Supplement. The Original Trial Protocol and Statistical Analysis Plan for The Institutional Review Board, Chang Gung Medical Foundation, Taipei, Taiwan, ROC

Protocol Title: Cognitive Style and Mobile Technology in E-Learning in Undergraduate Medical Education- A Randomized Controlled Trial of Otolaryngology-Head and Neck Surgery

Protocol No.: NSC-105-2511-S-182A-006-
IRB No.: 105-5290C
Principal Investigator(s): Li-Ang Lee
Co-Investigators: Cheng-Keng Chuang, Li-Jen Hsin, Shu-Ling Wang, Chung-Guei Huang, Hsueh-Yu Li, Chia-Hsiang Fu, Chung-Jan Kang, Wei-Chieh Chao

Original Protocol (Figure1):
Protocol No.: NSC-104-2511-S-182-010-
IRB No.: 103-6959B
Principal Investigator(s): Li-Ang Lee
Co-Investigators: Cheng-Keng Chuang, Li-Jen Hsin, Shu-Ling Wang, Chung-Guei Huang, Hsueh-Yu Li, Chia-Hsiang Fu, Chung-Jan Kang, Wei-Chieh Chao
Duration of Approval: From 2015/12/03 to 2017/12/02
Approved Protocol: 2014/12/10 V.1
Approved Informed Consent: 2014/12/10 Version 1
Date of Approval: 2015/12/03, was approved by the Institutional Review Board (the “IRB”) of Chang Gung Medical Foundation on 2016/10/28. The IRB is organized and operates according to Good Clinical Practice and the applicable laws and regulations.

Modified Protocol (Figure 2): (Add AttrakDiff2 questionnaire; sample size estimation of the validation study)
Protocol No.: NSC-105-2511-S-182A-006-
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Duration of Approval: From 2016/10/28 to 2017/12/02
Approved Protocol: 2014/12/10 V.1
Approved Informed Consent: 2014/12/10 Version 1
Date of Approval: 2016/10/28, was approved by the Institutional Review Board (the “IRB”) of Chang Gung Medical Foundation on 2016/10/28. The IRB is organized and operates according to Good Clinical Practice and the applicable laws and regulations.

Chairman: Tsang-Tang Hsieh, M.D., Institutional Review Board, Chang Gung Medical Foundation

Note: The study has been registered on the ClinicalTrials.gov (The study has been registered in the ClinicalTrials.gov).

Figure 1. Original IRB Certificate.

Chang Gung Medical Foundation
Institutional Review Board

199, TUNG HWA NORTH ROAD,
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Protocol Title：Cognitive Style and Mobile Technology in E-Learning in Undergraduate Medical Education- A Randomized Controlled Pilot Study of Otorhinolaryngology-Head and Neck Surgery

Protocol No. ：NSC-104-2511-S-182-010-

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Duration of Approval: From2015/12/03 TO 2017/12/02

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Approved Informed Consent：2014/12/10 Version 1

Date of Approval：2015/12/03

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Sincerely Yours,

T. T. Hsieh

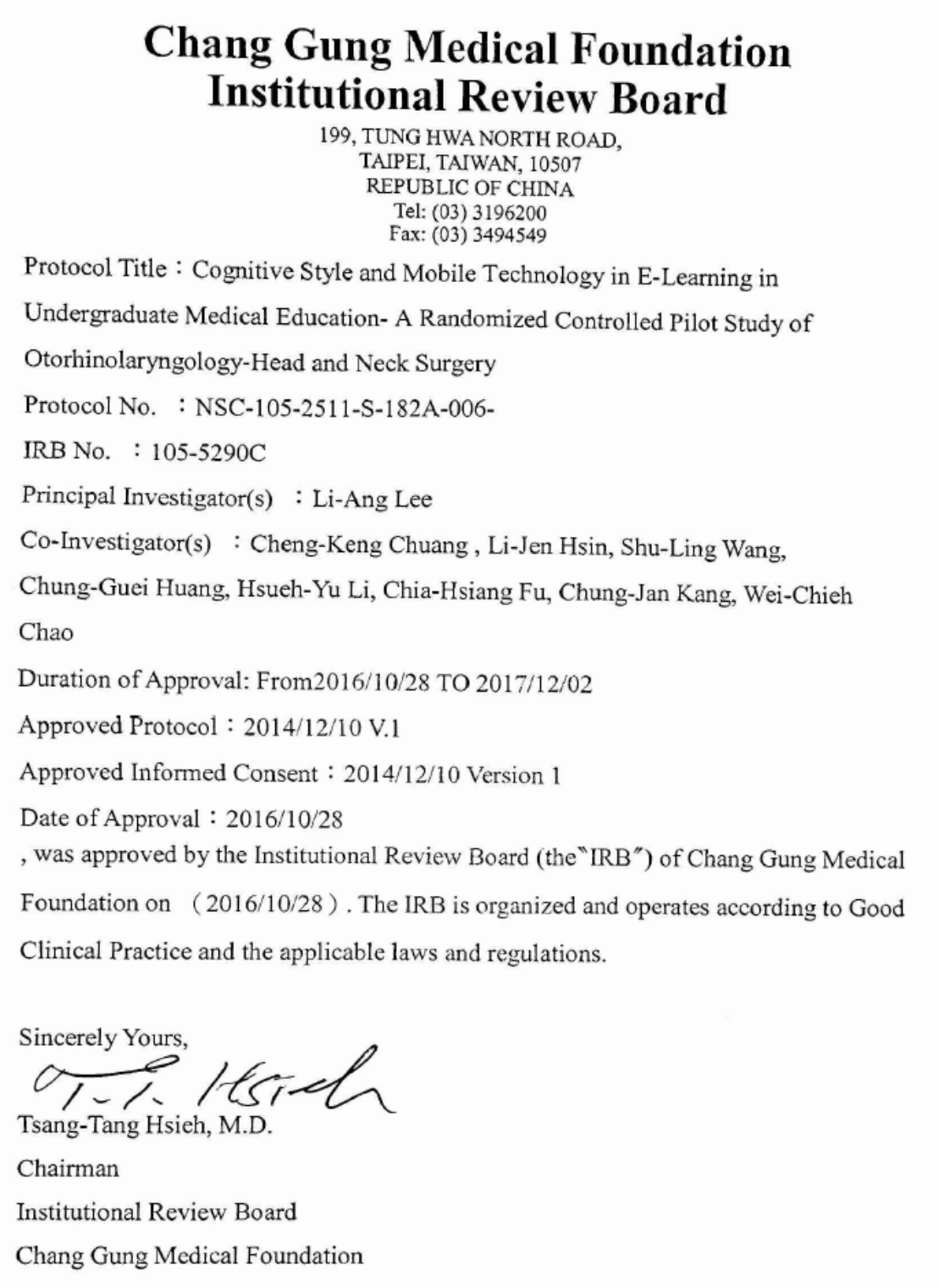
Tsang-Tang Hsieh, M.D.

