Implementing Patient-Reported Outcomes to Improve the Quality of Care for Weight of Patients with Schizophrenia

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Abstract

"*Enhancing QUality of Care In Psychosis*" *(EQUIP) was an eight-site clustered controlled trial of the implementation and effectiveness of patient-reported outcomes to support evidence-based practice and improve care for schizophrenia. Implementation sites chose to improve care for weight. Implementation included monitoring patient-reported outcomes using kiosks, patient and staff education, quality improvement teams, and phone care management. Qualitative and*

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quantitative methods compared implementation and effectiveness between sites for 13 months. Eighty percent of 801 randomly selected patients were overweight. Two hundred one clinicians varied in competency. Baseline use of behavioral weight services was low. At implementation sites, patients became 2.3 times more likely to use weight services compared with control sites (95% CI, 1.5–3.6; $\chi^2 = 14.4$; $p < 0.01$). There was no effect on the weight gain liability of medications prescribed. Controlling for baseline, patients' final weight at control sites was 5.9 ± 2.7 kg heavier than at implementation sites ($F = 4.8$, $p = 0.03$). Patient-reported outcomes can inform implementation of evidence-based practice and improvement in outcomes.

INTRODUCTION

Behavioral and pharmacologic treatments improve the outcomes of people with schizophrenia in clinical trials.[1] However, it has been difficult to implement evidence-based treatments into practice,[2] and many patients do not receive evidence-based care.[3] For example, weight management services have large effect sizes in efficacy studies yet outcomes in routine care are muted. In other areas of healthcare, patient-reported outcomes have been used to drive measurement-based care and improve treatment and outcomes.[4] In mental health, there have been calls for measurement-based care and some successes, especially in depression.[5] However, questions have been raised regarding the use of these methods with people who have serious mental illness or at public mental health clinics. It has been unclear whether patient-reported outcomes can be used to improve the treatment and outcomes of patients with schizophrenia.[6]

People with schizophrenia are at high risk for obesity, and many medications prescribed for schizophrenia cause substantial weight gain.[1] Obesity has detrimental health consequences, including diabetes, cardiovascular morbidity, and reduced life expectancy.[7, 8] Practice guidelines recommend both using medications with lower weight gain potential and also providing behavioral interventions. Behavioral interventions for weight have been tailored to meet the needs of people with serious mental illness and found in many efficacy trials to result in lower weight.[9, 10] The mean weight loss across 13 studies was 2.6 kg.[11] While weight loss is often modest, without interventions, the average patient continues to gain weight.[12] Modest weight loss has been associated with health benefits.[13, 14] Unfortunately, the majority of studies of weight interventions have limited external validity. Many studies have only enrolled highly motivated patients, or have compensated patients for travel or receipt of intervention.

Health systems often fail to fully support evidence-based psychiatric treatments. This is due in part to difficulty monitoring the value of services.[15] One barrier to monitoring has been an inability to routinely measure patient outcomes and feed these outcomes into databases. In other disorders, such as diabetes, it is possible to use routinely collected demographic, laboratory, and utilization data to identify patients who are not doing well or not receiving effective treatments. In schizophrenia, monitoring psychosocial services and outcomes is challenging due to limited clinician time and information infrastructure.[16, 17] Medical records in mental health often lack substantial accurate data on patients' clinical status, treatment preferences, and psychosocial treatments provided.[18] Therefore, at present, many widely used quality measures are based on billing or pharmacy data and, likely, have a weak relationship with outcomes.[19]

Health information technology can support routine assessment of outcomes.[2, 3, 16] Kiosks and other patient-facing devices can collect and monitor behavioral health needs, patient treatment preferences, service utilization, and outcomes.[20] Informatics can be updated on an ongoing basis to provide current scientific evidence and assessments to patients and clinicians. Providing feedback to patients can encourage shared decision-making. By providing administrators and clinicians with real-time access to patients' clinical status, organizations can identify at-risk patients, refer patients to evidence-based treatments, monitor uptake of services, and learn from treatment outcomes.

