FULL STUDY PROTOCOL,

STATISTICAL ANALYSIS PLAN (SAP)

& INFORMED CONSENT FORMS (ICF)

The Gaming for Medical Education Research (G4MER) Program

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2. Introduction

2.1 Lay Summary & Aims

Medicine has traditionally been learned through the face-to-face lecture, clinical experience on hospital wards, and student self-direction to additional resources such as textbooks and clinical guidelines. Recently educators have sought to improve student learning by providing adjuncts to these methods. The rapid development of computerized technology has seen the emergence of online educational packages in medical programs throughout the world. 'PlayMed' is a serious computer game that has been developed to teach paediatrics to medical students. It allows students to learn and apply clinical algorithms for managing patients in a safe, simulated environment. Preliminary data gained from a pilot study suggests that PlayMed improved students' knowledge of asthma management. However, the efficacy of PlayMed as a learning tool has not been tested against alternative online educational tools, therefore we propose to conduct a randomized control trial of PlayMed using an online educational package as a control. Furthermore, we aim to assess the utility of PlayMed in different populations including nurses and doctors.

We have targeted two common and important paediatric clinical presentations (asthma and seizures) as the focus of our teaching and assessment in this study. It is likely that students will be exposed to both of these conditions during their clinical attachments; the acute management of both conditions is outlined in current NSW Health Paediatric Clinical Practice Guidelines (CPG); and both asthma and seizure disorders are listed in the Australian Curriculum Framework For Junior Doctors. The current UNSW Phase 3 Children's Health course includes one lecture on each clinical problem.

Under the "G4MER" Program, we plan to perform a series of randomised control trials to see if PlayMed is an effective teaching adjunct to our standard course(s), and if this game is more effective than other online packages for medical students, doctors and nurses. We hypothesise that participants exposed to the game (in addition to standard teaching) will demonstrate superior knowledge and clinical skills compared to those exposed to the alternative online packages, and to those who only receive standard teaching. Additionally, we hypothesise that increased time spent playing the game will improve performance in knowledge-based and clinical assessments.

2.2 Background Literature Review

The efficacy of both online learning and simulation-based teaching have been well established in Medical Education.[1, 2] Online learning is most effective when students are required to interact either with the package or with each other, and feedback is provided.[1] Simulation is effective as it allows learners to engage in repetitive practice, in a safe environment, with a degree of clinical variation and a range of levels of difficulty. Timely feedback is also vital to effective learning.[3]

Computer-based simulation games can be defined as instruction delivered via personal computer that immerses trainees in a decision-making exercise in an artificial environment in order to learn the consequences of their decisions.[4] Computer-based simulation games combine the most effective elements of both online learning and simulation - the online environment provides an easily accessible, interactive yet safe space for students; feedback is provided to the student, and clinical variation with a range of levels of difficulty can be provided.

Little empirical evidence on the effectiveness of educational video games on students' educational outcomes is available. A recent innovative study at UNSW by Dobrescu et al[5] compared the effectiveness of teaching introductory economics via a video game or traditional textbook learning. This study suggested that there was no difference in exam performance for either modality; however, the video game was considerably more enjoyable as a learning tool. To our knowledge there are no educational role-playing games available on the market which targets the education of medical or nursing students. Currently online learning packages for paediatric clinical practice guidelines are available through HETI Online (https://hetionline.cit.health.nsw.gov.au/). At present these are not part of mandatory training.

The development of an online game is an expensive and resource intensive process but may well be an effective adjunct to current teaching programs. We wish to test this product to see if further investment is worthwhile.

3. Study Protocol

3.1 Research Design Outline

The "G4MER" Program aims to perform a series of randomised control trials on different groups at Sydney Children's Hospital Randwick:

(1) **Study 1A** (Formerly titled "Serious Games in Medical Education – a Randomised Control Trial") involves Phase 3 medical students at UNSW having 8 weeks access to the game, an Online Package (OP) or NSW State Guidelines on Asthma and Seizure management (control). Students are then assessed using multiple choice questions (MCQ) and two observed structure clinical examination (OSCE) stations (detailed below).

