Research title: Evaluation of Community Pharmacist-led Fall Prevention Program (CAREFREE) among Community-Dwelling Older Adults – A randomised Controlled Trial

Principal investigator (MMC No. if applicable):

Assoc. Prof. Dr. Balamurugan Tangiisuran, School of Pharmaceutical Sciences, Universiti Sains Malaysia

Co-researchers: (MMC No. if applicable):

1) Dr Fatimatuzzahra Binti Abd. Aziz, School of Pharmaceutical Sciences, Universiti Sains Malaysia
2) Nur Izzati Binti Shahabuddin, School of Pharmaceutical Sciences, Universiti Sains Malaysia

Introduction

There is a progressively increasing number of older persons worldwide including in Malaysia. In 2020, estimated of 2.3 million Malaysian population are aged 65 years and above which account for seven percent of total Malaysian population. This is according to the expected increment of aging population over the years and Malaysia is expected to become an Aged Nation by 2034 when this sub-population constitutes 14 percent of the population (Department of Statistics Malaysia, 2020).

This increase in aging population put substantial amount of burden on the Malaysian healthcare system. There is an increasing trends healthcare utilisation among older people with both inpatient and outpatient care are significantly associated with increasing age (NoorAni et al., 2018). Management of older adults are known to be very complex and require special attention. Apart from changes in pharmacokinetic and pharmacodynamics due to aging, they usually have multiple comorbidities and presence of few geriatric giants which consists of incontinence, immobility, instability, intellectual impairment and iatrogenic. Fall or inadvertently coming to rest on the ground or other level with or without loss of consciousness, is a part of geriatric giant, instability.

Falls in older adults is a growing health concern in Malaysia along with other countries across the globe. National Health and Morbidity Survey Elderly Health 2018 reported that one in seven Malaysian seniors had at least a fall in the past 12 months. Among those who fall, 63% had sustained injury after a fall. Malaysian Elders Longitudinal Research (MELoR) data also reported a high prevalence of fall among the elderly which was 18.9% which akin to other Asian countries. Among the three main Malaysian ethnics, being Indian is an independent predictor of falls (RR=1.45, 95% CI 1.08-1.85) (Alex et al., 2018).

Apart from the high prevalence of falls, fear of falling accounted for 20% to 39% among community-dwelling older adults (Whipple et al., 2018). Fear of falling is defined as "persistent feeling related to the risk of falling during one or more activities of daily living". Consequence of fall is may be destructive physically, socially and psychologically, leading to massive reduction in their quality of life. Fallers significantly had lower score of health-related quality of life and life satisfaction at baseline and after six-years compared to non-fallers among Swedish elderly populations (Stenhagen et al., 2014). Even fear of falling has been associated with reductions in physical and social activity as well as reduced quality of life (Whipple et al., 2018). In order to preserve this golden subpopulation from chronic depression and disability due to falls effective fall prevention strategies in the community is the key.

Independent factors associated for falls identified among urban-dwellers elderly are urinary incontinence, arthritis, cognitive impairment, depression and hearing impairment (Alex et al., 2020). Meanwhile, recent evidence from English Longitudinal Study of Ageing showed that polypharmacy is a risk factor hospital admission due to a fall (Zaninotto et al., 2020). This identification of risk factors aids to strategies fall prevention in this vulnerable population.

In Malaysia, comprehensive geriatric care is usually managed by multidisciplinary geriatric team lead by geriatricians in selected few major hospitals. At this stage, older patients have too many medical conditions to manage and optimise. Yet, based on the current trends of morbidity burdens in older adults, comprehensive geriatric care should be targeted towards long-term care at primary care level (NoorAni et al., 2018). Effective primary prevention targeting older people will improve health consequently greater potential to reduce disease burden arises from disability (Prince et al., 2015). However, it could be very time-consuming to conduct a screening and carrying out fall prevention programme routinely in a busy primary care setting such as health clinic. This is supported by findings from Jaafar et al. that found 54% and 67% of family physicians in Malaysia routinely did not ask elderly patients regarding falls and fear of falling respectively (Jaafar et al., 2020). These justified the need for involvement of other healthcare professionals in management of geriatric medical problems effectively such as utilising the expertise of community pharmacists in preventing fall.

A Cochrane Review recently revealed that multifactorial interventions that were commonly applied after assessment of risk profile including exercise, medication review, environment and psychological may reduce the rate of falls compared with usual care or attention control (Hopewell et al., 2018). However, majority of the conducted studies had been focusing on reducing frequency of falls or rate of falls as outcome measures. Many trials had failed in successfully showed effectiveness of their fall prevention interventions be it in community setting or hospital setting. In order to reduce future falls, tackling older adults' knowledge and health-related quality of life are crucial. This is because majority of the risk factors for falls among the older persons are preventable.

However, implementing multifactorial interventions as highlighted above in local settings may poses some difficulties due to being too complex and lack of evidence-based

effectiveness data in local settings. Moreover, in resource-limited settings where there is lack of resources and financial return, community pharmacies in low- and middle-income countries faced tremendous challenges to implement these models for reducing falls. Lack of resources Moreover, lack of training pharmacist staff and inability to sustain the program over time due to lack of support from the public and government to maintain the service may affect the implementation of these services. The development and implementation of a feasible, practical and evidence-based community pharmacists-led fall prevention program (CAREFREE) tailored to the local setting should be able to cater for the challenges. The CAREFREE program aimed to provide a fall prevention program to older adults at a primary care level by community pharmacists.

In view of these arguments, this study is the first randomised controlled trial to evaluate the effect of fall prevention interventions in the community pharmacy setting of a middle-income developing country. The study will examine the optimal provision of fall prevention interventions in this setting. The hypothesis of the study is that the fall prevention intervention implemented by community pharmacists will improve the knowledge, health-related quality of life, perspective on fall prevention engagement as well as reduce the risk of falls among the community-dwelling older adults.

Problem statement

Older adults are vulnerable group of populations but valuable to the society since they have many experiences and expertise. Falls, being a part of geriatric syndrome, should be prevented among the older adults to prevent the detrimental effect of falling such as fractures, immobility and mortality.

