Research

A Cluster Randomized Trial Study Protocol on Effectiveness of Health Education Module (HEAMOD) on Colorectal Cancer Screening Uptake among Workers in Kuantan District, Pahang State, Malaysia

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Abstract

Background

Colorectal Cancer (CRC), the third most common cancer in Malaysia, is a preventable disease if screened early. Health Education Module (HEAMOD) developed in accordance with the Preventive Health Model (PHM) framework is particularly useful in increasing screening uptake among health-insured workers and can improve productivity. The main objective of this study is to assess the effect of PHM-based health education module on CRC screening uptake using Faecal Immunochemical Test (FIT) among Social Security Organisation (SOCSO) health-insured workers in Kuantan.

Method/Design

A parallel, two arms, single-blind, cluster randomized trial utilizing stratified block randomization will be conducted, involving 12 workplace clusters of 32 workers in each. The intervention group receives HEAMOD comprising of group education, a practical session on FIT and WhatsApp group follow-up, while the control group receives CRC brochure. A validated questionnaire will be used to assess participant's background characteristics, risk factors, signs and symptoms, knowledge on CRC, attitude on CRC and acceptability of FIT. Validated weighing scale and stadiometer will be used for body mass index measurements. FIT will be used as the CRC screening tool. Descriptive and inferential statistics will be applied for data analysis using IBM Statistical Package for Social Sciences version 22. Longitudinal correlated data on knowledge, perception and acceptability score at baseline, immediate post intervention and 3 months post-intervention will be analyzed using generalized linear mixed model (GLMM). FIT uptake and its trend at immediate post intervention and 3 months post-intervention will be analyzed using GLMM and repeated measure Analysis of Variance (ANOVA) trend analysis, respectively.

Outcome

It is expected that CRC screening uptake rate is more in the intervention group as compared to the control group, indicating the effectiveness of the HEAMOD. Positive individuals for FIT will be referred to a specialist for further evaluation, while, negative individuals will be given reassurance.

Conclusion

It is hoped that the HEAMOD and CRC screening could potentially be included in SOCSO Health Screening Programme for workers' health benefit in the long-run.

Keywords: CRC Screening Uptake; Preventive Health Model; HEAMOD; FIT; Knowledge

Background

Worldwide, 8.2 million deaths occur due to cancer alone, which is 13% of the estimated total deaths [1]. Alarmingly, colorectal cancer is the third most common cancer in 2012. Locally, colorectal cancer is the most common cancer in men and third most common cancer in women in Peninsular Malaysia [2]. There is a magnitude of risk factors contributing to the development of the disease, namely a combination of modifiable and non-modifiable risk factors. With the increasing number of people affected by non-communicable disease (NCD) such as metabolic syndrome (MetS), the risk of

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acquiring CRC increases by three-fold if 2 or more features are present [3].

Most Asian countries have experienced an increase in the incidence of colorectal cancer by two or four-fold during the last few decades [4]. Due to advancement in technology and expertise, more and more high-tech surgical and medical equipment are developed for curative treatment. Unfortunately, certain less-developed countries with low awareness on the disease itself make preventive practice a less popular option than curative practice despite the low proportion of uptake of colorectal screening in Malaysia [5]. Therefore, there is a need for an effective screening program to detect and treat early. An easy to administer, cheap and efficient tool for CRC screening such as the FIT is one of the most recognized screening tools in the asymptomatic population.

Health awareness is a very important aspect of the decision-making process in preventive and curative care of cancers, especially colorectal cancer. According to the World Health Organization in 2009, it goes in tandem with health literacy, which may be defined as the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain well [6]. Thus, it can be regarded as one of the ways to tackle issues related to low uptake of colorectal cancer screening. Giving awareness through structured programs would make adherence to screening better and encourage non-compliant individuals to reconsider taking the screening. Ultimately, the aim is to prevent CRC and lead a healthy lifestyle.

In reaching out to the public, workplace organizations play a pivotal role in having a health policy for their workers. Workplace health awareness modules have been shown to increase knowledge on the importance of CRC screening, which in turn would lead to better perception towards the disease and its screening options [7]. Social Security Organization (SOCSO) in Malaysia is one of the major organization covering for compensation from invalidity due to chronic diseases for workers. Under SOCSO, Health Screening Programme (HSP) has already been established. However, for cancers, only breast and cervical cancers are offered for screening.

