

Development of a mobile application (MyLepto App) to improve knowledge, attitude, and practice regarding leptospirosis among wet market workers in Selangor, Malaysia: A study protocol

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Mas Norehan Merican Aljunid Merican^{1*} MBBS, MPH, PhD; Zaleha Md Isa¹ BSc, PhD; Rozita Hod^{2*} MD, MPH, PhD; Roszita Ibrahim^{2*} BSc, MSc, PhD; Zamtira Seman³ MS; Rusdi Abd Rashid⁴ MBBS, MPM

¹Department of Public Health Medicine Faculty of Medicine Universiti Kebangsaan Malaysia Kuala Lumpur MY

²Department of Public Health Medicine Faculty of Medicine Universiti Kebangsaan Malaysia Jalan Yaacob Latif, Bandar Tun Razak, Cheras, Kuala Lumpur, 56 MY

³Sector for Biostatistics & Data Repository National Institutes of Health Ministry of Health Malaysia Shah Alam MY

⁴Department of Psychological Medicine Faculty of Medicine University Malaya Kuala Lumpur MY

*these authors contributed equally

Corresponding Author:

Zaleha Md Isa BSc, PhD

Department of Public Health Medicine

Faculty of Medicine

Universiti Kebangsaan Malaysia

Jalan Yaacob Latif, Bandar Tun Razak, Cheras,

Bandar Tun Razak, Cheras,

Kuala Lumpur

MY

Abstract

Background: Leptospirosis is the most common zoonotic cause of disease and mortality, with the majority of its burden occurring in tropical regions and the poorest countries. Leptospirosis is becoming a significant public health issues, particularly in tropical developing nations. The disease is endemic in all Southeast and South Asian nations. Several outbreaks of leptospirosis occur after natural disasters. In Malaysia, the Communicable Diseases Control Information System (CDCIS e-Notification system) recorded 5,217 leptospirosis cases in 2019 with 32 fatalities (case fatality rate: 0.6%). The incidence rate was 15.61 per 100,000 people. Males comprised 67% of leptospirosis cases, while people aged 25–55 years accounted for 45% of cases. Furthermore, 50% of the 24 leptospirosis outbreaks recorded in 2019 occurred in households. Information and perception are crucial in influencing positive behavior. Nonetheless, information on urban and rural people's knowledge, attitude, and practice regarding the incidence of leptospirosis is limited.

Objective: This study aimed to develop a mobile application (app) with information on leptospirosis and measure its effectiveness in improving knowledge, attitude, and practice regarding leptospirosis among wet market workers in Selangor, Malaysia.

Methods: A three-phase study will be conducted and includes the development of a mobile app containing information about leptospirosis, analysis of its acceptability, and application of the intervention. The participants will be recruited based on specific inclusion criteria using purposive sampling. Four wet markets will be selected according to a list provided by local municipal councils. The respondents from each selected wet market will be all workers aged ≥18 years old. The mobile app development will begin with an idea description, storyboard creation, and content approval through the nominal group technique (NGT). The mobile application content will be constructed using the health belief model (HBM) theory. Subsequently, the usability of the mobile app prototype will be evaluated using the validated Malay version of the System Usability Scale Questionnaire for the Evaluation of Mobile Applications. The study protocol entails a 12-week intervention stage, in which the baseline assessment is regarded as a pre-test, the follow-up assessment as a post-test, and the participant selection will be based on inclusion and exclusion criteria. This study will incorporate a set of validated questionnaires created by a group of leptospirosis experts. The validated questionnaire will comprise nine sections with open-ended questions on sociodemographic data, knowledge, attitude, practice, and mobile app requirements.

Results: The main results will be the differences in the respondents' knowledge, attitude, and practice regarding leptospirosis between the baseline and immediate follow-up after the 12-week intervention.

Conclusions: This intervention study will be conducted in Hulu Langat district, Selangor, given the high number of reported leptospirosis cases there. With a mobile app, the results may contribute to improving wet market workers' knowledge, attitude, and practice regarding leptospirosis. **Clinical Trial:** This study employed a quasi-experimental design without random allocation or a control group. Although it involved a digital health intervention and outcome evaluation, it does not fulfill the International Committee of Medical Journal Editors definition of a clinical trial, which requires prospective registration in a public trial registry. Accordingly, this study was not registered in a clinical trials registry. However, ethical approval and methodological transparency were ensured throughout the research process.

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Original Manuscript

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Abstract

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Trial Registration: This study employed a quasi-experimental design without random allocation or a control group. Although it involved a digital health intervention and outcome evaluation, it does not fulfill the International Committee of Medical Journal Editors definition of a clinical trial, which requires prospective registration in a public trial registry. Accordingly, this study was not registered in a clinical trials registry. However, ethical approval and methodological transparency were ensured throughout the research process.

Keywords: Leptospirosis; mobile health application; Health Belief Model; wet market workers;

public health intervention

Introduction

Leptospirosis, also known as Weil's disease, is recognized by the World Health Organization as a neglected tropical illness with a large global health burden. Southeast Asia recorded the second-highest leptospirosis incidence after Oceania, with an estimated 1.03 million cases and 58,900 fatalities yearly. Hence, leptospirosis is the most common cause of zoonotic disease and mortality, with the majority of its burden occurring in tropical regions and the poorest countries. Given the dearth of current information from many countries, these statistics might be underestimated. The public health issue of leptospirosis is worsening in most tropical developing nations. Leptospirosis is endemic in South and Southeast Asia and several outbreaks have occurred after natural disasters [1].

Leptospirosis is present worldwide; however, it is primarily endemic in regions with humid subtropical and tropical climates. It is estimated that leptospirosis affects more than 500,000 people annually worldwide. Leptospirosis spreads rapidly, especially after a heavy rainy season or flooding. Most North and South American countries have recorded cases, where leptospirosis outbreaks have been reported in Brazil, Guyana, Nicaragua, and other Latin American countries. Severe symptoms and high mortality exceeding 10% are observed in most complex cases. The exact number of human cases is unknown due to under- or misdiagnosis, and flare-ups may be associated with tropical cyclones and floods [2].

