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The Effectiveness of Stroke Riskometer™ in Improving Stroke Risk Awareness in Malaysia: A Study Protocol of a Cluster-Randomized Controlled Trial

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Keywords
Stroke · Risk probability · Awareness · Mobile applications · mHealth

Abstract

Background: Stroke is considered the second leading cause of mortality and disability worldwide. The increasing burden of stroke is strong evidence that currently used primary prevention strategies are not sufficiently effective. The Stroke Riskometer™ application (app) represents a new stroke prevention strategy distinctly different from the conventional high-cardiovascular disease risk approach. ***Objective:*** This proposed study aims to evaluate the effectiveness of the Stroke Riskometer™ app in improving stroke awareness and stroke risk probability amongst the adult population in Malaysia. ***Methods:*** A non-blinded, parallel-group cluster-randomized controlled trial with a 1:1 allocation ratio will be implemented in Kelantan, Malaysia. Two groups with a sample size of 66 in each group will be recruited. The intervention group will be equipped with the Stroke Riskometer™ app and informational leaflets, while the control group will be provided with standard management, including information leaflets only. The Stroke Riskometer™ app was developed according to the self-management model of chronic diseases based on self-regulation and social cognitive theories. Data collection will be conducted at baseline and on the third week, sixth week, and sixth month follow-up via telephone interview or online questionnaire survey. The primary outcome measure is stroke risk awareness, including the domains of knowledge, perception, and intention to change. The secondary outcome measure is stroke risk probability within 5 and 10 years adjusted to each participant's sociodemographic and/or socio-economic status. An intention-to-treat approach will be used to evaluate these measures. Pearson's χ^2 or independent *t* test will be used to examine differences between the intervention and control groups. The generalized estimating equation and the linear mixed-effects model will be employed to test the overall effectiveness of the intervention. ***Conclusion:*** This study will evaluate the effect of Stroke Riskometer™ app on stroke awareness and stroke probability and briefly evaluate participant en-

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gagement to a pre-specified trial protocol. The findings from this will inform physicians and public health professionals of the benefit of mobile technology intervention and encourage more active mobile phone-based disease prevention apps. ***Trial Registration:*** ClinicalTrials.gov Identifier NCT04529681.

Introduction

Stroke is a global public health problem causing greatest burden to low- and middle-income countries because over 85% of the worldwide stroke mortality is attributed to these countries [1, 2]. The incidence of stroke in young adults (age 18–50 years) is approximately 10–15% of all stroke patients and gradually increasing [3, 4]. Stroke causes great impacts not only physically and psychologically but also socially and economically by leaving victims disabled before their most productive years [5, 6].

Effective management, including aggressive risk factor management, primary prevention, integration of prompt and effective treatment, and participation in well-designed rehabilitation programs are the key strategies to reduce the burden of stroke and other non-communicable diseases [7, 8]. Over 90% of the stroke burden is attributable to modifiable risk factors, such as high systolic blood pressure (SBP), high body mass index, diabetes, smoking, unhealthy diet, physical inactivity, and excessive alcohol intake [1, 9, 10]. Targeted interventions that aim to ameliorate these risk factors could substantially reduce the burden of stroke.

Mobile applications (apps) to promote health and prevent disease have been proven to facilitate health behavioural changes and outcomes across diverse population groups, especially in the adult population [11–13]. Indeed, several systematic reviews have demonstrated the effectiveness of mobile apps, particularly in terms of (i) conveyance of health education and promotion to the general population, (ii) enhanced risk perception and safety behaviours, and (iii) application of health behavioural changes to the general population [13–16].

The Stroke Riskometer™ app was developed based on a population-wide prevention strategy aimed at all stroke risk population levels, including the low-, moderate-, and high-risk groups [17]. The app assesses an individual's stroke risk and educates them about the factors of stroke risk and management of risk factors and early symptoms of stroke according to the international guidelines of primary stroke and cardiovascular disease (CVD) prevention [18, 19]. The app is mainly based on the self-management model of chronic disease and has been proven by numerous reviews to effectively improve individual self-efficacy, health behaviours, health status, and quality of life [17, 20]. The use of this app may be as efficient as conventional population-based approaches in spreading awareness about stroke and motivating the necessary behavioural changes at the individual level.