Theory-based health interventions are interventions that are based on human behaviour towards a particular issue. Interventions that increase cancer screening uptake, especially CRC, are highly effective when it is driven by theoretical models, especially among workers [8]. The Preventive Health Model (PHM) integrates Health Belief Model (HBM), Social Cognitive Theory (SCT) and Theory of Reasoned Action (TRA) into one framework to increase intention as well as increase screening behaviour [9]. Before the behavioural change, the acceptability of the screening tool is also important. Diffusion of Innovation Theory (DIT) covers for the domains of acceptability by looking at attributes of the screening tool which is beneficial, easy to use, compatible, observable, and trialable [10].

What are the issues surrounding CRC and its screening in Malaysia?

The majority of those diagnosed already have an advanced disease,

where the cost of curative management is high with increasing stage of the disease [11]. There is still a lack of nationwide colorectal cancer screening among SOCSO health-insured workers in Malaysian population eventhough the number of employed population in Malaysia is increasing over the years. To make matters worse, awareness on colorectal cancer screening among the working population is severely lacking, eventhough invalidity due to this cancer leads to loss of productivity years. This leads to poor acceptance and subsequently uptake of screening, including FIT which has shown to decrease mortality in randomized controlled trials [12].

Eventhough various standalone methods to increase uptakes such as client reminders, invitation, video-based decision aids or physician-directed approach has been employed, but a complex health awareness intervention module proves superior [13-15]. A strategy to increase CRC screening through complex interventions is by using the PHM to increase CRC screening behaviour and Diffusion of Innovation Theory to increase the rate of FIT adoption. Any new tool to screen for CRC would be considered as an innovation to them. Using DIT and behavioural change model such as the PHM has been proven effective in increasing rate of adoption of fecal-based screening for CRC as it tackles the barriers towards using the tool as a new screening tool [16].

PHM encompasses not just individual factors such as socio demographic background and psychological factors, but also external factors such as organizational program factors. It is aimed at breaking the barrier towards cancer screening and focuses on facilitating intention towards screening. This enables increased rate of diffusion of knowledge being given in a larger community such as workers in an organization.

Thus, a study will be conducted to measure the effect of health education module on colorectal screening uptake among SOCSO health-insured personnel in Kuantan, Pahang, Malaysia.

What does this study potentially bring?

This study will be able to contribute to the body of knowledge on colorectal cancer screening

uptake and ways to increase the uptake rate since Malaysian population have a very low uptake to screening [5]. Implementing an easy, cost effective CRC screening module using FIT among workers after receiving health education module would increase adoption of cancer screening and subsequently prevent the disease at an early, treatable stage.

In addition, the study would highlight the importance of inclusion of colorectal cancer screening in SOCSO Health Screening Program (HSP) through early detection in reducing the financial burden of payout *via* invalidity scheme, where there was 7.6% increase of those receiving the invalidity pension as of October 2014 compared to the previous year. This will promote a more sustainable and efficient workforce through early detection, prompt treatment and shorter time taken to return to work.

The study will potentially give impact to the society, economy

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and nation. The society, a largely working population due to the increasing cost of living, will be able to increase awareness of early detection and prompt treatment of CRC. This will improve the survival rate of CRC, thus improving the quality of life. Through detection at a pre-clinical phase, there will be a reduction in total healthcare cost of managing cancer patients. Using FIT as a screening tool for CRC detection will be able to decrease health expenditure, as screening colonoscopy requires expertise, surgery is expensive and maintaining colostomy is also expensive. The health education module will also promote a healthy lifestyle nation, which in turn, will potentially reduce the CRC incidence.

Research questions

1. Is health education module based on PHM effective in increasing colorectal cancer screening uptake among working population such as SOCSO-insured workers?

2. Does theory-based health education module improve the knowledge on CRC, attitude of CRC and acceptability of screening using FIT?

