Ethical issues arising in research with people with mental health conditions

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Case study
Ethical issues in research evaluating the implementation of community based sociotherapy in refugee settings in Rwanda and Uganda

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Brief description of the research project

The World Health Organization (WHO) indicates that the basis of effective mental health services is the prevention and management of simple mental health disorders at the community and primary health care level with an emphasis on self-care.[1] Since November 2018, the Community Based Sociotherapy Adapted for Refugees (COSTAR) project has been evaluating the community based sociotherapy (CBS) approach using a randomized controlled trial (RCT).[2] This evaluation aims to measure how sociotherapy contributes to the reduction of the depressive symptomatology of Congolese refugees in the Kyangwali settlement in Uganda and the Gihembe refugee camp in Rwanda. It is led by the University of Liverpool of UK, Makerere University of Uganda and University of Rwanda. Participants in the COSTAR research project are randomly recruited. After recruitment and a pre-intervention survey, some of them are randomly allocated to the sociotherapy intervention while others are allocated to the control arm in which the millennium sustainable development goals are discussed. In a post-intervention survey the effectiveness of both interventions are compared in terms of symptomatology reduction. The ethical issues described in this case study draw upon my involvement in the COSTAR project as a coordinator of the sociotherapy implementation, and my experience of conducting research in post-conflict settings.

Background

Sociotherapy originates from a therapeutic community approach used to treat military casualties of the Second World War in UK hospitals.[3] In the 1970s, sociotherapy was used in the Netherlands to support the psychiatric treatment of refugees in clinical settings.[4] In the process of introducing sociotherapy in Rwanda in 2005, it was adapted to become a community based approach to support Rwandans to deal with consequences of the 1994 genocide against the Tutsi. Currently, sociotherapy is implemented in communities, prisons and Congolese refugee camps in Rwanda, in the Democratic Republic of Congo (DRC), in Liberia, and in the Kyangwali refugee settlement in Uganda. In all these settings, sociotherapy as a group based approach intends to support people whose lives have been disrupted by violent conflict and ongoing daily stressors. Its primary objectives include regaining and strengthening a sense of human dignity and psychosocial healing among the sociotherapy group members (participants).

Sociotherapy participants are not necessarily people with diagnosable mental health problems, but include people with a variety of psychosocial problems. A sociotherapy group is composed of fifteen people who live in the same neighborhood. Groups meet on a weekly basis for three hours for fifteen sessions in total. Each group is facilitated by two trained facilitators (sociotherapists) from the same living environment as the participants. Discussion in group sessions follows six phases (safety, trust, care, respect, new life orientations and memory), while applying different participatory methods to keep participants engaged.

Ethical issues

In the COSTAR RCT, CBS was adapted to a predesigned trial protocol, so the trial evaluated the adapted approach instead of evaluating sociotherapy as usually practiced.
Sociotherapy is usually adapted to the local context in which it is implemented throughout the sociotherapy process. Sociotherapy participants are invited by sociotherapists who know their community well and are therefore, after being trained, able to identify which people are likely to benefit from the approach. During the invitation process, the sociotherapists lay the foundation for trust building between them and participants. Differently, in COSTAR, participants were randomly recruited by research assistants, external to the community, who interviewed them for the pre-intervention survey. After determining whom to assign to the sociotherapy arm and whom to the control arm, a different research assistant linked the selected participants to sociotherapists. This long process prior to the engagement of sociotherapists in the process might have reduced the motivation of people selected to participate in sociotherapy with potential negative impacts on attendance and evaluation results.

In the screening process, people who were considered to have severe mental health problems, such as suicidal ideation, were excluded from further involvement in the project to ensure that these people are referred for more specialist care. However, there were participants allocated to sociotherapy who didn't report having suicidal ideation in the pre-intervention and post-intervention surveys. However, during the sociotherapy process they indicated that they had planned to commit suicide, that sociotherapy led them to abandon the idea, and that there was no need to refer them to a specialist. In the usual practice of sociotherapy, there is no formal screening done to decide who participates in sociotherapy or not based on the level of mental health problems. The informal criterion is to exclude people manifesting noticeable severe mental illnesses. Once sociotherapists discover that a participant has a severe mental health problem which cannot be managed in group sessions, the person is referred to a specialist. In the COSTAR project, the screening process may exclude people who may be included in the usual practice of sociotherapy and benefit from it.

Denying the intervention to the control arm
Research participants were recruited by telling them that they may receive the sociotherapy intervention or the control intervention. Control arm participants, who were included in the trial based on the same screening criteria as sociotherapy participants, will not be given the chance to participate in sociotherapy after completion of the research even though they may benefit from sociotherapy.

Delaying the intervention for research participants
In the COSTAR project, any research adaptation had to be approved by the sponsor, the ethics committee of Liverpool University, and ethics committees in Uganda and Rwanda. The intervention was halted many times whilst the relevant approvals were obtained for this long and expensive process. These delays disrupted the intervention for participants, which sometimes led to demotivation of participants and sociotherapy group facilitators ceasing sessions of sociotherapy and the control arm.

Conclusion
At the heart of the ethical issues identified here is a tension between the implementation of sociotherapy as usually practiced, which highly values trust building between participants and sociotherapists during the recruitment process, against the rigid scientific procedures of random recruitment of participants by researchers in the RCT and timelines dictated by the research design.

Recommendations
- Research designs should be adapted to the intervention to be evaluated instead of the intervention being adapted to a research design which changes the nature of the intervention.

- Research participants in the control arm of a RCT should be given the opportunity to receive the intervention after completion of the research.
- The research procedures should not interrupt the intervention delivery. To minimize the interruptions caused by approval processes, local ethics committees based where the research is being conducted should give approval to the necessary adaptations.

References

1. Sayed, G., D. (2011) Mental Health in Afghanistan, Burden: Challenges and the Way Forward. The Development Bank for Reconstruction and Development / The World Bank, Washington, DC. https://documents1.worldbank.org/curated/en/692201467992810759/pdf/658840WP00PUBL0736B0MHinAfghanistan.pdf

2. Community Based Sociotherapy Adapted for Refugees (COSTAR) project https://www.liverpool.ac.uk/institute-of-life-and-human-sciences/schools-and-departments/department-of-psychological-sciences/research/costar/

3. Whiteley, S. (2004) The evolution of the therapeutic community. Psychiatric Quarterly 75(3):233-248.

4. Richters, A., Dekker, C. & Scholte, W.F. (2008) Community based sociotherapy in Byumba, Rwanda. Intervention 6(2):100-116. www.interventionjournal.comsitesdefaultfiles6.2_02_%20Richters.pdf

This case study was prepared for GFBR 2021, which took place virtually. Further details are available at www.gfbr.global.