Ethical issues arising in research with people with mental health conditions

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Case study
Ethics in child mental health research

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Brief description of the research project

Twenty percent of all children struggle with mental health challenges, most of whom will remain unrecognized, unsupported, and unable to access quality care (WHO). Task-shifting has been one widely used approach to closing mental health care gaps for adults and adolescents. However, alternative models for children's mental health care, including task-shifting, are rare. TeaLeaF (TEAchers LEAding the Frontlines) is a research program that aims to evaluate teacher-delivered transdiagnostic mental healthcare for school-aged children in rural India. As part of this research program, we will be conducting a three-pronged hybrid study of effectiveness, implementation, and context. The study is designed as a stepped-wedge cluster randomized controlled trial with an embedded mixed methods evaluation of implementation and qualitative study of context. For this study, which will be conducted from 2022-2025, 60 rural primary schools will be enrolled and allocated in a 1:1 ratio to trial arms with each school initially assigned to the control condition (Enhanced Usual Care) and sequentially transitioned to the intervention condition (*Tealeaf: Mansik Swastha)*. The results of this research are expected to contribute to the limited evidence base for alternative models of children's mental health care in low-resource settings and inform other efforts to close the care gap for children with mental health struggles.

Background

Our research is set in the rural Darjeeling Himalayas, a region of the State of West Bengal in India. Within India, the region is geographically and ethnically distinct. The site for the study is rural, low-cost community private schools.

In Darjeeling's current system of care, access to mental health services for rural families is essentially non-existent with a single psychiatrist available for only the most severe cases. Mental health issues may find cultural interpretations by the local communities where they identify the cause and symptoms and resort to possible treatment with some socially sanctioned therapist. Such a perspective may stand in contrast to diagnosis by bio-medical professionals based on symptoms and signs. But these are alternate and sometimes complementary ways of interpreting mental health issues and it may not be wrong as such. Children's mental health struggles are interpreted at times as spiritual possessions and addressed by traditional healers or religious figures such as monks.

Thus, in this setting "usual care" is typically "no care at all" in the medical field and care delivered during the research effectively constitutes the entirety of the mental health system accessible to children. Within this context, the task-shifting, alternative system of care is centered around teachers delivering care in a transdiagnostic manner across a range of problems and diagnostic categories. Mental health challenges are understood through a behavioural lens and children are identified for additional support based observable atypical behaviours.

Ethical issues

"Usual care" and ethical obligations to vulnerable children

A primary objective of the TeaLeaf trial is to evaluate the effectiveness of a novel model for children's mental healthcare in the real-world setting of rural primary schools of Darjeeling. To appropriately answer this research question, it is necessary to have a valid comparison condition

(i.e. control condition). A lack of a valid external comparison would undermine the rationale for conducting the trial, limit the likelihood of achieving the study objectives, and expose study participants (including children) to undue risk.

The decision to pursue a controlled trial raised significant ethical concerns. Principal among these is the ethical obligations to children who were identified as having mental health challenges and subsequently enrolled into the study. The original study protocol specified that children under the control condition would receive "usual care". However, usual care for children with mental health challenges in rural India is, in effect, no care at all.

In essence, the initial proposal was for a 'no treatment control' which potentially would expose children to undo risk resulting from i) stigma associated with identification and ii) the unstructured attempts of teachers to respond to struggling children. Additionally, upon reflection, it was clear that a 'no treatment control' would not be a valid comparator from a research perspective given that it has been repeatedly demonstrated that nearly all mental health interventions perform better than no treatment.[1,2]

Based on these concerns, the protocol was restructured so that rather than 'no treatment' the children in the control condition will receive Enhanced Usual Care (EUC). EUC was conceptualized as a scaled-down version of active treatment (*Tealeaf: Mansik Swastha)* that represents the most intensive form of care that could be envisioned as viable in the study setting in the foreseeable future without a significant increase in resource investment.

The EUC group receives a shorter version of the training and support from the team when required. The Tealeaf group receives an extended version of the training and support on a monthly basis and also when required. Along with the extended version of the training the Tealeaf group receives additional materials and tools with the support and coaching facilities for their delivery of therapeutic techniques.

