

STUDY PROTOCOL

Design of SCoPE Health Education Module on Internet Addiction Prevention Among Undergraduate Students: Study Protocol for a Cluster Randomized Controlled Trial

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ABSTRACT

Introduction: Internet addiction is prevalent among undergraduate students. A meta-analysis including 80 primary studies reports from 31 nations found a prevalence rate of 6% globally. However, a specific study of 480 undergraduates found a much higher prevalence of 78.7%, highlighting the urgent need for prevention studies in this area. Therefore, this study protocol outlines the methodology and design of the trial, which aims to develop, implement, and evaluate the effects of the SCoPE module based on the Health Belief Model in Internet addiction prevention among undergraduate students. **Methods:** The study is a single-blind cluster randomised controlled trial at a public university, focusing on undergraduate students. Faculties are the unit of randomisation. Twelve faculties will be randomised into intervention group and wait-list control group. The primary outcome of this study is Internet addiction test scores, while the secondary outcomes are knowledge of Internet addiction and six Health Belief Model's constructs. The SCoPE health education module includes six animated videos and synchronous WhatsApp group discussions. Participants will adhere to a structured six-day schedule, devoting 10 minutes to each video session and 20 minutes to discussion sessions daily. Measurements occur at baseline (T0), immediately post-intervention (T1), and 3-month post-intervention (T2). **Discussion:** The present study would demonstrate the successful application of the Health Belief Model in designing the SCoPE health education module which is aimed to prevent Internet addiction among undergraduate students at public universities, serving as a blueprint for future modules to mitigate Internet addiction among undergraduate students in Malaysia. **Trial Registration:** Clinical Trial Registry-Thailand (CTRT) TCTR20230408003.

Malaysian Journal of Medicine and Health Sciences (2025) 21(2): 267-273. doi:10.47836/mjmhs.21.2.33

Keywords: Health education intervention, Health belief model, Internet addiction, Undergraduate students, Cluster randomised controlled trial

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INTRODUCTION

The World Health Organization recognizes the significant public health impact of Internet addiction, primarily due to the deep reliance of modern society on the Internet (1). Internet addiction is characterized by excessive or poorly controlled preoccupations, urges, or behaviors related to computer use and Internet access, resulting in impairment or distress (2). Young proposed diagnostic criteria for Internet addiction, requiring the presence of five or more of eight criteria over six

months (3). As early as 1996, Young was among the first researchers to propose diagnosing Internet addiction by adapting the criteria for pathological gambling in the Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV). Various terms are used to describe Internet addiction, but due to inconsistent definitions, this study adopts the term Internet addiction to encompass excessive use and addictive behaviors, including online gaming, gambling, cybersex, social networking, and messaging (4).

The prevalence of Internet addiction shows significant variations, with a global rate of 6.0% in 2014 (5), escalating to 20.0% in 2020 (6). Moreover, within specific demographic groups, the prevalence varies notably, such as 35.4% among undergraduate students

in Nepal (7) and 44.7% among Chinese medical students (8). A study on foundation students in East Malaysia found that 21.4% exhibited problematic Internet usage, while an equal percentage (21.4%) were classified as pathological Internet users (9).

Although not formally acknowledged as a mental disorder, excessive Internet usage exhibits similarities to substance use disorders, contributing to diverse health issues including obesity, pain, and vision and hearing impairments (10, 11). Internet addiction correlates with diminished health-related quality of life (HRQOL) in young individuals (12), and a heightened risk of cyberbullying and sleep disturbances among students (11).

There is limited research on Internet addiction prevention, especially in Malaysia, where previous studies have mainly focused on identifying risk factors, consequences, and treatment approaches such as cognitive behavioral therapy and pharmacotherapy (13, 14). Most preventive initiatives have primarily targeted adolescent populations (15, 16) due to their susceptibility to engaging in risky behaviors (17). However, university students are also vulnerable to Internet addiction due to academic demands, readily available Internet access, independence, and peer interactions, often resorting to the Internet as a coping mechanism for anxiety and stress (9).

Therefore, the objective of this study protocol is to detail the methodology and design of the trial aimed at developing, implementing, and evaluating the effects of a health education intervention (SCoPE module; Self-efficacy, Cues to take action, and Perception), which is grounded in the Health Belief Model, for Internet addiction prevention among undergraduate students. Utilizing the HBM as a framework, this health education module addresses the risk factors associated with significance risk factors of Internet addiction among undergraduate students, which predominantly include individual factors such as time spent online, internet accessibility, and the constructs outlined in the HBM (18-20). Moreover, the HBM serves as a widely utilized theory for elucidating various health-related behaviors.

