STUDY PROTOCOL

1.**Project Title:**
A Pilot Randomized Controlled Trial: Effectiveness of Brief Smoking Cessation Counselling in Pre-Anaesthesia Assessment Clinic (PAAC)

Investigators Principal Investigator
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2.Study sites
The study will be conducted in the Pre-Anaesthesia Assessment Clinic in Pok Oi Hospital (POH).

3.Aims of the study
The aim of the study is to

a. evaluation the feasibility and preliminary effectiveness of a perioperative nurse-delivered AWARD brief intervention in the Pre-anaesthetic assessment clinic, compared with usual care, on smoking abstinence on the day of surgery among adult smokers scheduled for elective surgery.

b. establish the effectiveness of the nurse-delivered intervention in increasing pre-operative smoking cessation rates and ensure the methodology is sound, the intervention is deliverable, and the necessary statistical parameters are obtained to justify and design a large-scale trial.

c. To determine effectiveness of nurse-delivered brief counselling using the AWARD model plus active referral on increasing pre-operative smoking cessation rates in PAC POH.

The hypothesis

Is the brief counselling for the preoperative smoking patient can increase smoking cessation rate, defined as abstinence for at least 7 days prior to surgery.

4.Outcome measure(s)

Primary outcomes

A short-term Smoking Abstinence: The proportion of patients who report complete smoking abstinence (7-day point prevalence abstinence) biochemically validated by exhaled CO levels < 6 ppm on the day of surgery and negative result of Cotinine rapid salvia test and at 4 weeks post-counseling (1-Month Sustained Cessation Rate by self-report phone survey).

Secondary Outcomes

The average number of cigarettes smoked per day at surgery day and 4 weeks post -surgery among those who have not achieved complete abstinence. Self-reported daily cigarette consumption (percentage reduction compared to baseline).

The rate of major postoperative complications (e.g., pneumonia, wound infection, cardiovascular events) within 30 days post-surgery, as data will be extracted from electronic medical records (CDARS).

Patient Satisfaction Mean score on a 5-point Likert scale assessing satisfaction with smoking cessation support received, administered via questionnaire at 1 month's post-surgery. Assesses satisfaction with the counselling service, leaflet content, and overall care.

5.Literature Review

Smoking and Increased Surgical Risks

Smoking is a significant modifiable risk factor that negatively impacts surgical outcomes. It increases the likelihood of postoperative complications, including impaired wound healing, infections, cardiovascular events, and prolonged hospital stays. The physiological effects of smoking—such as reduced oxygen delivery, impaired immune response, and

vasoconstriction—directly contribute to these risks (Warner et al., 2020). Evidence shows that smokers have a 30–50% higher risk of surgical site infections and other complications compared to non-smokers (CDC, 2022).

Benefits of Preoperative Smoking Cessation

Preoperative smoking cessation has been shown to significantly improve surgical outcomes. According to a Cochrane Review, stopping smoking for 4–8 weeks prior to surgery reduces the risk of complications by up to 41%, particularly for wound healing and pulmonary complications (Moore et al., 2020). Furthermore, even brief interventions, such as quitting 48 hours before surgery, can improve oxygenation and reduce carbon monoxide levels in the blood, leading to better postoperative outcomes (Siddiqui et al., 2021).

The Role of Nurses in Smoking Cessation

Nurses are uniquely positioned to provide smoking cessation counseling due to their frequent interactions with patients. A meta-analysis by Rice et al. (2020) demonstrated that nurse-led smoking cessation interventions—including brief advice, education, and referrals to cessation programs—improve quit rates and reduce smoking-related complications. The American Nurses Association (ANA) emphasizes that nurses play a critical role in preoperative education and should incorporate smoking cessation advice as part of their routine care (ANA, 2021).

