

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



## Background of sociotherapy

- Sociotherapy is a group-based approach used to support people whose lives have been disrupted by violent conflict.
- Its primary objective includes regaining and strengthening a sense of human dignity and psychosocial healing.
- Each group is composed of 12-15 people, meet weekly for 3 hours, facilitated by 2 trained sociotherapy facilitators.
- Phases guiding the process: safety, trust, care, respect, new life orientations and memory. Different participatory methods are applied to keep participants engaged.
- Since 2005, I have been part of a team coordinating the implementation of sociotherapy in Rwanda, including in the COSTAR project.



## Sociotherapy group meetings



# COSTAR project

- The COSTAR project evaluates the effectiveness of sociotherapy in reducing depressive symptomatology in Gihembe refugee camp in Rwanda and Kyangwali refugee settlement in Uganda.
- The study is a randomized control trial where research participants were randomly recruited and assigned to the intervention or the control arm; pre- and post-surveys are conducted to compare both interventions in terms of symptomatology reduction.
- The ethical issues involved in the study concern the tensions between conducting a rigid randomized controlled trial study, and the sociotherapy psychosocial approach that seeks to meet the needs of the population in the best possible way.



# Group setting



## Ethical issues identified:

- CBS was adapted to a predesigned trial protocol that evaluated the adapted approach instead of evaluating sociotherapy as usually practiced.
- Denying the intervention to the control arm.
- Delays to intervention delivery due to ethical and other approvals, which negatively impacted the quality of the intervention.

# 1. CBS was adapted to a predesigned trial protocol that evaluated the adapted approach instead of evaluating sociotherapy as usually practiced

- Research participants were randomly recruited by researchers in the COSTAR project while they are usually recruited by group facilitators (sociotherapists).
- The recruitment by research assistants disrupted trust usually built from the start of the intervention onwards when, as usual, participants are recruited by sociotherapists.
- COSTAR was identifying people based on the outcome of the use of mental health screening tools, whereas CBS is usually designed to help people with a range of mental health, psychosocial, and social problems.
- Random recruitment and screening by research assistants may exclude people who may be recruited to receive the intervention if recruitment was done by sociotherapists.

## 2. Denying the intervention to the control arm

Research participants are recruited on the basis that they may receive either the sociotherapy intervention, or the control arm intervention. In the COSTAR project, people allocated to the control arm were unable to participate in sociotherapy, even if this may have benefitted them. Similarly, those in the sociotherapy intervention due to the recruitment procedures were not always in need of, or able to engage with, the sociotherapy intervention.



### 3. Delaying the intervention for research participants

- Waiting for approvals from the sponsor, ethics committee in the UK and in Rwanda and Uganda led to delays in delivering sociotherapy. This demotivated participants, who then benefitted less from the intervention.

# End of the training of sociotherapists in Gihembe-Rwanda and Kyangwali-Uganda



## Conclusion

The ethical issues identified relate to a tension between the implementation of sociotherapy as usually practiced - which highly values the sociotherapists' knowledge of their communities and trust building between participants and sociotherapists during the recruitment process - random recruitment by research assistants, rigid scientific procedures required by an RCT, and timelines dictated by the research design and ethical approvals.

# 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.