While previous research shows inconsistent effectiveness for patient-reported outcomes,[21] findings suggest that data can be used to improve treatment targets (symptom distress, interpersonal relationships, social role), physical health, and service engagement.[22] Reviews have identified mediating factors affecting effectiveness, including clinician unwillingness to document outcomes due to limited time,[23] limited commitment to using patient-reported outcomes,[24] and lack of discussion of outcomes.[25] Outcome feedback has been most effective when delivered to both clinician and patient, providing an opportunity to influence treatment.[22]

It has not been clear how to broadly implement patient-reported outcomes and evidence-based practices for schizophrenia. Prior studies have often lacked comparison groups and data on implementation processes, making it difficult to generalize findings beyond the study itself.[26] This manuscript reports on the effectiveness of patient-reported outcomes in, "Enhancing QUality of Care In Psychosis" (EQUIP), a pragmatic, prospective, clinic-level controlled trial that studied implementation of evidence-based treatment for schizophrenia at eight mental health clinics.[20, 27] It was hypothesized that patient-reported outcomes could be used to improve the quality of care. Organizational leaders chose among evidence-based and promising practices and chose to implement evidence-based services for weight. Implementation was driven using patient-reported outcomes and included evidence-based quality improvement teams, patient and staff education, and phone care management. Mixed methods studied implementation and effectiveness, relative to usual care. Analyses used a difference in different strategy that examined change in services and outcomes over time at intervention clinics compared with control clinics.

METHODS

This study was a partnership among researchers and leadership of the Veterans Health Administration (VHA) in four regions of the USA. These regions are known as Veterans Integrated Service Networks (VISNs). Mental health leadership in each VISN nominated two medical centers for study inclusion. To control for national changes in psychiatric treatment, VHA regional policy changes, and the course of patient illness, within each VISN, one site was assigned to implementation and the other to continue with care as usual (control), for a total of 4 implementation and 4 control clinics.

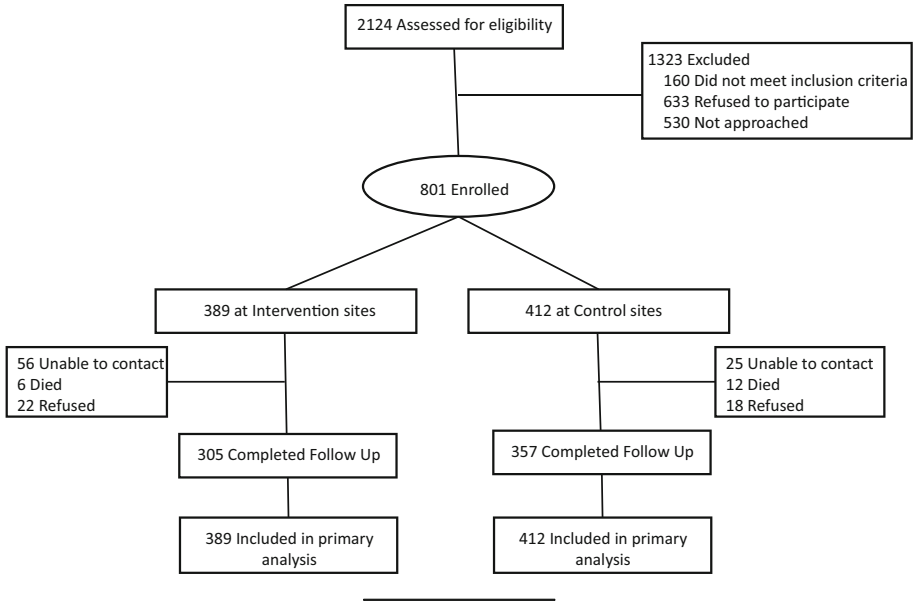
The research began in June 2007 with surveys and interviews of clinicians and administrators. Mid-way through implementation, clinicians at implementation sites participated in a qualitative interview. At follow-up, clinicians and administrators completed surveys and interviews. The outcomes study began in January 2008 with patient enrollment and a baseline patient interview. Patient enrollment lasted 13 months. Final patient interviews began in May 2009.

Participants

Adult patients were eligible if they had a diagnosis of schizophrenia or schizoaffective disorder and at least two clinic visits during a 6-month period. During a 12-month pre-baseline period, a random sample of potentially eligible patients was identified from administrative data. This list was used to conduct visit-based sampling during a 6-month period. To ensure that the sample was representative of the clinic population, each patient with a treatment visit during this 6-month period had a random determination regarding whether they were eligible for the study. One thousand nine hundred sixty-four patients were eligible, and 801 enrolled (41%). Figure 1 presents patient flow.

