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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Principal Investigator:
Chao-Yi Cheng

Institution:
Occupational Therapy Department, Rehabilitation Department, Far Eastern Memorial Hospital

Far Eastern Memorial Hospital
Participant Information and Consent Form

(This form should be personally explained by the research team to the participant, and the participant should sign only after careful consideration.)

You are invited to participate in this research study. This form provides information about this study. The principal investigator or research team will explain the study content to you and answer any questions you may have. Your participation in this study is voluntary, and not participating will not affect your existing rights or care.

Project Title: Exploring the Relationship Between Mini-Clinical Evaluation Exercise (Mini-CEX) and Entrustable Professional Activities (EPAs) in Occupational Therapy Clinical Interns' Independent Competence	
Principal Investigator: Chao-Yi Cheng	Title: Occupational Therapist
Co-Investigators: Yun Wang, Wei-Jiun Wang, Li-Chin Chang, Yu-Ming Huang, Sheng-Yuan Tso, Yu-Lin Chen	Title: Occupational Therapists
Contact Person: Chao-Yi Cheng	Contact Number: 02-8966700 ext. 1516
Executing Unit: Occupational Therapy Department, Rehabilitation Department, Far Eastern Memorial Hospital	Sponsor/Pharmaceutical Company: None
Participant's Name:	Medical Record Number:

1、 Research Background and Objectives:

Hello, we sincerely invite you to participate in a research study focusing on predictors related to clinical internships for occupational therapy students. In clinical occupational therapy in Taiwan, the Mini-Clinical Evaluation Exercise (Mini-CEX) is a commonly used assessment tool. It observes and rates interns' 7 core skills; however, it may not fully assess whether interns possess the ability to practice independently. Entrustable Professional Activities (EPAs) determine an intern's competency based on the level of supervision required. EPAs are a crucial medium for translating core competencies into actual clinical practice. Therefore, this study aims to investigate the impact of using Mini-CEX combined with EPAs on whether interns possess independent operational capabilities, and if there are correlations among the sub-items of these scales. It is expected that students performing well in EPAs and Mini-CEX will show a positive correlation with their clinical performance and skill operation during internships. We hope that EPAs will further confirm whether interns are competent to perform medical tasks independently.

According to regulations set by the health authorities, we must inform you about the method and purpose of data collection, the assessment items, and potential risks. Before you agree to participate in this study, the principal investigator or authorized research personnel will explain the content of this consent form, answer any questions you may have, and provide you with ample time for consideration. Please thoroughly read this consent form again and ask any questions. Finally, participation in this study is entirely voluntary. Your decision not to participate will not affect your clinical internship rights.

2、 Research Methods and Procedures:

1. This study plans to recruit 50 interns from the physiological domain of the Occupational Therapy Department, Rehabilitation Department, Far Eastern Memorial Hospital. Recruitment will be conducted by pediatric clinical instructors during the sixth week of their internship. Both EPAs and Mini-CEX will be administered simultaneously during their ward internship in the eighth week. The assessment time is approximately 20 minutes. The assessment results will be analyzed by research personnel two weeks after the instructors submit internship grades.
2. Inclusion/Exclusion Criteria:

(1) Inclusion Criteria: Interns in the physiological domain of the Occupational Therapy Department, Rehabilitation Department, Far Eastern Memorial Hospital, who fully understand this study during the sixth week and are willing to provide consent.

(2) Exclusion Criteria: None.

3、 Potential Side Effects, Discomfort, or Risks and Their Management:

This study involves routine teaching activities. Data analysis will be conducted two weeks after internship grades are submitted to minimize psychological pressure on participants regarding their clinical performance. Participation in the study is purely voluntary.

4、 Expected Research Effects/Benefits: It is expected that students who perform well in EPAs and Mini-CEX will show a positive correlation with their clinical performance and skill operation during internships. We hope that EPAs will further confirm whether interns are competent to perform medical tasks independently.

5、 Other Possible Treatment Options and Explanations:

This study does not involve treatment.

6、 Other Potential Losses or Benefits: If participating in this study causes you any physical or mental discomfort, please inform the principal investigator or co-investigators at any time.

7、 Compensation for Harm and Insurance:

(1) If, according to the human research protocol set forth in this study, harm occurs due to an adverse reaction, Far Eastern Memorial Hospital will bear the responsibility for compensation. However, adverse reactions listed as foreseeable in this participant consent form will not be compensated.

(2) If adverse physical or psychological reactions, side effects, or injuries are caused by the protocol of this study, this hospital and the principal investigator will provide you with professional medical care and consultation. You will not bear the necessary medical expenses for the treatment of adverse reactions or damages.

(3) Except for statutory compensation and medical care, this study does not provide other forms of compensation or remuneration. If you are unwilling to accept such risks, please do not participate in the study.

Your signing of this consent form will not waive any of your legal rights.

(This study is not covered by liability insurance.)

