Appendix 15: Information sheet and Consent form for phase three study

(i) (Chinese Version)

知情同意书

研究题目　　中国郴州市老年卒中患者移动应用干预模块 (e-MAIMES)的开发与效果评价
第三部分研究：e-MAIMES 的效果评价

主要研究者：曹文静， Dr. Intan Idiana Binti Hassan (MRN:34201)， Prof Azidah Binti Abdul Kadir (MMC no. 33310)， 王娟博士，王宇辉博士

研究简介

我们邀请您参与名为 e-MAIMES 的效果评价研究。本研究为博士课题“中国郴州市老年卒中患者移动应用干预模块 (e-MAIMES)的开发与效果评价”的第三部分。研究旨在评价 e-MAIMES 的干预效果。请您仔细阅读下列信息，决定是否参与本项研究。如果您同意参与，您将会收到一份该文件的复印件。

本研究为期三个月，需纳入约 84 名患者。

研究的目的

在全球范围内，中风仍然是继缺血性心脏病之后的第二大死因，也是第三大成人残疾因素。定期服药是防止中风复发和其他不良后果至关重要的因素。然而，中风幸存者的药物治疗依从性较差。随着智能化手机的新起，移动医疗干预应用越来越多，但移动医疗干预在老年脑卒中患者中的研究较少。 因此，本研究的目的是评价 e-MAIMES 的干预效果。

为什么邀请您参与研究

因为您在 60 岁或以上；有中风史和高血压病史；拥有智能手机并有网络使用；距离上次中风 1 个月以上；服用服用脑卒中药物至少一个月了；改良 rankin 评分在三分及以下；能够阅读中文，并用普通话或郴州本地方言交流。

研究过程

如您决定参与，请填写同意书，您可以保留这份知情同意书，以作日后参

考。这项研究是匿名进行的，不需要您透露您的身份。如果参与研究，您需要知道：

在第一次就诊时，如果您同意参与研究，您将被随机分为 2 组，对照组或干预组。这两组参与者将被要求填写人口统计学问卷(个人背景)和一般药物依从性量表(GMAS-C)、药物信念问卷(BMQ)和中风患者健康素养量表。完成此过程的预计时间为 25-30 分钟。这些问卷在干预前、干预一个月后和干预三个月后都会要求填写。此外，将在干预前、1 个月和 3 个月后收集血压。如果您在干预组，您还需要在干预后三个月填写系统可用性量表(SUS)。

如果您在干预组，项目组组长(曹文静)将亲自向您提供详细的 APP 使用说明。您将被要求在三个月内每天使用该应用程序，并在每天 19:00-21:00 收到一条推送通知，其中包含有用的自我保健管理提示。更重要的是，研究者会指导您在家测量并手动输入你的血压到应用程序，每周至少 3 天；然而，鼓励每天自我监督。e-MAIMES 由几个部分组成，包括药物管理部分、中风健康知识部分、社会交流部分和健康监测部分。下载应用程序需要一个应用程序市场的注册帐户且您只能通过分发一次性注册码来访问这个应用程序。

如果您在对照组，在研究期间您不会收到应用程序或应用程序中包含的任何材料。然而，在研究结束之后您也会获得该应用程序。

如果您有任何问题或不理解的地方，您可以咨询研究人员，他们将随时为您提供帮助。

风险

这项研究不会对你造成任何外部威胁。

个人意愿

参加这项研究与否，纯属自愿。您有权拒绝参加或中途退出此研究。您的参加与否不会产生任何负面的后果。如果您需要其它治疗,或者您没有遵守研究计划,或者发生了与研究相关的损伤或者有任何其它原因,研究者可以终止您继续参与本项研究。完成研究后，您将获得 100 元作为报酬。

可能的利益

这项研究的发现会全面地评价 e-MAIMES 的使用效果。它可以为医务人员、政策制定者和政府打开眼界，增加脑卒中信息化管理，以支持更好的中风管

理。移动应用程序技术的使用将会改善医疗服务的障碍，提高患者的药物治疗依从性，并增加患者自我管理的能力。

如您对这项研究有任何查询，请随时与研究负责人联系：马来西亚理科大学博士研究生曹文静（电话号码：0735-2325007/ 17373529520)。如果您对本研究的伦理有所疑问，请通过邮件 bazlan@usm.my 或 noramira@usm.my 以及电话 09-767 2354 / 09-767 2362/04-6536537 联系马来西亚理科大学相关人员。