Given its geographic proximity to the equator and significant Southeast Asian rainfall, especially during the monsoon season, Malaysia is prone to being leptospirosis-endemic. Local data indicated that leptospirosis cases in Malaysia increased from 1.03 cases per 100,000 people in 2004 to 30.2 cases per 100,000 people in 2015. In 2010, the Ministry of Health Malaysia published recommendations for leptospirosis diagnosis and treatment, with improved access to the microscopic agglutination test [3].

The CDCIS e-Notification system recorded 5,217 leptospirosis cases in 2019 with 32 fatalities (case fatality rate: 0.6%). Figure 1 demonstrates that the incidence rate was 15.61 per 100,000 people. Males comprised 67% of leptospirosis cases, while people aged 25–55 years accounted for 45% of cases. Furthermore, 50% percent of the 24 leptospirosis outbreaks recorded in 2019 occurred in households.

Figure 1. Leptospirosis incidence rate per 100,000 population in Malaysia (2010–2019).
Source. Adapted from Ministry of Health Malaysia [4].

Why Is This Study Important?

Most leptospirosis cases in Selangor, Malaysia, have not been reported and it is an endemic disease in Malaysia. This resulted from the metropolitan community's lack of awareness in this regard [5]. Nevertheless, the availability of scientific data has improved the knowledge of leptospirosis in Malaysia.

Knowledge and perception are significant factors in motivating constructive behavior [6]. Unfortunately, research on knowledge, attitude, and practice (KAP) in Malaysia is persistently subject to setbacks from the aspect of comprehending leptospirosis prevalence among urban and rural populations [7]. Thus, this protocol describes a study that will be conducted to develop a mobile application (app) that will educate the community on leptospirosis and substitute the current information dissemination methods. Additionally, this mobile app will enlighten the community on the disease and its prevention [8].

Objective

The primary aim of the study is to identify the requirements for developing a mobile app as an intervention in preventing leptospirosis among wet market workers in Hulu Langat district, Selangor. The secondary aim of the study is to design and develop a mobile app with information on leptospirosis to enhance KAP among wet market workers in Hulu Langat, and to measure the improvements in wet market workers' KAP regarding leptospirosis after a 12-week intervention through pre- and post-test evaluations. Leptospirosis is considered endemic in most tropical countries. Workers in the agriculture and domestic animal industries are at high risk of contracting leptospirosis. An association between rodent presence and environmental hygiene in wet markets has been related to leptospirosis. Thus, this study will be conducted to achieve the abovementioned objectives.

Current Leptospirosis Situation in Malaysia

Leptospirosis incidences in Malaysia have increased remarkably for more than a decade, resulting in a significant number of fatalities. Thus, there is a tremendous need for research and development to identify the methods of mitigating the disease and addressing the increasing case fatality. In Malaysia, leptospirosis is listed as a disease that must be reported under the Prevention and Control of Infectious Diseases Act of 1988 as of December 9, 2010 [9].

In 2020, a total of 2,914 leptospirosis cases were recorded in Malaysia (incidence rate: 8.63 per 100,000 population), and 38 deaths were recorded (death rate: 0.1 per 100,000 population). Eight leptospirosis outbreaks were recorded in 2020, of which 50% involved households [9]. A total of 1,763 leptospirosis cases were recorded in 2021 (incidence rate: 4.81 per 100,000 population). Concurrently, 25 deaths were recorded (death rate: 0.07 per 100,000 population) (Figure 2). The occurrence of some zoonoses declined during the COVID-19 pandemic, particularly leptospirosis incidence, which might be linked to the Movement Control Order (MCO), school closures, and reduced recreational activities.

Figure 2. Number of leptospirosis cases and deaths in Malaysia (2012–2021).

Source. Adapted from Ministry of Health Malaysia [10-19].

Risk Groups

Exposure to *Leptospira* in a contaminated environment, such as the wet market, increases the risk of leptospirosis among wet market employees. Thus, recognizing interventions to improve KAP regarding leptospirosis would aid wet market workers in effectively addressing the issues. Zulaikhah et al [20] stated that an effective antibody against the disease is required to mitigate the leptospirosis infection rate.

Ab Rahman et al [21] suggested that wet market workers were at risk of contracting leptospirosis, as proven by the high seroprevalence of leptospirosis. High-risk planters recorded a high seroprevalence of leptospiral antibodies (28.6%) [22], whereas the seroprevalence among wet market workers was 20–33.6% [21].

Mobile App Usage in Malaysia

Smartphones are small electronic devices that use cutting-edge technology to support various tasks and improve daily usability. Smartphones are multipurpose devices that enable internet access, communication, and app use, which all significantly influence users' behaviors and lifestyles. A smartphone is a mobile device with features similar to those of a personal computer. These devices have all of the basic computer features, such as web browsing, emailing, video and voice chat, and audio-video playback [23]. While traditional mobile phones are primarily used for texting and talking, recent versions can also send images and messages; however, they remain limited in comparison to smartphones [24].

The Malaysian Communications and Multimedia Commission (MCMC) Hand Phone Users Survey 2022 (HPUS) reported that Malaysia had 94.8% smartphone penetration in 2021 [25] (Figure 3). However, the percentage of people who use feature phones is decreasing, with only 7.5% expected by 2021.

Figure 3. Percentage distribution of smartphone and feature phone users in 2017–2021. The figure demonstrates an increase in smartphone users and exposure to more phone functions.

Source. Adapted from MCMC [25].

The digital healthcare market and awareness are currently prevalent in terms of practicality and commercialization, especially after the COVID-19 pandemic. Based on the 2027 projection, the Asia Pacific region digital healthcare market is expected to have a 21.2% increased rate of value, which would exceed Ringgit Malaysia (RM) 50 billion (Figure 4).