Clinicians were eligible if they had responsibility for eligible patients. Administrators were eligible if they had responsibilities at the clinics. Two hundred forty-two staff were eligible, and 201 enrolled (83%). Patients and clinicians received implementation or care as usual based on their clinic location. All clinicians were included in surveys. For semi-structured interviews, stratified purposeful sampling was used to select key stakeholders. Written informed consent was obtained from patients and clinicians after procedures were fully explained. When patients had a legally authorized representative, written informed consent was

Figure 1
Patient flow in CONSORT format.



obtained from that representative after procedures were fully explained. The study was approved by Institutional Review Boards of all sites.

Implementation

As described in prior publications, patient-facing kiosks were placed in the waiting room of each implementation clinic and used to collect patient-reported outcomes.[20, 28] Kiosks provided audio and visual presentation of questions, were designed for people with cognitive deficits or limited literacy, and included a touch screen monitor, computer, headphones, printer, and scale.[29] At every clinic visit, patients responded to questions, including entry of their weight and preferences regarding wellness services. If the individual was overweight, the kiosk printed "talking points," helping the patient advocate for a wellness program referral and for a change to medication with lower weight gain potential. Kiosk data were continuously reported to clinicians and care managers to identify potential referrals (patients with BMI >25 and interest in services), obese patients taking medications that cause weight gain, and to monitor quality improvement progress.

The EQUIP team developed and implemented a wellness program based on "Solutions for Wellness,"[30] an evidence-based weight management program for overweight individuals with cognitive disabilities. Group sessions utilized routine weigh-ins, psychoeducation, goal setting, knowledge quizzes, and learning principals that work in schizophrenia. The EQUIP care managers promoted provider selection of medications with lower weight gain potential.

Implementation strategies and tools An evidence-based quality improvement (EBQI) framework was utilized at implementation sites.[31] Strategies included opinion leaders, clinician and patient education, continuous feedback to staff, and multidisciplinary quality improvement teams.

Measures

Patient characteristics Diagnosis was confirmed using an abbreviated version of the Structured Clinical Interview for the *DSM-IV*.[32] Symptoms were rated using the Brief Psychiatric Rating Scale (BPRS)[33] and occupational, social, and symptomatic functioning using the Mental Illness Research, Education, and Clinical Center (MIRECC) GAF.[34] These were assessed by research staff trained to a high level of reliability, and quality assurance checks were completed during the study. Research staff collected baseline weight and height. Similar to other site-level controlled trials, it was not possible to blind research staff to clinic assignment. To reduce bias, research assistants had minimal contact with staff involved with implementation.

Medication and utilization data Antipsychotic and other prescription data were collected from a pharmacy database that included all prescriptions of the physicians. Each medication was categorized as having low, medium, or high weight gain potential.[35] Patients on multiple relevant medications were categorized according to the medication with the highest weight gain potential. For all patients, trained staff conducted structured chart reviews that examined all documentation to identify visits that included weight management psychoeducation.

Patients' experience This was assessed using the 8-item Client Satisfaction Questionnaire (CSQ; range of 1–4) and quantitative interviews that included reasons for attending or not attending the wellness program.

Clinician readiness for change Pre- and post-implementation, all clinicians and administrators were asked to complete the Organizational Readiness for Change (ORC).[36] The ORC assesses five domains: motivation for change (needs/pressure), resources, staff attributes, organizational climate, and training exposure and utilization.

Studying implementation Pre-, mid-, and post-implementation, a semi-structured interview assessed adoption, acceptability, and appropriateness of implementation. Interviews included questions about the respondent's role, patient needs, wellness utilization, organizational culture, readiness for change, and experience with quality improvement. Mid- and post-implementation interviews included barriers and facilitators to implementation and reflections on successes and failures, with attention to changes in the organizational context or culture.