隐私问题

如果您决定参加本项研究,您参加试验及在试验中的个人资料均属保密。您的问卷资料将以研究编号数字而非您的姓名加以标识，可以识别您身份的信息将不会透露给研究小组以外的成员,除非获得您的许可，所有的研究成员和研究申办方都被要求对您的身份保密，您的档案将保存在有锁的档案柜中,仅供研究人员查阅，为确保研究按照规定进行,必要时,政府管理部门或伦理审查委员会的成员按规定可以在研究单位查阅您的个人资料，这项研究结果发表时,将不会披露您个人的任何资料，除本研究以外,有可能在今后的其他研究中会再次利用您的医疗记录。签署本同意书，即表示您授权上述记录审查、信息存储和数据处理。

签名

要参与研究，您必须在签名页上签名并注明日期。

附件

知情同意书
(签署页)

研究题目: 中国郴州市老年卒中患者移动应用干预模块 (e-MAIMES)的开发与效果评价

研究者: 曹文静

如果要参与本次研究，您或您的法律监护人必须签署本页。通过签署本页，您确

认以下内容:

- 我已经阅读了知情同意书中的全部信息，对参加本研究可能产生的风险和受益充分了解，并且我有足够的时间考虑这些信息。
- 所有的疑问都得到满意的答复。
- 我自愿参与本次研究，遵守研究程序，并根据要求向医生、护士或其他工作人员提供必要信息。
- 我可以随时退出研究并不会受到任何惩罚或丧失本应获得的利益。
- 我将收到一份签过字的“知情同意书”副本，由我自己保存。

_____

参与者姓名

_____

参与者身份证号

_____ _____

参与者或其法律监护人签名

日期 **(　　年　　月　　日)**

_____

告知者姓名

_____ _____

告知者签名　　日期 **(　　年　　月　　日)**

_____ _____

见证者签名

日期 **(　　年　　月　　日)**

<u>注意:</u>　　i)　　我们不会给参与者购买保险.

研究结果发表知情同意书
(签署页)

研究题目: 中国郴州市老年卒中患者移动应用干预模块 (e-MAIMES)的开发与效果评价

研究者: 曹文静

如果要参与本次研究，您或您的法律监护人必须签署本页。通过签署本页，您确认以下内容:

- 我知道即使研究结果发表也不会暴露我的个人信息。
- 我已经阅读了所有信息的描述，并审查了我参与的所有可能公开的照片和图片。
- 我有机会阅读手稿并查看所有包含我的材料，但我放弃了这样做的权利。
- 所有发表的成果将会在世界范围内共享。
- 这些材料还将发表在当地杂志社、书籍出版社，并被世界各地的许多医务人员使用。
- 我授权发表但是需要满足几个前提:
- 这些材料既不会用作广告目的，也不会用作包装材料。
- 材料不会被用于上下文之外，即:样本图片不会被用于与图片主题无关的文章中。

_____

参与者姓名

_____ _____ _____

参与者身份证号 **参与者签名** 日期 **(年 月 日)**

_____ _____

告知者签名

日期 **(年 月 日))**

注意: **i) 我们不会给参与者购买保险.**

RESEARCH INFORMATION

Research Title: **DEVELOPMENT AND EVALUATION OF THE EFFECTIVENESS OF A MOBILE APPLICATION INTERVENTION MODULE (e-MAIMES) FOR ELDERLY STROKE SURVIVORS IN CHENZHOU, CHINA**

Phase 3 study: Effectiveness of a mobile application intervention module (e-MAIMES) for elderly stroke survivors in Chenzhou, China

Name of main and co-Researcher: Wenjing Cao， Dr. Intan Idiana Binti Hassan (MRN:34201) , Prof Azidah Binti Abdul Kadir (MMC no. 33310)， Dr. Juan Wang， Dr. Yuhui Wang

INTRODUCTION

You are invited to participate voluntarily in research entitled effectiveness of a mobile application intervention module (e-MAIMES) for elderly stroke survivors in Chenzhou, China. This study is Phase 3 study, part of the research entitled "DEVELOPMENT AND EVALUATION OF THE EFFECTIVENESS OF A MOBILE APPLICATION INTERVENTION MODULE (e-MAIMES) FOR ELDERLY STROKE SURVIVORS IN CHENZHOU, CHINA. This research is about getting to evaluate the efficacy of a mobile application module (e-MAIMES) for elderly stroke survivors in Chenzhou, China.