However, despite its perceived benefits, whether the app is genuinely effective is unknown because clear and trusted evidence to support its effects, especially in the middle- and low-income countries, is lacking. In addition, the failure to evaluate the effectiveness and appropriateness of mobile phone apps could compromise user health and safety. Hence, this proposed study aims to evaluate the effectiveness of the Stroke Riskometer™ app in improving stroke awareness and stroke risk probability amongst the adult population.

Methods

Study Design

A non-blinded, 6-month follow-up, parallel-group phase III cluster-randomized controlled trial (RCT) with a 1:1 allocation ratio will be conducted in Kelantan, located in the northeastern corner of Peninsular Malaysia. The study will involve 3 districts, namely, Kota Bharu, Pasir Mas, and Tumpat. The adult population of these districts contributes nearly 70% of the total adult population in Kelantan [21].

Inclusion criteria. *Cluster level:* Health clinics (HCs) located in Kelantan serving at least 1,000 residents in the age group 45–70 years will be eligible to participate. *Individual level:* (1) adults (either patients or accompanying relatives) residents aged 45–70 years who come to the selected HCs on recruitment days; (2) no prior history of vascular disease (e.g., stroke, transient ischaemic attack, angina, myocardial infarction, peripheral vascular disease, and atrial fibrillation), diabetes, or cognitive impairment (as judged by the treating physician) but with elevated SBP (≥120 mm Hg) [22] and/or one or more lifestyle risk factors, such as smoking, overweight, physical inactivity, or unbalanced/poor diet; (3) own or have access to a smartphone; and (4) know how to install mobile apps on their phones.

Exclusion criteria. *Cluster level:* HCs that have participated in a non-communicable disease-related pharmacological or lifestyle modification intervention trial in the past 12 months. *Individual level:* medically unstable; not comfortable reading and writing in the Malay language; severe hypertension (SBP ≥180 mm Hg or DBP ≥110 mm Hg) [22]; depression or other psychiatric disorders (through personal declaration) likely to affect the interventions; life expectancy <5 years; participation in another RCT; other conditions are rendering the individual unsuitable to participate in this research as judged by treating physicians.

This study will be conducted, analysed, and reported according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement: extension to cluster-randomized trials (see www.

karger.com/doi/10.1159/000518853) and strict adherence to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. Ethical approval for this study was obtained from the Medical Review and Ethical Committee of the National Institute of Health, Ministry of Health Malaysia (NMRR-19-3296-51864-IIR), Human Research and Ethics Committee, Universiti Sains Malaysia (USM/JEPeM/19110815), and Kelantan State Health Department. This study is registered at ClinicalTrials.gov under the identifier NCT04529681.

Clinics and Participant Recruitment

This study plans to recruit participants from 20 HCs in Kelantan (9 government HCs and 11 private HCs) from 3 main districts in the state of Kelantan: (a) Kota Bharu, (b) Pasir Mas, and (c) Tumpat. Participants in a particular HC will receive similar allocation (either intervention or control) since this is a cluster-randomized trial.

All selected HCs must comply with the study criteria and be considered amongst the most frequently visited clinics in the selected districts as characterized by patient attendance, types of facilities, and services provided. The selected clinics will receive an official invitation letter, along with descriptive materials related to this study.

To avoid unwanted contamination within the same clinic, we will randomly allocate participants to the intervention or control groups at the district level (e.g., Kota Bharu vs. non-Kota Bharu) such that 10 HCs will belong to the intervention group and another 10 HCs will belong to the control group. Each group will include both government and private HCs.

The participants will be recruited from government and private HCs through study advertisement and screening. Individuals who meet the study criteria will be shortlisted for study recruitment. Those who agree to consider participation will be provided with an introduction leaflet consisting of an invitation letter, an information sheet outlining the benefits and responsibilities of project participation, the baseline socio-demographic form, the stroke risk probability questionnaire, and the Attitudes and Beliefs about Cardiovascular Disease (ABCD) Risk questionnaire.

Written informed consent will be collected before the study, together with a statement informing the participants that their participation is entirely voluntary. They may reserve their right to withdraw from the study, refuse to answer any question, or withdraw whenever they wish without any penalty.

