

# Community-Based Rehabilitation for Persons with Severe Mental Illness in a Rural Community of Karnataka: Methodology of a Randomized Controlled Study

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## ABSTRACT

**Background:** Task shifting has been recommended as a strategy to reach out to persons with mental illness and bridge the treatment gap. There is a need to explore task-shifting using existing health staff like Accredited Social Health Activists (ASHAs).

**Aim and Context:** ASHAs are involved in ongoing community-based rehabilitation (CBR) program run with a public-private partnership over the last 5 years at Jagalur Taluk (an administrative block) in Davanagere district (Karnataka, India). This article aims to summarize a randomized controlled trial (RCT) to examine whether CBR delivered by ASHAs is more effective than treatment as usual (TAU) control group in reducing disability associated with severe mental illness (SMI).

**Method:** A group of proactive ASHAs is already working with us for a follow-up of persons with SMI. For the study, we would allocate areas that are currently not being covered proactively by ASHAs randomly in a 1:1 ratio via computer-generated randomization list to receive

either ASHAs delivered CBR arm or TAU control group. A sample size of about 100 in each arm is enough to identify an effect size of 0.5 in total IDEAS score between the intervention and control arms with a power of 90% and an alpha of 0.05. We use the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement to describe the methods of the trial.

**Result:** The study has been approved by the institute ethics committee and registered with CTRI (CTRI/2019/08/020585 dated 6th August 2019). The recruitment of subjects is ongoing. The patients will be followed up for 1 year and assessed. The trial is funded by the Indian Council of Medical Research, Government of India.

**Discussion:** The results of the study will be helpful from a public health perspective in delivering cost-effective and replicable CBR for persons with SMI through ASHAs. If the model turns successful, this could be expanded throughout the state/country. This would go a long way in bridging the huge treatment gap.

**Keywords:** Community-based rehabilitation, severe mental illness, rural, India, ASHA, task-shifting

**Key Messages:** The RCT will help us understand effectiveness of providing CBR for persons with SMI through ASHAs. If successful, it can be replicated across the country. If not, it will help us understand ground level challenges of involving ASHAs in CBR.

World Health Organization defines community-based rehabilitation (CBR) as a strategy within general community development for the rehabilitation, poverty reduction, equalization of opportunities, and social inclusion of all people with disabilities.<sup>1</sup>

Task-shifting has been demonstrated to be a feasible and effective strategy to reach out to persons with severe mental illness (SMI) in the community and address mhGAP.<sup>2-4</sup>

There are few CBR intervention studies for persons with mental illness from lower- and middle-income countries

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(LAMIC's). The most methodologically robust CBR intervention studies were conducted by Chatterjee et al. (2003, 2009, and 2014).<sup>5-7</sup> Chatterjee et al. (2003, 2009)<sup>5,6</sup> reported outcomes of the CBR program implemented by Ashagram Trust, a community-based nongovernmental organization (NGO) working toward the rehabilitation of people affected by leprosy, in Barwani district, Madhya Pradesh. Chatterjee et al. (2003) compared the effectiveness of CBR ( $n=127$ ) and outpatient care ( $n=80$ ) for consecutive series of patients diagnosed with chronic schizophrenia (ICD 10, duration >2 years) in Barwani district, Madhya Pradesh. In the outpatient care model, services were provided in a monthly clinic where patients were followed up, treatment reviewed, psychoeducated, family counseled, and rehabilitation strategies were discussed. Most patients were on risperidone. In addition to these interventions, the CBR model used mental health workers from the community who were trained for 60 days and local village health groups. Each mental health worker serviced 5–6 contiguous villages and catered to 25–30 patients. Local village health groups comprised family members and key community members to plan relevant rehabilitation measures and reduce social exclusion. At 12-month follow-up, CBR is more effective than standard out-patient treatment in fully compliant patients. The authors concluded that CBR was a feasible model of care for chronic schizophrenia in resource-poor settings.