The SCoPE module is a preventive intervention for Internet addiction prevention among undergraduate university students. The term “prevention” in this context includes primary prevention (preventing the onset of Internet addiction) and secondary and tertiary prevention (reducing the severity and preventing the worsening of existing Internet addiction). The primary outcome of this study is the Internet addiction test score, while secondary outcomes include knowledge of Internet addiction and constructs of the HBM, encompassing perceived susceptibility to Internet addiction, perceived severity of Internet addiction, perceived benefits of reducing Internet use, perceived barriers to reducing

Internet use, cues to take action to reduce Internet use, and self-efficacy for reducing Internet use.

METHODS

Trial Design

The research will utilize a single-blind cluster randomised controlled trial with two parallel groups. The intervention group will receive a health education animated video and participate in synchronous digital group discussion via WhatsApp, while the control group will be placed on a waiting list.

A cluster randomised controlled trial design will be chosen to prevent contamination between intervention and wait-list control groups by using faculties as the unit of randomisation. Randomising individual students within the same faculty would risk contamination due to interactions within the faculty and shared spaces such as residential colleges, libraries, and cafeterias.

Participants

The present study will be carried out among undergraduate students at the public university. Figure 1 displays the design and study flow. Sixteen faculties in the public university will be assessed for their eligibility. The screening and enrollment of the faculties will be carried out first. The eligible faculties will then be randomised to either intervention or control groups. Both groups will be evaluated before the intervention (baseline assessment (known as Time 0), immediately after the intervention (post measurement, known as Time 1), and 3-month follow-up after completing the programme (known as Time 2).

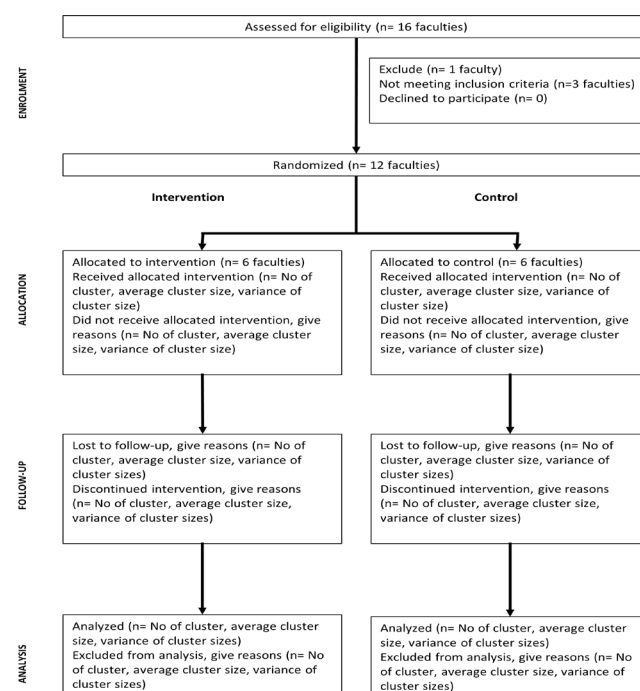


Figure 1: Study Flow Chart

The inclusion criteria for faculties are those offering bachelor courses in the public university. This focus ensures a consistent sample population of undergraduate students, minimizing variability that might arise from including students enrolled in diploma courses. The exclusion criteria for faculties are (i) faculties involved in the pilot study, and (ii) faculties located in the region of East Malaysia. Regarding participants, the inclusion criteria for undergraduate students selected from specific faculties for this study include: (i) aged 18 to 24 years, (ii) full-time students, (iii) Malaysian citizens, and (iv) being willing to complete pre- and post-assessments and engage in a 3-month follow-up. Conversely, this study will exclude undergraduate students who self-report any known psychiatric conditions, such as depressive disorder, anxiety disorder, or substance use disorder, and are currently under medical treatment. These conditions are excluded because they are significant risk factors for Internet addiction and could confound the study results by influencing Internet use behaviors independently of the intervention. This exclusion ensures that the effects of the SCoPE module can be more accurately assessed.

Intervention

The SCoPE (Self-efficacy, Cues to take action and Perception) health education module targets Internet addiction among undergraduate students. Developed based on the HBM, it aims to enhance knowledge and address perceived susceptibility and severity of addiction, perceived benefits and barriers to Internet use, cues for action, self-efficacy, and Internet addiction scores. Given its relevance to the heightened risk of Internet addiction among undergraduate students due to individual factors, the HBM will serve as the guiding framework for this module. These individual factors include time spent on online activities, ease of Internet accessibility, and components of the HBM (18-20). Widely utilized to explain various health-related behaviors, the HBM provides a comprehensive and applicable theoretical foundation for understanding and mitigating Internet addiction risk factors among undergraduate students.

