sibling-matched design than in the original cohort analysis. We believe that these paradoxical findings warrant more attention. For example, previous research has shown that it is important to consider whether the sibling was younger or older than the childhood cancer survivor,[7] and that within-pair estimates are more biased by non-shared confounders than the unpaired estimates when siblings are less similar with regard to confounders than to the exposure under study.[8]

As the population of childhood cancer survivors grows, there is a need to improve mental health after childhood cancer to improve overall quality of life. Additionally, interventions to vulnerable groups of survivors should be targeted to the entire family.

We declare no competing interests. We thank Buket Öztürk Esen (Department of Clinical Epidemiology, Aarhus University and Aarhus University Hospital, Aarhus, Denmark) for fruitful discussions about the strengths and limitations of the sibling design.

Oleguer Plana-Ripoll, Merete Nordentoft
opr@econ.au.dk

National Centre for Register-based Research, Aarhus University, 8210 Aarhus V, Denmark (OP-R); Department of Clinical Epidemiology, Aarhus University and Aarhus University Hospital, Aarhus, Denmark (OP-R); CORE—Copenhagen Research Centre for Mental Health, Copenhagen University Hospital, Copenhagen, Denmark (MN); Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark (MN); The Lundbeck Foundation Initiative for Integrative Psychiatric Research (iPSYCH), Aarhus, Denmark (MN)

1 SALiCCS. The socioeconomic consequences in Adult Life after Childhood Cancer in Scandinavia (SALiCCS) research program. 2018. https://www.cancer.dk/saliccs/the-saliccs-research-program/ (accessed Oct 5, 2021).
2 Steliarova-Foucher E, Colombet M, Ries LAG, et al. International incidence of childhood cancer, 2001–10: a population-based registry study. *Lancet Oncol* 2017; **18:** 719–31.
3 Frederiksen LE, Erdmann F, Mader L, et al. Psychiatric disorders in childhood cancer survivors in Denmark, Finland, and Sweden: a register-based cohort study from the SALiCCS research programme. *Lancet Psychiatry* 2021; **9:** 35–45.
4 Hamm NC, Hamad AF, Wall-Wieler E, Roos LL, Plana-Ripoll O, Lix LM. Multigenerational health research using population-based linked databases: an international review. *Int J Popul Data Sci* 2021; **6:** 1686.
5 Donovan SJ, Susser E. Commentary: advent of sibling designs. *Int J Epidemiol* 2011; **40:** 345–49.
6 van Warmerdam J, Sutradhar R, Kurdyak P, et al. Long-term mental health outcomes in mothers and siblings of children with cancer: a population-based, matched cohort study. *J Clin Oncol* 2020; **38:** 51–62.
7 Lund LW, Winther JF, Dalton SO, et al. Hospital contact for mental disorders in survivors of childhood cancer and their siblings in Denmark: a population-based cohort study. *Lancet Oncol* 2013; **14:** 971–80.
8 Frisell T, Öberg S, Kuja-Halkola R, Sjölander A. Sibling comparison designs: bias from non-shared confounders and measurement error. *Epidemiology* 2012; **23:** 713–20.

Quality care for people with severe mental disorders in low-resource settings

See **Articles** page 59

Findings from efforts to address the treatment gap for mental health conditions in low-income and middle-income countries (LMIC) suggest that non-specialist health providers can deliver effective evidence-based care for people with common mental disorders.[1] Severe mental disorders (SMD) are relatively less common, however, there is some evidence that parts of sub-Saharan Africa might have had one of the largest percentage increases in the prevalence of schizophrenia, the prototypical severe mental health condition, over the period 1990 to 2016.[2] Globally, SMD impose disproportionate burden on societies and affected individuals[2] in addition to the associated abuse and human rights violations.[3] In LMIC, the resources required to provide services for people with SMD, in particular mental health specialists, are generally insufficient and inequitably distributed, resulting in up to 90% of individuals with these conditions unable to access the mental health care they need.[4] Ideally, investigations into how best to extend care to people with these disorders should be a priority. Unfortunately, other than a few notable exceptions,[5] empirical evidence on how best to meet the needs of such individuals by use of available human resources in LMIC has been largely absent. The development of the Mental Health Gap Action Programme (mhGAP)[6] by WHO suggested that the most feasible pathway to extend mental health care in resource-constrained settings is to empower non-specialists to provide the bulk of the required service.

