

Official Title of Study:

Exploring the Relationship Between Mini-Clinical Evaluation Exercise (Mini-CEX) and Entrustable Professional Activities (EPAs) in Occupational Therapy Clinical Interns' Independent Competence

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Study Protocol and Statistical Analysis Plan

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Human Research/Clinical Trial Protocol

- 1、Project Title:
Exploring the Relationship Between Mini-Clinical Evaluation Exercise (Mini-CEX) and Entrustable Professional Activities (EPAs) in Occupational Therapy Clinical Interns' Independent Competence
- 2、Principal Investigator: Chao-Yi Cheng
- 3、Co-Investigators:
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- 4、Background:

Before entering clinical practice, medical graduates apply theoretical knowledge acquired during school combined with clinical experience from clinical instructors to enhance their professional skills. To comprehensively evaluate interns' professional competence during internships, workplace assessment tools that directly observe the intern's performance in specific cases and provide immediate feedback are commonly used (Pinilla et al., 2021). In Taiwanese occupational therapy clinical settings, the Mini-Clinical Evaluation Exercise (Mini-CEX) developed by the American Medical Association is commonly applied (Norcini et al., 2003). This tool takes about 20–30 minutes per assessment and rates seven core skills. However, such clinical assessment tools cannot fully determine whether interns are capable of independent practice.

Competency-Based Medical Education (CBME), focused on core competencies, is the current trend in medical education. Entrustable Professional Activities (EPAs) describe clinical tasks that interns are deemed competent to perform independently by the end of each training stage (Fu et al., 2023). EPAs, developed by Dutch medical education scholar Olle ten Cate from 2005 onwards, provide a curricular and assessment framework where supervision levels reflect intern competence and trustworthiness in clinical performance (ten Cate et al., 2015). Different medical professions in Taiwan have begun developing their own EPAs. For occupational therapy, under the facilitation of the Taiwanese Occupational Therapy Association, hospitals have started pilot EPA-based clinical assessments and research dissemination (Fu et al., 2023). In the field of physiological occupational therapy, three EPAs exist for hospital use: performing occupational therapy assessment, performing occupational therapy interventions, and providing health education and counseling.

Therefore, the ultimate goal during clinical internships is for students to acquire core competencies and translate them into workplace competencies. To determine if occupational therapy interns meet these goals, we need to use both Mini-CEX and EPAs. This study aims to examine the impact of using these two tools clinically to assess interns' ability to practice independently and whether correlations exist between subscale scores.

- 5、Objectives: This study aims to investigate the effects of combining Mini-CEX and EPAs on evaluating interns' independent practice capability and the correlations between scale sub-items. It is expected that students performing well on EPAs and Mini-CEX will demonstrate better clinical performance and operational skills during internships. We hope EPAs will provide stronger evidence of interns' readiness to independently perform medical tasks.
- 6、Methods:
 - (1) Selection criteria and sample size:
 - (a) Sample size: 50 subjects at Far Eastern Memorial Hospital; 0 at other centers
 - (b) Inclusion criteria:
 - (i) Occupational therapy interns in the physical domain at Far Eastern Memorial Hospital
 - (ii) Provide informed consent to participate
 - (c) Exclusion criteria: None
 - (d) Recruitment: Interns in the physiological domain will be recruited during the 6th week of their internship; assessment will be conducted in the 8th week.
 - (e) Study design:

This is a cross-sectional study involving physiotherapy interns receiving clinical training.

After obtaining consent at week 6, assessments using EPAs and Mini-CEX will be conducted

during the 8th week in the ward. Each assessment takes about 20 minutes. Results will be analyzed two weeks after submission of instructors' internship grades. Since the occupational therapy department covers physiological and pediatric domains with different clinical instructors, pediatric instructors provide consent forms and explain the study to physiological interns. Participation is voluntary and will not affect internship coursework or rights.

(f) Follow-up or rehabilitation plan:

Subjects will follow routine clinical training; EPA and Mini-CEX are routine tests at week 8. No additional follow-up or rehabilitation needed.

(g) Outcome measures and statistical analysis:

(i) Clinical performance evaluated by Mini-CEX and EPAs

(ii) Statistic analysis:

Descriptive statistics for demographics; Pearson's correlation to explore relationships between variables; multiple linear regression analyses for predictors of clinical performance including age, gender, average self-study time, prior university experience, parents' occupations, and residence. Significance set at $p < 0.05$.

(h) Questionnaires and data collection:

(i) Demographics collected by semi-structured questionnaire covering age, gender, average self-study time, prior university experience, parents' occupation, and residence.

(ii) Mini-Clinical Evaluation Exercise (Mini-CEX):

Developed by Norcini et al. (1995) and officially translated and authorized for use in Taiwan since 2004 (Chen, 2007), the Mini-CEX assesses clinical diagnostic skills of medical interns using structured forms and immediate feedback. The assessment covers seven core competencies and is scored on a scale from 1 to 9 for each item, where higher scores indicate better clinical performance. This tool has demonstrated good reliability and validity (Holmboe et al., 2003).