In a 4-year follow-up of a CBR program implemented in Bati subdistrict (Barwani district, Madhya Pradesh), Chatterjee et al. (2009)<sup>6</sup> reported a reduction in disability levels (on Indian Disability Evaluation and Assessment Scale [IDEAS]) in a cohort of 236 patients with psychotic disorders (follow-up 12–52 months; median 46 months). The patients were treated by a psychiatrist who visited a primary health clinic on predesignated days. Risperidone and olanzapine were preferred antipsychotics. A combination of methods, accessible and home-based services, psychoeducation, enlisting family and community support, were used to promote adherence and engagement with services. CBR workers were trained for 4 weeks about the recognition and management of people with mental disorders. In total, 4–5 CBR workers were

supervised weekly by a cluster coordinator and monthly by the psychiatrist. Self-help groups, comprising patients and community members, facilitated livelihood initiatives through microcredit facilities and social reintegration. In the initial 2 years of the program, 80% of referrals were made by CBR workers. Later, 80% of referrals were made by self-help groups. Adherence to psychotropic medication and participation in self-help groups predicted favorable outcomes in the patients.

Chatterjee et al. (2014)<sup>7</sup> compared the effectiveness of collaborative community-based care plus facility-based care model ( $n=187$ ) with facility-based care ( $n=95$ ) in a parallel group, randomized controlled trial (RCT) of schizophrenia patients at three Indian sites. Participants were recruited from new as well as existing patients at treatment facilities. Collaborative community-based care was delivered by community health workers trained for 6 weeks. They were supervised by intervention psychiatric social work coordinators and quarterly by a psychiatrist. Collaborative community-based care involved structured reviews, health promotion strategies, individualized rehabilitation strategies, inputs to deal with stigma/discrimination, linkage to self-help groups, and networking with community agencies. At 12-month follow-up ( $n=253$ ), the total Positive and Negative Syndrome Scale (PANSS) and IDEAS score were lower in the intervention group than the control group. However, no difference was shown in the proportion of participants who had a reduction of more than 20% in overall symptoms. Costs in the intervention group were greater than the intervention group.

In Indonesia, Puspitosari et al. (2016) reported that CBR interventions delivered by lay health workers in Indonesia improved quality of life (QoL) in persons with schizophrenia.<sup>8</sup> In total, 100 persons with schizophrenia were divided into an intervention group that received CBR intervention and control group with similar characteristics at baseline. CBR intervention comprised a psychoeducation module and social skill module delivered by local health workers, sub-district social welfare workers, and community health workers (called Kader in Indonesia) over 12 weeks. They were

supervised by a psychiatrist. The QoL was assessed using a validated measuring instrument at the baseline and end of study. Thirty-four persons (68%) of intervention group increased their QoL, whereas in the control group there were 23 persons (46%) increased their QoL. The QoL decrease occurred in one person (4%) from the control group. Others had constant QoL. Improvement of QoL in the intervention group is higher than the control group ( $P < 0.05$ ).

In the Indian context, the studies by Chatterjee et al. (2003, 2009, 2014)<sup>5-7</sup> did not use government grass-root level, health staff. It is not clear if the community health workers were volunteers or workers who were paid honorarium/full salary. Treatment in these studies was offered in the context of a project by NGO's. The use of public health infrastructure (including primary health centers, health staff, and psychotropic medications, district mental health program [DMHP]) was limited or nil. The replicability of these studies from the public health perspective is doubtful.

In LAMICs, it is necessary to develop and test models involving available infrastructure and staff. The 12th five-year plan of DMHP speaks about a cadre of "community mental health workers" who are people from the same community with 10 years of schooling and will be offered an honorarium for their services.<sup>9</sup> To our knowledge, this cadre is not functioning in any of the DMHPs to date. If adequately supported, Accredited Social Health Activists (ASHAs) can fulfill the role of community mental health workers for persons with SMI without additional burden to their existing duties.<sup>10</sup> ASHAs are honorary, literate female volunteers who offer multiple services related to maternal and child health for a honorarium.<sup>11</sup> ASHAs are not paid an honorarium for working with persons with mental illness.<sup>12</sup>

Assuming that an ASHA covers a village of 1,000 people, there are likely to be 7 persons with SMI.<sup>13</sup> SMI is relatively easy to identify, treat with available resources, and result in a reduction of disability and meaningful work functioning.<sup>2,14</sup> Treatment of persons with SMI would not pose an additional burden to the ASHAs who can cover them as part of their routine visits to community. Due to these reasons, ASHAs can be

a good resource for facilitating treatment and rehabilitation of persons with SMI. If proved successful, the intervention can be upscaled across the country. In this article, we describe the methodology of an RCT that is planned to be conducted in Jagalur taluk, Davanagere district, Karnataka state, India.