Sample Size

The sample size was calculated using the G*Power version 3.1.9.2 with the statistical test and type of power analysis chosen were "ANOVA: Repeated Measures, within-between interaction" and "A priori: Compute required sample size – given alpha, power and effect size," respectively [23]. As there was no previous repeated-measures study that used the ABCD Risk questionnaire, some parameters to calculate the sample size were based on our expert opinion. For example, in this study, we assumed the intraclass correlation will be poor (0.25) and non-sphericity will equal one. A low intraclass correlation value of 0.05 is chosen based on the estimates from previous studies and to increase the robustness of our study [24–27]. Given a repeated-measures design with 2 groups (intervention and control) and 4 measurement points, the alpha error probability of 0.05, power of 80%, and the ability to detect a small effect size (0.2), a sample of 54 subjects in each group is needed. The oversample was set to 20% of an attrition rate; thus, each group requires at least 66 participants. We also do not limit the minimum number of participants recruited by each HC (10 HCs for intervention and 10 HCs for control).

Randomization

Randomization took place at the HC level. The 20 HCs were randomly allocated to either the intervention group (10 HCs) or the control group (10 HCs) using simple random allocation. We used a Web-based randomization program [28]. The parameters for the number of sets to generate was set to one, the value for the numbers per set was set at 20 (representing 20 HCs), and the number range was 2 (one each for the intervention and the control group). Using the HC unit as the level of randomization minimizes the possible contamination of intervention effects that may occur amongst participants in the same district. The random allocation sequence was generated and administered by Z.M.S.

Blinding

Given the nature of cluster-randomized studies and intervention, neither the researchers nor the participants could be blinded to allocation. Similarly, most outcomes cannot be blinded because they rely on participants' reports.

Intervention and Control Groups

There will be 2 groups: (a) the intervention and (b) the control group. The intervention group will follow the standard clinical follow-up provided by the treating doctors and receive informational leaflets and a free interventional tool Stroke Riskometer™, throughout the study period [29, 30]. The control group will include participants who will be followed up using standard management. This group will only have access to information leaflets throughout the study period. At the beginning of the study, we will instruct all participants (in the intervention group) to download and install the Stroke Riskometer™ app. Following that, we will provide guidance on using the app to measure, monitor, and self-manage stroke risk.

The participants in the control group will be provided with informational leaflets usually distributed to the public during health screening programs and found at all health-care facilities. These leaflets contain information related to stroke, CVDs, and healthy eating behaviours, including disease introduction, risk factors, early symptoms, and preventive measures (shown in Fig. 1).

These materials were developed and published by the health education and promotion division of the Ministry of Health, Malaysia, in 2013–2016 [31]. All materials are printed in the Malay language only.

Both groups will be followed up for 6 months, and data collection will be conducted at 4 time points, that is, baseline and the third week, sixth week, and sixth month post-intervention. During the study period, all participants will be reminded weekly (for the first 6 weeks) and monthly (between 6 weeks and 6 months) basis via SMS/WhatsApp on engagement to the intervention modalities and part of the monitoring effort by the research team. All intervention-related tools were validated and based on international or national guidelines [18] (shown in Fig. 2).

We will be using the introduction leaflet (developed by the research team) to assist all participants in adhering to the trial protocol – able to use Stroke Riskometer™ app and the informational leaflets – properly. Moreover, during the study, participants will be monitored regularly to avoid confusion and increase compliance. Any feedback that involves the confusion or barriers related to the

Fig. 1. Examples of informational leaflets with stroke-related information, CVD-related information, and healthy eating behaviours. CVD, cardiovascular disease.

interventional modalities will be documented for further analysis and improvement.

Intervention Design

The Stroke Riskometer™ app was developed according to a self-management model of chronic disease based on self-regulation and social cognitive theories [17, 20, 32, 33]. The model has been used extensively to manage chronic diseases not only as a necessary part of treatment but also as a means to promote healthy behaviours and lifestyles [34]. The most common intervention methods of chronic disease self-management include small group meetings, Internet-based and mHealth technologies, and printed materials [20]. The app comprises 3 interfaces for (a) stroke risk measurement, (b) stroke risk factor monitoring, and (c) self-management (shown in Fig. 3).

The app can calculate a user's stroke risk probability within 5 and 10 years by providing absolute and relative risks compared with those of an average healthy individual of the same age and gender. For example, a 35-year-old female Malay with a family history of stroke, who eats fewer than 6 servings of fruits and/or vegetables a day, experiences emotional stress, and has an SBP of 128 mm Hg has an absolute risk of stroke of 0.72% and relative risk of stroke of 1.7 times higher than that of an individual with no contributing factor. By comparing one's risk of having a stroke with someone of a similar age and sex without additional risk factors, individuals may be motivated to control their risk factors and reduce their risk of having a stroke.

