Evaluation of Clinical Research Training Programs Using the Clinical Research Appraisal Inventory

Lauren Lipira, M.S.W.[1], Donna B. Jeffe, Ph.D.[2], Melissa Krauss, M.P.H.[3], Jane Garbutt, M.B.Ch.B., F.R.C.P.[4], Jay Piccirillo, M.D.[5], Bradley Evanoff, M.D., M.P.H.[6], and Victoria Fraser, M.D., F.A.C.P.[7]

Abstract

The purpose of this study was to measure change in clinical research self-efficacy after participating in KL2, postdoctoral and predoctoral clinical research training programs at Washington University School of Medicine. We surveyed program participants using a 76-item version of the Clinical Research Appraisal Inventory (CRAI). Principal components analysis (PCA) examined the CRAI's underlying factor structure; Cronbach alpha measured the internal consistency of items on each subscale and the overall CRAI. CRAI score changes from baseline to 1-year follow-up were assessed using repeated-measures analysis of variance. All 29 KL2, 47 postdoctoral, and 31 TL1 scholars enrolled 2006–2009 (mean age 31.6 years, range 22–44; 59.6% female; 65.4% white) completed baseline surveys. Of these participants, 22 KL2, 17 postdoctoral, and 21 TL1 scholars completed the 1-year follow-up assessment. PCA resulted in a seven-factor solution with 69 items (alphas > 0.849 for each subscale and 69-item CRAI). Significant improvements at 1-year follow-up were observed across all programs for Study Design/Data Analysis ($p = .016$), Interpreting/Reporting/Presenting ($p = .034$), and overall CRAI ($p = .050$). Differences between programs were observed for all but one subscale (each $p < .05$). Clinical research self-efficacy increased 1 year after clinical research training. Whether this short-term outcome correlates with long-term clinical research productivity, requires further study. Clin Trans Sci 2010; Volume 3: 243–248

Keywords: Clinical Research Appraisal Inventory, clinical research training, self-efficacy

Introduction

Clinical research, or the study of living human subjects, human disease mechanisms, human behavior, therapeutic interventions, healthcare processes, and epidemiology, serves as a bridge between basic biomedical research and better clinical practice.[1–2] Experts agree that clinical research is increasingly relevant to the future of medicine and critical for the advancement of modern healthcare.[2–5] However, experts have identified multiple barriers to the conduct of clinical research, including lack of qualified clinical researchers, difficulty recruiting research participants, fragmented institutional infrastructure, poor communication and collaboration between clinical investigators, and insufficient funding for clinical research.[6–8] Among these barriers, the lack of qualified, well-trained clinical investigators is recognized as the fundamental obstacle to the future of clinical research.[3,9–14] While the number of physicians engaged in patient care in the US steadily increased from 1985 to 2003, the percentage of physicians engaged in research declined from 4.6% in 1985 to 1.8% in 2003.[12] Proposed explanations for this decline include lack of protected time for research, lack of funding, insufficient mentoring, excessive medical school debt, and poor institutional support.[2,7–9,12,15]

Following the Nathan Committee Report in 1998,[1–2] the National Institutes of Health (NIH) responded earnestly to the vulnerability of clinical researchers.[5,12,16] The NIH has implemented a variety of projects to support the training of clinical researchers, such as loan repayment plans, the K30 curriculum development awards, the 2003 NIH Roadmap initiatives and most recently, the Clinical and Translational Science Award (CTSA).[5,12,16–18] The CTSA is a comprehensive initiative that seeks to address the assortment of existing barriers to clinical research at multiple institutional levels.[6] One objective of the CTSA is to foster the growth of new clinical researchers; therefore, a prominent component of the initiative is education and training.[6,10,19] More specifically, the CTSA proposal calls for academic medical institutions to develop "academic homes" for degree-granting and nondegree-granting clinical research training programs.[6]

Washington University School of Medicine received CTSA funding in September 2007 and created the Institute of Clinical and Translational Sciences (ICTS). The ICTS Clinical Research Training Center houses multiple CTSA-supported clinical research training programs, which incorporate, to varying degrees, didactic training in clinical research methodology, mentorship, protected time for research, and multidisciplinary collaboration.