Analyses

Quantitative analyses were conducted by using Statistical Software Package SAS. Baseline characteristics were compared between implementation and control groups using t tests for continuous and χ^2 statistics for categorical variables. A trichotomous variable denoted change in the weight gain potential of psychotropic prescriptions (decreased potential, increased potential, or no change). Utilization of wellness services was analyzed using a logistic model. A dichotomous variable denoted increased utilization of wellness services. This variable was equal to 1 if a patient did not utilize services in the year prior to baseline and did utilize services during the study and was equal to 0 otherwise. ANCOVA analyses are only conducted on subjects with complete data. Analyses controlled for baseline psychotic and negative symptom scores. Odds ratios were computed.

An ANCOVA model was used to examine weight gained during treatment in implementation versus control groups. The dependent variable was final weight. Baseline weight, weight 6 months prior to baseline, baseline psychotic and negative symptom subscales, and medication weight gain potential at baseline were included as covariates. The inclusion of weight 6 months prior to baseline accounted for subjects' weight gain/loss trajectories prior to the study. Two-way interactions of group by covariates were included in the model. The change in R^2 from model 1 (without medication weight gain potential at baseline) to model 2 (which included medication variable) was calculated.

A repeated measures mixed model with predictors of group, time, and interaction, or group × time was used to analyze CSQ scores and scales from the ORC. ORC scales in the Motivation for Change domain were program needs, training needs, and pressure for change. ORC scores in the Organizational Climate domain were mission, cohesion, autonomy, communication, and change.

For qualitative analyses, the constant comparative analytic approach was used[37] involving an iterative process of comparison and categorization, facilitated by tools in Atlas.ti. Every third patient participated in a semi-structured interview about their experiences in the study. Data were analyzed by site and clinic role, across sites, and over time. The a priori theme of "wellness target" was coded in all transcripts and was examined across waves of data. This theme was also examined, via axial coding in relation to the other a priori themes.[38]

RESULTS

Patient characteristics

At baseline, demographics and clinical characteristics did not differ among groups, with the exception of psychiatric symptoms (Table 1). Psychotic and negative symptoms were greater at the control sites, although these differences were small. These were controlled for in quantitative outcomes analyses. The mean BMI was obese (BMI > 30), and 80% ($n = 637$) of patients were overweight (BMI > 25).

Medication and utilization changes over time

From baseline to follow-up, there were no significant differences between intervention and control groups with regard to changes in the weight gain potential of prescribed medications ($\chi^2 = 1.8$, $p = 0.41$). In both control and intervention groups, 6% of patients were switched to a medication with lower weight gain potential, 5% were switched to medication with a higher potential, and 89% had no change in their medication's potential for weight gain.

Use of weight services was low at baseline. Nineteen percent of patients at implementation and 25% of patients at control sites received any services. At endpoint, these services were received by 35% of patients at implementation and 36% of patients at control sites. Among service users, at implementation sites, the mean number of weight sessions used increased from 2 to 11. At control sites, an average of two weight sessions were attended, and there were no changes over time. Overweight individuals at implementation sites were 2.3 times more likely to increase utilization compared to individuals at control sites (95% CI, 1.5, 3.6; $\chi^2 = 14.4$; $p < 0.01$). Control sites increased utilization in only 38 of 315 subjects (12.1%) whereas implementation sites increased utilization in 73 of 308 subjects (23.7%).

Weight changes over time

The model predicting weight at endpoint showed that when controlling for baseline weight, pre-baseline weight, and symptoms, the control group was on average 5.9 ± 2.7 kg (13.0 ± 5.9 lb)