In achieving these goals, the problem of falling in older adults have been focus of tremendous research in many countries over the recent years including in Malaysia. Many interventional studies across the globe have exceptional efforts on preventing falls for majority of inpatients, outpatients, post-discharge, institutionalized older adults. Increasingly, focus has been shifted towards preventing falls among older adults living in the community. Many studies investigate the effect of education, exercises and home modifications for falls preventions in community-dwelling older adults. These efforts were multidisciplinary most commonly, geriatricians, physiotherapists, occupational therapists, nurses and pharmacists with the latter being the least involved.

Pharmacists' role in fall preventions is mainly limited to the hospital setting and medication-related only, as outlined in the Ministry of Health Falls Guideline 2019. Public hospital settings are highly congested and limited in terms of manpower thus; hospital pharmacists are faced with a heavy workload. Meanwhile, community pharmacists being among the community, easily accessible, and having the convenience of time and space for counselling, are under-

utilised for fall prevention. Community pharmacists are the ideal healthcare provider for public health promotion. They should be utilized to educate older adults on fall prevention as well as medication reviews which is already the niche of pharmacists. Yet, there is no evidence to date of local community pharmacists conducting any fall prevention initiatives in the community pharmacy setting in Malaysia.

This calls for effective fall prevention programs. In addressing this, a pharmacist-led fall prevention program (CAREFREE) provides practical and feasible interventions to prevent falls among the community-dwelling older adults at a community pharmacy, one of the abundant primary care settings in the country. The efficacy of the CAREFREE program should then be assessed in improving the knowledge, health-related quality of life and perspective on fall prevention engagement which indirectly can help reducing falls among the community-dwelling older adults.

Research Question(s)

1) What is the impact of a community pharmacist-led fall prevention programme on older adults' knowledge of falls?

2) What is the impact of a community pharmacist-led fall prevention programme on older adults' health-related quality of life, perspective on fall prevention engagement, and number of falls?

Objective

General:

To evaluate community pharmacists-led intervention programs to improve the knowledge that can help prevent future falls among community-dwelling older adults in Malaysia.

Specific:

1. To assess the efficacy of a community pharmacist-led fall prevention program on older adults' knowledge of falls.
2. To assess the efficacy of a community pharmacist-led fall prevention program on older adults' health-related quality of life, perspective on fall prevention engagement and number of falls.

Literature review

Community pharmacists have been involved in fall prevention measures for community-dwelling older individuals for over a decade, primarily in the USA. There are limited number of randomised-controlled trials (RCT) being conducted in the community pharmacy setting by community pharmacists on falls prevention. To date, all the randomised controlled trials with involvement of community pharmacists are originated from the USA.

A team of researchers from University of North Carolina at Chapel Hill had conducted RCT to prevent falls through enhanced pharmaceutical care at community pharmacy setting (Ferreri et al., 2008). The study involved 186 participants aged 65 years or more that are at high-risk of future falls due to either previous fall, taking four or more medications and taking one of more of high-risk medications. Community pharmacists at the intervention group, delivered medication review with recommendations for changes in medication by the prescriber, With

intention-to-treat analysis, the study revealed no significant differences in all endpoints; rates of recurrent falls, injurious falls, or filling prescriptions for high-risk medications. As-treated analysis found numeric reductions in rates of falls (rate ratio = 0.76; 95% CI 0.53-1.09). The author concluded that larger sample size is needed to provide greater power, thus able to detect clinically meaningful effects of a reduction in the use of high-risk medications on preventing or reducing falls (Blalock et al., 2010). Further evaluation of the effectiveness of a medication review intervention on the rate of falls at community pharmacies showed that 45.2% of physicians responded to pharmacists' recommendations, and 32.3% authorised the changes (Casteel et al., 2011). The study highlights the need to improve care coordination between pharmacists and prescribers.

Centers for Disease Control and Prevention (CDC) developed the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) screening algorithm and toolkit in 2017 to aid healthcare professionals in fall prevention initiatives among older adults (Sarmiento & Lee, 2017). It incorporated the recommendations from American and British Geriatrics Societies' (AGS/BGS) practice guidelines. The STEADI materials were tested extensively for reliability and validity using interviews and focus groups. The tools are useful for the primary prevention of falls and recurrent falls (Stevens & Phelan, 2013). STEADI consists of three components, namely, screening patients for fall risk, assessing modifiable risk factors and intervene to reduce risk by using effective clinical and community strategies Combining all these components able to induce impactful reduction in falls as well as improving health outcomes. STEADI materials include education brochures about fall prevention for both patients and healthcare providers. They also provide training to healthcare professionals in preventing falls (*STEADI - Older Adult Fall Prevention | CDC*, 2021). A specific guide for community pharmacists, STEADI-Rx, was developed to help pharmacists to integrate fall prevention into pharmaceutical care.

An RCT was conducted to evaluate the effects of a community pharmacy-based fall prevention intervention, STEADI-Rx, in the risk of falling and use of medications associated with an increased risk of falling (Blalock et al., 2020). The study involved a total of 10,565 participants aged ≥ 65 years, using either ≥ 4 chronic medications or ≥ 1 medications associated with an increased risk of falling. A total of 65 community pharmacies in the North Carolina agreed to participate in the study with 31 pharmacies in intervention group. The intervention done include screening using STEADI questions and medication reviews. The pharmacists in the intervention group were first being trained to successfully implement fall prevention services (Robinson et al., 2019). The result revealed that the primary outcome measure, drug burden index (DBI) scores, decreased but not statistically significant after 12 month of follow-up. There was no changes in the risk of falling among the participants in control and intervention group as well as between pre- to post-intervention period. Blalock et al. justified that standardised outcome measures should be developed that sensitive enough to capture effectiveness in reducing falls.

In addition, an observational study was done at Iowa City, Iowa recently to investigate the integration of STEADI into community pharmacy practice (Hughes et al., 2020). The study also reported on the targeted medication management interventions that pharmacists made. Target population was patients aged ≥ 50 years with a fall risk potential. Positive screened patients had received comprehensive medication review by pharmacist along with education and medication recommendations. The study concluded that STEADI assessment was useful in identifying potentially at high-risk patients, but more studies should work on relating deprescribing of high-risk medications among these populations. This call attention to investigate the generalisability of STEADI assessment in the Malaysian population, a middle-income country.