Chairman

Institutional Review Board

Chang Gung Medical Foundation

Figure 2. Modified IRB Certificate.



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Chairman

Institutional Review Board

Chang Gung Medical Foundation

Topics：Cognitive style and mobile technology in e-learning in undergraduate medical education- A randomized controlled trial of otolaryngology-head and neck surgery

Abstract

Background: New designs of 6-year undergraduate medical education (UME) mainly include (1) integral curricula of body organ system, (2) multiple methods of clinical teaching and assessment, and (3) generalism in UME. UME is meant to enable graduates to become undifferentiated general physicians. Accompany with decreasing educational hours in the classrooms and hospital, essential but minor components of primary healthcare such as ophthalmology and otolaryngology–head and neck surgery (ORL-HNS) is disproportionately under-represented in UME. In Canada, substantial downstream effects on managing ORLHNS problems have been noted in family medicine residents. In order to improve learning insufficiency and enhance clinical competency without increasing extra-hours in the classrooms and hospitals, novel medical education stresses on enabling self-directory learning and increasing learning hours outside the classrooms. Accordingly, we hypothesize that innovations in educational technology can enhance the learning outcomes of ORL-HNS.

Purposes: This study is aimed to (1) setup up a mobile technology in e-learning (M-TEL) that can provide instant, interactive and reliable information, (2) to determine whether M-TEL is an effective tool for the instruction of ORL-HNS, and (3) to compare effects of different cognitive styles on learning outcomes of MTEL with various modules of medical education.

Material and Methods: This is a randomized controlled trial. Firstly, we will setup a e-learning platform of emergent ORL-HNS disorders with translating into an “app” function that can execute in mobile devices. We will enroll 10 academic physicians and 10 junior residents for assistance in developing, evaluating, and improving the e-learning instruction. Secondly, we will recruit 60 UME students without previous training in ORL-HNS to undergo the Group Embedded Figures Test to determine their cognitive styles such as field dependence or field-independence. After blinded randomization, students are instructed on two modules of emergent ORL-HNS disorders, using either a standard e-learning of text-figure PowerPoint show or an interactive multimedia module. Subjects are evaluated on emergent ORL-HNS disorders using a text-based assessment and a multimedia assessment take place prior to and following instruction.

Anticipating Outcome: This study can (1) establish a M-TEL of ORL-HNS that can deliver an innovatively mobile e-learning to supplement the deficiency of the classroom hours, (2) confirm M-TEL can enhance the efficiency of the instruction of ORL-HNS, and (3) understand differences in learning outcomes

of M-TEL with various modules of medical education between field dependence and filed independence using this platform.

Keywords: cognitive style, e-learning, mobile technology, randomized controlled trial, otolaryngology-head and neck surgery.