The health intervention module will undergo content validation by a panel of experts, including public health specialists and a developmental psychologist. The animated video, which is based on the Health Belief Model (HBM), will be validated using a questionnaire adapted from a previous study. This questionnaire will assess the video's objective, structure, presentation, and relevance (21). Face validity will be established through pilot testing with undergraduate students from a different faculty. A pilot study with sixteen students will assess the suitability of the health education module using WHO's formative assessment (22). Both quantitative and qualitative feedback will guide adjustments, particularly emphasizing enhancements in graphics and animation.

The SCoPE health education module will utilize animated videos for six sections and synchronous digital group discussions for five perception-related sections. Tailored messages will aim to motivate individuals, pinpoint behavior changes, and simplify decision-making. Each video section will be allotted 10 minutes, with an additional 20 minutes allocated for group discussions. The control group on the wait-list will receive SCoPE upon completion of the study.

Section 1: Knowledge related to Internet Addiction

This section emphasizes improving participants' comprehension of Internet addiction and their capacity to recognize its symptoms in themselves and others. The approach employed is in line with the behavioral change technique (BCT), particularly *shaping knowledge*, which involves providing information about Internet addiction. This information includes the definition of Internet addiction and its signs and symptoms.

Section 2: The dark side of Internet addiction!

In Section 2, the focus is on highlighting the severity of Internet addiction using real-life cases. The approach integrates the *natural consequence* aspect of the BCT and shares health and personal impacts based on media reports. Additionally, a 20-minute WhatsApp group discussion covers short- and long-term consequences and impaired activities due to excessive Internet use.

Section 3: Are you at risk of Internet addiction?

This section offers an overview of the susceptibility of Internet addiction pertaining to university students and its mechanisms. The BCT *shaping knowledge* will provide information on factors leading to Internet addiction, such as its addictive nature, reasons for college student susceptibility, and the addiction mechanism. A 20-minute WhatsApp group discussion will explore participants' perceptions of susceptibility to Internet addiction.

Section 4: What is good? And what stops you?

In Section 4, participants will be introduced to the barriers associated with reducing excessive Internet usage, as well as the benefits of reducing such usage.

Section 5: Let's take action!

This section aims to enhance participants' ability to identify cues for responsible Internet use and engage in self-monitoring practices. It utilizes the BCT of *shaping knowledge* by instructing participants in preventing Internet addiction. Additionally, *feedback and monitoring* is employed, allowing participants to self-monitor their Internet usage duration. During the WhatsApp group discussion, participants receive a PDF with exercises, reminder cards, hotline information, and online schedules for tracking Internet usage. They provide feedback on their preferred methods, and

barriers to implementation are discussed.

Section 6: Are you confident?

This section features a simulation scenario through an animated video, illustrating obstacles participants may encounter when reducing Internet use. It aims to boost self-efficacy. The BCT of *self-belief* entails mentally rehearsing overcoming Internet use barriers. Participants engage in *If-Then*, another aspect of BCT, activities to identify cues for improving their actions.

The SCoPE health education module will consist of various components designed to address multiple aspects of Internet addiction as outlined by the Health Belief Model. These components include educational animated videos and interactive group discussions that focus on enhancing knowledge and modifying perceptions related to Internet addiction. The content of the SCoPE health education module will be detailed in Table I.

Table I: The content of the SCoPE health education module

Section	Construct of HBM	Content	Mode of delivery and duration
<u>Section 1</u> Knowledge related to Internet Addiction	-	●Definition of internet addiction ●The signs and symptoms of internet addiction ●Exploration and recognition of internet addiction in self and others	●Animated video with 329 seconds duration
<u>Section 2</u> The dark side of internet addiction!	Perceived severity	●Health effects on internet addiction ●Cyber crime ●Cyber bully ●Paper cutting on real case.	●Animated introduction video with 256 seconds duration ●Synchronous digital (WhatsApp) group discussion
<u>Section 3</u> Are you at risk of internet addiction	Perceived susceptibility	●The addictive nature of internet ●Why University/ college students being susceptible for internet addiction. ●The mechanism involves in internet addiction.	●Animated introduction video with 160 seconds duration ●Synchronous digital (WhatsApp) group discussion
<u>Section 4</u> What is good? And what stops you?	Perceived benefit Perceived barrier	●The benefit and the barriers to reduce excessive use of internet	●Animated introduction video with 283 seconds duration ●Synchronous digital (WhatsApp) group discussion
<u>Section 5</u> let's take the actions!	cues to take action	●Steps in preventing internet addiction. ●Reminder card to act as cues for them to take action.	●Animated introduction video with 281 seconds duration ●Synchronous digital (WhatsApp) group discussion
<u>Section 6</u> Are you confident?	Self-efficacy Cues to take action.	●Simulation scenario on obstacles that they will face when they are trying to reduce their internet use. ●"If Then" individual activity to identify cue to action for improving their action.	●Animated introduction video with 393 seconds duration ●Synchronous digital (WhatsApp) group discussion