It is important that you read and understand this research information before agreeing to participate in this study. You will receive a copy of this form to keep for your records if you agree to participate.

Your participation in this study is expected to take about three months. This study is estimated to include up to 84 participants.

PURPOSE OF THE STUDY

Globally, stroke remained the second-leading cause of death after ischaemic heart disease and the third adult disability factor. Compliance with doctors'prescription medication is critical to prevent recurrence and other adverse outcomes of stroke after the first stroke has been controlled. However, medication adherence in stroke survivors is problematic.In line with recent changes in technology, smartphone applications (Apps) are increasingly being used to improve health in a number of areas. However, little is known about the use of Apps among elderly stroke survivors.

The purpose of this study are to evaluate the effectiveness of the mobile application intervention module (e-MAIMES) as a tool for elderly stroke survivors on medication adherence, medicine

beliefs, and health literacy on stroke and blood pressure.

PARTICIPANTS CRITERIA

The research team members will discuss your eligibility to participate in this study. This study will involve individuals with the following characteristics:

Inclusion Criteria

You are eligible for inclusion based on the following criteria: aged 60 years or older; have a history of stroke; having a diagnosis of hypertension, either in the patient's medical history or on admission to the hospital, defined as 140 mm Hg or higher for systolic blood pressure (SBP) and/or 90 mm Hg or higher for diastolic blood pressure by physicians; taking at least one medication in the previous month such as (but not limited to) anti-platelets, statins, and anti-hypertensives to control risk factors for strokes; Having a smart phone and internet access to download App; It had been more than a month since the last stroke episode; modified Rankin Score of three or less; able to read Chinese and communicate in Mandarin Chinese or the local Chenzhou dialect.

Exclusion Criteria

The persons who had diagnosed with cognitive impairment (Mini-Mental State Examination score ≤17 [for illiterate] or ≤20 [individuals with 1–6 years of education] or ≤24 [individuals with 7 or more years of education]); participating in another ongoing trial; psychiatric illness or deafness, aphasia, or other language barriers; secondary hypertension; had participated in the Beta testing study.

STUDY PROCEDURES

If you are eligible and agree to participate in this study, you must give consent either in writing by signing the attached participant consent form or online.

At your first visit, if you agree to participate in the study, you will be randomly divided into 2 groups, the control group, or the intervention group. These two groups of participates will be asked to fill in a demographic questionnaire (personal background) and the general medication adherence scale (GMAS-C), Beliefs about Medicines Questionnaire (BMQ), and Health literacy scale for stroke patients. Estimated time to complete this procedure is 25-30 minutes. These questionnaire must be filled before the intervention，one month and after 3 months. In addition, BP will be collected before the intervention，one month and after 3 months. If you are in e- intervention group, you also have to fill out the SUS questionaire.

For the intervention group, you will be provided a detailed explanation of the e-MAIMES in person by the project team leader (Wenjing Cao). You will be asked to utilize the app daily during a three-month period and receive one push notifications each day at 19:00-21:00, with helpful self-care management tips. What is more, you are instructed to measure and manually enter your BP to the app, at home, for a minimum of at least 3 days per week; however, daily self-monitoring is encouraged. The e-MAIMES has several components, including medication management component, stroke health knowledge component, social communication component and health monitoring component. A

registration account with an App market is needed to download the App. And you can get access to the App only through the distribution of single-use registration codes.

For the controlled group, they will not receive the app or any material included in the app during the study period. However, they will get access to the app after the 3-month trial.

If you have any questions or do not understand any part of the questionnaire, you can refer the problem to the researcher who will always be there to help you.

RISKS

The risks involved in this study are minimal, which means they are equal to the risks you would encounter in everyday life.