The app has an interface through which users can save their results for monitoring purposes. Explanations about non-modifiable and modifiable stroke risks, a list of informational videos, directions on using the Stroke Riskometer™ app, what a stroke is, what causes stroke, and information on smoking and diet from an expert speaker are provided in the self-management interface. By assessing the stroke risk earlier, the users will be guided on managing the risk accordingly based on validated CVD management.

In addition, the app also provides (a) the so-called "FAST" interface that informs users ways to identify stroke signs and symptoms, and (b) relevant and valid intervention should someone requires further actions. The validated Stroke Riskometer™ app provides the stroke probability score comparable to 2 well-known stroke prediction tools – the Framingham Stroke Risk Score and QSTROKE stroke risk prevention algorithms – commonly used in

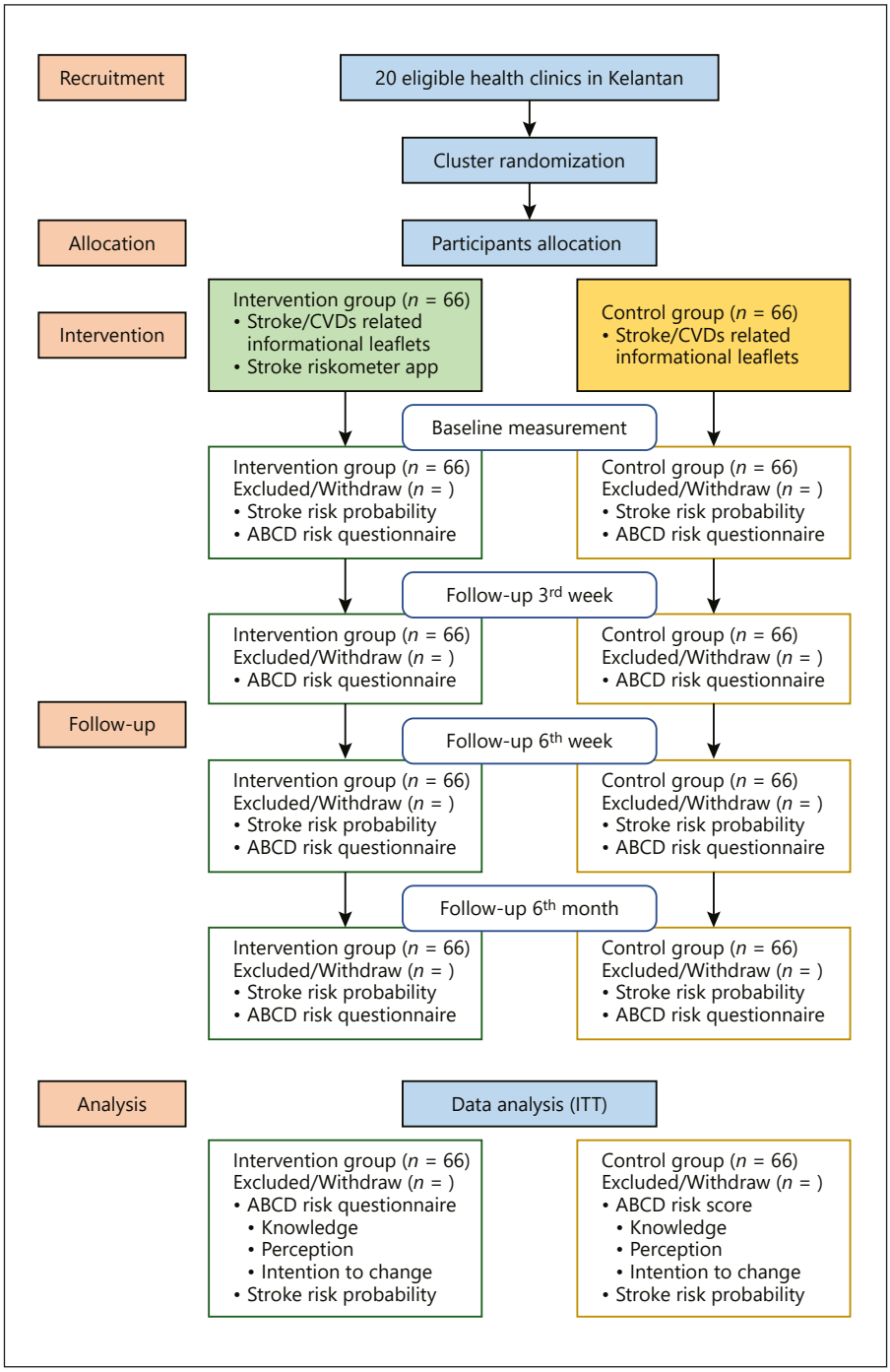

Fig. 2. Flow diagram of the study.

the medical field [18, 35]. The Stroke Riskometer™ app involves a high degree of interactivity and personalization and has received endorsement from the World Federation of Neurology, World Stroke Organization and World Heart Federation. After plugging 20 tested questions (demography, and social and clinical parameters), the app will provide 5-year and 10-year stroke risk probability. Additional features include health educational modules and videos, planning, and goal setting.

Primary Outcome Measure

The primary outcome of the trial is stroke risk awareness scores. The scores will be calculated from the validated ABCD risk questionnaire [36]. It is a self-administered questionnaire that comprises 26 items categorized into 4 main domains: (i) knowledge of stroke/CVDs (8 items), (ii) perceived risk of heart attack/stroke (8 items), (iii) perceived benefits (4 items), and (iv) intention to change lifestyle and eating behaviours (6 items). The