Objectives

General Objective

To develop a health education module (HEAMOD) using PHM, implement and measure its effectiveness on CRC screening uptake among SOCSO health-insured workers in in Kuantan, Pahang, Malaysia

Specific Objectives

i.   To develop HEAMOD, consisting of health talk, group discussion, practical session on FIT and WhatsApp group follow-up for the intervention group

ii.   To describe the socio demographic profile in terms of age, gender, ethnicity, race, education, occupation, income, body mass index, smoking status, as well as symptoms, and other risk factors for colorectal cancer among SOCSO health-insured workers in the intervention and control group

iii. To assess knowledge, attitude and acceptability score of colorectal cancer screening at baseline in intervention and control group

iv.   To implement HEAMOD in the intervention group and CRC brochure in the control group

v.   To compare baseline knowledge score, attitude score and acceptability score of colorectal cancer screening with immediate post-intervention and 3 months post-intervention scores in intervention and control group

vi.   To compare FIT uptake at immediate post-intervention and 3 months post-intervention between intervention and control group

vii. To measure the effectiveness of HEAMOD in terms of sufficiency of CRC screening uptake rate after 3 months post intervention

viii. To measure the trend of FIT uptake between intervention and control

Method/Design

Design and main hypothesis

A parallel, single-blind, cluster randomized trial will be used. Cluster in this study is defined as the organizations in Kuantan that are listed under SOCSO, that have the SOCSO health-insured personnel. There will be two arms; intervention arm and control arm. Both arms follow a parallel design until the end of the study. The cluster and participants will be blinded for the study. The intervention arm will receive the HEAMOD, while the control arm will receive a colorectal cancer brochure as usual care. The main hypothesis is that those who receive the HEAMOD intervention will have more CRC screening uptake using FIT as compared to the controls. The primary outcome will be the proportion of CRC screening uptake in both study arms. Secondary outcomes are the post-intervention knowledge score, post intervention attitude score, post intervention acceptability score and FIT outcome. An overview of the study design and process is provided in figure 1.

Participants, setting and procedure

SOCSO-insured workers in Kuantan, Pahang, Malaysia will be included as a study population. The inclusion criteria are organizations with SOCSO-insured workers in Kuantan and Malaysian citizens aged 18 years and above. The exclusion criterion, on the other hand, is those who have ever been diagnosed with CRC before the date of data collection starts. The sampling frame is the list of small, medium and large sized organizations with SOCSO health-insured workers in Kuantan, Pahang, while the sampling units are the small, medium and large sized organizations with SOCSO insured workers in Kuantan, Pahang.

After ethical approval from University Putra Malaysia (UPM) Ethics Committee for Human Research, the letter will be brought to SOCSO main office as to get the full list of organizations currently having SOCSO health-insured workers. Then, it will be shortlisted to 12 companies that grant permission to do the trial, where 6 intervention groups and 6 control groups will be randomized, respectively.

Study duration

The study will be conducted from January 2017 to May 2017.

Ethical issues

Ethical approval for this study has been obtained from UPM Ethics Committee for Human Research (FPSK(EXP16)P148). During data collection, a written and informed consent will be obtained from each of the respondents. All the data of the participants will be kept strictly confidential. Those who are in control group are considered on the waiting list, where they will receive the intervention module after the study trial has ended.