(iii) Entrustable Professional Activities (EPAs):

Developed by Olle ten Cate starting in 2005 (ten Cate et al., 2015), EPAs evaluate intern competence according to supervision levels required to perform professional tasks safely. Scores typically range from 1 to 5, with higher values indicating greater independence and readiness to carry out clinical activities autonomously. In Taiwan, EPAs have been progressively developed for various medical specialties, including occupational therapy. Promoted by the Taiwanese Occupational Therapy Association, initial pilot studies have been reported (Fu et al., 2023). This study specifically utilizes EPAs related to occupational therapy assessment tasks in the physiological domain.

(2) Duration and schedule:

Five physiological interns per rotation, three rotations per year (approx. 15 participants/year), with enrollment and data collection planned over four years.

(3) Research personnel, roles, and equipment:

No.	Name	Role	Responsibilities
1	Chao-Yi Cheng	Principal Investigator	Proposal submission, IRB application, progress monitoring
2	Yun Wang	Co-Investigator	Joint planning, writing, materials preparation, data collection and analysis
3	Yu-Ming Huang	Co-Investigator	Joint planning, writing, materials preparation, data collection and analysis
4	Li-Chin Chang	Co-Investigator	Joint planning, writing, materials preparation, data collection and analysis
5	Wei-Jiun Wang	Co-Investigator	Joint planning, writing, materials preparation, data collection and

			analysis
6	Yu-Lin Chen	Co-Investigator	Joint planning, writing, materials preparation, data collection and analysis
7	Sheng-Yuan Tso	Co-Investigator	Joint planning, writing, materials preparation, data collection and analysis

7、 Handling of research materials:

(1) Collection and management during study:

- (a) Paper records will be archived in locked cabinets accessible only to the principal investigator.
- (b) Electronic data will be encrypted and stored on Google Drive, password known only by the principal investigator.

(2) Post-study handling and storage duration:

- (a) Paper records archived securely in locked cabinets for 7 years, access restricted to principal investigator only.
- (b) Electronic data stored encrypted on designated computers, de-identified by replacing names with study codes. Password access limited to the principal investigator; others require PI's permission. Data will be securely destroyed by the principal investigator after 7 years.

8、 Protection of participant rights:

(1) Potential physical, psychological, or social harm and remedies:

- No risks expected as participants only need to complete questionnaires.

(2) Conditions and mechanisms for suspension/termination or withdrawal:

- Participants may withdraw at any time if concerns arise, with assurance that withdrawal will not affect internship rights or coursework.

(3) Participant compensation: None.

9、 Expected outcomes:

(1) This study aims to explore the combined use of Mini-CEX and EPAs for assessing interns' independent functioning and correlations between subscale scores, expecting positive correlation between EPA/Mini-CEX performance and clinical skills. This may confirm intern competency for independent practice.

(2) Research ownership and utilization:

- Results belong to the Rehabilitation Department of Far Eastern Memorial Hospital. Findings may be used by occupational therapy clinical instructors to improve teaching effectiveness.

10、 Funding and budget:

- Internal research grant (Project No.: FEMH-2025-C-091)

Item	Description	Amount (NTD)
Operational expenses	Consumables, supplies, books, and miscellaneous (including study personnel costs, wages, labor insurances, health insurances, and labor pension contributions)	135,000
Management fee	10% of operational expenses	13,500
Total		148,500

11、 Conflict of interest:

- This study is solely an internal initiative for new domain research within the unit, with no external collaborations, commercial involvement, or patent issues.

12、 References:

Fu, C. P., Chiang, F. M., Lee, C. Y., Chi, H. Y., Wu, J. L., Lin, Y. J., Li, M. W., Chen, Y. J., Chang, W. Y., Chang, W. D., Huang, S. M., Liao, W. S., Yang, Y. C., Huang, C. K., Kuo, N. J., Liu, T. H., & Chen, Y. L. (2023). Developing the topics of entrustable professional activities in pediatric

occupational therapy in Taiwan: A pilot study. *Taiwan Journal of Occupational Therapy*, 41(2), 91–110. [https://doi.org/10.6594/tjot.202308_41\(2\).0001](https://doi.org/10.6594/tjot.202308_41(2).0001)

Norcini, J. J., Blank, L. L., Duffy, F. D., & Fortna, G. S. (2003). The mini-CEX: a method for assessing clinical skills. *Ann Intern Med*, 138(6), 476-481. <https://doi.org/10.7326/0003-4819-138-6-200303180-00012>

Pinilla, S., Kyrou, A., Klöppel, S., Strik, W., Nissen, C., & Huwendiek, S. (2021). Workplace-based assessments of entrustable professional activities in a psychiatry core clerkship: an observational study. *BMC Med Educ*, 21(1), 223. <https://doi.org/10.1186/s12909-021-02637-4>

ten Cate, O., Chen, H. C., Hoff, R. G., Peters, H., Bok, H., & van der Schaaf, M. (2015). Curriculum development for the workplace using Entrustable Professional Activities (EPAs): AMEE Guide No. 99. *Medical Teacher*, 37(11), 983-1002. <https://doi.org/10.3109/0142159X.2015.1060308>