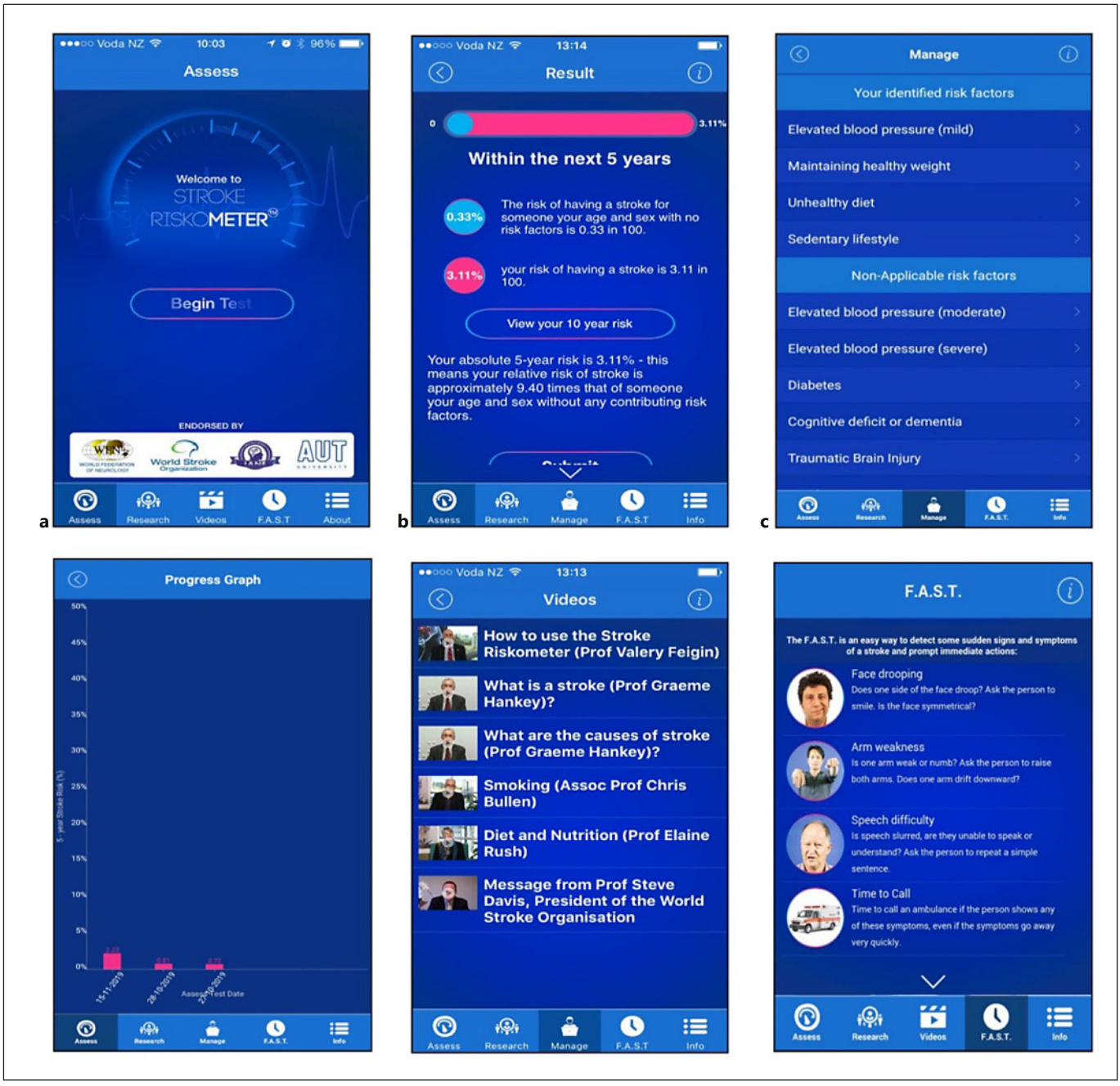

Fig. 3. User interfaces of the Stroke Riskometer app: Stroke risk measurement (**a**), stroke risk factor monitoring (**b**), and self-management (**c**).

knowledge domain requires a true/false/do-not-know response, while the rest of the questions are in the four-point Likert scale format (strongly disagree, disagree, agree, strongly agree). The total score will be calculated as percentage; the higher the percentage, the better the awareness of stroke risk. The ABCD risk questionnaire was developed based on the health belief and trans-theoretical models, and it has satisfactory reliability and validity [37, 38].

Secondary Outcome Measures

The secondary outcome is the percentage of stroke risk probability within 5 and 10 years (the 5-year and 10-year stroke probability). This outcome will be measured using the Stroke Riskometer™ app (the control group will use the same assessment translated into the question set). The participant will install the Stroke Riskometer™ app on their phone and will enter data for 20 questions – consisting of stroke risk factors (smoking, alcohol con-

sumption, diet, physical activities), related comorbidities (diabetes, hypertension, heart disease, traumatic brain injury), body mass index (in kg/m^2), and blood pressure.

Data Collection

Stroke risk probability will be measured at 3 times: (1) baseline, (2) 6 weeks, and (3) 6 months post-intervention, while stroke awareness will be measured 4 times – similar to stroke probability-but with the additional measurement as the third week. The participants will either answer the online ABCD risk questionnaire or will receive telephone interview.

Several approaches will be implemented to encourage participation and increase participant compliance. Firstly, participants will be monitored for 6 months, which is a suitable duration to maintain participant engagement with the intervention and ensure a positive effect on the study outcomes [39, 40]. Secondly, the study participants will be reminded regularly