Active referral

The importance of active referral is not only supported by recent clinical data but is also a core tenet of international tobacco control policy. The WHO Framework Convention on Tobacco Control (FCTC), specifically Article 14 (Demand reduction measures concerning tobacco dependence and cessation), provides the global blueprint for effective cessation services. The importance of active referral is not only supported by recent clinical data but is also a core tenet of international tobacco control policy. The WHO Framework Convention on Tobacco Control (FCTC), specifically Article 14 (Demand reduction measures concerning tobacco dependence and cessation), provides the global blueprint for effective cessation services.

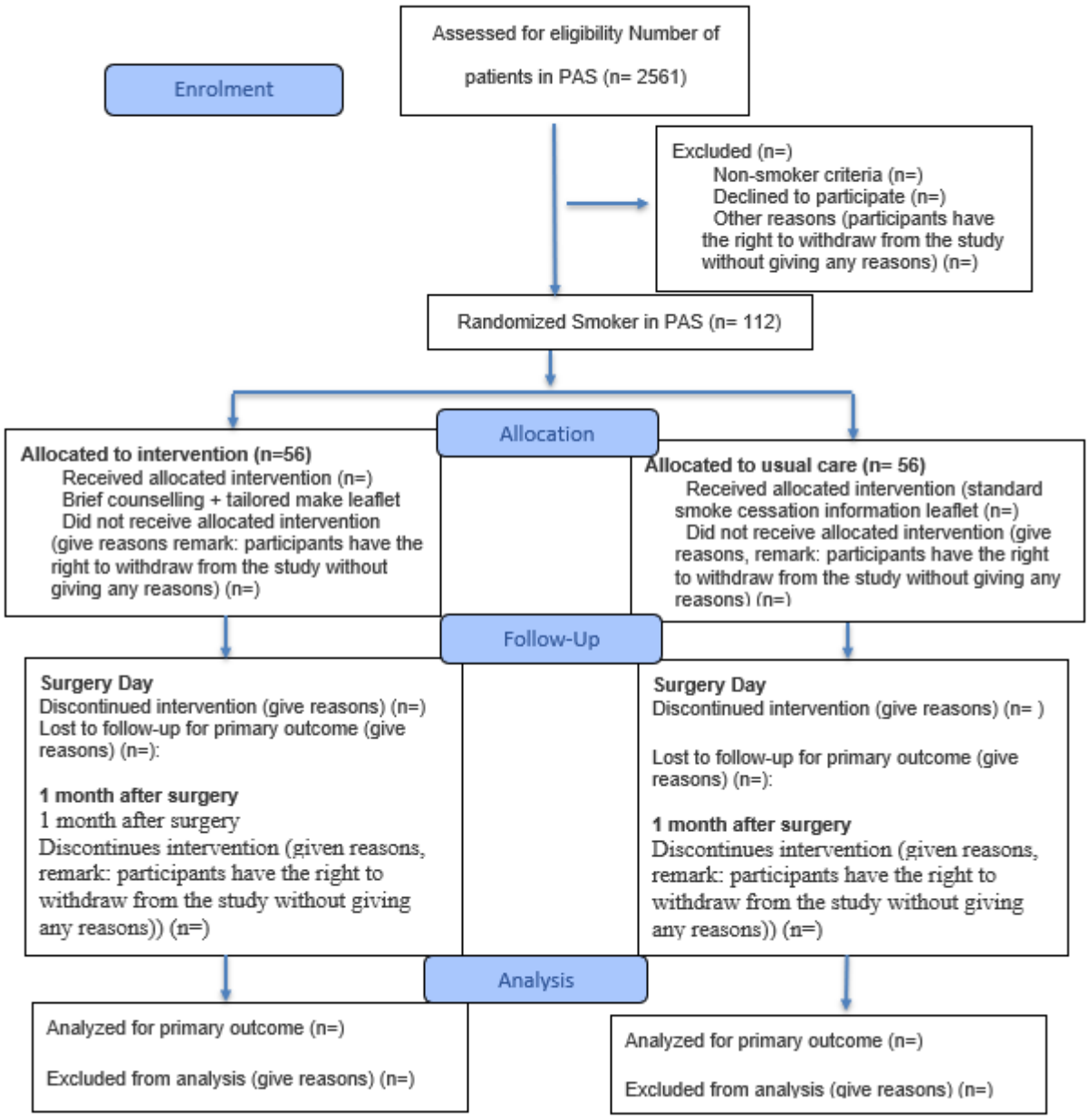
6.Methodology

Study Design

This is a two-arm parallel, assessor-blinded, pilot randomized controlled trial (RCT) design. The study will be conducted at the Nurse-led Pre-operative Anaesthetic Assessment Clinics (PAC) of Pok Oi Hospital (POH). The intervention included using of a brief counselling intervention (AWARD model) with active referral plus tailored made booklet to increase the smoke cessation rate on the day of surgery / referral rate in PAC. The design adheres to the CONSORT (Consolidated Standards of Reporting Trals) statement. (Figure 1).

Perioperative nurses will be recruited and trained as counselors to provide brief cessation advice to the intervention group smoker in the PAC.

Figure 1: CONSORT Flow Diagram



<u>Recruitment and Randomization</u>

Screening of eligible smoking patients will be done at the pre-operative assessment clinic. All smokers will be given a general smoke advice leaflet provided from smoke cessation

service and will provide active referral if they are willing for. They will be invited to join the study and to sign the written consent; to complete a self-administrated baseline questionnaire (e.g sex, age, number of tobaccos use daily, proposed operation….) and exhaling carbon monoxide >=4ppm. Then they will be randomly allocated to the intervention or control group with 1:1 ratio.
For the randomization method, it will be done by using serially numbered, opaque and sealed envelopes (SNOSEs). The cards inside envelopes will involve either intervention or control. A project assistant will create a random sequence for group allocation using a random number generator, accompany by serially numbered identifiers for the envelopes. After obtaining informed consent, the assistant opens a sequential number envelope to maintain allocation concealment. Blinding of the participants and counsellors are impossible due to the nature of the intervention. Assessors and statistical analysts will be masked until the predefined analyses are completed. Data analysts will be blinded to group allocation. Due to the nature of the intervention, the nurses delivering the counselling cannot be blinded. Randomization: Computer-generated random sequence will be used, and allocation concealment will be maintained using sealed, opaque envelopes.