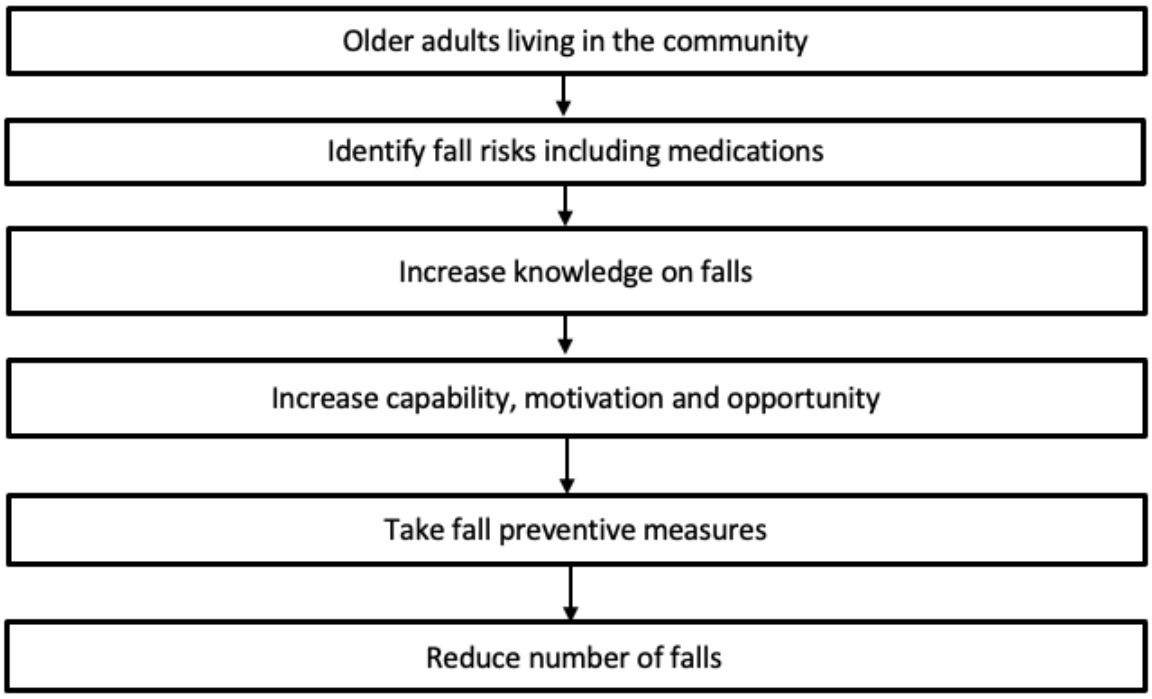
Another RCT with involvement of community pharmacists for fall prevention among community-dwelling older adults was done through medication therapy management (MTM) (Mott et al., 2016). The aim of the conducted pilot was to examine the preliminary effects of MTM intervention focusing on fall-risk increasing drugs (FRIDs). The primary outcome measures were the rate of discontinuing FRIDs and the risk and rate of falling while the secondary outcome measures were characteristics of recommendations made related to FRIDs and the acceptance rate by provider. Unlike the RCT by Blalock et al. that used the prescription profile records excluding OTC use, Mott et al. had relied on participants' self-reporting of medications including the use of OTC. The pilot study included 81 high-risk community-dwelling older adults were followed up through telephone interviews five monthly. Despite no significant changes in the risk and rate of falling, there was significant higher modification of FRID use in the intervention group compared to control. The inclusion of OTC in the medication review, increases the chance of older adults making self-adjustment to their own medication regimen.

In Malaysia, an RCT aiming to reduce recurrent falls was done in teaching hospital in Kuala Lumpur (Tan et al., 2018). The MyFAIT trial had involved 268 participants recruited at emergency room, medical outpatient and primary care clinic. It targeted older adults (65 years and above) with two or more previous falls. Tailored-multifactorial interventions were done including an exercise programme, home modifications, medication review, cardiovascular and visual intervention as well as fall education. Participants were followed for a period of 12 months and primary outcome measure, recurrence of fall showed no difference between intervention and control groups [RR=1.037; 95% CI (0.613-1.753)]. Similarly, there were no difference in the secondary outcomes, rate of fall [RR = 1.155; 95% CI (0.846- 1.576)] and mortality rate [RR = 0.896; 95% CI (0.335-2.400)]. The authors argue that fall recurrence may not necessarily be the most useful outcome measure in intervention studies but should consider evaluating the relative contribution of each component of intervention. Besides, there was no involvement of pharmacists in conducting medication review process, instead, it was conducted by medical practitioner and evaluated by a professional geriatrician highlight that involvement of pharmacists is lacking. The study identified the need for more appropriate and affordable solutions for the management of high-risk fallers in the country.

In addition, the study was only applicable to urban, community-dwelling older adults limiting its generalisability.