As Charlotte Hanlon and colleagues noted in their Article published in *Lancet Psychiatry*,[7] the task-shared model specified in the mhGAP has been evaluated only for common mental disorders and not for SMD.[8] To fill this gap, the authors present the report of a phase 3, randomised, controlled, non-inferiority trial (TaSCS) conducted in Ethiopia comparing two models of mental health care for people with SMD. Participants with SMD were recruited from an ongoing cohort with enduring symptoms and complex needs. They

were randomly assigned to two groups: one group continued with ongoing care delivered by psychiatric nurses at Butajira hospital (the PSY group) and the other consisted of patients who were referred back to primary health centres for follow-up care provided by the trained primary health care workers based on mhGAP specifications and supervised by psychiatric nurses (the TSC group). Both groups had their primary diagnostic assessments and initiation of pharmacological treatment done by the hospital-based psychiatric nurses. Outcomes at the 12 month primary endpoint showed that TSC was not inferior to PSY (mean Brief Psychiatric Rating Scale, Expanded version score was 27·7 [SD 4·7] for TSC and 27·8 (SD 4·6) for PSY, with an adjusted mean difference of 0·06 (90% CI −0·80 to 0·89, above the 6 point non-inferiority margin) as did outcomes in a range of secondary clinical measures. However, two aspects of the results were not in consonance with what would have been expected: TSC was not cheaper than PSY because there was no difference in the overall costs between the two groups; also participants in the TSC group, who were receiving care closer to where they lived, made fewer than six follow-up visits and were more likely to miss appointments than those in the PSY group. Nevertheless, it is reassuring that the participants in the TSC group still received operationally defined minimally adequate care and were also more likely to be investigated or referred for physical health comorbidity.[7]

TaSCS is a rigorously done trial with transparently reported results. Notable strengths include the selection of some of the participants from the long-running Butajira cohort study and the low attrition rate. The Butajira study is a community-based cohort study on the course and outcome of SMD (schizophrenia and bipolar disorder) in Ethiopia that has been going on since 1998,[9] thus, providing a rich source of potential participants for this kind of trial. The results of the trial show that non-specialist public health-care workers could provide follow-up treatment to patients with SMD, making the required decisions about dosage adjustment, responding to emerging side-effects, and detecting relapse. In essence, the care provided by the non-specialist primary health care workers was not inferior to that provided by the specialist nurses.

The results of the trial are of major relevance to any attempt to expand quality care to this underserved population of patients. People with SMD often require long-term, personalised, and integrated care, which is best delivered closer to where they live.[10] Primary health-care workers providing such service need supervision and support from mental health specialists and psychiatric nurses are more readily available in LMIC to fulfill that role than are psychiatrists. Future studies should explore more closely some of the features of this study to see in what way they could affect the outcomes. First, given that it is unlikely to be routinely sustainable, what would the results be if, unlike in this trial, participants in the PSY group were not reimbursed for travel expenses? Second, given that psychological intervention is an important part of the mhGAP care specifications, what effect would a more specific set of skills to deliver adjunct psychological intervention by the primary health-care providers have on improving patients' compliance to follow-up and retention in care? And third, as most of the public health-care workers in TaSCS had degree-level education, it would be interesting to see whether these findings can be replicated in settings in sub-Saharan Africa in which the average public health-care worker has received no more than 2 years of training in the health service after high school.

We declare no competing interests.

*Oye Gureje, Bibilola D Oladeji
ogureje@com.ui.edu.ng

Department of Psychiatry, College of Medicine, University College Hospital, PMB 5116, Ibadan, Nigeria (OG); Department of Psychiatry, Stellenbosch University, Stellenbosch, South Africa (OG); Department of Psychiatry, College of Medicine, University of Ibada, Ibadan, Nigeria (BDO)

1 van Ginneken N, Tharyan P, Lewin S, et al. Non-specialist health worker interventions for the care of mental, neurological and substance-abuse disorders in low- and middle-income countries. *Cochrane Database Syst Rev* 2013; **11:** CD009149.
2 Charlson FJ, Ferrari AJ, Santomauro DF, et al. Global epidemiology and burden of schizophrenia: findings from the Global Burden of Disease Study 2016. *Schizophr Bull* 2018; **44:** 1195–203.
3 Drew N, Funk M, Tang S, et al. Human rights violations of people with mental and psychosocial disabilities: an unresolved global crisis. *Lancet* 2011; **378:** 1664–75.
4 Lora A, Kohn R, Levav I, McBain R, Morris J, Saxena S. Service availability and utilization and treatment gap for schizophrenic disorders: a survey in 50 low- and middle-income countries. *Bull World Health Organ* 2012; **90:** 47–54.
5 Gureje O, Appiah-Poku J, Bello T, et al. Effect of collaborative care between traditional and faith healers and primary health-care workers on psychosis outcomes in Nigeria and Ghana (COSIMPO): a cluster randomised controlled trial. *Lancet* 2020; **396:** 612–22.
6 WHO. mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings: mental health Gap Action Programme (mhGAP). Geneva: World Health Organization, 2010. http://www.who.int/mental_health/evidence/mhGAP_intervention_guide/en/index.html.
7 Hanlon C, Medhin G, Dewey ME, et al. Effectiveness and cost-effectiveness of task-shared care for people with severe mental disorders (TaSCS) in Ethiopia: a single-blind, phase 3, randomised, controlled, non-inferiority trial. *Lancet Psychiatry* 2022; **9:** 59–71.