Inclusion Criteria

Adult elective surgical patients who are current smokers, aged 18 years or above, scheduled for elective surgery, attending the Pre-Anaesthetic Assessment Clinic (PAAC), who have smoked with the past 7 days with exhaled carbon monoxide >=4ppm and can understand and speak Cantonese.

Exclusion Criteria

Includes patients undergoing emergency surgery; patients having surgery day less than 7 days; willing to be referred the smoke cessation service on admission of PAC after receiving the standard leaflet of smoking cessation from hospital smoking cessation service; patient with cognitive impairment or inability to comply with counselling and follow-up or patients already receiving active treatment from other smoking cessation services or patients diagnosed with a mental disease or on regular psychotropic drugs.

Intervention and Control Group

The intervention group participants will be assigned to attend Nurse Pre-Anaesthetic Assessment Clinic (NPAC). They will receive smoke intervention (AWARD model counselling) and active referral plus tailored made booklet regarding hazard related to increasing anaesthteic and surgery risk by the perioperative nurse.

The control group participants will be provided with usual care (visiting surgeons and anaesthetists without visiting NPAC). Unstandardized smoke advice maybe provided during the Pre-anaesthetic assessment service visit.

The sample size

For this pilot RCT on the effectiveness of brief smoke counseling in the perioperative anesthetic clinic is determined pragmatically to obtain stable estimates of key parameters (e.g., variance, recruitment rate) necessary for designing a definitive main trial (Whitehead, Julious, Cooper and Campbell, 2016). This approach is crucial for minimizing the overall sample size of the subsequent full-scale trial (Ying, Freedland, Powell, Stuart, Ehrhardt & Mayo-Wilson, 2025). We have chosen a sample size of 50 participants per group, which is generally considered sufficient to provide robust estimates of the parameters required for the main trial's power calculation. For our two-arm design (intervention vs. control), this requires a total of 100 completed participants. To account for a projected 20% attrition rate, the total recruitment target is adjusted to 125 participants ($100 / 0.80 \approx 125$) over 4-6 months.