## Background of Existing Work

Jagaluru is a rural taluk and agriculture is predominant occupation. It is drought-prone and economically backward area. While the taluk has ten Primary Health Centres (PHCs) and one Taluk hospital, there are no psychiatrists in the Taluk. The district headquarters town has a government district hospital with psychiatrists. In addition, there are two private medical colleges in the district that have a Department of Psychiatry. There are a few private psychiatrists.

As part of our ongoing CBR program, mental health camps are conducted fortnightly on Tuesdays at PHCs and the taluk hospital since August 2015 in partnership with the Government of Karnataka and NGOs. Free medicines are dispensed. Two social workers organize the camps. In addition, the social workers visit patients at their homes and remind the families to come for camps by telephone. When necessary, the psychiatrist also visits patient homes for treatment. We are working closely with the DMHP team. We have demonstrated that the provision of CBR in partnership with the public health system and NGOs leads to a dramatic fall in the “out-of-pocket” health expenditure of families of persons with SMI.<sup>15</sup>

ASHAs in the taluk have been trained by a psychiatrist about symptoms, course, outcome, and treatment of SMI and to use “symptoms in others” tool.<sup>16</sup> ASHAs have been referring patients with SMI to the mental health camps for consultation. Besides, we have kept in touch with all ASHAs of Jagalur to date to clarify their doubts and they have been provided ongoing guidance in providing CBR for persons with SMI. We have demonstrated that engaging ASHAs in the identification, referral, and treatment of persons with SMI positively changes their attitudes toward persons with mental illness.<sup>12</sup>

A proportion of ASHAs have proactively identified patients with SMI and referred them for treatment. After initiating treatment, ASHAs are supervising treatment and following up the patients. ASHAs accompany social workers while visiting patient homes. ASHAs have observed and learnt from social workers about psychoeducation and importance of medication adherence. So far, more than 800 persons with mental health issues have benefited from the program. More than 200 persons with SMI are being offered free treatment close to their residence under the program.

## Aims and Objectives

To examine whether CBR delivered by ASHAs is more effective than the treatment as usual (TAU) control group in reducing disability associated with SMI.

*Secondary objectives:* To examine whether ASHAs delivered CBR is more effective than the TAU control group in the following:

1. Enhancing the duration of clinical remission of persons with SMI
2. Improving the work/income of persons with SMI
3. Reducing self-stigma of persons with SMI
4. Improving community attitude towards persons with SMI

*Hypothesis:* The outcome of ASHAs delivered CBR intervention arm on disability will be better than the TAU control arm.

*Trial design:* Randomized parallel-group trial. For the study, we would allocate areas that are currently not being covered proactively by ASHAs randomly in a 1:1 ratio via computer-generated randomization list to receive either ASHAs delivered CBR arm or TAU control arm.

## Arms of the Study

There are 172 ASHA workers in Jagalur taluk.

*Proactive ASHAs:* As part of our ongoing work at Jagalur, we had trained ASHAs. Thirty ASHAs had shown interest in identification, treatment, and follow-up of persons with mental illness from villages under their care. They have proactively worked with us for coordination of treatment of persons with mental illness without incentives. They will comprise the proactive ASHAs arm.

Patients in remaining areas covered by other ASHAs (142) will be randomly allotted to the following:

1. *TAU control:* Intervention will be delivered by a Junior research fellow recruited under project and staff from The Association for people with disability (NGO partner).
2. *Intervention:* Intervention will be delivered by ASHAs.

## Materials and Methods

### Study Setting

The study is being conducted in Jagalur, a taluk (an administrative block) of Davanagere district, Karnataka state, India.

*Operational definition:* SMI includes bipolar disorder, schizophrenia, schizotypal, delusional, and other non-mood psychotic disorders.

### Eligibility Criteria

*Inclusion criteria:* Persons with SMI, aged 18 years to 99 years, residing in the taluk, availing treatment from our program at PHC/ taluk hospital.

*Exclusion criteria:* Persons with SMI who refuse consent.