Original Trial Protocol:
Protocol No.: NSC-104-2511-S-182-010-
IRB No.: 103-6959B

Background

Since 2013, there was an important revolution medical education in Taiwan: shortening to six years and moving internship to postgraduate level. New designs for 6-year program of medical education mainly include (1) integral curriculum for body organ system, (2) multiple methods of clinical teaching and assessment, and (3) generalism in undergraduate medical education (UME).[1] The ultimate goal of UME (defined as the 5 or 6 years of medical school training) is meant to enable graduates with core knowledge and skills at the highest level of performance competency to become undifferentiated general physicians.[2] Clinical problems associated with otorhinolaryngology–head and neck surgery (ORL-HNS) are frequently encountered, especially in primary care providers. Therefore, educating UME students is an extremely important privilege and responsibility given to all otolaryngologists associated with a medical school. However, the shortening of overall education hours in classrooms and hospitals, essential but minor components of primary healthcare such as ophthalmology and ORL-HNS is disproportionately under-represented in UME. This mismatch between this educational need and existing curricular delivery has been thought to result in substantial downstream effects on managing ORL-HNS problems in family medicine residents in Canada.[3]

In order to improve learning insufficiency and enhance clinical competency without increasing classroom/hospital time, novel medical education lays stress on enabling self-directed learning and augmenting learning outside the classroom.[4-9] Adequate use of different learning strategies is one of the most important prerequisites of academic success. The actual use of learning strategies is the result of an interaction between individual and situational variables and can change during the academic years.[10] Medical educations must encourage autonomous learning behaviors among UME students to present a positive attitude towards learning and research. A series of novel teaching methods have been developed and validated using e-learning and simulation. Selected technologies may have a role in medical student teaching such as 3D computer-assisted instruction,[11] interactive virtual

patient,[12] and e-learning modules.[13] Of note, web-based multimedia instruction provides learners with self-directed independent learning opportunities based on didactic material enhanced with multimedia features such as video and animations and can be used to replace other didactic events (e.g. lectures) or it may be provided in addition to other learning opportunities.[8] However, e-learning has limited value in teaching complex spatial anatomy to novice learners, but good value in teaching basic clinical knowledge and selected technical skills.[14]

Mobile technology is gaining popularity in recent years, as a means of immediate interactive multimedia communication and access to the Internet. It represents the next natural frontier in the evolution of e-learning and we hereby call “mobile technology in e-learning (M-TEL)”. Utilizing M-TEL can result in greater educational opportunities for UME students while simultaneously enhancing faculty effectiveness and efficiency. However, institutional readiness for e-learning or M-TEL adoption ensures the alignment of new tools to the educational and economic context.[15] Clinical teachers looking to use e-learning need to make sure that it will meet both their UME learners' needs and the program's needs, and it has to align to the contexts in which it is used. The absence of a proper dialogue regarding issues about expectations and beliefs for learners may put up a barrier to creating alignment and supportive professional relationshp.[16] Even novel e-learning cannot completely replace traditional face-to-face lectures, because students indicate that they consider traditional teaching as the basis of their education.[17] Besides, learning constructs were established for identifying learners’ learning styles who would most likely benefit from a problem-based or computer-assisted curriculum in a UME population.[18]A recent investigation found a relatively high (nearly 80%) prevalence of daily using the iDoc application (App) in primary care providers and they were particularly interested in ORL-HNS information within the limitations previously identified in medical school curricula.[19] Fung[14] and Lewis[20] anticipated that over the next few years there will be a rapid emergence of M-TEL, many of which will have direct implications for teaching ORL-HNS. Accordingly, we can hypothesize that innovations in educational technology such as M-TEL can improve the learning outcomes of ORL-HNS.

Prior to deployment into the UME curriculum, initial enthusiasm of M-TEL should be tempered with an objective approach to critical pedagogical evaluation. To our best knowledge, there are no known peer-reviewed publications specifically related to the use of M-TEL in teaching ORL-HNS to UME students.

Objectives

This study aims: (1) setup up a M-TEL that can provide instant, interactive, and reliable information; (2) to determine whether M-TEL is an effective tool for the instruction of ORL-HNS; and (3) to compare effects of different cognitive styles on learning outcomes of M-TEL with various modules of medical education.

Importance

1. Development of an innovative M-TEL teaching tool of ORL-HNS that have been verified by academic otolaryngologists and junior residents.
2. Validation of the novel M-TEL of ORL-HNS in UME students.
3. Real understanding of the differences in performance on two e-learning modules: text-figure PowerPoint show (PPS) and interactive multimedia (IM) module.
4. Better recognition of the differences in performance on two cognitive styles: field dependence and field independence. Reasonable comprehension of the interaction of cognitive style and e-learning modules.
5. Critically pedagogical evaluation and improvement of this educational innovation in order to implement this M-TEL in UME curricula to reform the current ORL-HNS education.

Reviews of Literatures

More recently, the smartphone and tablet featuring with faster processors, improved memory, and smaller batteries, can not only provide mobile communication but also advanced functions such app utilities. Embedded e-learning in such mobile devices can affect our educational environments. For example, the European Society of Cardiology engaged to develop an e-learning platform to provide a very systematic 360º approach to ensure every participant will have the skills, knowledge, and professional attitude.[21] Hardyman *et al*.[19] found a high prevalence of iDoc usage in house staffs, a project offering a smartphone library of medical textbooks to medical trainees and concluded that

the iDoc app was found to facilitate several aspects of medical training, including: (1) learning from observation, (2) transitioning from medical student to resident to independent practice, (3) interactive discussions with colleagues and peers, and (4) real-time rapid access to reliable information. The flipped classroom approach in a professional skills course using a mobile device has been rated more positively than the traditional classroom on many different characteristics despite no significantly improved performance as assessed by a written multiple-choice examination.[22] Tablets can enhance students' ability to develop and employ self-regulatory skills in a clinical context.[23] An important point highlighted and worth developing is the difficulties associated with accurately comparing and assessing different medical apps for smartphones. With thousands of medical apps available, it is highly improbable that a clinician has a working knowledge of the complete range available and can evaluate its utility.[24] Therefore, Lewis has proposed a systematic self-certification model for M-TEL apps including (1) information must be authoritative; (2) purpose of the website; (3) confidentiality; (4) information must be documented: referenced and dated; (5) justification of claims, (6) contact details, (7) financial disclosure, and (8) advertising policy.[20]