Counsellor nurses Training and Supervision

Prior to start participant enrollment, all designated research perioperative nurse will participate in a mandatory training. This training is structured around three core modules essential for the study's success within the Perioperative Anaesthetic Clinic (PAC) setting. The modules will focus on: (1) comprehensive instruction on the AWARD model counselling protocol, including its application in brief sessions, the specific support mechanisms utilized, and effective recruitment techniques tailored for the PAAC environment, such as the use of exhaled carbon monoxide (CO) test; (2) in-depth education regarding the physiological risks associated with smoking and the clinical advantages of cessation (the content involved in the counselling will be guide by the tailor made perioperative booklet). The booklet was designed by the perioperative team nurses and the content is verified by consultant anaesthetist. and (3) mastery of general smoking cessation methodologies and AWARDS model interviewing skills.

To ensure fidelity to the intervention, the counsellor nurses' competency will be assessed using a pre- and post-training evaluation tool designed to measure their knowledge, attitudes, and practical application skills concerning smoking cessation.

Ongoing supervision and support will be provided by experienced research personnel throughout the recruitment phase. Furthermore, to assess recruitment feasibility, detailed records will be kept on all eligible smokers approached in the PAC. Interventionists will meticulously document the total number of individuals approached and record the reasons

provided by those who decline participation if available. A weekly group case review will be implemented to discuss active cases and address any emerging challenges.

CO exhaled reading result will be done and will be used for part of counselling. Active referral and booklet will be provided and facilitate the counselling. The participants will be informed that they may withdraw from the study at any time without giving a reason. Participants who self-report abstinence for more than 7 days will be invited for biochemical validation and Cotinine test). Reinforcement about the benefit of quit smoking will also be done on the surgery day.

7. Procedure

Baseline Assessment

In order to determine the baseline differences in current usual care and prepare the necessary resources for implementing the intervention. The participants will be assessed at baseline in PAC. The baseline questionnaire will measure the participants' smoking behavior (eg, daily cigarette takes, age to start smoking, and quit attempts), readiness to quit, reasons for quitting, social support, perceived self-efficacy of quitting (importance, difficulties and confidence), depression and anxiety, alcohol consumption, and sociodemographic characteristics.

Data Collection

An independent operating theatre nurse (blinded to group allocation) will collect the primary outcome data on the day of surgery, including self-reported at least 7-day PPA and CO test results and negative result of the salivary cotinine test.

On the day of surgery, self-reported 7-day smoking abstinence status and repeat exhaled CO testing and Cotinine salivary test by OT nurses. Recording of any intraoperative or early postoperative complications from medical records.

In order to collect secondary outcome data and perform statistical analysis, follow-up via telephone to collect self-reported smoking status, smoking reduction, and patient satisfaction survey data. The post-operative complication rate will also be assessed in electronic medical record data at discharge or within 30 days post-operatively. Blinded researchers will assess post-operative complications using the Clavien-Dindo classification system.

Postoperative phone follow up 1 month after surgery for sustained smoking status (Self-reported 7-day point-prevalence tobacco abstinence); patients satisfaction and self-efficacy questionnaires regarding smoking cessation support. The data collected will follow to data protection standards.

	Intervention Group	Control Group
Leaflet from hospital smoke cessation service	✓	✓
Brief counselling (AWARD) + active refer + tailor made booklet for preoperative smoking cessation	✓	

8. Data Analysis

Descriptive Statistics for Staff Survey before intervention start

Calculate frequencies and percentages for categorical variables such as awareness levels, frequency of smoking cessation counselling, and referral practices.