As the national CTSA initiative expands, these clinical research training programs have an obligation to rigorously evaluate their effectiveness to produce productive and committed clinical researchers.[6,20] Acquisition of independent funding is a universal indicator for the success and stability of a clinical investigator.[1,16,21] However, for many young investigators, especially predoctoral program trainees, this benchmark may occur many years after completing a training program.[14] Consequently, evaluators have sought to identify more immediate indicators of program success, such as program satisfaction, research interest, training-program relevance to one's career path, and research self-efficacy.[4,14,22,23] The purpose of the present study was to investigate change in scholars' clinical research self-efficacy, or confidence in one's ability to perform clinical research-related tasks, as a short-term indicator of program impact after 1 year in a clinical research training program at Washington University School of Medicine.

[1]Clinical Research Training Center, Washington University School of Medicine, St. Louis, Missouri, USA; [2]Alvin J. Siteman Cancer Center, Barnes-Jewish Hospital, Washington University School of Medicine, St. Louis, Missouri, USA; [3]Institute of Clinical and Translational Sciences Research Design and Biostatistics Group, Washington University School of Medicine, St. Louis, Missouri, USA; [4]Co-Director of the Clinical Research Training Center and Director of the Postdoctoral Program at Washington University School of Medicine; [5]Professor of Otolaryngology, Co-Director of the Clinical Research Training Center and Director of the TL1 Predoctoral Clinical Research Training program at Washington University School of Medicine; [6]Richard A. and Elizabeth Herby Sutter Professor of Occupational, Industrial and Environmental Medicine, Chief of the Division of General Medical Sciences, Co-Director of the Clinical Research Training Center at Washington University School of Medicine and head of the Masters in Science and Clinical Investigation; [7]J. William Campbell Professor of Medicine and Co-Director of the Infectious Disease Division, Co-Director of the Clinical Research Training Center and Director of the KL2 Career Development Awards Program at Washington University School of Medicine.

Correspondence: V Fraser (vfraser@dom.wustl.edu)

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Methods

Setting and participants

Washington University School of Medicine is a large, private, research-intensive medical school located in St. Louis, Missouri, with approximately 1,800 faculty members, 1,200 students, 1,000 house staff, and 760 fellows and trainees. The Clinical Research Training Center was founded in 2004 for scholars with K12 Roadmap Career Development and K30 curriculum development awards and for trainees in T32 predoctoral clinical research training programs. Now funded by the CTSA to Washington University and part of the ICTS, the Clinical Research Training Center provides a cohesive and supportive infrastructure to foster clinical research training through the KL2 (former K12) Career Development Award program, the postdoctoral (former K30) program and the TL1 (former T32) predoctoral program. A summary of each program's components is found in *Table 1*. Eligible participants included all 107 scholars who entered one of these three clinical research training programs from 2006 to 2009.

This research was approved by the Institutional Review Board at Washington University in St. Louis.

Program component	TL1 predoctoral award	Postdoctoral program award	KL2 career development award
Protected time	1 year	2–3 years	2–3 years
Mentorship	X	X	X
Hands-on research experience	X	X	X
Multidisciplinary collaboration	X	X	X
Career development seminars, workshops, retreats	X	X	X
Didactic courses			
Ethical and regulatory issues in clinical research	X	X	X
Analysis of clinical data	X		
Designing outcomes and clinical research	X	X	
Scientific writing and publishing	X	X	
Grantsmanship	X	X	
Introduction to statistics		X	
Intermediate statistics		X	
Epidemiology for clinical research		X	

X, required.

Table 1. Program components of clinical research training programs at Washington University School of Medicine.