Outcome

In this study, the primary outcome will be assessed through the Internet Addiction Test, measuring the extent of engagement in online activities. This scale consisted of 20 items with a five-point Likert scale. Higher scores indicated a higher degree of Internet Addiction. The validation of the questionnaire among Malaysian samples revealed a high value of Cronbach's alpha of 0.91 (23).

Secondary outcomes include knowledge of Internet addiction and the six HBM constructs. The six constructs of the HBM encompassing perceived susceptibility, severity, benefit, barriers, cues to action, and self-efficacy will be evaluated using a 5-point Likert scale questionnaire adapted from previous studies. While the health education module was developed in Bahasa Malaysia to enhance cultural relevance and engagement, the questionnaire will be administered in English. This decision was made because most university students are proficient in English, balancing academic research requirements with effective communication. This approach minimizes language barriers and maximizes

the study's impact. The questionnaire treats responses as continuous data, with higher scores indicating increased levels of beliefs towards Internet addiction. The secondary outcome assessment draws on established scales and methodologies from previous studies (24, 25). The content validity of the questionnaire will be ensured through expert evaluations, utilizing the Content Validity Index. Face validity will be confirmed through input from ten undergraduate students. Reliability will be assessed using Cronbach's alpha, with a value of 0.6 or more considered acceptable (26).

The study will gather participants' socio-demographic information, including gender (male/female), race (Malay, Chinese, Indian, others), family income in Ringgit Malaysia, and Grade Point Average (GPA). It will also collect data on Internet usage time (average hours per day, excluding study hours) on weekdays and weekends, as well as participants' Internet accessibility.

Sample Size

In this study, the sample size calculation will follow the formula for two population means (27). The formula is

given as below:

$$\frac{2\sigma^2 \left[z_{1-\frac{\alpha}{2}} + z_{1-\beta} \right]^2}{(\mu_1 - \mu_2)^2}$$

Where,

n = Sample size

$Z_{1-\alpha/2}$ = Z statistic for level of confidence of 95% = 1.96

$Z_{1-\beta}$ = Z statistic for 80% power = 0.842

σ = Pooled standard deviation

μ = Mean score (group 1 and 2)

The means and standard deviation for the intervention and control groups will be based on the estimation offered from previous RCT finding (28). These values are; $\mu_1 = 76.41$, $\mu_2 = 84.91$, $SD_1 = 13.85$, $SD_2 = 18.72$, $n_1 = 32$, and $n_2 = 32$. Therefore, the total sample (n) will be 57 per arm. Considering an intraclass correlation (ICC) of 0.05 to account for the potential design size effect, the cluster size (m) will be determined with a fixed number of clusters ($k = 6$), resulting in $m = [n_1(1-\rho)]/[k-n_1\rho] = [57(1-0.05)]/[6-57(0.05)] = 17$. The required minimum sample size for each cluster after adjusting for design effect, $m = 17$. Therefore, the total sample size needed per group will be 102 participants. After accounting for potential dropout (20%) (29), the adjusted sample size (N_{new}) will be calculated as $N_{new} = n/(1-d)$, resulting in $N_{new} = 102/(1-0.2) = 127$. Hence, 254 undergraduate students will be needed for the sample size in both groups, with 21 participants in each cluster.

Randomisation

A comprehensive approach will be taken to ensure effective sequence generation, allocation concealment, and blinding processes. Randomization will be conducted by two impartial research assistants not involved in the intervention. Faculties will be used as the unit of randomization to minimize contamination between groups. Using the computer-generated sequence software Random.org, randomization will be facilitated through a simple random sampling technique, distributing twelve faculties evenly into control and intervention arms at a 1:1 ratio.