The role of M-TEL, especially as it pertains to the UME learner, is evolving. Important factors to consider during development of this tool include: (1) knowledge base of the learner, (2) complexity and nature of the learning objectives, (3) learning style of the learner, (4) understanding the features and limitations of different technological genres, and (5) a team approach to module development.[14] A previous study indicated that M-TEL in a medical educational course has the potential to reduce the need for face-to-face lectures. At the same time examination results are not impaired.[17] Therefore, M-TEL should augment, but not replace, interactive discussion with colleagues and mentors in medical training.[14] Furthermore, good learners' readiness may imply that the instructional designer can rely on e-learning strategies and build the course upon them. However, according to the slightly lower scores in "motivation" and "online discussion" subscales, it is recommended to stress more on strategies that improve these two components.[25] Accordingly, it is needed to test students' readiness or cognitive style in more different degree programs to generalize the results. As learning management system could enhance UME students' learning and gained more knowledge, M-TEL should allow teacher-led and student-led platforms to be integrated in the future for an enhanced student-centered experience.[26] Graff used the Cognitive Styles Analysis to determine The participant's cognitive style and found verbalisers are typically superior at

working with verbal information and long page segmentation of web-based instructional system.[27] The Group Embedded Figures Test (GEFT) was firstly applied to assess cognitive style and instructional materials for medical students in 1981.[28] Initial results showed few effects favoring matching cognitive style with instructional materials. Field-independent students performed better than field-dependent ones in all of the subjects.[29] Again, pre-instructional determination of cognitive style may help the students to match their suitable instructional materials by themselves willingness.

It is well recognized that medical students are required to retain vast amounts of medical knowledge on the path to becoming physicians. An idea M-TEL can provide several ways of problem solving for UME students. Firstly, PowerPoint modules with case-based questions can significantly enhance learning in the short-term comparing with PowerPoint modules without case-based questions.[30] Secondly, a well-designed, integrated, and interactive e-learning solution can be an efficient method for facilitating the application, integration, and contextualization of ORL-HNS anatomy and radiology.[31] Thirdly, an adaptive computer supporting collaborative learning system to manage study sessions using instructional design and learning object principles can gather strong positive feedback from students and take an important step towards bringing information management tools to support study decisions and improving learning outcomes.[32] Fourthly, game-based e-learning promises a higher motivation of learners by presenting funny contents in an interactive, rule-based and competitive way, and can be used as an effective teaching method for self-instruction.[33] Finally, a multimedia web-based learning platform may be able to deliver audiovisual mnemonics designed to improve memory retention of medical sciences.[34]

In UME, there remains a role for traditional teaching paradigms such as lectures, labs, and standardized patients; the choice of instructional type should be essentially tailored to the nature of the learning outcomes. Although M-TEL is broadly accepted and desirable by today's medical students, this technology should be woven into the fabric of UME pedagogical principles in a sensible and careful way, only after empiric assessment. The development and implementation of M-TEL is the framework of standardized competency-based learning objectives, common to all graduating medical students.

