Ethical issues arising in research with people with mental health conditions

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Case study: Ethical issues in randomised clinical trials for adolescents who self-harm in Pakistan: the limits of equipoise and evidence in cultural context

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Description of the research project

My research aims to examine the main conceptions of equipoise and apply them in a different cultural context. My case study is that of a Randomised Clinical Trial (RCT) being conducted in Pakistan, which is investigating a psychological intervention *versus* treatment as usual for young people with risk of self-harm or suicide (Y-CMAP reference BMJ Open). The main focus of my research is whether the clinicians' recruiting patients in this cultural context have a personal preference for one or other treatment, especially since there already exists evidence of benefit from RCTs in young people in other countries and cultural contexts. If recruiting clinicians do have a treatment preference, I am interested in which they favour, and whether they regard participation in another RCT as scientifically and ethically important and necessary because of the cultural context despite these personal preferences. An understanding of cultural, religious and social paradigms will thus strengthen my conceptual analysis of so called 'clinical' or collective equipoise amongst healthcare professionals by illuminating the locally accepted trade-offs in values between the individual, social structures underpinning, and social benefits from, clinical trials within the cultural context of Pakistan.

Background

Self-harm is a major risk factor for eventual suicide, and the prevention of self-harm is therefore a key focus for suicide prevention efforts[1]. Young people are especially at risk of suicide and self-harm[2]. For example, the prevalence of self-harm over three months in young people in India was 3.9% to 25.4%[i3]. As such young people with a history of self-harm are a priority group for interventions. There is growing evidence that psychological therapies, including those based upon Cognitive Behavioural Therapy (CBT) principles, can help prevent further self-harm in those at risk, including in young people[1,4]. However, while there have been robust RCTs establishing efficacy, the available evidence has been limited to western and higher income countries. Therapies that work in western countries cannot necessarily be implemented in their current form, but need to be adapted to account for cultural differences (differences in the understanding of mental health and self-harm e.g., stoicism and fatalism). As well as adapting the intervention itself, Pakistan is a challenging context in which to evaluate treatments through RCTs. The Youth-Culturally adapted Manually Assisted Programme (Y-CMAP) has been adapted with permission from a self-help guide called "Life After Self-Harm" and "Cutting down: A CBT workbook for treating young people who self-harm"[5]. Equipoise as the state of epistemic uncertainty is traditionally regarded as a necessary ethical condition to justify randomisation in clinical trials[6]. However, there is little literature on its potential role in justifying randomisation within two arms where the intervention is psychological plus Treatment As Usual (TAU) vs TAU which can include drug therapy in this case in the cultural and religious context and backdrop of Pakistan. This study examines the main culturally relevant aspects of the intervention, RCT methods designed to evaluate them, and conceptions of equipoise raised by the Y-CMAP programme.

Research Methods
The study is part of a bigger PhD thesis using exploratory mixed methods.

This paper, written up for publication (Memon et al. in preparation), reports findings from the community engagement work with clinicians, parents, researchers, school teachers etc. for Y-CMAP based on a theory of change framework, a focus group of indigenous researchers to develop a cultural protocol for recruitment, and a quantitative survey of clinicians to capture the views and values regarding treatment preferences, role of psychological therapies within Islamic practices, and justification for RCTs amongst N=75 practitioners both recruiting patients within Y-CMAP and those treating patients outside the trial.

Ethical issues

1. **Which conception of equipoise is morally appropriate for Y-CMAP?**

The survey data helps inform this issue. The majority (89.3%) of health professionals considered Y-CMAP as an effective treatment for young patients at risk of self-harm or suicide before the trial. Although there was acknowledgement of individual treatment preferences, there was consensus on the need to conduct an RCT for reaching an evidence-based decision. This was specifically due to the reason to reduce bias. This suggests that there seems to be enough evidence of uncertainty and the existence of clinical equipoise as moral justification of conducting the randomised clinical trial. Individual level or theoretical equipoise was not considered ethically necessary. However, the requirement to capture the cultural, religious factors and nuances when gathering 'home grown evidence base' was deemed necessary.

2. **Individual consent may be regarded as less morally important than it is in liberal contexts with families making collective or patriarchal decisions: to what extent should individual consent be imposed by researchers?**

The role of the family in obtaining consent and in providing treatment and in care management of the patient remains pivotal in the context of Pakistan and interconnectedness was valued above the moral self. In focus group discussions, researchers emphasised the importance of shared decision making in Pakistani families. Accepting decisions made by elder members of the family is considered as matter of respect and young people think that influence of elders is propitious for their life[6].

3. **How can Y-CMAP complement rather than compete with cultural norms especially the role of religion and spiritual guidance?**

It is interesting but not surprising to observe that religiosity was a dominant thread across all the themes from the cultural analyses. From the community engagement exercise, there was recognition that spiritual advice was often the first point of contact for patients rather than health professionals. The trial was not designed to try to replace such religious norms but to work alongside them while recognising that there could be delays in referrals. There was also no restriction on accessing spiritual guidance making professional psychological therapies an addition not a substitute for such support. Importantly, mental health concerns are stigmatising and suicide a criminal offense. Working with religious leaders was therefore a critical part of community engagement with Y-CMAP and its evaluation through the RCT[8] (submitted to BMJ Open). The concept of 'dawa and dua' medicine and prayer going hand in hand as part of therapy tend to promote compliance and engagement.

4. **Should cultural values which are incompatible with human rights be respected and accommodated for research?**

The role of the family in the collectivist culture poses limitations towards individual autonomy in a society where interconnectedness is valued. However, the cultural, religious and social aspect of the conservative society is a hindrance particularly to women accessing help. There were issues of confidentiality and privacy and issues of women/girls not being allowed to consult the doctor in privacy. In addition, the societal denial towards mental health being an area requiring health care is a huge barrier. Also, self-harm and attempting suicide being a criminal offence is an immense barrier to seeking help.

Conclusion

Based on these emerging findings we infer that the clinical community in Pakistan regards RCTs as underpinned by the ethical framework of equipoise as a gold standard to develop home grown evidence base. However, it has to be emphasised that there is an outstanding apparent tension which needs to be resolved between clinician's personal preference for psychological therapies and spiritual advice and acceptance of need for RCT on the basis of collective equipoise. Thus far, the data from the focus group and the community engagement process suggest that it is important to acknowledge and recognise the differences in cultural, moral and religious beliefs and values of different societal constructs. Firstly, clinical rather than theoretical equipoise in the West is still controversial, as illustrated by early access to medical products and COVID-19, and secondly clearly not sufficient to make culturally appropriate. Therefore, it would be culturally blind to transpose western individualistic, principle-based ethics into a society where culture and religion are so intertwined.

Recommendations

1. More research needs to happen in the cultural context of Pakistan so we are able to meet the challenges of geographical, emotional, psychosocial, religious, personal and family circumstances of the indigenous population.
2. There is a need to acknowledge the value of keeping the families engaged for support and ensuring compliance but at the same time to raise awareness and training on human rights and mental health issues and in particular women/girls education and empowerment.
3. A positive drive for the health professionals to work with faith healers, religious leaders, policy and law makers is required.
4. Some of the means of raising awareness and reducing stigma would be engaging community and religious leaders, schools and colleges and using social media and television as channels of health promotion.
5. Engaging policy makers by providing locally produced evidence base was important to put political pressure on policy makers both around decriminalising self-harm and suicide and also improving mental health care services.

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[i] Wide range may denote uncertainty of scale