The application of an enhanced version of usual care has been utilized in other global mental health trials focused on adults.[3,4] Our study is among the first to apply this strategy to children, a particularly vulnerable group. By creating a baseline standard of care (external to existing care systems in the study context), all children enrolled in the study may receive access to higher quality care than they would otherwise. There is genuine clinical equipoise regarding whether there is a difference between the two intervention conditions, and thus, the trial remains ethical while maintaining an appropriate balance between potential risks and benefits to participating children.

Labelling, language, and understanding children's struggles

Our team, grounded in the traditions of Western psychiatry, approached child mental health from a diagnostic framework. Challenges faced by children were expressed through labels of disorder derived from the DSM IV, for example "conduct disorder" and "attention deficit hyperactivity disorder". Use of disorder and diagnostic labels though provoked underlying concepts of stigma around mental illness and stood in direct contrast to community understanding of children's behaviour.

Early versions of the intervention incorporated diagnostic labelling of children. The research team perceived these words as a way to technically capture and define common childhood struggles; however, parents responded strongly fearing that they were being told that their child was "mental/crazy". Parents reacted to the notion of a "disorder" with a feeling that they needed to keep this secret from their neighbours while simultaneously desiring a biomedical intervention to "cure" their child. The use of an external framework to describe, identify, and label children requiring extra support and care was resulting in the pathologization and stigmatization of already vulnerable children.

In exploring how communities understood the children that we were labelling with a diagnosis, we recognized that parents and teachers perceived these same children as struggling or different from their peers. They understood these children through behaviors, such as being easily distracted,

struggling to follow directions, and difficulty with academic tasks, that were more pervasive or prominent than those witnessed in their peers. In communicating about a child's struggle, they would frequently describe a child as "naughty", "bad", or "disobedient" and reacted with harsh disciplinary practices (including corporal punishment) in an attempt to normalize the child's behaviours.

Ethically intervening on child mental health in the rural Darjeeling Himalayas required the use of a more culturally relevant conceptual framework. We decided to distil much of the mental health struggles children experience into observable behaviours, with modifiable antecedents and consequences in their environments. Three behaviour categories were created for the intervention to help teachers understand different behaviour types through a concrete, tangible paradigm. They were based on an examination of child mental health epidemiology literature in which common diagnoses were regularly grouped into behaviour types of anxious, disruptive, or mood.[5] The category names of "anxious, disagreeable, and withdrawn" were chosen based on consultation with local experts to find terms understandable to teachers but with minimal connotation so as to avoid further contributing to stigma around mental illness. Rather than focusing on symptoms, focusing on behaviour also allowed us to consider the importance of context around the behaviours, pursuing a richer, ecological understanding of children's mental health struggles and creating an intervention with many more tools to target their struggles.

In an attempt to normalize the concept of mental health in a culturally acceptable way, we shifted our language and began to describe the intervention as a "behavioural health" intervention. However, there seemed to be some confusion amongst the community about what "behavioural health" may have been. In light of the successes of the pilot and the strides we felt we had made during this pilot in more openly calling the intervention one targeting "mental health", we decided to call our trial that of a "mental health" intervention. There appeared to be greater concern about a "mental health" intervention amongst the families of students, particularly when their child was chosen for further individual attention in the intervention. After holding numerous, sensitive conversations around the details of the intervention to demonstrate its possible benefit to their child, families of students showed acceptance to take forward the intervention. In the intervention itself the teachers are trained to build relation with caregivers and larger communities and bring about a supportive system not just in the schools but also in their homes and communities. We also provided subtle psychoeducation, allowing families to discuss their child struggles without fully attributing them to a mental health etiology.

Conclusions

As we proceed with our research, discussions are ongoing with stakeholders and our Ethics Committee, about how to remain committed to decreasing the stigma around mental health while being mindful of the community's reservations.

We offer the following recommendation to others:

1. Enhanced usual care may offer a path forward to ethically responding to the needs of vulnerable children with mental illness while also conducting rigorous controlled research.
2. Reconciling the language and understanding of mental illness between researchers and community stakeholders is a process of continuous listening, reflection, and iteration. Combining perspectives may ultimately yield to less stigmatizing interventions and research.

References

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