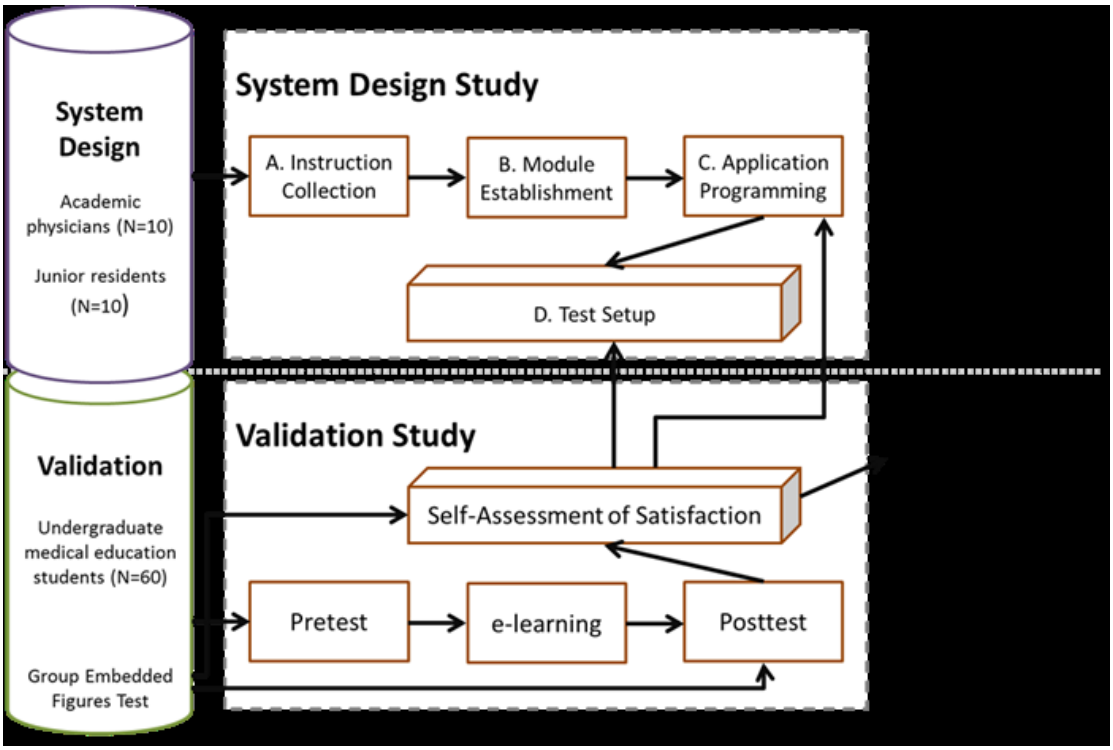
Materials and Methods

1. Study Proposal and Reasons:

1.1. Study design

This study is a prospective, randomized, parallel-controlled, blinded trial that will be conducting from August 1, 2015 to July 31, 2017 at a university (Department of ORL-HNS, School of Medicine, College of Medicine, Chang Gung University, Taoyuan, Taiwan). **Figure 3** shows the study protocol.