Table 1
Baseline characteristics of patients at intervention and control sites

	Intervention ($N = 389$)		Care as usual ($N = 412$)			
	n	%	*n*	%	Chi-square	*p*
Male gender	359	92.3	373	91.0	0.45	0.50
Psychotropics prescribed						
Risperidone	106	33.0	110	34.7	0.20	0.65
Aripiprazole	58	18.1	52	16.4	0.31	0.58
Quetiapine	49	15.3	49	15.5	0.005	0.95
Olanzapine	46	14.3	46	14.5	0.004	0.95
Valproate	53	16.5	37	11.7	3.08	0.08
Ziprasidone	31	9.7	18	5.7	3.56	0.06
Clozapine	25	7.8	19	6.0	0.80	0.37
Other	175	54.5	180	56.8	0.33	0.56
With diabetes	120	30.9	118	28.7	0.47	0.49
	Mean	95% CI	Mean	95% CI	ANOVA	*p*
Age (years)	54.0	53.1, 55.0	54.5	53.5, 55.4	0.62	0.54
Illness duration (years)	26.2	25.0, 27.4	25.8	24.6, 27.1	0.47	0.64
Weight (kg)	94.4	92.4, 96.4	92.8	90.9, 94.8	1.13	0.26
Body mass index	30.2	29.6, 30.8	29.9	29.3, 30.6	0.63	0.53
Waist circumference (cm)	104.9	103.2, 106.5	104.3	102.8, 105.9	0.47	0.64
Client Satisfaction Questionnaire	3.52	3.47, 3.57	3.28	3.22, 3.35	5.80	0.00
Brief Psychiatric Rating Scale						
Positive symptom subscale	2.3	2.2, 2.5	2.5	2.4, 2.7	2.08	0.04
Negative symptom subscale	1.5	1.5, 1.6	2.0	1.9, 2.0	7.19	0.00
Global Assessment of Functioning						
Occupational subscale	39.5	37.4, 41.6	38.2	36.6, 39.8	0.96	0.34
Social subscale	53.4	52.0, 54.8	54.4	53.2, 55.7	1.08	0.28
Symptom subscale	53.4	51.9, 55.0	50.2	48.8, 51.5	3.15	0.00

heavier than the implementation group ($F = 4.8$, $p = 0.03$). Two-way interactions between group by baseline weight and group by weight 6 months prior were not significant. This model explained 89% of the variation in weight at end of study. A second model added medication weight gain category at baseline. This model also explained 89% of the variation in weight at the end of the study, indicating that the influence of the baseline medication on weight did not affect the model or its explanatory power ($F = 1.3$, $p = 0.25$).

Patient experience

Patients were usually supportive of automated collection of patient-reported outcomes data, believing that their clinicians found these data useful. As previously reported, they generally had a positive impression of the kiosks and found them easy to use.[20] Patients reported being satisfied with wellness services, especially learning how to select and cook appropriate foods, having

opportunities to exercise, and sharing their experiences with one another and the facilitator. Illness factors were not among the most important determinants of kiosk use or wellness service use. Patients who did not attend groups gave reasons for not attending (in order of frequency): dislike groups, weight services not necessary, too far/no transportation/not convenient, unaware of services, too sick, and preferred not to attend. The intervention did not have a significant effect on patients' satisfaction with care ($F = 0.44$, $p = 0.51$).

Clinician readiness for change

Before implementation, 42% (42/102) of implementation and 63% (62/99) of control clinicians completed the ORC (Table 2). At post-implementation, 53% (54/102) of implementation and 43% (43/99) of control clinicians completed the survey. Implementation and control sites were similar in readiness for change, which fell in the normative range.[39] However, notable differences on the motivation for change subscale (program needs, training needs, pressure for change) were evident by site, with some sites having higher training needs and pressures for change. The intervention did not have a significant effect on clinicians' readiness for change. There was no significant effect on program needs ($F = 0.00$, $p = 0.97$), training needs ($F = 0.00$, $p = 0.97$), pressure for change ($F = 0.91$, $p = 0.34$), mission ($F = 0.20$, $p = 0.66$), cohesion ($F = 0.48$, $p = 0.49$), autonomy ($F = 0.67$, $p = 0.42$), communication ($F = 0.05$, $p = 0.83$), or change ($F = 0.03$, $p = 0.85$).

Implementation, clinician, and staff perspectives

At mid-implementation, clinicians were aware of patients who attended wellness groups and were more aware of the need for monitoring labs and weight. The kiosk had an important role in heightening awareness of wellness issues. A small of number of clinicians did not like having outcomes data and told their patients they would not use such data. However, the vast majority were accepting integrating these data into their practice. One clinician noted, "The availability of the computer has made it easy for [patients] to monitor how they're doing." At post-implementation, there was a concern about the sustainability of services. One stakeholder said her site decided to create clinician reports regarding patients who have high BMIs and give them a