via *SMS/WhatsApp* to monitor their engagement with the study intervention. Three contact numbers (one from the participants and two from close family members) will be collected prior to the study to prevent dropout or other technical issues. Thirdly, participants will be given a choice to either answer the questionnaire by telephone interview or using online form. Finally, we will offer tokens of appreciation to the participants at the end of the study to avoid any undue influence on their decision to participate in this research.

All participants will be given unique numbers to preserve their confidentiality and all data will be entered into the REDCap system [41, 42] on the Universiti Sains Malaysia server. The data and questionnaires will be kept confidential, safeguarded with passwords, and accessible only to the researchers involved in this study.

Fidelity of Intervention

To ensure the intervention plans will be effective, we will assess 2 fidelity factors: (a) adherence and (b) high-quality delivery. For adherence, all components in the intervention modules will be used as stipulated in the intervention manuals. No critical content will be added or removed. To ensure high-quality delivery of intervention, it is delivered by qualified and expert staff (the medical officers and the staff nurses at the HCs).

The implementation of fidelity will be assessed based on 2 parameters at the final stage of the study: (a) the participant attendance log by calculating the number of participants who complete 100% of the expected assessments (as per the study protocol), (b) evaluation survey by calculating the participant's ratings and responses to the post-study acceptance survey (to be developed). However, due to resource constraints, the study will not perform a full-length process evaluation to assess intervention implementation or quantify the effect of each component of intervention or mechanism of action, such as assessment of mediation in the study. The study will also not assess the barriers to uptake and adherence.