Figure 3. Block Diagram of the Study Protocol

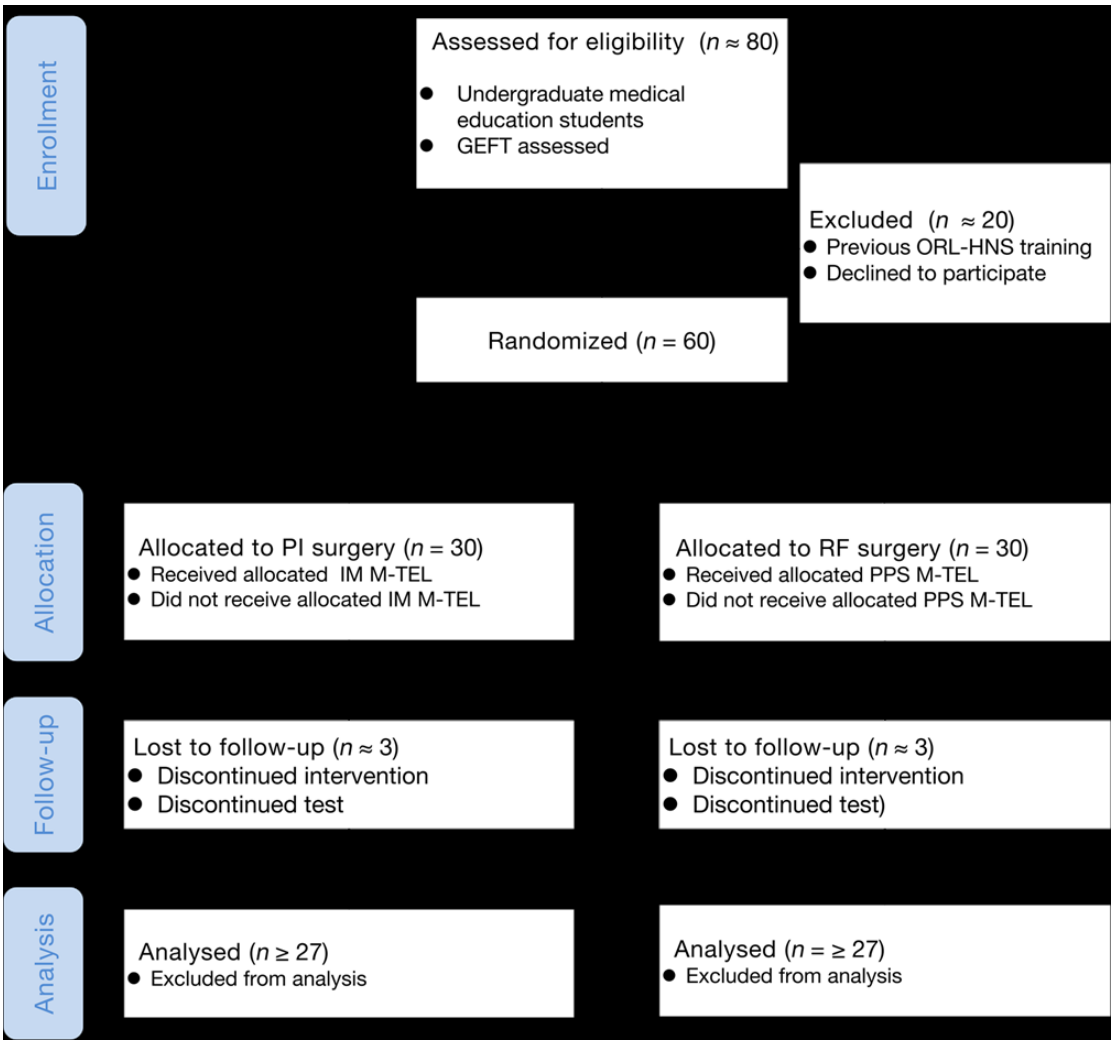


System-design study (n = 20; 10 academic physicians and 10 junior residents) in which an e-learning platform of emergent ORL-HNS disorders with translating into an App that is executable on the mobile device will be designed. (A) Instructions of the most common 10 emergent ORL-HNS disorders according to our previously unpublished data will be collected. (B) Two different e-learning modules (visual-auditory text-figure PPS or an IM) will be established. (C) The App software of two e-learning modules will be programmed; and (D) Tests including a multiple-choice test and a multimedia situational test assessment will be set. The participants will assist our developing, evaluating, and improving the e-learning instruction.

Validation study will be performed on 60 UME subjects without previous

ORL-HNS training by pretest-posttest and self-assessment of satisfaction using the randomly assigned M-TEL instructions. Prior to the validation study, all participants will be assessed by the GEFT test for determination of their cognitive style (field dependence or field independence). The flowchart diagram following the CONSORT 2010 guideline demonstrated our study design (**Figure 4**).[35]

Figure 4. CONSORT Flowchart of the Validation Study



After randomization, students are instructed on two modules of emergent ORL-HNS disorders, using either a PPS or an IM module. Subjects are evaluated on emergent ORL-HNS disorders using a text-based assessment (multiple-choice test) and a multimedia assessment (situational test) take place prior to and following instruction. Self-reported satisfaction with the study materials by the participants was obtained after examination. The interactions

of field dependence/independence, PPS/IM, and learners' satisfaction will be investigated in order to improve the preliminary version of M-TEL.

1.2. System-design study (*the first year*)

1.2.1. Instruction Collection

We will arrange a ADDIE team for instruction design: 1) Analysis, 2) Design, 3) Development, 4) Implementation, and 5) Evaluation.[36] We will organize an ADDIE team for instruction design. For 5- or 6-year UME student who has no previous ORL-HNS knowledge and skill, we aim to deliver the training to management of emergent ORL-HNS dis- orders frequently encountered by general medical residents for helping them to fill a gap in professional knowledge and skills.

Accordingly, we analyze our data bank. From August 21, 2004 to September 28, 2004, there were 300 consecutive patients visited the Department of Emergency, Linkou-Chang Gung Memorial Hospital, Taoyuan, Taiwan, and consulted the otolaryngologist (mean age 33.3±24.5 years [range, 0-89]; 91 (30%) children and 209 (70%) adults; 180 (60%) men and 120 women (40%). We selected the 10 most common emergent ORL-HNS disorders, in descending order based on consultation frequency, including foreign body (44.7%), epistaxis (9.3%), ear trauma (7.3%), acute otitis externa (7.0%), deep neck infection (4.7%), head and neck cancer and associated complications (4.0%), acute otitis media (3.7%), nasal trauma (2.7%), acute pharyngotonsillitis (2.7%), and sudden deafness (2.3%).

We further categorize these disorders according to anatomic location. The mostly encountered ORL-HNS disorders are listed in descending order of the prevalence: throat, ear, nose problems, and head & neck problems. Despite emergent head & neck disorders such as tumor bleeding, upper airway obstruction and deep neck infection are uncommon (9%), they are frequently severe and lethal. We will develop four illustration courses (ear, nose, throat, and head & neck) covered the top 10 emergent ORL-HNS disorders and 10 virtual patient cases. The content for each case was based on learning objectives already established for the ORL-HNS pre-clerkship curriculum. Twenty guest investigators including 10 academic physicians (5 ORL-HNS and 5 non-ORL-HNS) and 10 junior residents (first- or second-year resident; 5 ORL-HNS and 5 non-ORL-HNS) will assist our developing at this moment.

1.2.2. Module Establishment

An overview of four courses, 10 disorders, and 10 cases will be provided. The guest investigators will assist the evaluation of these two models.

1.2.2.1. PPS: Instructions and cases are constructed with integrated text, images/videos, and audio as classroom lectures and will be processing as a PPS format. In this module, the learners can only read the text, see the images, and hear the audio fixedly.

1.2.2.2. IM: Instructions and cases are constructed with the use of hyperlink with integrated text, images, and audio. An interactive instruction illustrates the short-page text accompany with audio and demonstrates the figures or videos with audio according the choice of learners without time limitation. A typical case describes a patient who presents with specific concerns. UME students are then presented with options for the next most appropriate steps and are guided through appropriate diagnostic tests and management of the patient with the assistance of text, pop-up windows, images, and audio.

1.2.3. Application Programming

We will need computer programmers to code our M-TEL platform to the Apple or Android app and to establish a web-based host computer that can provide an internet databank. Leaners using mobile devices can download the instructive materials from our host computer anytime and anywhere and upload their learning records to our data bank. This platform can also collect learner's study profiles in order to improve our M-TEL system and UME students' performance. At this moment, the guest investigators will try out system and feedback their experience to us.