Summarize Likert scale responses (e.g., confidence or attitude scores) using means and standard deviations or medians and interquartile ranges, depending on distribution. Comparative Analysis is used as Chi-square tests or Fisher's exact tests (if expected counts are low) to compare categorical responses between different professional groups (surgeons vs anaesthetists vs nurses).For Likert scale or ordinal data, use ANOVA or Kruskal-Wallis tests to detect differences among groups.

Statistical Methods

The primary outcome will be analyzed using Chi-square tests .7-day smoking abstinence on the day of surgery to compare proportions between intervention and control groups under an intention-to-treat (ITT) approach. The Chi-square test is appropriate for categorical binary outcomes like abstinence rates. Parametric or non-parametric tests allow for continuous data handling based on distribution.

Secondary continuous outcomes, such as reduction in cigarettes per day, will be analyzed with independent t-tests or Mann-Whitney U tests if non-normal. Postoperative complications will be analyzed using logistic regression to adjust for confounders such as age, sex, and comorbidities. Longitudinal abstinence data at 1-month will be assessed using survival analysis techniques like Kaplan-Meier curves and log-rank tests. Logistic regression adjusts for potential confounders and allows estimation of the intervention effect on postoperative complications. Survival analysis effectively models time-to-relapse over the follow-up period.

9. Software:

Data will be analyzed using Statistical Package for the Social Sciences (SPSS) version 28 or R software version 4.2.
Significance Thresholds:
A two-sided p-value of < 0.05 will be considered statistically significant. Confidence intervals at 95% will be reported for effect size estimates (e.g., relative risk, odds ratios).

10.Human Subjects Protection

The eligible patients will be invited to participant voluntarily. The purpose and the procedures of the study will be explained and informed consent will be obtained from each patient. The study will get approval from Hospital Authority Central Institutional Review Board. And will be registered with ClinicalTrails.gov.

11.Ethical Considerations

This study has been submitted to Hospital Authority Central Institutional Review Board (Central IRB) for approval. The data will be recorded in a manner that does not allow the participants to be identified (i.e. using a non-recognizable code). To protect privacy, all research data will be handled in line with HA / Hospital's policy in handling / storage / destruction of medical records. Written consent will be obtained from participants and emphasized in the consent form that participation will be on a voluntary basis and can withdraw any time without penalty.

Potential Risks
Some patients may experience increased anxiety or stress when discussing their smoking habits and the associated risks. This could impact their overall preoperative well-being. Provide a supportive and empathetic environment during counseling sessions. Patients may be resistant to receiving smoking cessation advice, leading to feelings of frustration or defensiveness. Foster open communication, allowing patients to express their concerns and feelings regarding smoking cessation.

12.Data Handling, Data Access and Record Keeping

The hard copies of the study data will be locked in cabinet during the course of the study while the soft copy would be encrypted/ password-protected. The study data will also be permanently deleted and unrecoverable after the 5 years storage period. IRB has the right to access for data monitoring propose. Only authorized research staff will have access to the data. Principal Investigator will be responsible for safekeeping of the personal and study data during and after the study. All patients data will be removed from the data set before analysis to ensure confidentiality. Exhaled carbon monoxide samples will be collected by research staff with a piCO Smokerlyzer (Bedfont Scientific Ltd), and saliva cotinine samples will be measured using a test strip (to be confirm the brand of company).

13.Financial Funding and Budget

No research funding is applied and the Cotinine test kit is supported by department. The CO analyzer and their consumable is supported by hospital smoke cessation service.

14.Indemnity and Insurance

Nil concern about of this study is raised.

15. Publications:

The results of this study may be presented at scientific meetings and published in academic or medical journals. Any reports or publications will only use aggregated data. No individual participant will be identified in any publication, and no personal identifiers (such as name or Hong Kong Identity Card number) will be disclosed.

If data obtained from the Hospital Authority databases are used, the research team will acknowledge the Hospital Authority in all publications and will strictly follow its requirements on data use and confidentiality.

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