Theoretical framework

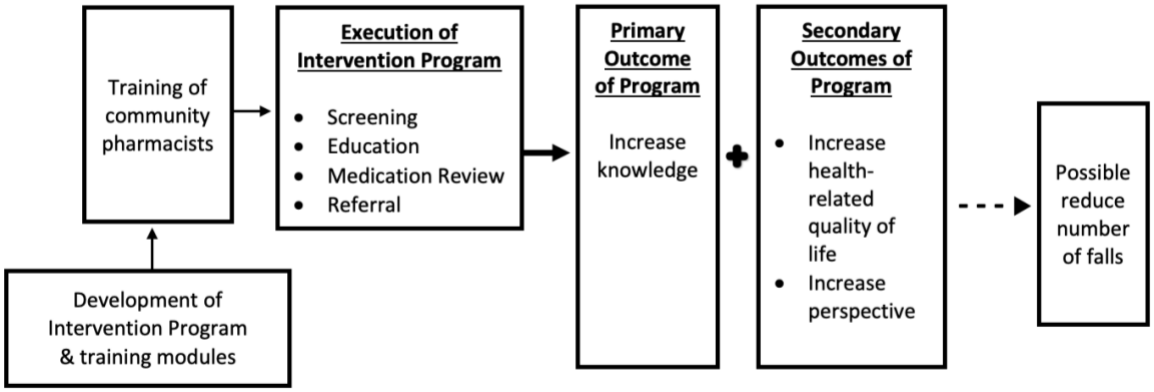
The theoretical framework of this study, as shown in the figure below, is based on behavioural change theory, called the COM-B model. The COM-B model is a psychological model that explains human behavior to determine different possible mechanisms involved in making a behavior change (Michie et al., 2011). This model hypothesized that behavior occurs as an interaction between three necessary conditions: capability, opportunity and motivation. It is anticipated that improving older adults' knowledge on falls and its preventive measures will then be a drive for other things including increase in the capability, motivation and opportunity of older adults to take fall preventive measures. Subsequently, the number of falls may be reduced among the community-dwelling older adults by preserving their independence.



Theoretical framework of the study

Conceptual framework

Community pharmacists will be first trained to ensure they are knowledgeable with the necessary skills to execute the CAREFREE program. The conceptual framework of this study assumes that the multi-interventions done by the community pharmacists ultimately will improve the older adults on the knowledge of falls which is the primary outcome measure. The interventions may also improve the older adults' health-related quality of life and perspective on fall prevention engagement. In the long term, lower accidents of falls may be seen among these older adults.



Conceptual framework of the study

Training of Pharmacists

All participating pharmacists (full-time community pharmacists) will need to attend a 7-hour training (1 day) conducted face-to-face by the researchers. This is to ensure the reliability of the intervention provided. The training will follow a set of modules adapted from previously published and established modules which then will be reviewed by a selected panel of experts, including geriatricians, pharmacists, and academicians in the area of falls (*Certified Fall Prevention Specialist (CFPS) - Evergreen Certifications*, 2022; *STEADI - Older Adult Fall Prevention | CDC*, 2021; Khong et al., 2017; Mott et al., 2016; Robinson et al., 2019; Shaw et al., 2020). During the training, pharmacists will be instructed about every aspect of the study to standardise the delivery of the program to target participants. Pharmacists will also be equipped with all the relevant fall-related knowledge such as the definition of falls, falls statistics about the nature and incidence of falls in the community, the risk factors contributing to falls, including medications, possible preventions strategies and the roles of pharmacist in falls preventions. This will establish them as credible sources of information when delivering the interventions. In addition, they will be provided with the necessary materials to conduct the intervention. Motivational interviewing, the principle of adult learning and behaviour change techniques will also be shared with them (Khong et al., 2017;

Mott et al., 2016; Robinson et al., 2019). The session will be recorded and distributed to the pharmacists afterwards for reference. A pre-and post-training assessment will be distributed before and after completion of the training, respectively. This will help in assessing the understanding and opinion of the community pharmacists on the given training. Post-training assessment will also be utilised to explore some of the community pharmacists' capability, opportunity, and motivation in providing fall prevention services to older adults through online interviews facilitated by six validated semi-structured interview questions (Keyworth et al., 2020; Kirkpatrick & Kirkpatrick, 2016; Webb et al., 2016).

Research design

It is an interventional study of a randomised controlled trial. It is a prospective, two-arm, parallel, cluster-randomised trial with 6 months of follow-up. Blinding of the community pharmacists and participants would not be possible due to the nature of the intervention. Cluster randomisation will be used to prevent contamination between patients using the same pharmacy.

Study area

Community pharmacies throughout the country who are willing to participate and willing to be trained to conduct fall prevention program including both chain and independent pharmacies. List are identified through Malaysian Pharmaceutical Society (MPS) and Malaysian Community Pharmacy Guild (MCPG). In order to ensure the practicality and generalisability of the intervention in the community pharmacy setting, the involved community pharmacies are not specific to either rural or urban.

Study population

Community-dwelling older adults visiting community pharmacy for any reason.

Subject criteria

Inclusion criteria:

1) Older adults aged 60 years and above
2) Consuming four or more chronic medications per day
3) Willingness to document self-reporting of falls at home (monthly calendar)
4) Capable of providing own consent

Exclusion criteria:

1) Unable to communicate or writing in Malay or English language

2) Having sensory impairment
3) Participants are on palliative care
4) Resided in residential care facilities
5) Participate in other study related to falls
6) Diagnosed with mental disorder or neurological disease that might affect cognition
7) Cognitively impaired
8) An expected life expectancy shorter than six months

Chronic use of at least one medication is defined as consumption of the medication for at least three months in the last 12 months.

Sample size estimation

The primary outcome variable in this study is improvement in the knowledge score from baseline. The sample size calculated must be able to detect the difference in the knowledge between the intervention and control groups at the end of the intervention period.

It is postulated that the intervention (personalised fall prevention model) can improve the knowledge score of the participants up to 20%, which was considered to be realistic and clinically relevant. With this rationale and setting the type 1 error of 5% (alpha=0.05) and power of 85% to detect a difference between the intervention and control group; by using the Power and Sample Size Calculation program version 3.1.2 (Dupont & Plummer, 1998), a sample size of minimum 89 participants per arm will be required for the analysis. Based on reported literature and allowing for a potential 30% possible post-randomization exclusion, loss to follow-up and drop-out (Wittes, 2002), a minimum sample size of 116 participants will be needed in each arm, making a total of 232 participants will be recruited.

Sampling method and subject recruitment

A recruitment advertisement highlighting the inclusion criteria stated above will be advertised at the study community pharmacies. To aid in participant recruitment, word of mouth and flyers may also be distributed to nearby communities of the participating community pharmacies. The recruitment advertisement is outlined in Appendix A. Individuals interested in participating in the study on a voluntary basis will be screened whether they fit all the inclusion and exclusion criteria by participating community pharmacists. All potential participants will be assessed on cognitive impairment using a 6-item screener, which is derived from a mini-mental state examination (Callahan et al., 2002). Those who score with more than three errors will be classified as cognitively impaired and will be excluded from the study. Each participant will be followed up for 6 months period.