Table 2
Baseline clinician readiness to change at intervention and control sites

	Intervention ($N = 102$)		Care as usual ($N = 99$)			
	Mean	**95% CI**	**Mean**	**95% CI**	**ANOVA**	*p*
Motivation for change						
Program needs	33.0	30.1, 35.9	33.6	31.3, 35.9	0.33	0.74
Training needs	29.7	27.3, 32.1	28.8	26.4, 31.1	0.54	0.59
Pressure for change	33.7	32.0, 35.4	31.6	29.7, 33.4	1.63	0.11
Organizational climate						
Mission	36.4	35.2, 37.6	34.0	32.5, 35.5	2.52	0.01
Cohesion	33.8	32.5, 35.0	32.0	30.8, 33.1	2.10	0.04
Autonomy	32.4	31.3, 33.4	31.4	30.3, 32.6	1.21	0.23
Communication	35.1	33.5, 36.6	33.0	31.2, 34.9	1.72	0.09
Change	30.9	29.3, 32.4	30.4	29.2, 31.6	0.49	0.63

benchmark to reach with those patients. She remarked that providing data to clinicians is essential, and that the study's routine feedback to clinicians would be missed. Stakeholders observed that clinics had made shifts away from illness, toward wellness. As one summarized, "We weren't doing a bad job before, but now we are doing an enhanced job."

DISCUSSION

Results are reported from a controlled trial of the implementation and effectiveness of an intervention at public mental health clinics to improve treatment for schizophrenia. The intervention used patient-reported outcomes to inform efforts that improved services and outcomes. Implementation led to substantial increases in the use of weight services, though no change in the prescribing of medications with weight gain potential. Treatment and outcomes were improved by identifying patients' needs and preferences and increasing appropriate utilization of services. Patients were representative of the population in care, there were no exclusions for comorbidities, patients were not self-selected, patients were not provided compensation for participating in the intervention, and existing clinicians provided services. Because this was a study to improve care for schizophrenia, all patients with schizophrenia were eligible, regardless of their weight. Despite this, the level of weight loss achieved was comparable to that seen in efficacy studies.

It is likely that implementing a wellness program tailored to the clinic, utilizing mental health clinicians to deliver services, and locating services at the clinics contributed to the outcomes. Tailoring of implementation was achieved by investigating readiness for change prior to implementation and working with each site's strengths and weaknesses. Formative evaluation continued throughout the project, enabling further tailoring based on emergent barriers and facilitators. Routine computerized patient-reported outcomes were feasible and well-accepted and informed quality improvement.

Potential limitations include a lack of random assignment of patients to intervention or control. Patient-level randomization is typically not possible with interventions that implement improved care at the organizational level. With a small number of organizations, randomization at the organizational level does not balance unmeasured characteristics between groups. There is evidence that well-designed, prospective, controlled cohort studies typically provide valid, generalizable results.[40] This study found little or no change in services and outcomes at control clinics. Another limitation is that the intervention had multiple components, only one of which was patient-reported outcomes. It is not possible to know which intervention component resulted in the observed improvement in service delivery and outcomes. For example, while both intervention and control groups received weight services, these services were different. The intervention was designed to deliver services with fidelity to evidence-based practices for weight in patients with schizophrenia, whereas services at control sites were usually not tailored for people with mental illness and not designed to be consistent with evidence-based practices for schizophrenia.

Although implementation increased the use of evidence-based weight services and reduced patients' weight, use of services remained limited to a minority of patients who could have benefited. Patient barriers included limited motivation to change, a dislike of groups, and limited transportation options. Also, it is remarkable that psychiatrists did not change their prescribing, despite patient advocacy, education, and feedback regarding specific patients who could benefit. Other intensive efforts to make this type of change in physician prescribing have also failed.[41] One challenge cited by psychiatrists was that a heavy workload prevented frequent patient visits, and medication changes without frequent follow-up could cause undetected psychotic relapse with severe adverse consequences.

IMPLICATIONS for BEHAVIORAL HEALTH

The prevailing quality of care for schizophrenia appears to be poor to moderate.[42] It has not been clear how to improve the quality of this care. This was a study of the implementation and effectiveness of using

patient-reported outcomes to guide evidence-based practice at eight mental health clinics. Sites engaged in efforts to improve care using data, and were able to substantially improve the processes of care for weight, and weight outcomes. At present, mental health organizations often lack routine, automated clinical data to support patient care. It is possible to implement automated patient-reported outcomes at busy mental health clinics with patients who have serious mental illness. These data can be used to inform evidence-based practice and improve treatment and outcomes, though quality gaps remain and concerted efforts continue to be needed with this population.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

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