge.[3,4] The relationship between a person with a MHC and caregiver may also be complicated by the caregiver's complicity in coercive practices, including restraint or covert administration of medication.[5]

(3) In order to maximise the possibility for the person with a MHC to consent to involvement, we planned to formally reassess capacity whenever there was an indication that the person might have regained capacity (identified by the family or through contacts with health care professionals and recorded in the clinical assessment sheets) and at each trial time-point (baseline, 12 and 18 month). However, in practice this only took place at the trial time-points because of lack of communication of changes in mental health status to trial staff from family members or health workers.

(4) The trial intervention was based on out-patient mental health care and was unlikely to include exposure to coercive care beyond the existing risk. Participation in the study did not indicate consent to mental health care, which the person could refuse at any stage. However, this was undermined by the absence of mental health legislation in Ethiopia to protect the autonomy people with MHC with respect to deciding to accept mental health treatment.

(5) In view of the potential risk of receiving inferior care (the main research question of the trial), the trial Data Safety and Monitoring Board regularly reviewed proxy outcomes for potential inferiority of care and reviewed an interim analysis at 12 months. This potential risk was also disclosed in the information sheet and discussed during the consent process including the measures which were in place to minimize the anticipated risks. In addition, project psychiatric nurses conducted weekly supervision of the primary care workers delivering task-shared care for the first 3 months in the intervention arm and reviewed their follow up clinical sheets.

(6) In people who had capacity at baseline, we asked for an advance directive from the person to guide what should happen if they subsequently lost capacity. They were asked whether they were willing to stay in the study if their mental health deteriorated to the extent that they lost the capacity to consent, as long as their caregiver who brought the person to screening and registered as a caregiver provided permission. With the permission of the participant, the contact details of the caregiver were recorded at baseline so that they could be contacted if the person lost capacity during the course of the study.

Recommendations for future studies

In mental health intervention research, it is important to include people with severe MHCs who lack decisional capacity where the harms of involvement are deemed to be low since these groups need the care the most. Hence, we argue that the value of collecting data on the impact on individuals who could not consent for themselves (ethical principle of equity) justified the possibility of exposing them to some research risks. Future studies should ensure that capacity to consent is assessed well and regularly examine if participants have regained decisional capacity during the study to obtain informed consent from the participants themselves. Consideration should be given to how to identify caregivers who are best placed to act in the best interests of the individual. Involvement of people with MHCs on research advisory boards could help to ensure that safeguards are adequate, especially in settings where mental health legislation is absent or not adequately enforced.

References

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