(2) **Study 1B** is also a randomised control trial similar in design to Study 1A, however it will involve doctors and nurses employed at Sydney Children's Hospital. PlayMed will be compared against the HETI Learning Path Paediatric Clinical Practice Guidelines (Online Package for staff).

(3) **Study 2A** is identical to Study 1A except participants will have 5 days access to their educational tool. Participants will then undergo the same assessment using multiple choice questions (MCQ) and two observed structure clinical examination (OSCE) stations.

(4) **Study 2B** is identical to Study 1B except participants will have 5 days access to their educational tool. Participants will then undergo the same assessment using multiple choice questions (MCQ) and two observed structure clinical examination (OSCE) stations.

The proposed study designs are all investigator blinded randomised control trials. Participants may only be involved in Study 1 or Study 2, not both.

3.2 Participants

Studies 1A and 2A

Medical students in their second phase (years 3 or 4) and final phase (years five and six) of their medical degree (the BMed/MD program) at UNSW, currently completing their Children's Health course at Sydney Children's Hospital, will be eligible to participate in this study.

Studies 1B and 2B

Doctors and Nurses employed at Sydney Children's Hospital will be eligible to participate in this study.

Study investigators will not be eligible to participate.

Participants will require a personal computer and access to the internet to participate.

3.3 Recruitment

Studies 1A and 2A

All students enrolled in the UNSW Phase 3 Children's Health course will be informed of the study during their face-to-face orientation by the Course co-ordinators (the course co-ordinators are neither involved in the research nor in student assessment); a slide outlining

what will be said has been attached. Students will be told that a computer game, developed to teach medical students paediatrics, is being tested by randomised control trial, and that volunteer Children's Health students are invited to participate. Additionally, they will be informed that all participants will have the opportunity to go to the simulation laboratory and manage a sick child as a formative assessment with feedback provided.

Students will be informed at this time that their decision to participate, or not to participate, in the study, will not affect their relationship with the university or with the hospital in any way. Neither will the results of their study assessment contribute to their summative course assessment. Feedback with the answers to the MCQs will be available at completion of study, which should be before their end of 6th year summative assessment.

The participation information and consent sheet will be distributed which details including inclusion and exclusion criteria. Interested students will be invited to attend an information session scheduled in a break in their lecture timetable, this information session will allow study co-ordinators to answer questions from potential participants.

Studies 1B and 2B

All medical and nursing staff at Sydney Children's Hospital will be approached during Grand Rounds, lunchtime and evening teaching sessions, and via a concurrent staff email. Study advertisement posters will also be placed around the hospital. Recruitment will occur periodically throughout the calendar year (4 time points). Participants will be told that a computer game, developed to initially teach medical students paediatrics is being tested by randomised control trial, and that volunteer medical and nursing staff are also invited to participate. Given that the teaching tools are aimed at patient management, they are appropriate to administer to medical and nursing staff. Furthermore, the HETI Online Paediatric Clinical Practice Guidelines and NSW state guidelines are applicable to staff at

Sydney Children's Hospital. Additionally, they will be informed that all participants will have the opportunity to go to the simulation laboratory and manage a sick child as a formative assessment with feedback provided.

Participants will be informed at this time that their decision to participate, or not to participate, in the study, will not affect their relationship with the hospital in any way.

Feedback with the answers to the MCQs will be available at completion of study. Participants will be asked not to share the answers with other staff.

The participation information and consent sheet will be distributed which details including inclusion and exclusion criteria. Interested staff will be invited to attend an information session scheduled at Grand Rounds, this information session will allow study co-ordinators to answer questions from potential participants.

All participants will have to return a signed consent form to the student coordinators prior to random allocation to a study group.