8、 Data Retention Period and Storage Method:

(1) The original data you provide will be used exclusively for this study (Exploring the Relationship Between Mini-Clinical Evaluation Exercise (Mini-CEX) and Entrustable Professional Activities (EPAs) in Occupational Therapy Clinical Interns' Independent Competence) and will not be provided to other individuals or entities. If other entities or research projects related to public welfare require the use of your data, we will seek your consent again.

(2) The data you provide will be managed and stored by the principal investigator and co-investigators. Electronic data will be stored encrypted on Google Drive, and relevant documents will be kept in locked cabinets with keys held by the principal investigator. The principal investigator will maintain the confidentiality of your research data, and a research ID number will replace your name. Except for legal investigations by relevant authorities, the principal investigator will carefully protect your privacy. Your data will be destroyed by the principal investigator 7 years after the study concludes.

(3) Research findings may be published in academic journals, but your name will not be disclosed. The principal investigator will carefully protect your privacy, treating identifying information such as your name and ID number as confidential and storing it securely.

(4) You also understand that Far Eastern Memorial Hospital, the Ministry of Health and Welfare, the Ministry of Education, and the Research Ethics Review Committee, Far Eastern Memorial Hospital, have the right to review your data in accordance with the law, without compromising your personal privacy, to ensure that the research process and data comply with relevant laws and regulations. The aforementioned personnel will also adhere to ethical principles of confidentiality.

9、 Handling of Personal Data if Participant Withdraws Mid-Study:
Participants have the freedom to choose to participate in the study and to withdraw their consent at any time during the study. If you choose to participate, you may also withdraw your consent and discontinue participation at any time, and this decision will not affect your clinical internship rights. If you wish to discontinue your participation for any reason, please contact the principal investigator, Chao-Yi Cheng, at 02-8966700 ext. 1516.

Method for handling participant's personal data after withdrawal (Participant, please select one):

☐ Destroyed by Far Eastern Memorial Hospital (or destroyed by

Rehabilitation Department, Far Eastern Memorial Hospital)

☐ Returned

10、 Participant Rights:

(1) During the research process, any significant findings related to your health or condition that may affect your willingness to continue participating in human research will be promptly provided to you. If you have any questions about the study, you may also contact the contact person.

(2) If you have questions about the nature of the research during the study, have concerns about your rights as a research participant, or suspect harm from participating, you may contact the Human Research Ethics Committee of this hospital for consultation at (02) 7728-2152, or contact the Participant Protection Center at (02) 7728-2546. To ensure the integrity of the informed consent process, the committee may contact you by phone during or after the study. You have the right to refuse.

(3) This consent form is issued in two copies. The principal investigator or their authorized personnel has provided you with a copy of the consent form and has fully explained the nature and purpose of this study. The research team has answered your questions regarding this study.

11、 Confidentiality:

Far Eastern Memorial Hospital will treat your data as confidential to the extent permitted by law. You also understand that the health authorities and the Research Ethics Review Committee, Far Eastern Memorial Hospital, have the right to review your data and will adhere to ethical principles of confidentiality.

12、 Conflict of Interest: This is an academic study initiated by the principal investigator. The funding source is an internal project grant from Far Eastern Memorial Hospital, with no potential commercial interests involved.

13、 Signatures:

(I) The principal investigator, co-investigators, or authorized research personnel have thoroughly explained and answered questions regarding the nature and purpose of the aforementioned research methods and any potential risks and benefits in this research project.

□Principal Investigator /□Co-Investigator /□Authorized

Signature: _____ Date:_____

(II) The participant has thoroughly understood the aforementioned research methods and

their potential risks and benefits. Questions regarding this research project have been fully explained by the research team. I agree to voluntarily participate in this human research project.

Participant's Signature: _____ Date: _____

Date of Birth: _____ Year ____ Month ____ Day Phone:

National ID Number:

Mailing Address:

Participant's Notice:

1. What is human research?

"Research" is an investigation conducted to answer a question. "Research" is different from "treatment." Participation in research is not mandatory. Therefore, before participating in research, you must clearly understand the following: the purpose of the study, what will happen during the study process, what adverse reactions might occur, and the personal benefits and expected outcomes of the study.

2. Human Research Ethics Committee

This committee is an ethics review body established to ensure that human research meets scientific and ethical appropriateness. It comprises medical professionals with expertise, as well as legal experts, public figures, or representatives from non-medical backgrounds, to help researchers understand the participants' situation and protect their rights. This committee will track approved research projects and may contact you by phone to confirm the integrity of the consent process. You have the right to refuse.

3. Participant Rights

To be fully informed, to freely decide whether to participate in the research, to ask questions about the research at any time, to privacy and confidentiality, to retain your existing legal rights, and to be treated with dignity and respect throughout your participation in the research project.

More detailed information can be found on the committee's website: https://www.femh-irb.org