Figure 4. Percentage of smartphone and feature phone users demonstrating an increase in the number of smartphone users and exposure to more phone functions.

Source. Adapted from MCMC [26].

These points reflect the need for research to improve the KAP and prevention of leptospirosis among wet market workers in Hulu Langat. The use of a mobile app is expected to be beneficial in Malaysia. A mobile app will be very important when creating leptospirosis awareness among Malaysians. Furthermore, a mobile app will enlighten the community on the disease and its prevention [8].

Methods

Study Design and Study Area

The study will comprise three phases. The first phase will develop a mobile app: MyLepto App. The second phase will analyze the acceptability of the mobile app, while the third phase will involve the intervention. The study will be conducted in Hulu Langat and involve pre- and post-intervention. This study will use a quasi-experimental design. Eligible respondents from four wet markets in Hulu Langat will be selected through simple random sampling [27].

The study will be conducted in Hulu Langat, which is well-known for having high incidence rates of leptospirosis due to the large concentration of wet markets and other high-risk locations. Hulu Langat was selected given its numerous wet markets where workers regularly encounter possible leptospirosis sources such as tainted water and rodent populations [28].

Target Population

The target population will be wet market workers in Hulu Langat, who are frequently exposed to risk factors for leptospirosis due to their jobs. High population densities, frequent contact with organic waste, and close contact with live animals are all characteristics of wet markets that increase the risk of zoonotic illnesses such as leptospirosis [29].

Sample Population

The sample population will comprise wet market workers from four selected locations in Hulu Langat and who fulfill the inclusion criteria

Inclusion Criteria

This study will include Malaysian wet market workers aged ≥ 18 years who have worked at one of the four selected Hulu Langat wet markets for at least 6 months. The potential participants must also have access to a mobile device compatible with the app of the intervention and be willing to interact with it to participate in the study. All potential participants will be required to provide their informed consent before their inclusion in the study.

Exclusion Criteria

The exclusion criteria are people with cognitive or physical disabilities that would render it difficult for them to use a mobile app or complete the study. People who have participated in comparable leptospirosis-related intervention programs within the last 6 months will be excluded to reduce bias. Furthermore, people who do not frequent the four wet markets, such as temporary or part-time workers who work < 2 days per week, will also be excluded. Wet market workers will also be excluded from the study if they refuse to participate or withdraw their consent at any time.

Sample Size Calculation and Sampling Technique

An effect size of 0.26 was derived based on the means (standard deviations [SD]) before and after the intervention [75.2 (13.29) and 78.65 (13.19), respectively] [21]. A calculated sample size of 118 was obtained using two dependent means (matched pairs) at a 5% level of significance and 80% power. With the assumption of a 10% dropout rate, the final sample size needed for the study is 130. The figure was obtained using G*Power version 3.1.9.4.

Phase 1: Mobile App Development

The mobile app development involves seven main steps. Step 1 involves the idea description, followed by storyboard creation (Step 2). In Step 3, the content is to be approved by the nominal group technique (NGT), followed by finalizing the content in Android Package File format. The last two steps are publication in the Google Play Store and copyright acquisition from the Malaysian Intellectual Property Corporation. Figure 5 depicts the general design process for the mobile app.

The NGT will be used in the development of the mobile app content. Wet market workers will act as the target users to identify vital communication strategies and health information, including the elements for a user-friendly mobile app. Additionally, public health specialists, family medicine specialists, and health inspectors will be combined as the target users.

The NGT is a structured meeting that aims to create a systematic process for collecting qualitative data from the target groups most intimately associated with the current issue [30]. In 2006, the Centers for Disease Control and Prevention stated that a small group discussion would aid decision-making. The participants will be instructed to answer questions presented by a moderator or a researcher to obtain data for the NGT. Next, the participants will be instructed to rank the recommendations or thoughts arising from each group member (<https://www.cdc.gov/healthyyouth/evaluation/pdf/brief7>). This method was created by Delbecq and Van de Ven and comprises four important phases: silent generation, round robin, clarification, and voting (rating or ranking) [31].

Content development

The mobile app content will be developed using the health belief model theory (HBM). The mobile app will undergo several content development stages. The first step reviews all available studies on leptospirosis, including the signs, symptoms, transmission methods, related complications, prevention, and control measures. This step will also gather information on the mobile app features for health education and intervention. The next step in identifying the relevant content for the target users will be based on the appropriate information synthesized. For example, users may find it difficult to express their thoughts if they are unfamiliar with the mobile app features. Hence, researchers will determine the features that users anticipate in a mobile app based on existing data.

Figure 5. MyLepto mobile app development process.

Phase 2: Mobile Application Acceptability Analysis

The usability of the mobile app prototype will be evaluated in Malay (Skala Kebolehgunaan Aplikasi Mudah Alih) using the validated Malay version of the System Usability Scale (SUS) Questionnaire for the Evaluation of Mobile Applications. The SUS questionnaire was originally designed in English and comprises 10 items, and will be translated into Malay using forward-backward translation. Two translators (one linguistic expert and one field expert) will translate the questionnaire from English to

Malay, while another two experts (one linguistic expert and one field expert) will back-translate the questionnaire from Malay to English. Finally, the researchers and translators will discuss to finalize the Malay version of the questionnaire. The Malay version will be validated to test the mobile app usability as described by Marzuki et al [32]. The response score will be determined using a 5-point Likert scale, ranging from 1 = strongly disagree to 5 = strongly agree. The total score (range: 0–100) will be determined by the sum of all item scores and multiplied by 25. The original author suggested a standard usability score value of 68 to signify the good usability of an app [33].

The data used in constructing the mobile app were obtained from trusted sources. Initially, information on the introduction, prevention, causes, and treatment of leptospirosis was collected from the Ministry of Health Malaysia MyHealth Portal (<http://www.myhealth.gov.my/>). Subsequently, the information was reviewed by epidemiology experts comprising public health and family medicine specialists.