3.4 Randomisation

Students and Staff who consent to participate will be randomly allocated (within their study) to one of three groups (at a ratio of 1:1:1): the game, the OP, and no intervention (ie standard teaching only with NSW State Guidelines on Asthma and Seizure management provided). Computer randomisation (https://www.sealedenvelope.com) and concealed envelopes will be used. We will use a separate unique block randomisation for each study (1A, 1B, 2A and 2B) with block sizes of 3, 6 and 9. A strata for job (Doctor / Nurse) will be incorporated for staff

in studies 2A and 2B. Participants will be allocated a unique identification number, and this will be recorded against their student or staff number and group allocation in an electronic database. This will be done by the student co-ordinators at the School of Women's and Children's Health to ensure the investigators remain blinded.

3.5 Administration

Studies 1A and 1B

Participants allocated to PlayMed and to the OP will be given the appropriate access for 8 weeks (instructions provided in the study envelope). Participants allocated to the control guidelines will receive a print-out of the guidelines. Participants will be encouraged to engage with their additional educational tool as often as they wish during their eight weeks. In the 8th last week participants will have their knowledge and clinical performance assessed as outlined below.

Studies 2A and 2B

Participants allocated to PlayMed, OP and control guidelines will be given 5 days to utilise their assigned teaching tool. Five days was selected as an appropriate time-frame in which participants would be able complete all cases of the game or online package, or read through the guidelines with minimal impact on their personal and academic schedules. Participants will receive an email with access to their intervention from an unblinded administrator. Participants will have their knowledge and clinical performance assessed as outlined below.

3.6 Assessment & Outcomes Measures

Studies 1A and 2A

Participants will be assessed for:

1. Primary outcomes

- Knowledge acquisition
    - Participant knowledge will be assessed using a 10-point single-best option multiple-choice questionnaire (MCQ); correct answers, with an explanation, will be provided to all participants at the end of the study via email.
- Clinical performance
    - Participant clinical skills will be assessed via an observed structured clinical examination (OSCE) administered in the simulation laboratory (immediately after the knowledge test); participants will be tested across two clinical scenarios. Strict marking criteria will be used to ensure standardisation, with a total possible maximum score of 30. Individual feedback will be provided by assessors immediately after each scenario.

2. Secondary outcomes

- Educational experience
    - Participants will be asked to complete a short survey using 5-point Likert scale (strongly agree, agree, neutral, disagree, strongly disagree). Students will be asked for comments (free text responses) regarding their engagement with, and perception of the educational value, of the learning tool.

The time commitment required of participants for assessment will be approximately 60 mins.

Studies 1B and 2B

Participants will be assessed for:

1. Primary outcomes

- Knowledge acquisition
    - Participant knowledge will be assessed using a 15-point single-best option MCQ; correct answers, with an explanation, will be provided to all participants at the end of the study via email.
- Clinical performance
    - Participant clinical skills will be assessed via an OSCE administered in the simulation laboratory (immediately after the knowledge test); participants will be tested across two clinical scenarios. Strict marking criteria will be used to ensure standardisation, with a total possible maximum score of 50. Individual feedback will be provided by assessors at the conclusion of the OSCE portion of the assessment.

2. Secondary outcomes

- Educational experience
    - Participants will be asked to complete a short survey using 5-point Likert scale (strongly agree, agree, neutral, disagree, strongly disagree). Students

will be asked for comments (free text responses) regarding their engagement with, and perception of the educational value, of the learning tool.

- Future impact on clinical practice
    - Participants will also complete a short post-assessment survey 3 months after their formative assessment date. The short survey contains 7 questions and should take 5 minutes to complete. This survey is powered by Qualtrics (https://www.qualtrics.com/au/).

3.7 Sample Size

Study 1A

GLIMMPSE (http://glimmpse.samplesizeshop.org/#/) was utilised for sample size calculation with equal group sizes (i.e ratio of groups 1:1:1). In our initial pilot study, the mean quiz scores were 7.0 (SD 1.4) and 6.0 (SD 1.4) for the PlayMed and control cohorts (standard teaching only) respectively.[6] If we assume that students in the OP cohort will achieve quiz scores of 50% the difference between PlayMed and controls (i.e. score of 6.5), then the following sample size is required:

- A total of 54 subjects (i.e. 18 in each group) to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.
- Assuming a total drop-out rate of 20%, we will recruit 22 subjects for each group, i.e. 18 PlayMed, 18 OP and 18 controls.