Cluster randomisation will be used in the current study at the community pharmacy level to reduce the risk of contaminants and the introduction of biasness across the study group. The principle investigator will randomise the CP into intervention and control groups in a 1:1 ratio. Randomisation of the CP into will be decided using pre-generated randomised number lists generated by the investigator using Random Allocation Software Version 1.0.

Intervention

Participants in the randomised intervention group of community pharmacies will receive a pharmacist-led fall prevention intervention program. The program consists of three main interventions that are screening for fall risk, fall education, medication review and referral. **Participants are required to fill up the questionnaires for knowledge, health-related quality of life and perspective on fall prevention engagement prior to commencement of the interventions by the study pharmacists for baseline data (pre-intervention).**

Screening for increased fall risk in the intervention participants will be done by asking three key questions by the study pharmacists. It serves to aid in the subsequent educational session and also to inform relevant healthcare providers (in referral), so they are alert of the participants' risk of falling. Indirectly, the referral will make the participant feel safer and more confident living their everyday life.

Community pharmacists will provide falls education using printed materials adapted primarily from Stopping Elderly Accidents, Injuries, and Deaths (STEADI) and the National Council on Aging (NCOA). The printed materials that will be translated into Malay will have information about common risk factors and simple ways to avoid falling. Community pharmacists may make recommendations for modifying simple home hazards, medications, and diets. The content of the falls education will be based on the findings of previous research utilising falls education as an intervention (Chidume, 2021; Hill et al., 2017; Ott, 2018). It aims to increase participants' awareness of their personal falls risk and promote behaviour change toward fall prevention (Hill et al., 2017).

For medication review, participant will be requested to bring along their medications including any supplements or over-the counter (OTC) products for a review at their preferred day and time within a week of recruitment. This aim to captures the exact information on what the participants actually consumed (Lim et al., 2017). This is an advantage over screening through participants' prescription only as compliance can be an issue and participants may be self-purchasing medications (Chang et al., 2021). Moreover, participants would also be given education that some medications can potentially cause fall particularly benzodiazepines, opioids, sedatives and hypnotics (Seppala, Wermelink, et al., 2018).

During the second session, which will be scheduled after one month, the participants will be requested to visit the CPs. Participants are required to fill up the questionnaires for knowledge, health-related quality of life and perspective on fall prevention engagement the

second time (first post-intervention). The objective of the follow-up session is to evaluate the short-term effect of the intervention and to explore the subjects' experiences and challenges faced in implementing suggested intervention. In addition, the second session also will be used to provide additional information or intervention which was not addressed during the first session.

The subsequent follow-up at 3-month will be done through telephone interviews to assess the participants number of falls. The final follow-up will be done at 6-month and participants will be requested to visit the CPs the final time. Participants are required to fill up the questionnaires for knowledge, health-related quality of life and perspective on fall prevention engagement (second-time post-intervention) the final time. The participants will need to bring back the given fall calendar to the study pharmacists for data collection.

Control

Meanwhile, participants that fit the study criteria in the randomised control group of community pharmacies will be provided with health advice as per usual standard pharmacy services (SPS) by community pharmacists in the community pharmacy setting without any educational materials supplied to the pharmacists. The usual SPS of the community pharmacists is responsible for selling over-the-counter (OTC) drugs and prescribed medications as well as giving advice on minor health problems. They are focused on counselling for nutritional supplements and providing screening tests for blood pressure and blood sugar levels (Ooi et al., 2016). Moreover, they are also involved in several regular health promotion activities such as diabetes counselling, diet counselling, physical activity counselling and weight management (Hamidi et al., 2021).

At baseline, participants must fill out the questionnaires for knowledge, health-related quality of life and perspective on fall prevention engagement. The participant will be requested to bring along their medications, including any supplements or over-the-counter (OTC) products, for a review at their preferred day and time within a week of recruitment. This aim is to captures the exact information on what the participants consumed as a background data (Lim et al., 2017). However, there will be no specific education, medication review, nor referral will be done to the participants in the control group. A second session will be scheduled after one month, where the participants will be requested to revisit the CPs. Participants must fill out the questionnaires for knowledge, health-related quality of life and perspective on fall prevention engagement again. The follow-up at 3 months will be done through telephone interview to assess the number of falls. The final follow-up will be done at 6-month and participants will be requested to visit the CPs the last time. Participants must fill out the questionnaires for knowledge, health-related quality of life and perspective on fall prevention engagement the final time. The participants will need to bring the given fall calendar back to the study pharmacists for data collection.

Research tool

STEADI fall risk screening will be used to screen and report the proportions of participants at increased risk (Blalock et al., 2020; *STEADI - Older Adult Fall Prevention | CDC*, 2021) by study community pharmacists. This will be done during the first session. This will be translated into Malay language through a linguistic translation process with forward and backward translation as well as an established expert committee (Tsang et al., 2017).

Fall Risk Assessment Questionnaire (FRAQ) will be used to measure knowledge on falls which includes risk factors and medication risks components. The questionnaire consisted of 22 questions with 4 main domains of behavioural, environmental, medical and drugs aspects. The questionnaire was used previously in fall education intervention trials among community-dwelling older adults (Howard et al., 2016; Ott, 2018; Wiens et al., 2006). This will be done during the first session and at 1-month and 6-month follow-up. Fall Risk Assessment Questionnaires (FRAQ) has been translated and validated in the Malaysian population previously (Goh et al., 2021). Approval for use both the original and translated Malay version have been obtained from the respective authors.

Perspective Questionnaire will be used to assess participants' perspectives in engaging with fall prevention strategies in terms of beliefs, knowledge, motivation and intention. This questionnaire consists of 7 questions as outlined in Appendix B. The questionnaire was developed and validated among community-dwelling older adults (Khong et al., 2017). With the authors' permission for use in this study, the questions will be translated into the Malay language through a linguistic translation process. This involved two bilingual researchers translating individually, and a final version is obtained once the two researchers reach a consensus. Another bilingual researcher takes the Malay version and back-translated it to English to ensure the adequacy of the meaning of the translation. Finally, an expert panel committee opinion will be included to ensure the words used by the native speakers would understand by (Chen & Boore, 2010). The translated Malay version will then be validated in the Malaysian community-dwelling older adults. This will be done during the first session and 1-month and 6-month follow-up.