*Sample size:* For the study, we would allocate areas that are currently not being covered proactively by ASHAs to either “intervention” or “control” arms. A sample size of about 100 in each arm is enough to identify an effect size of 0.5 in total IDEAS score between the intervention and control arms with a power of 90% and an alpha of 0.05.

*Randomization:* For the study, we would allocate areas that are currently not being covered proactively by ASHAs (who consent to be randomized) randomly in a 1:1 ratio via computer-generated randomization list to receive either “intervention” or “control” group. Randomization will be stratified at the level of PHC. For each PHC, the randomization list will be generated independently by the investigators and transferred to the research staff. The patients will be enrolled by research staff. Participants who give informed consent will be assigned to “control” or “intervention.”

*Participant recruitment timeline:* From the time of randomization of ASHAs areas to “intervention” and “control” group,

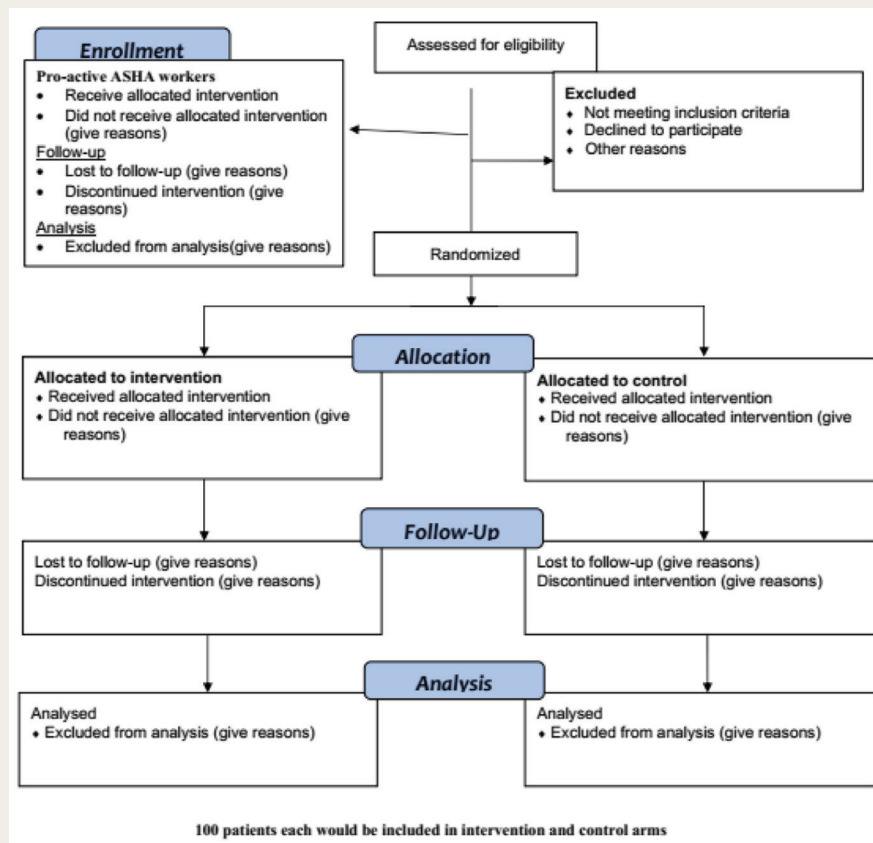
TABLE 1.

**Timeline**

August to October 2019	November 2019 to September 2020	September 2020 to March 2021	April to June 2021	July to Sep 2021
Informed consent and randomization of ASHAs				
Handholding of ASHAs and monitoring of intervention				
	Recruitment of persons with SMI (100 in ASHAs and control arm) for trial and baseline assessment			
	Follow-up of persons with SMI (minimum 1-year follow-up)			
			Outcome assessment of recruited subjects by new research staff who is blind to group allocation	

ASHAs: Accredited Social Health Activists, SMI: severe mental illness.

FIGURE 1.

**CONSORT 2010 Flow Diagram**

ASHAs: Accredited Social Health Activists.