Data collection

A shortened Clinical Research Appraisal Inventory (CRAI) survey was used to measure participants' clinical research self-efficacy before and 1 year after participating in one of the clinical research training programs. The original CRAI, developed by Mullikin et al.,[24] contained 92 items in 10 conceptual domains, using an 11-point confidence scale (0–10). The 10 domains included conceptualizing a study, designing a study, collaborating with others, funding a study, planning and managing your research study, protecting research subjects and responsible conduct of research, collecting, recording and analyzing data, interpreting data, reporting a study, and presenting your study. Mullikin et al. used factor analysis to reduce this instrument to 88 items loading on eight factors.[24]

Before unification under the CTSA, the directors of the Clinical Research Training Center training programs (K12, K30, and T32) utilized different versions of the original CRAI, adding or omitting questions to accommodate the individual needs of each program. When the programs combined under the CTSA in September 2007, the Center began using a common measure containing 76 items using a 10-point response scale (1 = no confidence, 10 = total confidence). Selected items from each of the 10 domains were maintained from the original instrument.

All clinical research scholars in these three programs were asked to complete the 76-item CRAI before beginning their training program and again annually, at the end of each year, until they completed the training program. The survey was completed online using software developed by Qualtrics (Qualtrics Inc., v7546, Provo, UT).

Statistical analysis

Statistical analyses were performed using SPSS 17.0.3 (SPSS Inc., Chicago, IL, 2009).

An iterative process of exploratory principal components analysis (PCA) with varimax rotation was used to determine the factor structure of the 76-item CRAI. PCA was run using eigenvalues >1.000 as the criterion for determining the number of factors as well as by forcing an eight-factor solution, following the method reported previously for the 88-item CRAI.[24] Although Mullikin et al. retained items with factor loadings >0.400 and dropped items with loadings >0.490 on multiple factors,[24] we required factor loadings >0.500 for retention (due to smaller sample) and dropped items with factor loadings >0.490 on multiple factors. Cronbach alpha was used to assess the internal consistency of items on each subscale resulting from the PCA and the overall CRAI score. Mean scores were computed for each subscale and overall CRAI measure.

Associations between training program and each of gender and race were measured using chi-square tests and between training program and age using analysis of variance (ANOVA). Change in mean subscale scores and overall CRAI score from baseline to 1-year follow-up was assessed using repeated-measures ANOVA (RM-ANOVA), grouping by training program. In the RM-ANOVAs, we examined the change in research self-efficacy for each subscale and the overall CRAI measure across all training programs, the effect of the interaction between change in research self-efficacy and type of training program, as well as pairwise contrasts using Bonferroni adjustment for multiple comparisons to test the differences in scores on each subscale and overall CRAI measure between each pair of training programs (across both time points).

Results

CRAI data collected from KL2 and TL1 scholars, who began training in 2006 to 2009, were included in the analyses. Data from postdoctoral scholars, who began training in 2007–2009,