Phase 3: Intervention Study

The study will be conducted in Hulu Langat and involve pre- and post-intervention. Figure 6 demonstrates that the main procedures in the 12-week intervention stage and study protocol involve a pre-test characterized by baseline assessment, followed by a post-test. Participants will be recruited based on specific inclusion and exclusion criteria. The local municipal council of the workers' areas will cooperate with the research team to select and educate the participants on the research objectives during the initial recruitment stage. The researcher will organize a meeting at this stage.

Questionnaire

This study will use a validated KAP questionnaire on leptospirosis in Malaysia, which will be adopted and modified as needed [34]. The content validity of the study instrument will be ensured by cross-checking and authentication by experts in the field. Before the study begins, the questionnaire will be pre-tested with 30 wet market workers from Hulu Langat. The questionnaire contains nine sections with open-ended questions on sociodemographic data and KAP [34-35].

Four of the nine sections will focus on KAP, including sociodemographic characteristics and place of residence. The participants will be required to disclose their age, gender, ethnicity, household income, and highest level of education.

Data Collection

The data will be collected through self-administered questionnaires. Typically, the questionnaire will be completed in 30 minutes. This study will be conducted in Hulu Langat and involve pre-and post-intervention. Measurements will be made from May 2025 to July 2025.

The recruitment and screening will be based on specific inclusion and exclusion criteria. The duration of the intervention phase will be 12 weeks, and the follow-up phase is a post-test phase (Figure 6). The researcher will conduct a meeting with the participants' leader. During this phase, the leader will cooperate with the research team to select and educate the participants on the research

objectives during the initial recruitment stage. The participants will receive a flyer describing the study details and respondents' eligibility criteria. Next, the participants will be instructed to complete a validated, self-administered pre-intervention questionnaire.

All research facilitators will be trained (a 3-day hands-on workshop) before the program commences for a better program outcome. Data will be collected to evaluate the success of the program after the 12-week intervention.

Figure 6. Data collection methods during the intervention study.

Data analysis

All data collected will be entered and analyzed using the Statistical Package for the Social Sciences (SPSS) version 24.0 (SPSS Inc., Chicago, IL, USA). The means and SD will be presented for numerical variables, while frequencies and percentages will be presented for categorical data. The adjustment in the outcome measurement between the initial and intervention stages will be compared using a paired t-test to assess the effectiveness of the mobile application.

Participants and Public Involvement

Wet market workers and an expert group were actively involved in the development process from the beginning to the final stages to ensure that the intervention was applicable, practical, and grounded in behavioral change theories, particularly the HBM. A cross-sectional study of wet market workers was conducted to identify major gaps in their KAP regarding leptospirosis. Their responses influenced the development of the mobile app content. A consensus on the elements and features of the mobile app emerged after an expert group engaged in an NGT session. This process ensured that the mobile app design incorporated end-user requirements and expert-driven insights. During the development stage, wet market workers participated in usability testing sessions to evaluate and enhance the mobile app. During the intervention phase, the wet market workers will assess how effectively the mobile app improves their KAP regarding leptospirosis.

Ethical approval

This study was conducted in accordance with the principles of the Declaration of Helsinki and received ethical approval from the Universiti Kebangsaan Malaysia (UKM) Research Ethics Committee (Project Code: UKM PPI/111/8/JEP-2023-069). As the study does not involve data, patients, or facilities under the jurisdiction of the Ministry of Health (MOH), approval from the MOH Medical Research and Ethics Committee (MREC) was not required. However, the study is registered with the National Medical Research Register (NMRR) under the identifier NMRR-ID-23-01054-DVX. Prior to participation, all respondents provided written informed consent.

Results

The development of the mobile application, incorporating content based on the Health Belief Model

(HBM) and validated through the Nominal Group Technique (NGT), was completed by January 2024. Data collection for the **intervention study** is scheduled to begin in May 2025, with completion anticipated by July 2025. As of manuscript submission, participant recruitment has not yet commenced. Data analysis is expected to be finalized by September 2025, with the study results anticipated for publication by the end of 2025.

Discussion

Overall Aim

The aim of this study is to develop and evaluate a mobile health application designed to improve knowledge, attitude, and practice (KAP) regarding leptospirosis among wet market workers in Selangor, Malaysia. Grounded in the Health Belief Model, the intervention seeks to raise awareness and promote preventive behaviors. The study will assess the app's usability and effectiveness in influencing health outcomes, with a focus on providing contextually relevant and accessible health information to a high-risk population.

Strengths and Limitations

This study protocol is strengthened by its focus on wet market workers in Selangor, a high-risk group for leptospirosis, ensuring a relevant and context-specific intervention. The three-phase development process guarantees a well-designed, validated mobile app, while the use of validated KAP and System Usability Scale questionnaires ensures reliable outcome measurements. However, the 12-week intervention may not capture long-term behavior change, requiring further follow-up, and varying levels of technical literacy among participants may affect app engagement and its overall effectiveness.

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Conflicts of Interest

None declared.

Abbreviations

HBM: health belief model
HPUS: Hand Phone Users Survey 2022
KAP: knowledge, attitude, and practice
MCMC: Malaysian Communications and Multimedia Commission
MOH: Ministry of Health
NGT: nominal group technique
NMRR: National Medical Research Register
SD: standard deviations
SPSS: Statistical Package for the Social Sciences
SUS: System Usability Scale
UKM: Universiti Kebangsaan Malaysia