**Assessment Tools**

1. Sociodemographic pro forma: A semi-structured pro forma would be developed for the study to collect the sociodemographic information of the patient and family members.
2. Symptoms in others<sup>16</sup>: It is a questionnaire containing screening questions covering major psychiatric disorders, epilepsy, mental retardation, and substance use. There are 15 questions, and it does not take more than 5 minutes to apply this instrument. This can be easily applied even by the grass-root level staff. The tool has been well validated in a rural area of India for case-finding. We will use the screening questions for SMI for purpose of the study.
3. Indian Disability Evaluation and Assessment Scale (IDEAS)<sup>17</sup>: The IDEAS had been originally developed for measuring and certifying disability for psychiatric patients in India. It assesses disability across four domains: self-care, interpersonal relationships, communication and understanding, and work. It has good face validity, criterion validity, and internal consistency.
4. World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0)<sup>18</sup>: WHODAS 2.0 was developed in synchrony with the international classification of functioning (ICF) to measure health status and disability across different cultures and settings. It can be used to measure disability across all diseases including mental and substance use disorders. The instrument was

patients will be enrolled for 6–9 months. The minimum duration of the intervention will be a minimum of 1 year for each person with SMI. CONSORT guidelines will be followed for the trial. The timeline and CONSORT diagram are shown in Table 1 and Figure 1, respectively.

**Blinding:** The investigators, research staff, ASHAs, persons with SMI, and their family will be aware of the allocation

status. The baseline assessment will be done by investigators and research staff. A new research staff who will be recruited to conduct outcome assessment at a 1-year follow-up will be blind to group allocation. ASHAs, persons with SMI, and family members will be requested at the time of outcome assessments to not disclose whether they are in the intervention arm or control arm.

developed through an international collaborative approach and has excellent psychometric properties. We would be translating the instrument into the local vernacular, Kannada. We would be using the 12-item interviewer-administered questionnaire for this study.

5. CGI-SCH<sup>19</sup> and CGI-BP<sup>20</sup>: Clinical global impressions scale (CGI) has been modified for use in assessing global illness severity and change in patients with schizophrenia and bipolar disorder. CGI-SCH rates the severity of illness over the last one week and degree of change as compared to a previous evaluation in positive, negative, depressive, cognitive symptoms, and overall severity.<sup>19</sup> It is a simple, valid, reliable instrument to evaluate severity and treatment response in schizophrenia.<sup>19</sup> CGI-BP can be used for acute and prophylactic assessments of the severity of illness, change from the preceding phase, and change from the worst phase of illness.<sup>20</sup> The investigators have obtained permission from the authors for use in studies at our center.
6. World Health Organization community-based rehabilitation matrix (WHO CBR matrix): The CBR matrix gives a visual representation of CBR. It consists of five key components, each divided into five key elements. It offers a “pick and mix” series of options: a set of components and elements from which the practitioner can select. The matrix is not sequential. The WHO CBR matrix will be used to understand the rehabilitation needs of persons with SMI.
7. Community Attitude toward Mental Illness (CAMI)<sup>21</sup>: It consists of four subdomains namely authoritarianism, benevolence, social restrictiveness, and community mental health ideology total of 40 items, measured on a 5-point scale. This scale has been used in Indian studies (James et al., 2019). The investigators have obtained permission from the authors for translation into Kannada and use them in studies at our center.
8. Internalized stigma of mental illness (ISMI) scale<sup>22</sup>: The ISMI contains 29 items that produce five subscales (namely alienation, stereotype endorsement, discrimination experience,

social withdrawal, stigma resistance) scores and a total score. The scale has sound psychometric properties across a variety of languages, cultures, conditions, and situations. The investigators have obtained permission from the authors for translation into Kannada and use them in studies at our center.

The research staff will be trained in the administration of “symptoms in others,” WHO-DAS 12 item interviewer-administered version, CAMI, and ISMI.

## Interventions

The nature and structure of the proposed intervention will be the same in both arms. Persons with SMI will be informed about the dates of mental health camps. During home visits, the clinical status of a person with SMI will be enquired from the patient, family, and neighbors. Concerns related to illness/ medication side-effects will be addressed. The family will be advised on the need for taking medications regularly. The person with SMI will be helped to avail of a disability certificate and associated benefits including disability pension. An individualized plan addressing five domains of the WHO-CBR matrix (namely health, education, livelihood, social, and empowerment)<sup>1</sup> will be made for addressing the rehabilitation needs of the person with SMI in the context of local realities. These interventions are supposed to be carried out by staffs of both the arms.

