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Evaluation of a Cultural Dexterity Training Program for Surgeons: The PACTS Trial

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Statistical Analysis Plan

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PACTS ANALYSIS PLAN: The multi-year cluster-randomized study design will enable us to examine differences between and within the Early Intervention and Control/Delayed PACTS training groups across three unique time points (Year 2 pre-intervention, Year 2 post-intervention and Year 3 post-intervention). Details of statistical measures/methods and power calculations appear below.

Table 7. Sample Size Calculations

Example Measure	Proportional Difference to be Measured	Expected Minimum Number of Participants Per Group	Minimum Detectable Difference (80% power and α=0.05)
	Sample size/power calculations for repeated measures		
Within group resident knowledge/ skills/attitudes	Pre- vs. Post-test proportion achieving "Adequate" vs. "sub-optimal" dichotomized assessments	Pre-intervention: 160 Post-intervention: 160 (Repeated Measures)	Pre-intervention: 50.0% Post-intervention: 61.0% Thus, we expect to be able to detect a proportional absolute difference of 11% for within-group assessments.
	Sample size/power calculations for independent measures.		
Between group resident knowledge/ Skills/attitudes	Post-test proportion in Early Group vs. Delayed Group achieving "adequate" vs. "sub-optimal" dichotomized assessments	Early Group : 159 Delayed Group : 159 (Independent Measures)	Change from 50% to 65.5% Assuming remains at 50% with no change from baseline assessment. Thus, we would be able to detect a 15% relative proportional difference between groups associated with exposure to PACTS training.
	Patient-reported within and between-group differences		
Patient-reported outcomes	Pre- vs. Post-test proportion of patients reporting pain-satisfaction scores in the uppermost standardized quintile	Pre-intervention: 361 Post-intervention: 361 (Independent Measures)	Proportion of Patients with scores Pre-intervention: 63.0% Post-intervention: 73.0% Thus, we expect to be able to detect an absolute proportional difference of 10%.
	Sample size/power calculation for NSQIP outcomes		
Readmissions	Pre- vs. Post-test proportion of patients readmitted	Pre-Intervention:377 Post-intervention:377	Proportion of Patients readmitted Pre-intervention: 23% Post-intervention:15%

Within-group differences (repeated measures). Repeated measure differences on dichotomous outcomes will be examined using Chi-square and Fisher's exact tests, as well as unadjusted logistic regression models controlling for resident-specific demographic factors (e.g. age, IAT, post-graduate year, and sex). Differences in ordinal outcomes (e.g. three- or five-point Likert scale reporting or ordered category scores) between pre- and post-intervention testing will be examined using Chi-square tests, unadjusted ordered logistic regression, and ordered logistic regression adjusted for resident- and program-specific factors. Table 7 depicts our sample size/power calculations, according to which we will be able to detect an 11% absolute difference in the proportion achieving "adequate" vs. "sub-optimal" dichotomized assessments before and after PACTS training. This accounts for an up to 20% sample loss from the expected 200 enrolled residents per group.

Between-group differences (independent measures). Pre- vs. post- differences in both self-reported and observer-assessed ordinal outcomes between the Early and Delayed Intervention groups will be assessed at the end of the first training period using Chi-square tests and unadjusted ordered logistic regression, as well as ordered logistic regression models controlling for resident- and program-specific factors. Previous work demonstrated that exposure to training similar to PACTS was associated with a 20-25% increase in the proportion of trainees achieving "adequate" scores on an OSCE-based assessment. Based on the number of residents in each arm (n=200), we anticipate that we will be able to detect a much smaller between-group difference even with up to 20% sample attrition over time (Table 7).

Pre- and post-intervention patient-reported satisfaction and NSQIP outcomes. Management of pain will be assessed using elements of the Pain Treatment Satisfaction Scale (PTSS).[140] Previous work by Gupta et al suggests that, on average, 63% of patients provided assessments of pain control satisfaction in the upper quintile of a standardized 10-point satisfaction scale.[141] Subsequent to the intervention, it is estimated that 73% of patients treated by PACTS-trained residents will report satisfaction in the uppermost PTSS quintile. We expect an 8% decrease in readmissions, from 23% to 15% post-intervention. Pre-post intervention differences in patient-reported satisfaction and NSQIP outcomes will be assessed using Chi-square, Fisher's exact tests, or t-tests as appropriate, and ordinal scale differences will be assessed using Chi-Square tests and ordered logistic regression, both without adjustment and controlled for patient-, clinician-, and facility-level factors. It is important to note that the patient groups represent independent samples, and these pre- and post-intervention measures are independent measures, not repeated measures (Table 8). To achieve this, we will recruit 100 patients per site for each data collection phase. Thus, we will collect 300 patients per site over the entire study (2,400 total), giving ample power for both patient and clinical outcomes.