1.2.4. Test Setup

Figure 7 demonstrates the Kirkpatrick's four levels of evaluation include: level 1, reactions; level 2, learning; level 3, transfer; and level 4, results.[37] We will set three multidimensional evaluations in our validation study: self-assessment of satisfaction (level 1), multiple-choice test (level 2), and multimedia situational test (level 3). The guest investigators will answer the multiple-choice test and multimedia situational test to improve the questions.

1.2.4.1. Multiple-choice test: Questions are obtained from previously developed examinations of emergent ORL-HNS disorders and undergraduate final examinations. Questions that are not adequately addressed in both self-study materials were removed. Then a nine-question multiple-choice test will be set. The test is then uploaded onto the M-TEL platform such that students can answer online and submit the test once completed.

1.2.4.2. Multimedia situational test: Virtual patient cases with specific emergent ORL-HNS disorders are newly developed. Situational questions that are not adequately addressed in both self-study materials were removed. Then a multiple-choice test with nine situational questions will be set. The test is then uploaded onto the M-TEL platform such that students can answer online and submit the test once completed.

1.3. Validation study (*the second year*)

1.3.1. Participants

For the relative small sample size of the present study, we analyzed all variables using non-parametric approaches. The sample size for this study was estimated using the primary outcome effects (mean posttest score) in two previously published studies.[12,30] Using a two-tailed Wilcoxon signed-rank test for calculating the sample size (normal parent distribution; effect size, 0.8; type I error, 0.05; power, 80%), we got a sample size of 27 in each group at the minimum power of 0.80. For considering a 10% drop-out rate to fulfill the criteria of intention-to-treat analysis, we needed at least 30 participants to attend this study.

1.3.1.1. The **inclusion criteria** of the present study are:

1) Age > 20 years old & < 70 years.
2) UME students (defined as the 5 or 6 years of medical school training).

1.3.1.2. The **exclusion criteria** are:

1) Previous ORL-HNS training;
2) Declining to participate.

1.3.2. Randomization procedure

Therefore, 60 participants are enrolled in the present study. Subjective assessments of GEFT are conducted after enrollment. The randomization procedure assures balanced design in subjective snoring severity and we stratified our subjects into two subgroups: 'field dependence' and 'field independence' subgroups. Computer-generated lists of random numbers are created using Random Number Generators of SPSS software for allocation of the participants and are stratified by center with a 1:1 allocation using a fixed block size of 6 (Rv. Uniform [0, 1]) in both subgroups. The allocation sequence is concealed from the blinded researcher (CGH) before instruction adhering to our computer-generated randomization protocol. Participants are randomly allocated to either IM or PPS group (**Figure 4**). Half of the patients are randomized to the IM group and the remaining patients are randomized to the PPS group. Subjects are evaluated on emergent ORL-HNS disorders using a multiple-choice test and a multimedia situational test take place prior to and following instruction. Self-reported satisfaction with the study materials by the participants was obtained one week after examination.

1.3.3. The GEFT

The GEFT test which is the most widely used version of pencil-and-paper tests in field dependence/ independence investigations.[38] The GEFT has a relatively high Spearman-Brown reliability coefficient of 0.82 for their instrument.[39] The GEFT is a 25-item test that requires participants to locate and trace simple geometric figures embedded within progressively more complex ones. This test has three sections. The first section is a practice section that contains seven simple embedded figures, and it is not scored. The time limit on this section is two minutes. The real task begins at the second set and into the third one, where the participants have to find the simple geometric figures inside two 9-itemed set within the time limit of five minutes for each. Based on the number of correct answers given by subjects, the scores on GEFT range from 0 (the most field dependent) to 18 (the most field independent). Those who intend to rely on external cues are less able to find the simple figures (field dependence), and those who hinge on internal cues are abler to find figures (field independence).[40] In this study, we will apply a Chinese version of the GEFT that GEFT scores ≤ 12 are considered as 'field dependence' and those with GEFT scores > 12 are regarded as 'field independence.[41]

1.3.4. Outcomes

1.3.4.1. The mean change in test scores before and after two instructive modules is the primary outcome measurement.

1.3.4.2. GEFT score and self-assessment of satisfaction are the secondary outcome measurements.

1.3.5. Statistical analysis:

Data are analyzed using the SPSS 22.0 software (SPSS Inc., an IBM company, Chicago, IL, USA) and GraphPad Prism 5 software (GraphPad Software, Inc., San Diego, CA, USA). The Kolmogorov-Smirnov test is used to assess the normal distribution of variables. Statistical significance will be determined using the Student *t* test for continuous variables and the Mann-Whitney *U* test or Wilcoxon rank test for skewed variables. Percentage (%) of change ([posttest value - pretest value]/[pretest value] × 100) in multiple-choice test as well as in multimedia situational test. Categorical variables are analyzed using the chi-square test or the Fisher's exact test when sample sizes were small. Two-sided *P* values < 0.05 are considered statistically significant.