Data Analysis Plan

Data analysis will follow the intention-to-treat approach and be performed using R software [43]. Descriptive data on socio-demographic and baseline characteristics will be presented in terms of frequencies and percentages for categorical variables and means, standard deviations or medians and interquartile ranges for numerical variables.

Pearson's χ^2 or independent *t* test will be used to examine differences in socio-demographic and baseline characteristics between the intervention and control groups. The variables included are socio-demographic (age, gender, ethnicity, marital status), socio-economic status (education level, income/occupational level) and stroke risk probability.

Primary and secondary analyses will be conducted using the linear mixed-effect model in the *lme4* package of R software. The model will test the effectiveness of the Stroke Riskometer™ app based on the interaction of groups (intervention vs. control) with time (baseline, third week, sixth week, sixth month) after adjusting for potential confounders presented by socio-demographic (age, gender, ethnicity, marital status) or socio-economic (education level, income/occupational level) factors. Linear mixed-effects modelling examines the condition of interest while also considering the variability within and across participants and items simultaneously. It also handles missing data and unbalanced designs quite well; it has a much smaller effect in the mixed-modelling framework than the other methods. All participant responses are considered part of the same observation [44–47]. Statistical significance will be based on 2-sided tests at the level of 0.05.

Commonly, there are 3 models useful for the analysis of longitudinal cluster randomized trials: (a) repeated measure ANOVA, (b) generalized estimating equations (GEEs), and (c) generalized linear mixed models (GLMMs). For this study, we propose to analyse them using GEEs and then GLMMs. As there are always baseline imbalances in the independent variables, we will perform descriptive statistics (grouping them based on the treatment allocation – intervention group and control group – separately) to identify potential imbalances.

During GEE analysis, the outcome variable variables (the ABCD scores) will be regressed on the primary variable, the treatment group, and become the basic model. Next, for the model building process, other independent variables including those with imbalances will be added to the model, sequentially or in groups. The GEE requires a stricter assumption on missing data, and that data are missing completely at random. However, for the following analysis, we will perform similar model building steps using the GLMM. The advantage of the GLMM is that it only requires missing data to be missing at random. The GLMM also handles missing data and unbalanced designs quite well; it has a much smaller effect in the mixed-modelling framework than the other methods. All participant responses are considered part of the same observation [48–50].

In the GLMM, there will be 3 random-effects variables, (a) the study participants, (b) the health centers, and (c) the age of the participants. Because of these, the analysis will follow the following sequence: firstly, the random intercept model with participants as the random factor; secondly, the random intercept with participants and health centres as the random factors, and lastly, the random slope model participants, health centres, and age of participants as the random factors [51].

The analysis will be performed in RStudio [52] using *geepack* package and *nlme* package [48–50]. Results from models will be presented as crude and adjusted regression coefficients along with 95% CI and *p* values. Model assessment and comparison will be performed based on ANOVA and/or information criterion.

During the GEE analysis, we will perform the analysis for each of the following correlation structures: (a) independence, (b) fixed, (c) exchangeable (also known as a compound symmetry structure), and (d) unstructured (repeated measurements are uncorrelated [53]). The results from each working correlation structure

will be presented. In nlme, the default is set as no correlation structure because we will run nlme with the no correlation structure in addition to the correlation structure mentioned in the GEE [53]. To check the suitable correlation structure, we will also plot the variograms and lorellograms to visualize the correlation [53].

Discussion

The unexpectedly high frequency of modifiable risk factors leading to increased stroke incidences indicates a need for aggressive primary and secondary prevention strategies. Personalized designs in many mobile apps accommodate various user impairments, and the provision of interfaces for navigation, self-reporting, and education has positive effects on medical and functional outcomes, especially those related to user health behaviours [54].

The Stroke Riskometer™ app represents a new stroke prevention strategy that could differentiate those with a low, moderate, and high risk of developing stroke and create personalized warnings and lifestyle correction messages to encourage behavioural changes [55, 56]. The self-management model employed in the development of this application has been shown in multiple studies to produce modest and significant improvements in patient self-efficacy, health behaviours, health status, and quality of life at low cost [12, 57–60].

Strengths and Limitations

This study is unique in that it presents a relevant and robust methodology. Firstly, RCT is considered the "gold standard" in evaluating the effects of intervention and provides a valuable source of evidence in research; thus, it is treated as a powerful experimental tool to examine intervention effectiveness [58, 61]. The repetitive measurement used in this study could decrease intra-patient variability and thus increase statistical power, enhance the precision of estimates, and reduce sample sizes by 35–70% [62].