Characteristic	TL1	Postdoctoral	KL2	All
Total, *n* (%)	31 (29.0)	47 (43.9)	29 (27.1)	107
Age, mean years (SD)	25.7 (3.6)	33.6 (4.1)	34.7 (3.1)	31.6 (5.3)
Gender, *n* (%)				
Female	23 (74.2)	28 (58.9)	18 (62.1)	69 (59.6)
Male	8 (25.8)	19 (41.1)	11 (37.9)	38 (35.5)
Race/ethnicity, *n* (%)				
African-American/black	3 (9.7)	0 (0.0)	1 (3.4)	4 (3.7)
Asian	4 (12.9)	4 (8.5)	3 (10.3)	11 (10.3)
White (non-Hispanic)	21 (67.7)	36 (76.6)	18 (62.1)	75 (65.4)
Hispanic/Latino	2 (6.5)	3 (6.4)	4 (13.8)	9 (8.4)
More than one	1 (3.2)	0 (0.0)	1 (3.4)	2 (1.9)
Not reported	0 (0.0)	4 (8.5)	2 (6.9)	6 (5.6)
Baseline year, *n* (%)				
2006	3 (9.6)	9 (19.1)	7 (24.1)	19 (17.8)
2007	11 (35.5)	11 (23.4)	10 (34.5)	32 (29.9)
2008	10 (32.2)	14 (29.8)	5 (17.2)	29 (27.1)
2009	7 (22.6)	13 (27.7)	7 (24.1)	27 (25.2)
Field of study, *n* (%)				
Anesthesiology	0 (0.0)	1 (2.1)	0 (0.0)	1 (0.9)
Audiology	3 (9.7)	0 (0.0)	0 (0.0)	3 (2.8)
Education	0 (0.0)	1 (2.1)	0 (0.0)	1 (0.9)
Epidemiology	3 (9.7)	0 (0.0)	0 (0.0)	3 (2.8)
Health services	1 (3.2)	0 (0.0)	0 (0.0)	1 (0.9)
Internal medicine	2 (6.45)	11 (23.4)	11 (37.9)	24 (22.4)
Neurology/neurosurgery	1 (3.2)	6 (12.8)	6 (20.7)	13 (12.1)
Obstetrics and gynecology	3 (9.7)	9 (19.1)	2 (6.9)	14 (13.1)
Occupational therapy	2 (6.45)	1 (2.1)	2 (6.9)	5 (4.7)
Ophthalmology	2 (6.45)	0 (0.0)	0 (0.0)	2 (1.9)
Orthopedic surgery	2 (6.45)	1 (2.1)	0 (0.0)	3 (2.8)
Otolaryngology	2 (6.45)	0 (0.0)	0 (0.0)	2 (1.9)
Pediatrics	2 (6.45)	8 (17.0)	4 (13.8)	14 (13.1)
Pharmacy	0 (0.0)	1 (2.1)	0 (0.0)	1 (0.9)
Physical therapy	3 (9.7)	2 (4.3)	0 (0.0)	5 (4.7)
Psychiatry/psychology	1 (3.2)	3 (6.4)	2 (6.9)	6 (5.6)
Public health	0 (0.0)	0 (0.0)	1 (3.4)	1 (0.9)
Radiation oncology	1 (3.2)	0 (0.0)	0 (0.0)	1 (0.9)
Social work	0 (0.0)	0 (0.0)	1 (3.4)	1 (0.9)
Surgery	0 (0.0)	4 (8.5)	0 (0.0)	4 (3.7)
Other	2 (6.45)	0 (0.0)	0 (0.0)	2 (1.9)

Table 2. Characteristics of scholars in the clinical research training programs at Washington University School of Medicine, 2006–2009.

were included, because the postdoctoral program scholars in 2006 did not complete the same CRAI instrument that the other two program trainees completed. *Table 2* shows the demographic characteristics of these 107 scholars. Fields of study covered a wide range of disciplines, with the highest concentration in internal medicine (22.4%), obstetrics and gynecology (13.1%), neurology/neurosurgery (12.1%), and pediatrics (13.1%).

Of the 107 scholars who entered one of the training programs between 2006 and 2009, 96 completed the CRAI at baseline. Of the 11 scholars who did not complete a baseline assessment, 9 had started the postdoctoral program in 2006 and were not included due to the different format of the CRAI instrument for that program in 2006, and 2 had started their respective programs late without completing a baseline questionnaire. Of the 96 scholars who completed a baseline questionnaire, 60 (62.5%) also completed the CRAI after 1 year. Among those 36 scholars without follow-up assessments, 9 had started programs but later dropped out. The remaining 27 began training in 2009 and had not yet completed their first training year at the time of analysis. Only the data for the 60 scholars, who entered training programs from 2006 to 2009 and completed the CRAI at baseline and 1-year follow-up, were included in the analysis.