EQ-5D-5L tool will be used to assess the health-related quality of life (HRQoL) which has been proven to be valid and reliable in variety of patient groups (EuroQol Foundation Research, 2019; Verdoorn et al., 2018; Zhou et al., 2021). This tool has been well-validated in Malaysian population (Shafie et al., 2019). Both English and Malay paper self-complete versions need to be obtained from EuroQol office. This will be done during the first session as well as 1-month and 6-month follow-up.

Fall-risk increasing drugs list will be used to aid community pharmacists in identification of these medications during the medication review. Special attention will be given to these medications and participants will be counselled and educated regarding this accordingly. A referral for changes of these medications may be given by the community pharmacists. The

list of medications that can cause increased risk of falling in older adults will be obtained from CDC and literatures (Blalock et al., 2020; de Vries et al., 2018; Ferreri et al., 2008; Seppala, van de Glind, et al., 2018; Seppala, Wermelink, et al., 2018). This will be done during the first session.

Patient's monthly calendar and ***telephone interview*** will be used to assess the occurrence of falls subsequently rate of falls. Patient's monthly calendar provides a prospective recording methods while telephone interview provides retrospective falls recalls. Combination of retrospective and prospective falls recording is the best for an intervention study with frailer older population (Romli et al., 2021). Six-month falls calendar will be given during the first session. Participant need to submit back the calendar after 6-month through post or hand back to their respective community pharmacy. Telephone interview will be done during the 1-month, 3-month and 6-month follow-up.

Standard referral form will be used for community pharmacists to fill and give to the participants to pass to their respective healthcare provider(s). The form will be developed specifically for this purpose and it is based on CDC STEADI referral form and other pharmacy intervention trials (Verdoorn et al., 2018). This is to ensure systematic referral process. With participant's agreement, a referral, if deem necessary, will be made for additional diagnostic and prevention methods, change in medications or require a more comprehensive medication review by primary care or hospital pharmacists, informing outcome of screening of fall risk. This will be done during the first session. The standard referral form is outlined at Appendix C.

Operational definition

Occurrence of fall : an event that results in a person unintentionally coming to rest on the ground, floor or other lower level.

Fear of fall : persistent feeling related to the risk of falling during one or more activities.

Rate of fall : number of fall events occurring over the 6-month study period.

Difference in the knowledge scores : the difference between the intervention & the control group in the change in knowledge score from baseline to a 3-month follow-up.

Data collection method

Baseline information on patient demographic, socio-demographic, education level, medical history, current medications are obtained from patient through face-to-face interview and completed by the investigator on the prepared data collection form (DCF). The DCF would not

contain participant's information that could lead to identification of the participants maintaining anonymity of the participants.

During the first session, baseline knowledge, health-related quality of life (HR-QoL) and perspective on fall prevention engagement will be assessed through prepared questionnaires, IPQ-R and EQ-5D-5L tool respectively in both control and intervention groups. A fall calendar will be given to all participants to record any occurrence of falls that happen throughout the study period. During this session, participants in intervention group will be screened for fall risk, will be given fall education and medication review will also be done. A referral using a standard referral form will be given to patient if necessary. Knowledge of participants will be assessed on the participants awareness to risk factors of falls as well as beliefs and motivation for falls preventive strategies.

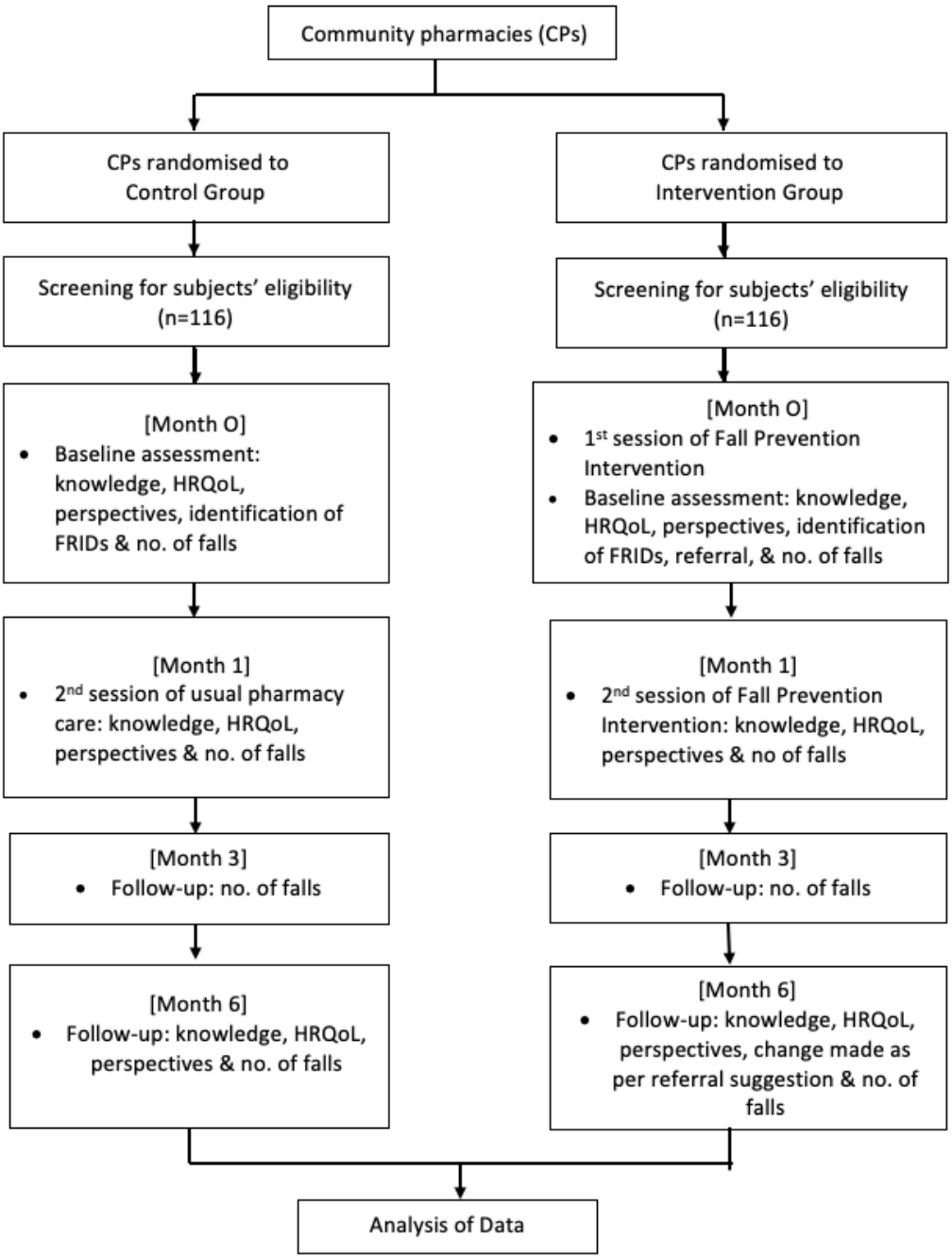
During the second session, participants in both control and intervention groups will be assessed on their falls knowledge, HR-QoL, perspective on fall prevention engagement and number of falls. Participants in both arms will be followed up again after 3 months through telephone interviews to review if any occurrence of falls had occurred. At 6-month follow-up, participants will be assessed on long-term effect of falls knowledge, HR-QoL, perspective on fall prevention engagement and number of falls. Study pharmacists will also query the participants that have been given referral whether the recommendations in the referral have been implemented or otherwise. The number of falls throughout the study period will be obtained both from the participants' history recall and participants' fall calendar.