Randomization and allocation concealment

A stratified block randomization method will be used. Organizations will be stratified by size of the organization, which
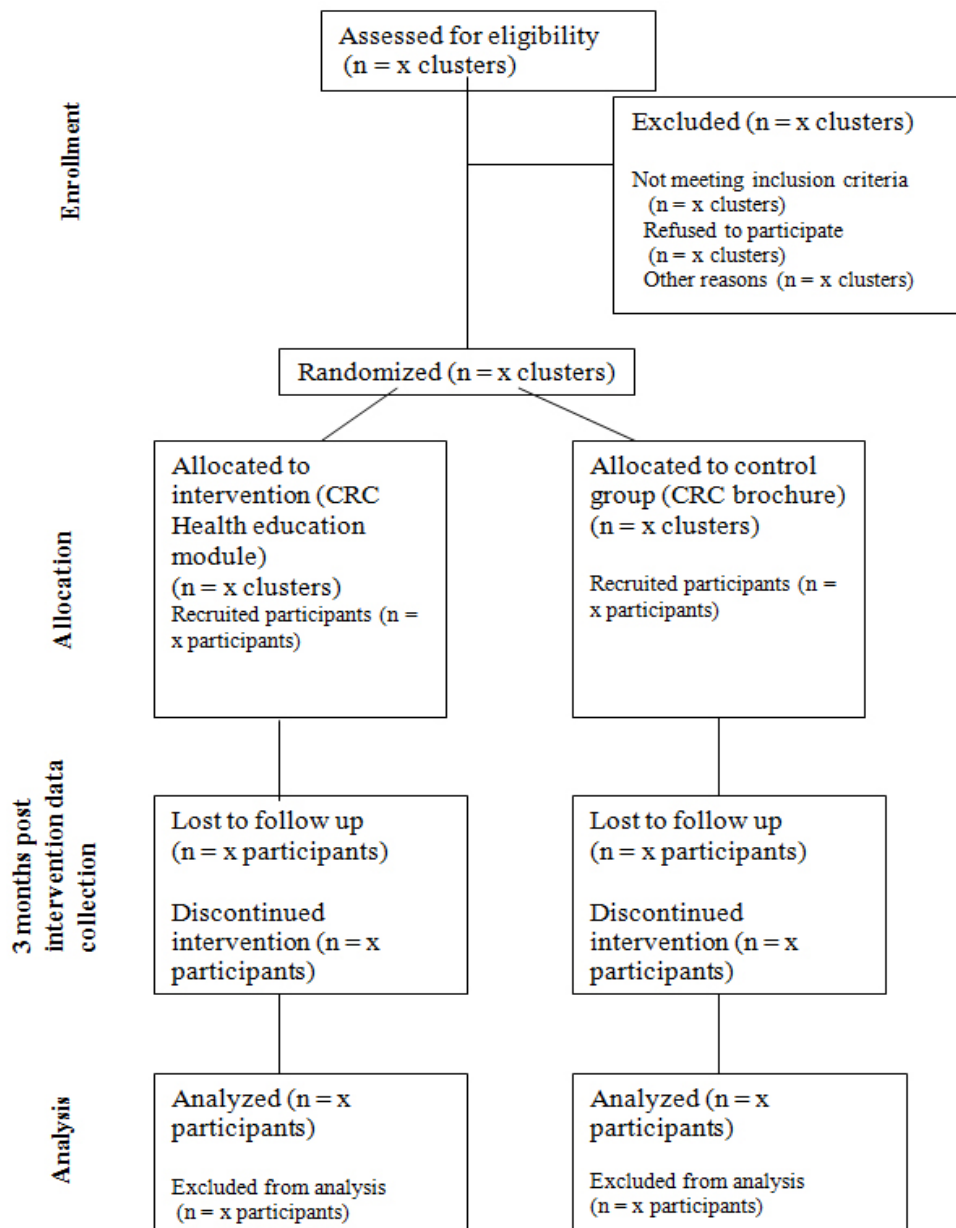
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Figure 1: Flow chart diagram of the study using CONSORT statement

are small, medium and large organizations. This is done to control possible influence from covariates towards the outcome such as organizational health policy. Blocks of 4 will be utilized with 6 possible combinations, which are ABBA, ABAB, BABA, BAAB, BBAA, and AABB. For each stratum, blocks of 4 are stacked in an envelope containing either intervention(labelled as 'A') or control (labelled as "B"). Then, random allocation will be done by enumerator sequentially to achieve a balance between both arms using the table of random numbers, selecting only numbers 1 to 6 according to the possible combinations. The randomization concealment process using sealed, the opaque envelope will be done by enumerator to reduce bias.

Sample size calculation

The sample size estimation is based on Sample Size Determination in Health Studies by Lemeshow and Lwanga [16]. Two population proportions formula is used due to it being analytical in nature and comparing 2 groups for hypothesis testing. The effect of the intervention is proposed to increase the uptake by equal or more than 30% compared to the control group. Given the power of 80% to detect a true difference with 95% confidence, the sample size required after adjusting for the clustered design effect is 380 participants, with 190 participants in each arm coming from 6 intervention groups and 6 control groups.

Intervention

The intervention arm will receive the preventive intervention module (HEAMOD), developed using the PHM and theory of diffusion of innovation, which consist of:

Group education: There will be 2 methods of group education delivery. First, the health talk will be given by the researcher in the form of a Power Point presentation. The PowerPoint will be constructed together with a consultant colorectal surgeon for content verification. This will focus on giving awareness of the relative advantage of the FIT. The first PowerPoint presentation will focus on the background on CRC and importance of early screening. The second PowerPoint presentation will focus on treatment options should they be positive of the FIT. The second mode of delivery would be a group discussion. Participants will be divided into several small groups. With the help of enumerators, barriers and obstacles in taking up screening will be explored. Further reinforcement of CRC screening knowledge will be given. The participant will be assisted if any issue or question arises. This will cover the key constructs in the PHM which are perceived susceptibility, perceived barriers, perceived benefits, social influence and self-efficacy, in addition to knowledge component.