Study 2A

Given we have no preliminary data for doctors and nurses, the same sample size estimate will be used for this study. We will recruit 22 subjects for each group, i.e. 22 PlayMed, 22 OP and 22 controls.

Studies 1B and 2B

The same sample size estimates will be utilised for these studies. For each study we will recruit 22 subjects for each group, i.e. 22 PlayMed, 22 OP and 22 controls.

4. Statistical Analysis Plan (SAP)

All Studies

Descriptive and inferential statistics will be used. Normally distributed data will be presented by mean and standard deviation (SD) and non-normally distributed data will be presented by median and interquartile range (IQR). Binary and categorical data will be presented using counts and percentages. R v3.4.4 will be used for all statistical analyses.

4.1 Primary Outcomes

All Studies

The primary analyses will compare: (1) PlayMed vs OP; and (2) PlayMed vs control guidelines on their mean/median: (i) MCQ score, and (ii) OSCE scores. Comparisons will be made using an unpaired t-test or a Mann-Whitney test for parametric and non-parametric data, respectively. P-values <0.05 will be considered statistically significant.

Effect sizes for will be calculated using Cohen's d (*d*) with 95% confidence intervals (95%CI) using the 'effsize' package.[7] Effect sizes will be considered small if $0.2 \leq d < 0.5$, medium if $0.5 \leq d < 0.8$, and large if $d \geq 0.8$.

4.2. Secondary Outcomes

All Studies

Descriptive statistics will be used to explore Likert scale data and reported as percentage of participants who “strongly agree”, “agree”, “neutral”, “disagree”, or “strongly disagree”. Qualitative data will be explored thematically using a document analysis approach. Data will be manually transcribed into NVIVO ™ which will assist with data immersion. Labels will be created and assigned to text, which describe key meanings and ideas; with each successive pass codes will move from descriptive to interpretive as key themes are identified.

4.3 Missing Data

The primary analyses will be performed using a modified intention-to-treat (ITT) basis. For participants who are randomised and do not attend for assessment, a mean imputation of the assessment scores from their allocation group will used. A sensitivity, per-protocol analysis will also be performed, with no restrictions placed on the minimum time spent using the allocated intervention.

5. Informed Consent Forms (ICF)

Studies 1A and 2A

Written consent will be gained from the Medical students using the consent forms attached to the application.

Studies 1B and 2B

Written consent will be gained from the medical and nursing staff using the consent forms attached to the application.

5.1 Risks to participants

The benefits outweigh the risks to participants. Participants have access to an additional formative assessment; they all will also have access to an additional learning resource as all participants will be given access to the additional online learning tools (games and online package) at the completion of the study. All participants will receive feedback about the OSCE and the answers to the MCQs after study completion, which are further opportunities for learning.

There are few risks to participants. All participants would have experience of high stake OSCEs from previous examinations and personal development training and all will be very experienced in MCQ exams. We do not expect that either assessment for the purpose of this study will be overly stressful. All students will be made aware that the study assessments will not contribute to their course grades. The feedback provided after the OSCE will be

supportive and clearly explained as formative in nature. There will be no coercion to take part in either assessment task. All students will have access to student support services should they suffer significant stress or anxiety. All staff will have access to staff support services should they suffer significant stress or anxiety.

5.2 Privacy and Confidentiality

All study participants will be de-identified and given a unique ID number at the time of enrolment; this will be recorded by the School of Women's and Children's Health student co-ordinators and emailed to the participant. The key linking study participants to their unique ID number will only be accessed by the student co-ordinators and will be stored in the password protected UNSW folder on the secure hospital (South Eastern Sydney Local Health District) hard drive. This will be destroyed after the 7-year retention period. Participants will not be able to be identified from any results published.

6. References

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