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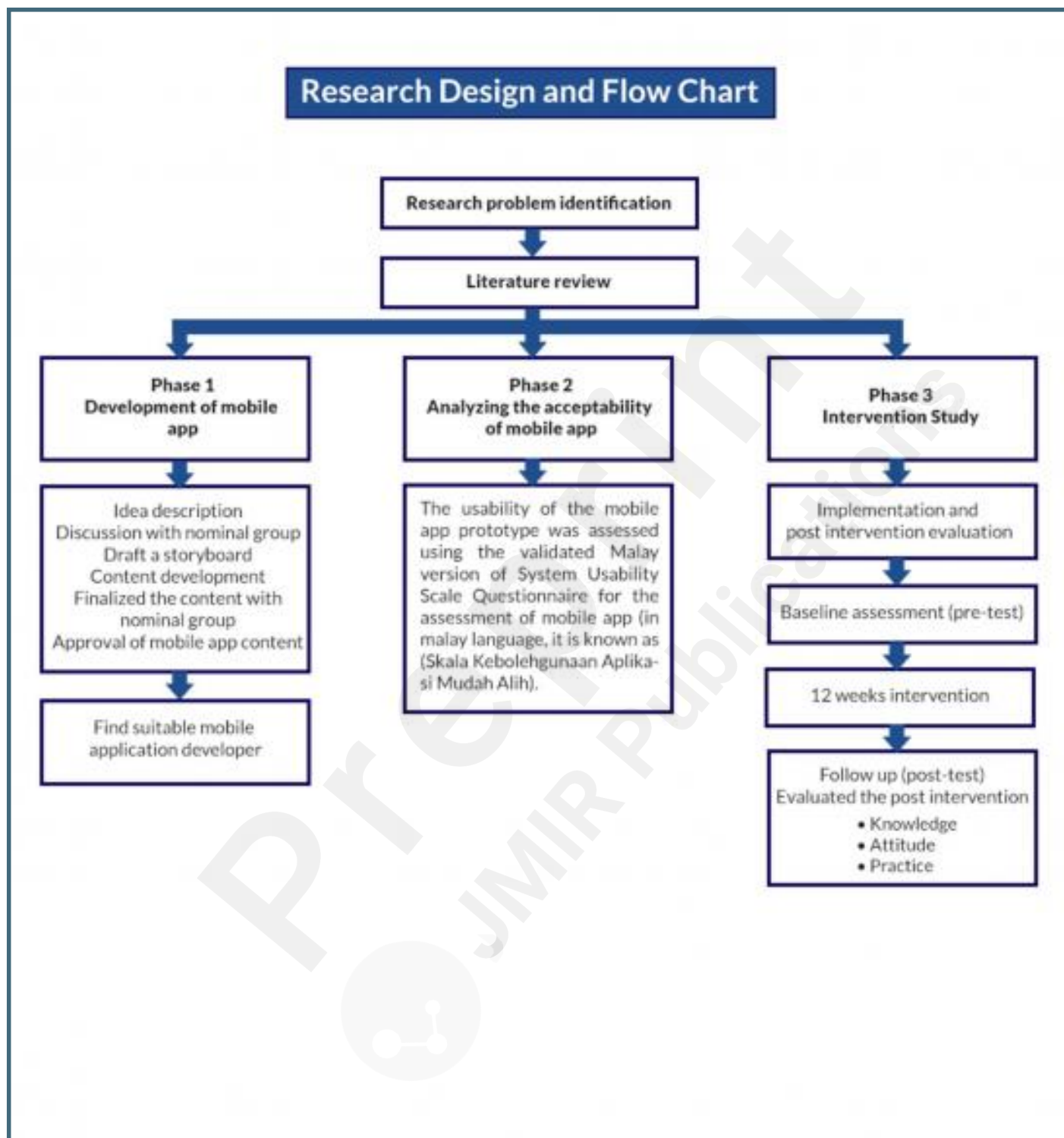
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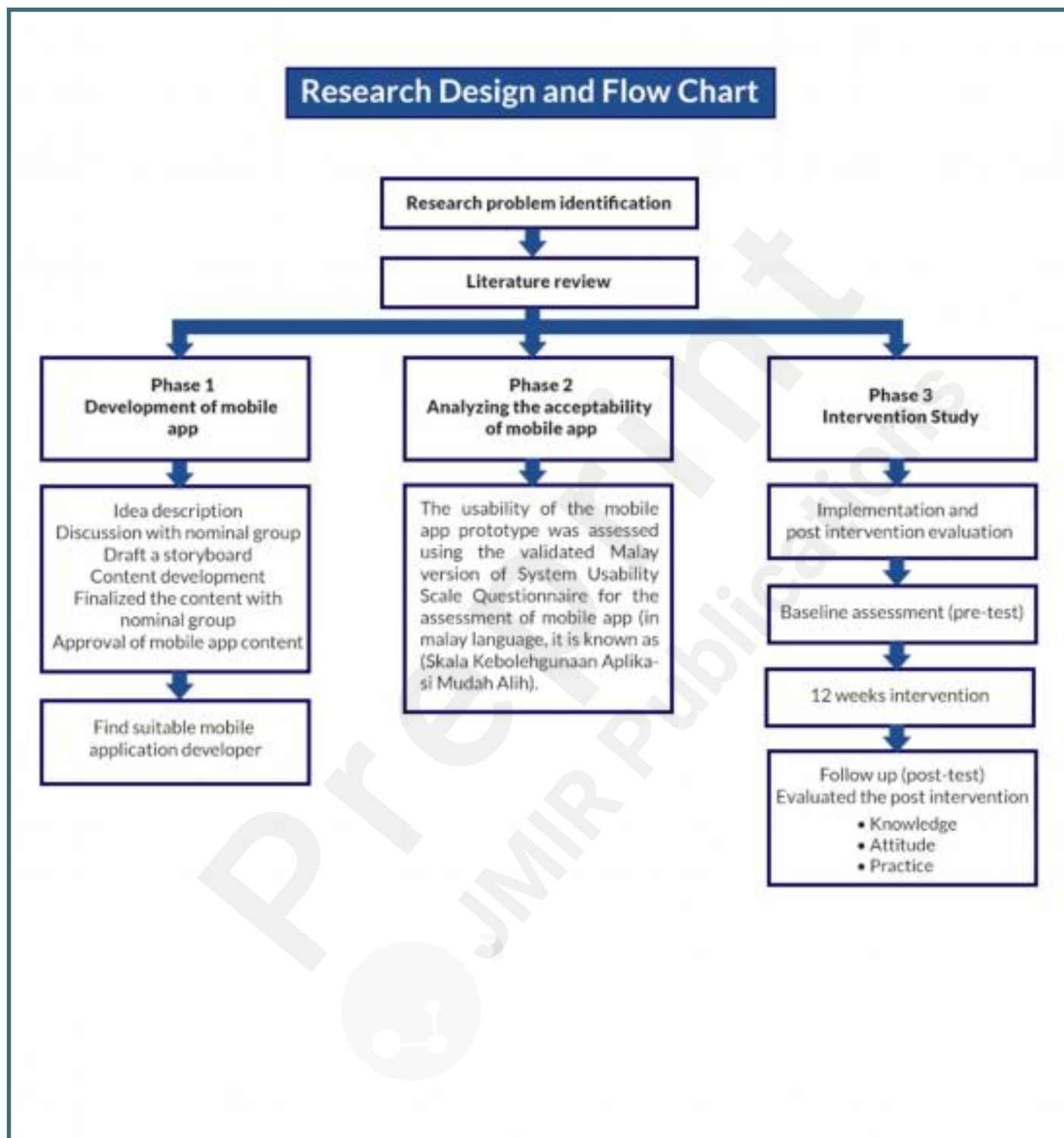