Practical session on FIT: There will be a demonstration on FIT by enumerators consisting of healthcare workers to show how to do the test in a correct manner. Participants will be asked to take 2 faecal samples for 2 consecutive days. This will test for four DIT constructs on the acceptability of FIT which are relative advantage, complexity, compatibility and trial ability.

WhatsApp group follow-up: Every follow-up of the trial will be communicated using WhatsApp. A reminder mechanism will be implemented to remind participants to do the screening and return it to the research team as soon as possible. In addition, those who have done the test will report to the WhatsApp group, facilitating those who have not done it to do the test too. This covers the domain of observability in the DIT.

Control

The control group will receive a CRC brochure developed by the research team. The brochure covers the background on CRC and screening using FIT.

Data collection method

Baseline, immediate post-intervention (3 weeks after baseline) and 3 months post-intervention data collection will be done using a validated questionnaire. FIT will be offered at immediate post intervention and 3 months post intervention.

Participants are required to collect 2 stool samples in 2 consecutive natural bowel openings using the freely-distributed FIT kits.

Table 1: Summary of HEAMOD and its application in relation to the theoretical model

Stage	HEAMOD components	Theoretical model constructs	What and how it is delivered
Knowledge and Persuasion	Group education (health talk+group discussion)	Knowledge	General knowledge on CRC screening is assessed at baseline and disseminated during the intervention
		Perceived susceptibility	Perceived risk of getting CRC will be assessed and tackled during the discussion
		Perceived benefit	Benefits of early screening will be highlighted
		Perceived barrier	The barriers of screening using FIT, such as embarrassment, will be assessed and dealt with
		Self-efficacy	Each individual or company will be assessed on how motivated they are to undergo screening for the first time and continue to do so later
		Social influence	Family support will be assessed and discussed, focusing on those who deter and those who encourages screening
	Practical session on FIT	Relative advantage	Information on how advantage it is to screen using FIT compared to no screening at all
		Compatibility	Information on how compatible the FIT kit is towards one's belief
		Complexity	Information on the ease of using FIT
		Trialability	Information on how FIT can be used to determine the likelihood of getting CRC
Decision, Implementation and Confirmation	WhatsApp group follow up	Observability	Information on how others, after completing the test, are able to lead a healthier life through early screening and prompt treatment. The decision implies if they agree or not for the screening. Implementation implies completion of screening, while confirmation implies the intention and future plan on doing regular CRC screening

Participants will be reminded not to force the bowel openings by any means such as using laxatives or digital manipulation, as this may give the potential risk of injury or spoilt specimens. Participants will also be reminded that if they need any assistance, they can contact the research team at any time.

Project monitoring and quality control

Internal Validity: Threats to internal validity are taken into consideration in this research. First, the threat by history is when there are unplanned events between measurements. For example, the control group participant knows some of the intervention group participants and asks him for the content of the intervention module and knowledge on CRC. A way to tackle this is by doing the cluster randomization to decrease the chance of contamination.

Maturation means the participant's change during the course of the trial. For example, a participant who answered the questionnaire at baseline was depressed at that time, forcing him not to think properly and answer incorrectly. During post-intervention data collection, he/she is happy and answered confidently, resulting in an erroneous increase in score from the test, thus masking the true effect of the intervention. A way to counter this is by getting consent in the beginning and not forcing the potential personnel to participate in the study at baseline if he or she is unwell. This principle applies to both intervention and control group as it will improve comparability of data results.

Pre-testing denotes exposure to a baseline data collection may affect participants' performance on the post-intervention regardless of the independent variables. The participants are sensitized on risk factors of CRC in the beginning and will answer much better in the post-intervention due to him remembering the same question and same page of the question given to him at baseline and not due to the knowledge gained from the intervention. A way to counter this is by rearranging the questions for post-test data.

Those who scored the worst (outlier) at baseline will perform better at post-intervention data collection. This is because of it is likely there is regression to the mean rather than the effect of the intervention. The solution is by analyzing any outliers and control for it.

There may be selection bias in choosing which organization will the in the intervention arm or the control arm. Randomization will solve this, as well as look at the similarity of baseline characteristics of both arms to check if the randomization works. Balancing the arms requires the use of permuted block randomization method rather than simple randomization method.

Some participants might drop out of the study due to some reasons. A way to control this is by recruiting enough participants to achieve the effective sample size. Different instrumentation leads to less valid results. Thus, a standard and same tool must be used for pre and post test.