Anticipated Works, Outcomes, and Effects

1. Anticipated progression of the study

1.1. We will conduct a 2-year study between August 1, 2015 and July 30, 2017. I

1.2. n the first year, we plan to establish an M-TEL platform in App format and invite 20 testing personnel (academic physicians in teacher's aspects and junior residents in beginners' aspects) to help developing and verification.

1.3. In the second year, we plan to recruit 60 subjects to undergo pretest-instruction-posttest experiments and correlate anthropological characteristics, cognitive style, M-TEL modules, test category, performances, and satisfactions.

2. Anticipated possible problems and resolutions

2.1. Although we investigate the performance of M-TEL by pretest and posttest without any invasive procedure, participants may decline to attend this study due to unfavorable allocation and instruction after randomization. Moreover, we aim to control the age, gender, and GEFT

ratios in the present study. Accordingly, we need more eligible candidates as anticipated. Fortunately, there are approximate 150 UME students in our university each year. However, we need a study assistant to obtain written ICFs and manage our experimental data.

2.2. Despite e-learning is useful in many medical education studies, its use is still limited due to deficient resource of mobile technology in UME students, unstable internet connection in Gueishan district of Taoyuan city, and difficulty in executing the M-TEL App software on different mobile devises. In this study, we have to develop a M-TEL platform to simultaneous teaching, interaction, and assessment on tablets and smart phones. We need a team work to overcome this technical problem. Our investigators including academic physicians, expert in web-based learning, and medical technician who have many experiences in preparing instructive materials, teaching UME students, and assessing performance of medical learning. Nevertheless, we need a full-time study assistant to help us to process the computer programming.

2.3. In view of the online safety issues involved in handling participants' privacy, the M-TEK will be enabling to protect personal information from hacking. Our need expert helps in maintaining internet security. Otherwise, anonymous using of M-TEL will provide the highest safety but cannot enhance the learners' long-term performance.

3. Anticipated contributions to academic research, national development, and other clinical applications

As mentioned above, the presence of a paucity of ORL-HNS learning in current UME curricula highlight the need to enhance the learning performance inside and outside the classrooms in order to enhance ORL-HNS knowledge and clinical skills for UME students and postgraduate general physicians. This study will set up the important M-TEL platform for self-directed learning. Moreover, identification of personally cognitive style to choose a proper instructional material on the M-TEL platform can reform the ORL-HNS learnings in UME. Finally, the UME students may use the M-TEL anytime and anywhere without significant increasing their cognitive loads and improve learning outcomes.

4. Anticipation of trainings for study researchers

The medical teachers can be familiar with the design of the M-TEL system and increase their ability of handling e-learning to effectively blend instructional

design and learning objective principles. The professors of web-based learning can extend researches in the UME level. The computer programmers can train their ability to establish an innovative learning tool to deliver UME education.

Modified Protocol (Figure 2): (Add AttrakDiff2 questionnaire; sample size estimation of the validation study)
Protocol No.: NSC-105-2511-S-182A-006-
IRB No.: 105-5290C

User Experience- the AttrackDiff2

Global satisfaction score is measured using a visual analogue scale from 0 to 10 as mentioned above. For more delicately evaluate the acceptance of technical innovations, we will assess “user experience” using the AttrakDiff2.[42]

AttrakDiff2 is developed as a tool by Hassenzahl’s research group to be able to quantify attractive, identifiable, stimulating, and pragmatic qualities. The tool uses 4x7 anchor scales, in total 28 questions. The anchors are presented in the form of semantic differentials and a 7-point Likert scale is employed for rating the intensity of the items. The poles of each item are opposite adjectives (eg, “confusing-clear”, “unusual-ordinary”, “good-bad”). Table 4 demonstrate the AttakDiff2. Each of the mean values of an item group creates a scale value for pragmatic quality (PQ), hedonic stimulation (HQ-S), hedonic identification (HQ-I), and attractiveness (ATT).

Attributes in the PQ group describe how easy the user finds it to work with the provided program or environment. Attributes belonging to HQ-S describe factors that encourage the personal growth of users and provide stimulation to give them the opportunity to enhance their knowledge and development. The attributes falling into the HQ-I category make it possible to identify the social impact that using a product can have for users, including the “messages” that are communicated by using the evaluated product. Last, the attributes of the ATT group depict the overall experience a product has to offer to its users, that is, its attractiveness.

Sample Size Estimation of the Validation Study

The sample size for this study has been estimated using the primary outcome effect (change in multiple-choice test scores) among six undergraduate medical students in the system-design study: increased 43±18 [IM module] & 35±21 [PPS module]) in the pilot study. Using a two-tailed Wilcoxon signed-rank test for calculating the sample size (normal parent distribution; effect size, 0.41; type I error, 0.05; power, 80%) using G*Power 3.1.9.2 software, we get a sample size of 26 in each group at the minimum

power of 0.80. For considering an approximate 10% drop-out rate to fulfill the criteria of intention-to-treat analysis, we need at least 30 participants to attend this study. Accordingly, we estimate that a total of 60 participants included in analysis is suitable for the validation study (Part II of the present study). For better characterization and comparison of primary outcome after team discussion, we decide to use “percentage change” in addition to “change” in the future study.

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