Supplementary Files

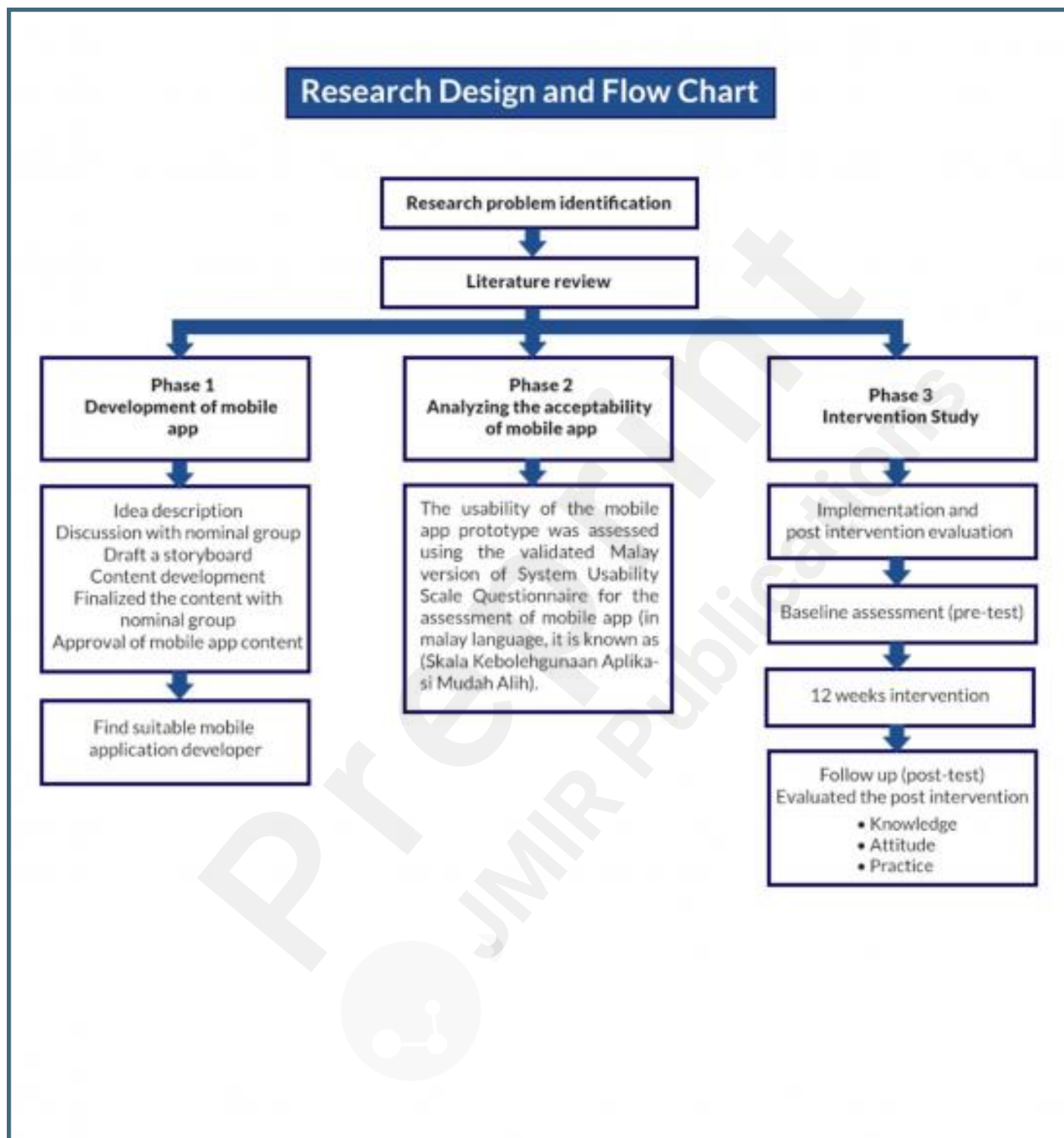
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