Ethical issues arising in research with people with mental health conditions

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Case study: Adolescents' Resilience and Treatment Needs for Mental health in Indian Slums (ARTEMIS)

Pallab K. Maulik (presenter), Sandhya K Yatirajula, Sudha Kallakuri, Srilatha Paslawar
George Institute for Global Health India

Brief description of the research project

Background
Adolescents (10-19 years) are vulnerable to stress, depression and increased suicide risk which are leading causes of death and disability for this group, in India. There are around 250 million adolescents in India. Depression and self-harm account for a major share of the burden of death and disability in this age group. A study from rural India found that suicide rates amongst adolescents are amongst the highest in the world (148/100,000 and 58/100,000 for females and males, respectively) (Aaron R et al., Lancet, 363(9415), 1117-1118). Of those with depressive disorders, only 1 in 27 people receive effective treatment in low- and middle-income countries, such as India (Thornicroft et al., Br J Psychiatry, 210(2), 119-124). Barriers to care include both demand and supply side factors such as lack of awareness of mental health needs, public and internalised stigma, and few accessible health staff. These problems are exacerbated in urban slums where rates of poverty, unemployment, and interpersonal violence lead to increased rates of mental disorders, with less access to mental health care.

Our preliminary work has underlined the importance of the anti-stigma component in tackling the problem of mental ill-health, especially given the low level of knowledge about mental disorders in the community and myths surrounding it. The role of stigma in help-seeking is well documented. Additionally, it is important that affordable, accessible, effective treatments are available to tackle mental disorders, and individual resilience is strengthened, by providing healthcare support and an avenue to discuss problems in a non-stigmatizing manner.

Aim
1. To identify if a community-based anti-stigma campaign leads to significant improvements in community behaviours toward adolescents with mental disorders residing in urban slums.
2. To use a mobile device-based decision support system for primary healthcare staff (PHC) and find its impact on lowering depression and suicide risk in adolescents living in the same community.

Research Methodology
The proposed trial will be an implementation cluster randomised trial assessing effectiveness and cost-effectiveness, with slums within wards/blocks being the unit of allocation. The trial will test clinical effectiveness and implementation strategies across two geographical locations in India and draws on pilot research on similar interventions with rural adult populations in India. It is in line with current national and international policies related to reduction of the burden of mental illness among adolescents. The key components of the trial will be an anti-stigma component, and a mHealth component. The mHealth component will involve screening of adolescents for depression and

increased suicide risk. The ASHAs (lay village health workers) will follow those identified and refer them to the doctor in the primary health centres for clinical diagnosis and treatment using WHO's mhGAP tool which will also be based on a tablet. The ASHAs will follow-up on the patients once they have visited the doctor to ensure treatment adherence.

Background

The study will be conducted in two sites in India: the slums of Vijayawada and north-west area slums in New Delhi, and enroll ~35000 adolescents at each site. These are highly dense communities with populations close to 175000 at each site. Small houses are cramped in narrow lanes with poor sanitation, drainage, health facilities and schools. Urban slums have been found to have worse health indicators compared to even rural areas of India in government reports. Stressors for adolescents are many in the form of those related to their normal growth and development such as relationship-based issues, academic pressures, and parental pressures. In addition, slums may have higher rates of domestic violence, exposure to physical violence, job insecurity of parents, poorer health and hygiene in the community. These lead to higher levels of stress and depression which if unattended can lead to even self-harm and suicide. Through ARTEMIS we aim to identify and manage depression and increased suicide risks in adolescents and use a complex intervention involving increasing mental health awareness, reducing stigma perceptions related to mental health and developing technology-enabled mental health services for primary health workers to manage such cases in the community itself.

Ethical issues with commentary on each issue

a. *Maximising impactful, locally-relevant research*

It is critical to conduct research that is meaningful and relevant to local context. The ARTEMIS project was based on an extensive pilot project. Results from the pilot study were supplemented with qualitative research with 60 adolescents across both our study sites to understand how they perceived mental health; what could be possible barriers and facilitators to uptake of mental health services if made available; and what were key agencies to deliver such interventions. In LMICs such as India, it is important to conduct community-based translational research especially in mental health, given the lack of research and services to address mental disorders in the community. Hence ethically, any proposal should factor in relevance of research to local settings and a key aspect of the ethics process is to ensure that the tools being used are culturally relevant and the research impacts the widest possible group of beneficiaries. In that respect ARTEMIS has been developed as a hybrid implementation trial across two cities. It is especially mindful of existing mental health resources and so proposes to conduct the project without the need for additional mental health resources. It focuses on task sharing and training of existing primary health workers to deliver the interventions and embed them within existing health systems. Implementation trials integrated within existing health systems and policy have been identified as a key step for mental health research for LMICs (Petersen et al, Epidemiol Psychiatr Sci. 2020;29:e101).

b. *Engagement and co-creating*

In addition, the anti-stigma campaign which is an integral part of the complex intervention would be guided by an adolescent expert advisory group which will not only inform the components of the anti-stigma campaign but also the best modalities of delivering them. We will undertake wider stakeholder engagement and their suggestions will supplement strategies identified by adolescents. We hope that this co-created campaign will make it more inclusive and potentially more scalable, as it will be embedded in local beliefs and practices about mental health and ways to address it.

c. *Stigma leading to discrimination and abuse*

Stigma is a major barrier to uptake of mental health care in LMICs and from a researcher's perspective working in providing mental health services in the community, it is my personal belief that addressing stigma that leads to discrimination and abuse is vital. During our earlier pilot work we have been able to demonstrate how effective strategies for addressing stigma are not only feasible in LMICs if done

using culturally appropriate strategies, but also lead to sustainable effects (Maulik et al, Br J Psychiatry 2019;214(2):90-95). We were also able to demonstrate that the community appreciated the anti-stigma campaign (Tewari et al, BMC Psychiatry. 2017 Dec 4;17(1):385. doi: 10.1186/s12888-017-1525-6) and the campaign was feasible. A key element was to ground the development of the campaign in sound formative research and involving stakeholders in informing the process. (Maulik et al, Psychol Med, 2017;47(3):565-575). In ARTEMIS we take those learnings further by co-creating the campaign with adolescents as outlined above. As part of other research that I am involved in, we are developing culturally appropriate tools using detailed tools adaptations to local context, doing focused ethnographic research to identify local perceptions about mental health, and contextualizing the interventions to local settings.

d. Increasing access

Some challenges have been added to conducting research due to COVID such as e-consenting and online interactions, and the difficulties of engaging with the 10-14 year olds or the poorer who have limited access to SMART phones or tablets/computers. We also had to develop separate operating processes to ensure that physical or intellectually disability is not a constraint for inclusion to the extent that the adolescent is able to understand the interventions and follows the directions to a reasonable extent.

e. Supporting adolescents in need of ancillary services

There was also the additional issue of engaging with adolescents who reported domestic violence or sexual abuse. A separate agency was contracted to deal with such cases given their prior experience in managing issues around gender-based violence and abuse. We also had to take special steps to ensure that we were inclusive in our approach.

Conclusions and recommendations

ARTEMIS and our experience conducting other mental health research have outlined some basic steps that are absolutely essential for conducting ethical research in LMICs. First, research needs to benefit the community and should be relevant to the needs of the community, hence researchers need to ensure that the research benefits the community directly and/or indirectly. Second, it is important to involve the community and key stakeholders and include their opinions in developing strategies for implementing the project. This enhances the chances of acceptability and makes the strategies more scalable. This also makes the research more inclusive and gives the community a sense of ownership.