There were no statistically significant differences in terms of age, gender, and race/ethnicity between scholars who were and were not included in the analysis. Scholars included in the analysis started their respective programs in the years 2006 (16.6%), 2007 (41.7%) and 2008 (41.7%). Fields of study among the 60 scholars who completed both surveys were similar to those of the 107 in the larger study population, with the highest concentrations again in internal medicine (18.3%), obstetrics and gynecology (15.0%), neurology/neuroscience (13.3%) and pediatrics (11.7%).

The PCA using minimum eigenvalue >1.000 as the criterion for determining number of factors resulted in a 10-factor solution; however none of the items had factor loadings >0.400 on the 10th factor, and 22 items had cross loadings of >0.400 on multiple factors. We next forced an eight-factor solution, as reported previously;[24] here, too, none of the items had factor loadings >0.400 on the 8th factor, and 20 items had cross loadings of >0.400 on multiple factors. We finally forced a seven-factor solution, with a factor loading >0.500 selected as the criterion for retention of an item on a factor. Only 9 items had cross loadings >0.400 on more than one factor, and none of these cross loadings were >0.490. The Kaiser–Meyer–Olkin measure of sampling adequacy for the seven-factor solution was 0.88. The seven-factor solution explained 78.0% of the total variance.

Table 3 shows the number of items in each subscale, the Cronbach alpha coefficients for each subscale at baseline and follow-up, and the mean subscale and overall CRAI scores for each training program for the 60 scholars with both assessments. Alphas were high for each subscale and 69-item measure at baseline and

Subscale (no. of items)	Cronbach alpha	TL1 mean (SD)	Postdoctoral mean (SD)	KL2 mean (SD)	RM-ANOVA across all programs *p*	RM-ANOVA scale × program interaction *p*	Between-programs *p*
Study design/data analysis (20)					.016	.131	.001*,†
Baseline	(0.976)	4.76 (1.82)	4.76 (2.15)	6.91 (1.50)			
Year 1	(0.967)	8.01 (1.01)	6.96 (1.60)	8.15 (0.92)			
Interpreting/reporting/presenting (16)					.034	.047	.008‡
Baseline	(0.977)	4.89 (2.00)	5.90 (1.81)	7.74 (1.24)			
Year 1	(0.947)	7.62 (1.27)	7.76 (1.07)	8.55 (0.74)			
Responsible research conduct (10)					.143	.030	.001†,¶
Baseline	(0.949)	5.53 (2.00)	5.51 (1.91)	7.79 (1.30)			
Year 1	(0.905)	8.16 (1.31)	7.70 (1.21)	8.48 (0.93)			
Collaboration (8)					.617	.173	.030§
Baseline	(0.933)	6.14 (1.70)	6.16 (1.41)	7.31 (1.33)			
Year 1	(0.921)	7.86 (1.23)	7.26 (1.48)	8.18 (1.09)			
Funding a study (7)					.226	.297	<.001†
Baseline	(0.968)	3.82 (1.78)	4.37 (2.19)	6.95 (1.11)			
Year 1	(0.934)	6.33 (1.95)	6.20 (2.11)	7.78 (1.21)			
Conceptualizing a study (6)					.077	.086	.147
Baseline	(0.940)	6.63 (1.54)	6.21 (1.60)	7.35 (1.23)			
Year 1	(0.924)	7.90 (1.12)	7.84 (1.29)	8.17 (0.63)			
Planning and managing a study (2)					.884	.788	.003†
Baseline	(0.875)	5.81 (2.31)	4.76 (1.66)	6.73 (1.76)			
Year 1	(0.849)	7.02 (1.36)	5.85 (2.60)	7.66 (1.55)			
Overall CRAI score (69)					.050	.048	.001†
Baseline	(0.987)	5.16 (1.54)	5.38 (1.60)	7.31 (1.05)			
Year 1	(0.981)	7.72 (1.13)	7.26 (1.29)	8.25 (0.68)			

* Pairwise contrasts of TL1 and postdoctoral programs differed significantly at $p < .05$.
† Pairwise contrasts of postdoctoral and KL2 programs differed significantly at $p \leq .001$.
‡ Pairwise contrasts of postdoctoral and KL2 programs differed significantly at $p \leq .005$.
¶ Pairwise contrasts of TL1 and KL2 programs differed significantly at $p < .05$.
§ Pairwise contrasts of postdoctoral and KL2 programs differed significantly at $p \leq .01$.