Pharmacists document any relevant findings, suggestions and recommendations made to each subject in a prepared DCF. Dropout and loss to follow-up will be recorded together with the reason(s). If participants did not answer phone call for follow-up more than three times, next of kin will be contacted for update on participant contact and fall status.

A pilot study will be conducted prior to the commencement of the larger study. The main aim of conducting pilot study is to determine whether providing fall education in community pharmacy setting would have the desired effect of raising participants' level of knowledge. Moreover, through pilot study, it is possible to determine whether the humanistic and clinical outcomes could be collected concurrently and the tools used able to detect the effect of the intervention. Ease of participants recruitment and time taken to conduct the session (screening, education and medication review, referral) were also of interest to establish the feasibility of providing this type of intervention in a community pharmacy setting.

The investigator may decide to terminate the study at any time. Subjects will be informed if the study is terminated and follow-up visits will be arranged if needed. Subjects will be terminated from study follow-up once they have completed 6-month follow-up after recruitment date or event of death occur.

Study flowchart



Flow diagram of the cluster randomised-controlled trial procedure

Data analysis

All data will be entered and analysed using the Statistical Package for Social Science (SPSS) version 27. A significance level of 0.05 was used to test for statistical differences. If p-value calculated is less than 0.05, the effect is significantly different i.e. there is a difference in the results of the analysis. After data entry, a preliminary data screening will be conducted to identify any missing values and to correct data points. Following this editing process, the original data will be checked again to ensure no mistakes were made during the initial phase. Subsequently, the data sets will be investigated for any outliers or out-of-range values by graphical means (histogram or boxplots) and statistical means (Kolmogorov-Smirnov). If any outliers is detected, a thorough review will be performed to identify any likely inaccuracies or mistakes during the process of recording data or data entry.

Continuous variables (example include age, body-mass-index and number of previous fall) will be presented as mean (SD) or median (IQR) based on their normality distribution. Meanwhile, discrete or categorical variables (example include gender, ethnicity, living status, and education level) will be presented as frequency (percentage).

In order to determine differences in proportion or association between the intervention and control groups for categorical or discreet variables, cross tabulation by means of Chi-square test will be utilised for this purpose. Fisher's exact test, on the other hand, will be employed in analysing 2x2 tables of categorical data when one or more cells had an expected count of less than five. Comparison of continuous data between intervention and control groups was carried out by using the independent samples t-test. In order to identify any changes in the knowledge scores between and within both groups at three different time intervals, the two-way repeated measures ANOVA test will be employed. Data will be analysed through the use of descriptive statistics by describing all the components of the questionnaires in a quantitative manner.

Summary of the data analysis is as shown in a table below.

Research questions	Data analysis
1) What is the effect of a community pharmacist-led fall prevention programme on older adults' knowledge of falls?	Two-way repeated measures ANOVA test for parametric test
2) What is the effect of a community pharmacist-led fall prevention programme on older adults' health-related quality of life, perspective on fall prevention engagement and number of falls?	Two-way repeated measures ANOVA test for parametric test

Expected result(s)

Demographic and background characteristics of participants

Table 1: Characteristics of participants

General characteristics	Respondents, n (%)
Age	
Gender	
BMI	
Ethnicity	
Mobility aid use No Yes	
Education level	
Employment	
Living status Alone With spouse only With family	
Past medical history	
Past medication history	
Identification of FRIDs from medication history	
Under follow-up Hospital Clinic None	

Table 2 : Screening outcomes

Screening questions	Respondents, n (%)
Feels unsteady when standing or walking?	
Worries about falling?	
Fell in the past year?	

Table 3: Knowledge score at baseline, 1-month and 6-month.

	Knowledge Score			p-value
	Baseline	1-month	6-month	
Control Group				
Intervention Group				

Table 4: Health-related quality of life score at baseline, 1-month and 6-month.

	Health-Related Quality of Life Score			p-value
	Baseline	1-month	6-month	
Control Group				
Intervention Group				

Table 5: Perspectives score at baseline, 1-month and 6-month.