8 Keynejad R, Spagnolo J, Thornicroft G. WHO mental health gap action programme (mhGAP) intervention guide: updated systematic review on evidence and impact. *Evid Based Ment Health* 2021; **24:** 124–30.
9 Kebede D, Fekadu A, Kelkile TS, et al. The 10-year functional outcome of schizophrenia in Butajira, Ethiopia. *Heliyon* 2019; **5:** e01272.
10 Thornicroft G, Ahuja S, Barber S, et al. Integrated care for people with long-term mental and physical health conditions in low-income and middle-income countries. *Lancet Psychiatry* 2019; **6:** 174–86.

Risk, responsibility, and choice in research ethics

In health-care settings, routine enquiry about experiences of trauma is good practice. Yet in research studies, whether to address trauma and how is contested. Some studies prioritise inclusive samples and questions about people's lived experience. Others avoid potentially retraumatising topics and exclude people considered too vulnerable to participate.

Safeguarding is essential, but when does protection become paternalism, and who gets to decide this? These questions matter and contribute to why we know so little about the extent and nature of domestic violence and of self-harm during the COVID-19 pandemic.[1]

In 2000, Jon Nicholl wrote that it was immoral for ethics committees to have become barriers to ethical research that could help to improve health care.[2] Although the ethical review process has since become more efficient, Nicholl highlights a still relevant tension: how can we balance maximising the benefit of research to society while minimising risk of harm to the individuals taking part?

With the onset of the COVID-19 pandemic, face-to-face survey fieldwork around the world largely ceased (and 18 months later, few surveys have fully resumed). As new data needs emerged, all parts of the research process moved faster.[3] Research that was recognised as a priority for the COVID-19 evidence base was given streamlined permissions, including expediated ethical reviews. However, this change in pace also contributed to a fall in lived experience involvement. Before the pandemic, patients and the public were involved in 80% of the research reviewed by the UK Health Research Agency. In March, 2020, public involvement was 22%. A related effect was a pause on research on specific topics, such as research asking probability samples of the general population about experiences of domestic violence or self-harm, and research focused specifically on affected individuals.[1]

Although university and other ethics committees convened more regularly and processed applications more swiftly than before the COVID-19 pandemic, this came with increased risk aversion. Researchers avoided asking for approaches that were anticipated to maybe cause delay. Committee members were understandably concerned about approving research on sensitive topics, given the reduced ability to direct participants to curtailed and remote services or support. Since the start of the pandemic, few general population surveys have been permitted to ask about violence, abuse, or self-harm. This omission continues to have substantial consequences for the evidence base in England, UK, and elsewhere, serving to hide the scale of harm, and preventing people in need, including victims and survivors, from being heard.

As harm to participants is unethical, might exclusion from research also be considered unethical and an epistemic harm? Some standard mechanisms for protection, such as requiring participants to sign quasi-legal documents stating that their consent is full and informed, might serve to protect researchers, data guardians, and institutions more than participants. People who prefer not to sign such declarations are often excluded from research, constituting a hermeneutic injustice in itself. Those participants deemed too vulnerable—or too difficult—to ask might also be excluded on the basis of what others consider to be in their best interests. Even if participants can be informed about a study, that questions can be skipped, and that they might withdraw at any time, decisions about their fitness to be asked are pre-emptively made by a remote external regulatory body.

What assumptions are made about competency and protection when research about domestic violence or self-harm is not approved? We know, for example, that assumptions about vulnerability and victimisation intersect with inequalities related to ethnicity, gender, sexual identity, and age. Women have historically been left out of research,[4] as have children[7] and older people. Bayer and Tadd's study of ageism in research found that "of the 155 studies that were of relevance

For more on **enquiring about trauma in health-care settings** see https://www.nice.org.uk/guidance/ph50/chapter/4-Considerations

For more on **public involvement in research** see https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/public-involvement-pandemic-lessons-uk-covid-19-public-involvement-matching-service/