The linear mixed-effects model to be used in this study considers between-individual heterogeneity by adding random effects to a subset of covariates of interest. The results allow covariate coefficients to vary randomly from one individual to another, thus providing an individual response trajectory over time [45, 46]. Therefore, this model is more suitable than other traditional methods, such as RM ANOVA or even generalized estimating equations, for analysing cases where an intervention is likely to affect some individuals differently from others. Besides increasing the internal validity of the study, the linear mixed-effects model offers greater flexibility, especially in handling skewed data, changes in variance over time, and missing or drop out samples [45].

Some limitations that may affect the outcomes of this study should be taken into consideration. Firstly, the study duration is limited to 6 months. While the results obtained are expected to be sufficiently relevant to the primary outcome of the study, a longer duration may be necessary to confirm the secondary outcome, that is, stroke risk changes. Nevertheless, the literature indicates that the interactive features of apps such as Stroke Riskometer™ could increase self-awareness and facilitate prompt behavioural changes even when the duration of the intervention is less than 10 weeks [12, 63–65]. Secondly, the sample size used in this study is modest (>100 participants) as most studies done before used a sample with <100 participants [11, 66]. Definitely, studies with larger samples have been proven to be more reliable for appraising the effectiveness of the intervention [67, 68]; however, in LMIC, the size is significant to interpret the applicability of study results to the targeted population [62, 66, 69].

Finally, the generalizability of this study may be limited because the work is mainly conducted in the Kelantan region, primarily involved Malay populations, which may not portray the comprehensive characteristics of the multiracial population of Malaysia. However, because a large proportion of the residents of Kelantan are of Malay ethnicity, this study may be applicable to other regions in the country and other countries (e.g., southern Thailand, Brunei, and Indonesia) with a large population of Malays.

Conclusion

This study addresses an important area of mobile technologies and will contribute to the growing evidence concerning the role of mobile technologies for the control and prevention of stroke in the community, specifically in Malaysia. This study evaluates the effect of Stroke Riskometer™ app on stroke awareness as measured by the ABCD risk questionnaire and stroke probability. This study also briefly evaluates participant engagement with the technology and their adherence to a pre-specified trial protocol. The findings from this will inform physicians and public health professionals the benefit of mobile technologies intervention which is easily scalable compared to the traditional public health intervention. Moreover, it may also lead to more active development of mobile phone-based disease prevention apps in Malaysia.

Acknowledgments

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Statement of Ethics

The study was conducted, analysed, and reported according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement and strict adherence to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines. Ethical approval was obtained from the Medical Review and Ethical Committee of the National Institute of Health, Ministry of Health Malaysia (NMRR-19-3296-51864-IIR), Human Research and Ethics Committee, Universiti Sains Malaysia (USM/JEPeM/19110815), and Kelantan State Health Department. This study is registered at ClinicalTrials.gov under the identifier NCT04529681. Participants' confidentiality is maintained. Prior to the data collection, an explanation describing the purpose, methods, and ethical considerations about the study was given to the participants. This informs the participants that their participation is entirely voluntary, and they may reserve their rights to withdraw from the study, refuse to answer any question, or withdraw whenever they want without any penalty. Written inform consent was provided along. The questionnaire survey and intervention are conducted only if the respondents signed the written consent form. Data are presented as grouped data and do not identify the subjects individually. Permission from the Director General of Health Malaysia and other relevant authorities will be obtained prior to the publication. The published findings will be shared with the respondents upon request.

Conflict of Interest Statement

The authors declare no conflicts of interest.

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Author Contributions

Z.M.S., K.I.M., R.S., and V.F. contributed to conception and design. Z.M.S., K.I.M., T.A.T.I., R.S., and V.F. contributed to drafting of the protocol. Z.M.S., K.I.M., and A.H. contributed to collection and assembly data.K.I.M., T.A.T.I., A.H., R.S., Z.A., and V.F. contributed to critical revision of the protocol. Z.M.S., K.I.M., A.H., and V.F. contributed to administrative, technical, and logistic support.

Data Availability Statement

Data availability policy is not applicable to this article as no datasets were generated or analysed prior to the current phase study.

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