In terms of questionnaire validity, the content and face validity of the questionnaire will be assured by reviews by experts in Public Health Medicine and consultant colorectal surgeon. Forward and backwards translation will be performed by independent individuals to ensure face validity. The participants will evaluate:

1. whether the questionnaire measures what it intends to measure in terms of the comprehensiveness and clarity of the questionnaire;

2. whether the questionnaire is simple, easily understood, any inappropriate, redundant or missing items, and how likely the questionnaire was to address the research objective;

3. the relevancy, flow and arrangement of the questionnaire; and

4. the wording of the questionnaire.

Exploratory and confirmatory factor analysis will be done to ensure construct validity since the adopted questionnaire is intended to be used to a different population demography.

Other tools such as the FIT kit and SECA body weight and stadiometer have been validated by the respective companies. All of the completed FIT kits will be tested qualitatively in a controlled laboratory environment in our university.

External validity: Proper randomization will be done by trained enumerator to equalize known and unknown confounders in intervention and control group. To ensure randomization is done properly, baseline characteristics of the participants after randomization should not differ much in both groups.

The inadequate description leads to other studies unable to replicate the methods of the current study. For example, due to limited time, the methodology cannot be used to acquire longitudinal outcome such as CRC detection through Histopathological Examination (HPE) after screening if another researcher wishes to do it for a shorter duration. The solution to this is by delineating a comprehensive methodology covering potential benefits and limitation of the study which can be improved in future researches.

Hawthorne effect occurs when the dependent variable is influenced more when participantis observed. For example during data collection of post-test, participants erroneously answer incorrectly because feeling nervous due to the researcher is in the room watching him. A way to tackle this is by letting participants answer in a structured room with no or minimal interruption but still can avoid the issue of copying.

Demand characteristics are when participants detect the purpose of the study and behave accordingly. For example, a control group participant knows he is not receiving an intervention like in the intervention arm. Thus he makes an effort to read more through other sources such as journals and not just the brochure. The solution is blinding. Here only single blinding of the participants will be utilized, as a researcher could not be blinded due to the researcher himself delivering the HEAMOD.

Operationalization also means ecological validity, where the dependent variable must be realistic and have relevance in the real world. Thus, a thorough literature review must be done to choose the correct DV and classifying it correctly. Here, colorectal cancer screening uptake rate, or effectiveness, follows standard definition [17].

Reliability: The questionnaire will be pre-tested to ensure reliability

before the final version is used. It will also be translated to Malay as it is the national language. Reliability will be assured by pretesting to a different population of a different location. Cronbach's alpha will be analyzed for the questionnaire for reliability in terms of internal consistency. Cronbach's alpha of equal or more than 0.7 for the Likert scale questions indicate good internal consistency. For dichotomous questions, cohen's kappa will be analyzed and taken into consideration. In addition, enumerators will be trained to reduce the inter-interviewer variability of data collection.

Data analysis

Data will be analyzed using Statistical Package for Social Science (SPSS) version 22.0. Descriptive statistic using continuous data will be analyzed either by mean or median, depending on normality, while categorical data analyzed using frequency (n) and percentage (%). Cluster level analysis will be utilized to cater for the clustering effect. Multivariate analysis on FIT uptake, knowledge score, perception score and acceptability score will be done using generalized linear mixed model. This will cater for both fixed effect and random effects as well as the clustering effect. On the other hand, trend analysis using repeated measure ANOVA will be done to measure FIT uptake from immediate post intervention to 3 months follow-up after the post-intervention data collection. Intention-to-treat (ITT) and per-protocol (PP) analysis will be utilized as a component of sensitivity analysis.

Expected outcomes

It is expected that giving multiple ways of cancer education such as the HEAMOD is able to increase CRC FIT screening uptake more than just giving a single module such as the CRC brochure. For those who agree and complete the screening, positive results from FIT will be referred to IIUM specialist clinic for evaluation for colonoscopy by a colorectal surgeon or gastroenterologist. Those who are negative for FIT will be given reassurance.

The HEAMOD is hoped to be part of CRC screening programme for SOCSO-insured workers, which aims to increase awareness on early screening and detection for prompt treatment. This will help in increasing the productivity of work by improving the quality of life of affected workers, which in turn reduces the burden of increasing healthcare cost.

Acknowledgements

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