PARTICIPATION IN THE STUDY

Your taking part in this study is entirely voluntary. You may refuse to take part in the study or you may stop your participation in the study at any time, without any penalty or loss of benefits, to which you are otherwise entitled to, otherwise. Your decision whether or not to participate will not affect your current or future relations with hospitals or your doctor. Your participation also may be stopped by the research team without your consent, if in any form you have violated the study eligibility criteria. The research team member will discuss with you if the matter arises. Upon completion of the study, you will be reimbursed 100 CNY for your effors, time.

POSSIBLE BENEFITS [Benefit to Individual, Community, University]

This study's findings may give a whole picture of the effectiveness of the app. It can also serve as an eye-opener for HCP, policy-makers, and the government, to increase availability of disease management techniques to endorse better stroke management. The utilization of mobile app technology improves barriers to healthcare access, improves patient medication adherence, and increases patient exposure to self-care management techniques.

QUESTIONS

If you have any questions about this study or your rights, please contact

Wenjing Cao
USM ID No: P-SKD0053/21(R)
Contact information:
School of Health Sciences,
Universiti Sains Malaysia
16150, Kubang, Kerian, Kelantan, Malaysia
Email: **caowenjing@student.usm.my**
Tel. No: **8617373529520**

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Mr. Mohd Bazlan Hafidz Mukrim
Secretary of Human Research Ethics Committee USM
Division of Research & Innovation (R&I)
USM Health Campus
Tel. No. : 09-767 2354 / 09-767 2362
Email : bazlan@usm.my

OR

Miss Nor Amira Khurshid Ahmed
Secretariat of Human Research Ethics Committee USM
Research Creativity & Management Office (RCMO)
USM Main Campus, Penang
Tel. No. : 04-6536537
Email : noramira@usm.my

CONFIDENTIALITY

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

By signing this consent form, you authorize the record review, information storage and data process described above.

SIGNATURES

To be entered into the study, you must sign and date the signature page

ATTACHMENTS

Subject Information and Consent Form
(Signature Page)

Research Title: **DEVELOPMENT AND EVALUATION OF THE EFFECTIVENESS OF A MOBILE APPLICATION INTERVENTION MODULE (e-MAIMES) FOR ELDERLY STROKE SURVIVORS IN CHENZHOU, CHINA**

Researcher's Name: **Wenjing Cao**

To become a part this study, you or your legal representative must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form including any information regarding the risk in this study and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Participant Information and Consent Form to keep for myself.

_____

Participant Name

_____

Participant Identification No

_____ _____

Signature of Participant or Legal Representative
Date (dd/MM/yy)

_____

Name of Individual

Conducting Consent Discussion

Signature of Individual

Date (dd/MM/yy)

Conducting Consent Discussion

Name & Signature of Witness

Date (dd/MM/yy)

Note: **i) All participants who are involved in this study will not be covered by insurance.**

ATTACHMENTS

Participant's Material Publication Consent Form
Signature Page

Research Title: **DEVELOPMENT AND EVALUATION OF THE EFFECTIVENESS OF A MOBILE APPLICATION INTERVENTION MODULE (e-MAIMES) FOR ELDERLY STROKE SURVIVORS IN CHENZHOU, CHINA**

Researcher's Name: **Wenjing Cao**

To become a part this study, you or your legal representative must sign this page.
By signing this page, I am confirming the following:

- I understood that my name will not appear on the materials published and there have been efforts to make sure that the privacy of my name is kept confidential although the confidentiality is not completely guaranteed due to unexpected circumstances.
- I have read the materials or general description of what the material contains and reviewed all photographs and figures in which I am included that could be published.
- I have been offered the opportunity to read the manuscript and to see all materials in which I am included, but have waived my right to do so.
- All the published materials will be shared among the medical practitioners, scientists and journalist world wide.
- The materials will also be used in local publications, book publications and accessed by many local and international doctors world wide.
- I hereby agree and allow the materials to be used in other publications required by other publishers with these conditions:
- The materials will not be used as advertisement purposes nor as packaging materials.

- The materials will not be used out of contex – i.e.: Sample pictures will not be used in an article which is unrelated subject to the picture.

_____

Participant Name

_____ _____ _____

Participant Identification (dd/MM/yy) **Participant's Signature** **Date**

_____ _____

Name and Signature of Individual Conducting Consent Discussion **Date (dd/MM/yy)**

Note: **i) All participants who are involved in this study will not be covered by insurance.**