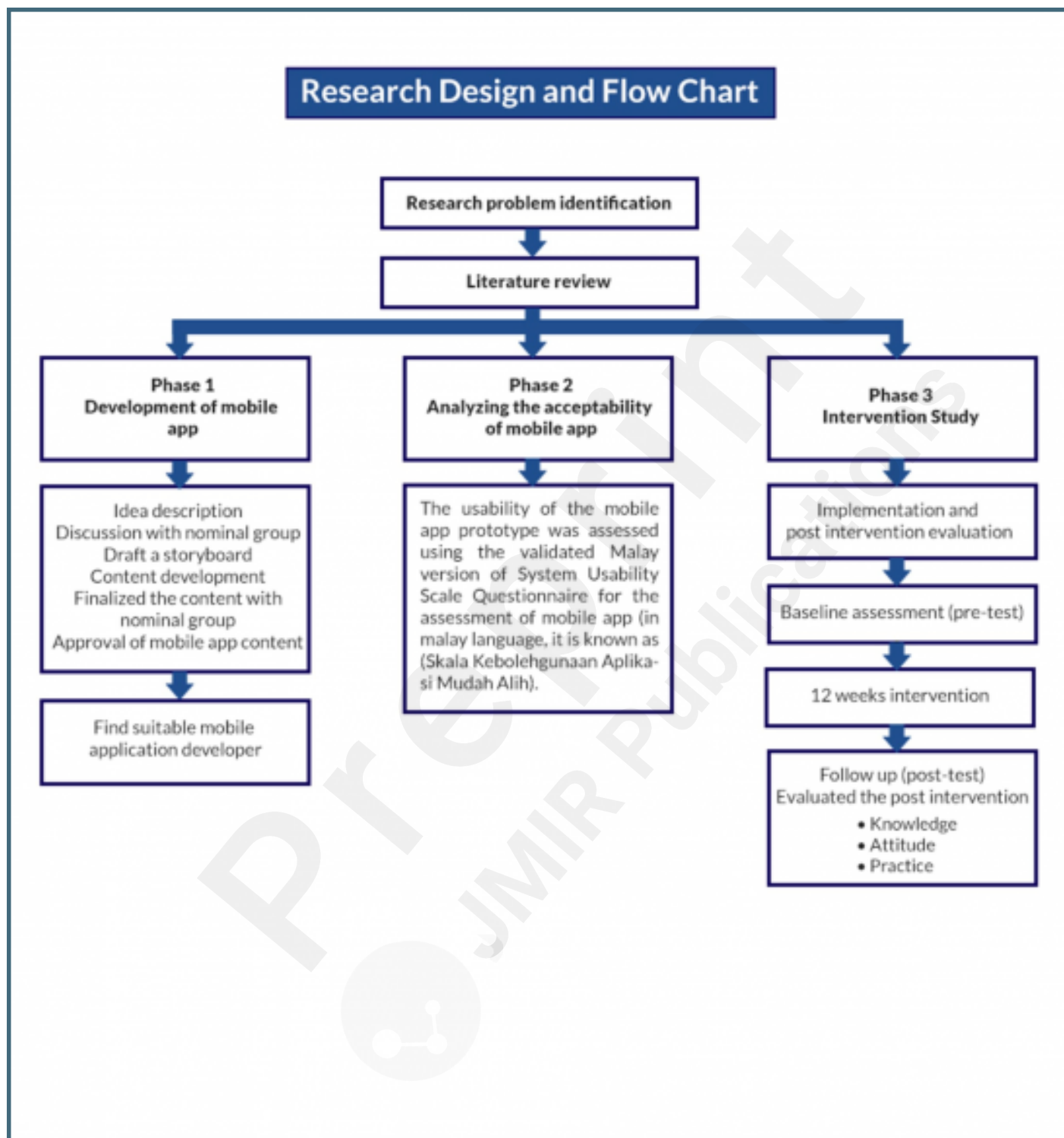
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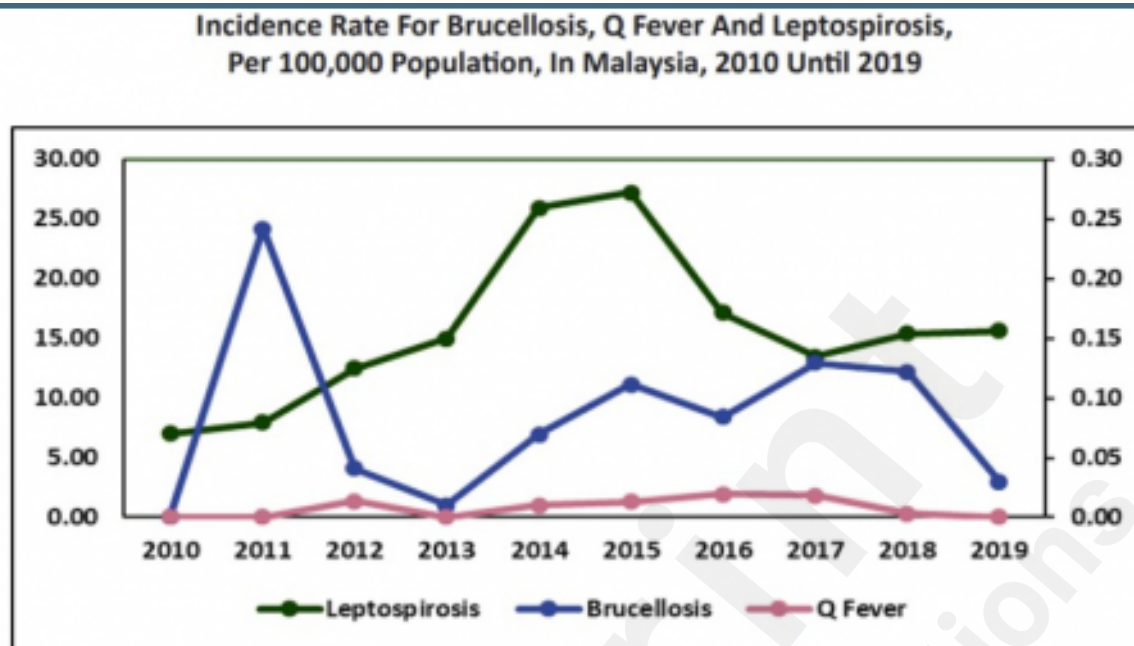