Table 3. Repeated-measures analysis of variance (RM-ANOVA) for each subscale and the overall CRAI measure, grouping by training program and controlling for age at enrollment ($n = 60$).

follow-up. Also shown in this table are the *p* value for the change in each subscale and 69-item CRAI measure across all three programs using RM-ANOVA, and the *p* value for the difference in subscale and overall CRAI scores between training programs across both time points. In addition, the last column shows the results of pairwise contrasts for differences between programs that were examined in the RM-ANOVA for each subscale and overall CRAI measure; significant differences between pairs of programs are indicated in the footnotes to the table. We controlled for age in the RM-ANOVA, since age was correlated with several subscales and overall CRAI measure (data not shown).

Significant improvements at 1-year follow-up, across all programs, were observed for study design/data analysis ($p = .016$), interpreting/reporting/presenting ($p = .034$), and overall CRAI ($p = .050$) measures. In addition, there was a significant interaction between the change in perceived research self-efficacy and training program in the RM-ANOVA of two subscales—interpreting/reporting/presenting ($p = .047$) and responsible research conduct ($p = .030$)—and the overall CRAI ($p = .048$), with TL1 and postdoctoral program participants, but not KL2 participants, showing significant rates of improvement in these measures (based on nonoverlapping 95% confidence intervals from baseline to follow-up; data not shown).

The KL2 participants reported higher research self-efficacy on each subscale and the overall CRAI measure at both baseline and follow-up than the TL1 and postdoctoral program participants. Significant differences between programs (across both time points) were observed for six subscales and for the 69-item CRAI measure (*Table 3*). Pairwise contrasts between training programs indicated that the differences between postdoctoral and KL2 scholars were significant for each of these six subscales and the overall CRAI measure.

Discussion

The Clinical Research Training Center at Washington University School of Medicine supports clinical research training programs

that incorporate didactic training in research methodology, mentorship, protected time for research, and multidisciplinary collaboration to foster the growth of new clinical investigators. We administered a 76-item CRAI measure to evaluate the short-term effectiveness of three of these training programs to increase clinical research self-efficacy before and 1 year after participating in one of the programs. Following the methods reported previously,[24] we further reduced the number of items on the CRAI to 69. Our PCA and tests of internal consistency of items on each factor (Cronbach alpha) indicated that items on some of the original 10 conceptual domains could be combined for analysis to create fewer subscales that are both meaningful and reliable. After dropping 7 items, we used seven subscales and the overall 69-item CRAI measure in our analysis. However, based on our PCA results in which 9 items cross loaded >0.400 on more than one factor, and on the Cronbach alphas, which were >0.90 for most subscales, it is likely that the CRAI could be further shortened to reduce response burden of trainees completing the survey. Re-evaluating the PCA results with a larger sample is recommended.

Using RM-ANOVA, we found that, on average after a year of training-program participation, scholars' research self-efficacy increased on two of the CRAI subscales, study design/data analysis and interpreting/reporting/presenting, and on the overall CRAI (across all programs), indicating that the training programs were effective in improving scholars' confidence in their clinical research skills. Our results add to earlier findings that a 1-year structured clinical research training program can successfully increase participants' knowledge and self-assessed research competence.[4] An increase in clinical research self-efficacy, as shown in our study, may prove to be an important short-term indicator of long-term program success. Research self-efficacy has been correlated with research productivity as well as with decisions to pursue a career in research.[24–26] Traditional long-term indicators of clinical research success include publications, presentations, academic appointments, and acquisition of independent funding for one's research.[1,16,21] Future studies will track these indicators for scholars in these training programs to compare long- and short-term outcomes, which would provide evidence of program success to foster development of a cadre of productive clinical researchers as well as test the predictive power of the CRAI.[14,24]