However, the intensity of interventions will differ. The ASHAs, residents of the same community, would be accepted by the local community and is readily available 24×7 to families of persons with SMI. In comparison, the JRF/ NGO staff visit the villages once in 2 months but are available over the phone. As a part of the government health machinery, ASHAs will be ideally placed to address the health concerns of the persons with SMI by referring them to the health system. As a member of the same community, ASHAs will be aware of local realities and be in a better position to offer individualized interventions catering to education, livelihood, social, and empowerment domains of the WHO-CBR matrix.

If persons with SMI drop out of treatment, they will be followed by up by respective ASHAs/JRF depending on allocation. Home visits also will be done for dropouts

## Outcomes

The primary outcome will be a change in the disability status of persons with SMI. Secondary outcomes will be the duration of clinical remission, work status/income, self-stigma, and community attitude toward persons with SMI.

Change in disability status of persons with SMI in “intervention” versus “control” groups will be assessed by IDEAS at the time of enrollment, 6-month, and 1-year follow-up. Change in duration of clinical remission (measured by CGI-SCH and CGI-BP), work status/income (by work domain of IDEAS), self-stigma (measured by ISMI) among persons with SMI in “intervention” versus “control” groups will be assessed at baseline and 1-year follow-up.

Community attitude toward persons with SMI (measured by CAMI) will be measured among community members in “intervention” and “control” groups at end of the study.

## Statistical Methods

Descriptive statistics of clinical status, disability, community attitude toward persons with SMI, self-stigma would provide important indices of the intervention versus control arms. Also, we would use appropriate univariate as well as multivariate statistical tests. The challenges and opportunities in involving ASHAs delivered CBR to persons with SMI availing DMHP in Jagaluru taluk of DMPH will be documented.

## Ethical Issues

Written informed consent would be taken from all patients by research staff. In cases, where the person with SMI is unable to give consent, then we would treat them without their consent as part of routine clinical care and wait for them to be competent before we randomize them under this study. We would also take consent from relatives. When obtaining the informed consent of the subjects/societies, we would ensure that “societal pressures” are not at work. The clinical status of identified patients would be ascertained, and necessary action would be taken including consultation and starting treatment, psychoeducation, disability certification, referral, and organizing follow-up services. The patients

will be given the option of availing free treatment in mental health camps without being a part of the study. Efforts would be made to link the care of identified patients into the existing health care infrastructure. Consent of the communities (village leaders, key-informants, panchayat heads, etc.) would be taken wherever it is needed.

Confidentiality would be maintained. In the informed consent form, subjects would be informed that some aspects of their health and behavior would be discussed with family members and neighbors. Only when patients agree to this, they would be recruited. ASHAs and project staff would be trained to maintain confidentiality.

The protocol has been approved by the institutional ethics committee. It has been registered in Clinical Trials Registry India (CTRI) CTRI/2019/08/020585, dated August 6th, 2019.

## Discussion

As ASHAs live in the same community, we hypothesize that they will be able to supervise psychotropic medications effectively, identify early signs of relapse, contact treating psychiatrist, and initiate remedial measures to ensure better overall outcomes, including clinical stability, longer duration of clinical remission, stable work/income, reduced stigma. This may also lead the ASHAs to facilitate the unmet rehabilitation needs of persons with SMI.

The ASHAs will be more receptive to mental health issues as they see the change in the lives of families of persons with SMI in their community. They will also be empowered in the process and be seen as “agents of change” in the local community. As residents of the same community, it is expected that their expertise will remain in the same community continuing to benefit it.

The ASHAs will be paid an honorarium for their work in the project. By the end of the project, the same honorarium can be continued as per guidelines for “community mental health worker” in the 12th five-year plan of the district mental health program. This will ensure the sustainability of the program.

The results of the study will be helpful from a public health perspective in delivering cost-effective and replicable CBR

for persons with SMI through ASHAs in resource-poor settings like India. No such information is available as of now. If the model turns successful, this could be expanded throughout the state/country. This would go a long way in bridging the huge treatment gap. If the model is not successful, we would at least come to know the ground level challenges of involving ASHAs in implementing CBR for persons with SMI. These could help formulate policies in the future.

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## Declaration of Conflicting Interests

We declare that we have not submitted this article in any other journal.

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