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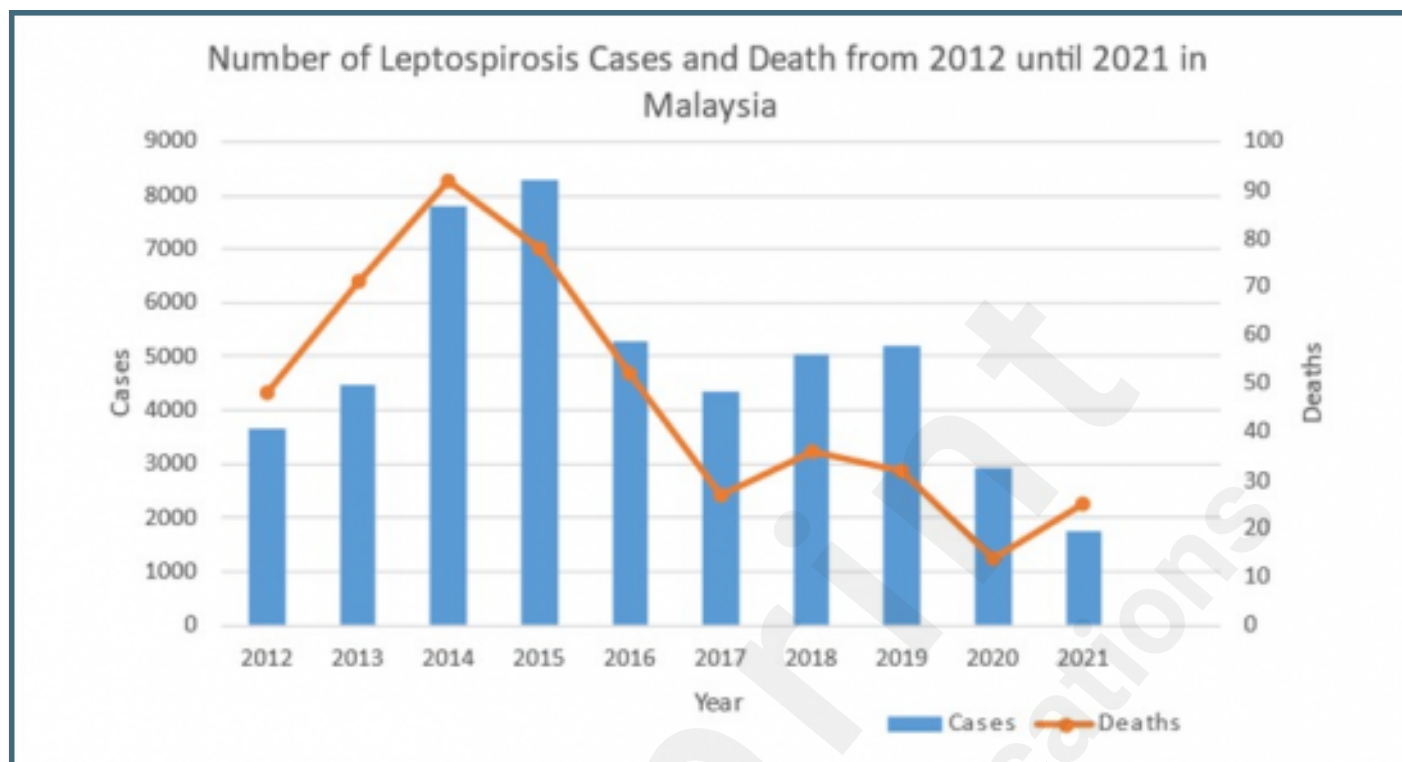
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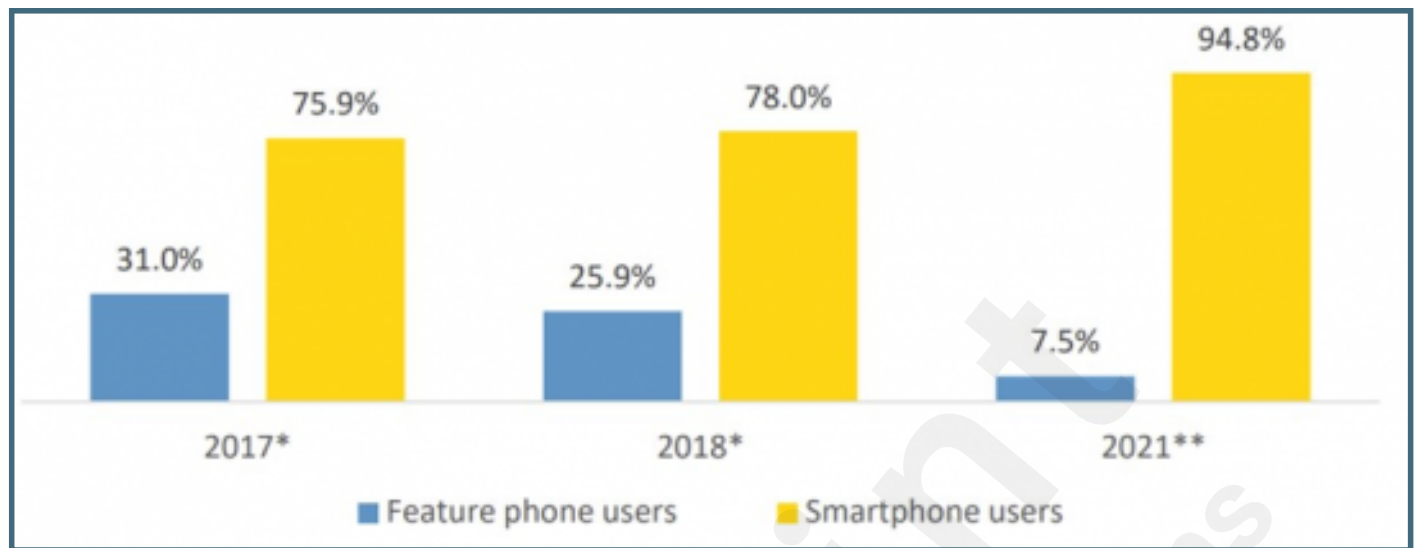


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