We also observed a significant interaction between the change in perceived research self-efficacy and training program in the RM-ANOVAs of the interpreting/reporting/ presenting and responsible research conduct subscales and of the overall CRAI. There was a significant improvement in each of these measures for the TL1 and postdoctoral program participants, but not KL2 participants. Perhaps with less research experience at baseline compared with KL2 scholars, TL1, and postdoctoral program participants had more to gain in terms of their research self-efficacy.

With regard to the change in overall CRAI specifically, the TL1 scholars showed greater improvement in their perceived research self-efficacy than the postdoctoral scholars after 1 year of training in the program. One possible reason for this phenomenon is rooted in self-efficacy theory. Self-efficacy is formed through a complex, on-going process of task and experience analysis. Therefore, it is thought that greater experience will correlate with greater accuracy of self-assessed confidence.[27] The mean age of TL1 scholars in this study was 9 years younger than the mean age of postdoctoral scholars, and, since TL1 program participants were still students, they likely had less clinical research experience. Thus, TL1 scholars may appear to be overconfident in their clinical-research skills after completing just 1 year of training. However, the TL1 program is a research-intensive program allowing for 1 year of a focused research experience and training, whereas the research experiences provided to participants in the postdoctoral training program are spread out over 2 or 3 years. Future studies that integrate other measurements of self-efficacy and competence (e.g., knowledge, grants awarded, and publications) will be necessary to further explore the CRAI's construct and predictive validity.[24]

As would be expected, KL2 scholars reported higher research self-efficacy at baseline on each of the subscales, and the rates of change for this group were not as great as for the other two programs. Although participants across all three training programs showed a significant improvement in research self-efficacy for only two subscales (study design/data analysis and interpreting/reporting/presenting) and the overall CRAI measure, significant differences between programs were observed for all subscales but conceptualizing a study. In the pairwise contrasts, research self-efficacy on each of these six subscales and the overall CRAI measure differed significantly between the postdoctoral and KL2 scholars, in particular. This, somewhat counterintuitive finding, mirrors the results reported in the cross-sectional instrument-development study, in which faculty-level participants' scores were highest, and medical students' and residents' scores were higher than postdoctoral fellows' scores.[24] Whether these findings are due to differences in aspects of the training programs themselves or in postdoctoral fellows' relative lack of clinical research experience before entering the training program remains to be determined.

Conclusion

This study had several limitations. First, the study was an observational cohort study of training-program participants at one medical school; therefore, causal inferences based on our data cannot be made. Second, the sample size was limited by the capacity of each of the training programs and the time during which the three programs utilized the same CRAI instrument to measure scholars' confidence. Self-assessed confidence, as all self-report measures, has the potential for bias.[27–31] In addition, our analysis did not include other variables (unmeasured confounders) that could impact clinical research self-efficacy, including number of years of previous research experience, specific courses taken during the first year, the nature of a scholar's individual research project, and the scholars' mentors' areas of expertise. A multi-institutional study that includes some of these unmeasured confounders, a larger sample, and measurable outcomes, such as publications and receipt of grant funding, is needed to support the generalizability of our findings and to establish the predictive validity of the CRAI.

In summary, participation in clinical research training programs at Washington University School of Medicine was associated with improved clinical research self-efficacy among all scholars. Further research is necessary to validate this 69-item CRAI (or a shorter version) as a short-term indicator of training-program success in increasing scholars' confidence in their clinical research skills and in contributing to the growth of a cadre of independent clinical researchers. In addition, future research might demonstrate how various program components affect the different subscales of the instrument.

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