	Perspective Score			p-value
	Baseline	1-month	6-month	
Control Group				
Intervention Group				

Table 6: Referral made to participants' healthcare providers

	Respondents, n (%)
Number of referral made	
Suggestion in the referral Informing positive outcome of increased risk from the screening done Informing on patient-specific medication-related suggestion (ie. switching medication, adjusting dose etc) Recommending patient to undergo further thorough falls assessment (eg. eye check and gait, strength & balance evaluation)	
Any change made as per referral suggestion during the 6-month follow-up Yes No	

Table 7: Occurrence of falls at the different period of time and rate of falls over 6 month.

	Number of falls				Rate of falls over 6 months	p-value
	In the past year (if any)	1-month	3-month	6-month		
Control Group						
Intervention Group						

Gantt chart & milestone

The estimated starting date of pilot study and subsequently the study, would be on 1st of August 2022 and estimated to finish data collection by 27th of Dec 2023.

Year/Month	2022			2023				2024
	Mar-Jun	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	July-Sep	Oct-Dec	Jan-Mar
Proposal preparation and ethics approval								
Training of participating community pharmacists								
Pilot study								
Initiate subject recruitment & randomisation into control & intervention community pharmacies								
Follow-up of subjects								
Data analysis								
Manuscript/ thesis writing								

Milestone	Achievement Date
Training of community pharmacists	04/07/2022
Commencement of pilot study	25/07/2022
End of follow-up	30/09/2023
Completion of data analysis and writing	31/03/2024

Budget proposal [If applicable]:

Fundamental Research Grant Scheme (FRGS), application ID, 401088-425097, with budget estimates granted of RM114,000.

Ethical consideration(s) [if applicable]:

1. **Subject vulnerability**

   The current study includes those who are independent and cognitively intact with good mobility as they need to be able to come to the pharmacy in person and those that are able to be educated by the community pharmacists as per the inclusion and exclusion criteria. Older persons are considered vulnerable populations only if they are cognitively impaired and immobile. In addition, this study intervention poses a low risk to them. All information collected will remain strictly confidential and will never be associated with their identity. All potential participants will be provided with a plain language statement, and a detailed explanation of what participation in the study involves. The patient information sheet will also be made visible for them to read at the point of recruitment. They have complete freedom to decide whether they want to participate in this study or not. Written consent will be taken from all individuals who agree to be involved in the study. Regardless of their decision, it will not affect their health and medical management at all as participants in both arms will still need to continue their follow-up whether at hospital or clinic. Participants will also have the right to withdraw from the study whenever they want.

2. **Declaration of absence of conflict of interest**

   The investigators declare that they have no conflict of interest.

3. **Privacy and confidentiality**

Only the researcher will have access to the participants' data. The participants' personal details will be kept on a password-protected computer. Only the researcher knows the password, and therefore, the researcher is the only person who can access the computer. A number will be allocated to each participant during data entry into the SPSS™ software in the same password protected computer to protect the participants' identity. Data analysis will also be performed in the same computer. Once the study has been completed, the data in the computer will be copied into CDs first before being deleted from said computer. The CDs will be stored in a locked office within Universiti Sains Malaysia (USM) for a minimum of three years, after which it will be destroyed. The participants are not allowed to access their personal data, but they may contact the researcher to request the results of this study.

4. Community sensitivities and benefits

This study indirectly increase knowledge regarding fall and fall prevention in primary care level perceived by community-dwelling older persons as well as community pharmacists. The results of this study may reveal important and novel insights into factors that may influence the implementation of complex fall prevention intervention in our cultural settings as well as. This information will be invaluable information for implementing effective falls prevention strategies specifically at community pharmacy setting. Effective fall prevention among older persons are crucial to ensure continuity of active aging and good health-related quality of life. This indirectly will promote this group of golden population to remain active and productive as well as to provide them opportunities to continue to live independently.

5. **Honorarium and incentives**

An honorarium will be given to the participant at the 1-month follow-up of RM 20 and the remaining RM 35 at the end of the follow-up, making a total of RM 55. In addition, an honorarium for participating study community pharmacists will be given RM 18 per subject recruitment.

6. Other ethical review board approval [if applicable]

Not applicable.

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APPENDIX A : Participant Recruitment Advertisement

Are you 60 years old & above?

Do you consume 4 or more medications every day?

If **yes,**
We need you to participate in research!

Your participation will make a difference to older population in the country.

Research is about community pharmacist helping to **prevent accident of falls among older adults.**

All your information will be kept confidential and will be used solely for research purposes.

At the end of the research, you would receive a remuneration of RM 55.

Talk to the pharmacist now for more information!

The research is under the direction of
Assoc. Prof. Dr. Balamurugan & Ms Nur Izzati (Pharmacist)

APPENDIX B : Perspective on Fall Prevention Engagement Questionnaire

Likert scale:

1 – strongly disagree; 2 – Disagree; 3 – Undecided; 4 – Agree; 5 – Strongly Agree

1. For me, taking measures to reduce my risk of falling would be useful	1	2	3	4	5
2. Most people whose opinion I value approve of me taking measures to reduce my risk of falling	1	2	3	4	5
3. I am aware of the measures needed to reduce my risk of falling	1	2	3	4	5
4. I feel positive about reducing my overall risk of falling	1	2	3	4	5
5. I am confident that if I wanted to, I could reduce my risk of falling	1	2	3	4	5
6. In the next month, I intended to take measures to reduce falls or my risk of falling	1	2	3	4	5
7. I have a clear plan of how I will take measures to reduce falls or my risk of falling	1	2	3	4	5

APPENDIX C : Standard Referral Form

Community Pharmacist-led Fall Prevention Program (CAREFREE)

REFERRAL FORM

Patient Name:	
Date of Birth:	

Pharmacist has reviewed the patient's fall-related risk factors and current medications. The following are the results of the review.

Fall Risk Factor (s) Identified (through screening):

Any falls in the past year	○ Yes	○ No
Worries about falling?	○ Yes	○ No
Feels unsteady when standing or walking?	○ Yes	○ No
Symptoms of lightheadedness or dizziness from lying to standing?	○ Yes	○ No
Taking 4+ chronic medications?	○ Yes	○ No
Taking 1+ high-risk medications?	○ Yes	○ No

Medication Review Result:

Recommendation by Pharmacist:

Pharmacist Name: Signature & Chop: Contact:	
Date of Referral:	