Allocation concealment will be achieved using an "opaque, sealed envelope" method. A third-party research assistant will handle sequence generation and assign unique codes to the faculties, which will be sealed in two opaque envelopes labeled as the SCoPE group or wait-list control group. Another research assistant, unaware of the assignments, will recruit participants in each cluster. Participants' involvement will be determined by the clusters or faculties they represent, ensuring effective communication avoidance between the intervention and control groups.

The randomization codes will be revealed only after recruitment and baseline measurements, a

precautionary step designed to eliminate selection bias and ensure allocation concealment. The codes will be entrusted to a third party responsible for sequence generation. The blinding process will employ a single-blinding technique, where participants remain unaware of their intervention allocation, while researchers, as the intervention providers, possess this knowledge. These rigorous methodological steps will enhance the study's credibility, minimize bias, and strengthen the reliability of its findings.

Statistical Methods

The analysis will follow an intention-to-treat approach, including all randomised participants regardless of programme completion or outcome measurement. Data will be analysed using SPSS version 25.0 (IBM Corp, 2016), starting with data cleaning and checking for normal distribution. A significance level of 0.05 will be used.

The analysis begins with a demographic profile examination using descriptive statistics such as percentages and frequencies. Personal characteristics will be presented as the mean and standard deviation for continuous data and the median and interquartile range for non-normally distributed data. Student t-tests and chi-square/Fisher's exact tests will assess baseline differences between control and intervention groups for various factors.

Data will then be subjected to generalized linear mixed model (GLMM) analysis, chosen for its flexibility, ability to handle missing data, and nonlinear data modelling advantages over repeated measure ANOVA.

Assessment and Data Management

The intervention and data collection will be conducted online using Google Forms. Even outside the context of the COVID-19 pandemic, lectures are often given in hybrid or online formats, leading to situations where not all students are physically present on campus. This approach will ensure accessibility and convenience for all participants.

Ethics statement

Ethical approval will be obtained from the Ethics Committee for Research Involving Human Subjects University Putra Malaysia. Before participating in this survey, respondents will provide consent. Respondents' identities are kept anonymous, and data collected in this study is kept confidential. Participation in the study is completely voluntary, and participants can opt-out at any time. In addition, Clinical Trial Registry registration had been approved by the Clinical Trial Registry-Thailand (CTRT) in October 2022 (TCTR20230408003).

DISCUSSION

This trial aims to develop, implement and evaluate a

theory-based health education intervention for Internet addiction prevention in undergraduate university students. The hypothesis is that SCoPE will reduce Internet Addiction Test (IAT) scores in the intervention group, as compared to the control group. Existing research indicates that Internet addiction can lead to negative physical health outcomes including conditions like obesity, back and neck pain, and vision and hearing problems (10). Additionally, it is linked to social issues such as poor quality of life, lack of time management, lackluster academic performance, interpersonal conflicts, and cyberbullying (11). Internet addiction also correlates with mental health problems like depression, anxiety, stress, and emotional instability (30).

Despite the vulnerability of young adults, particularly university students, there is a lack of research on primary prevention strategies for Internet addiction among this group. Therefore, this health education module aims to enhance knowledge, perception of susceptibility, benefits of reducing Internet use, cues to action, and self-efficacy of undergraduate students; and at the same time, reduce perceived severity and barriers, thus reducing participants' risk of developing Internet addiction. Additionally, this module can serve as a valuable resource for organisers and policymakers seeking to combat Internet addiction in Malaysia. The module is designed as an Internet-based and mobile-based module for easy access and appeal to the target audience, offering flexibility in terms of location and timing for engagement.

The health education module's effectiveness will be enhanced by tailoring its content to the study's participants, allowing real-time choices that address specific content based on preference or need. Moreover, facilitators will be highly engaged throughout the study, offering feedback on completed sessions and consultation to boost adherence.

The study has notable strengths. It employs a randomised controlled trial, recognised as the gold standard for intervention studies. Additionally, the health education intervention is rooted in a behavioural theory of the health belief model, thus enhancing its effectiveness.

ACKNOWLEDGEMENT

The authors express their gratitude to the Director General of Health Malaysia for granting approval to publish this article, acknowledging the critical support provided by the Faculty of Medicine and Health Sciences at the University Putra Malaysia. This study received institutional grant with the grant number 6302011-14001, highlighting the commitment of the university in advancing research endeavours. Special appreciation is extended to the deans of all faculties for their invaluable assistance in facilitating data collection, underscoring the collaborative nature of this academic pursuit. The authors also extend their thanks to the dedicated participants who contributed to the study, thus emphasising the collective efforts and collaboration

all of which greatly enriched the research process.

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