




Effectiveness of a concise malaria training program on knowledge, attitudes and practices among patent medicine vendors: A study protocol

Yahaya Mohammed Katagum^{1*} and Halima Oge Katagum²

¹Department of Clinical Pharmacy and Pharmacy Administration, Faculty of Pharmaceutical Sciences, Bauchi State University, Gadua, Nigeria.

²Department of Community Health and Primary Care, College of Medicine, University of Lagos, Lagos, Nigeria.

*Correspondence: mkyahaya@basug.edu.ng, +2348036064563

Abstract	Article History
<p>Despite several regional and global containment efforts by various government and non-governmental agencies, malaria still continues to ravage populations. Most notable is Africa, which accounts for 90% of the global cases and corresponding estimated total deaths. High mortality and morbidity have been associated with a shortage of health manpower, with the disease having overburdened the health systems. Patent Medicine Vendors (PMVs) are common sources of over-the-counter medicines and services throughout sub-Saharan Africa, thanks to their already established close-to-client infrastructure. Many people patronize PMVs as an alternative to formal health institutions. However, various literature has shown evidence that the knowledge, attitudes, and practices (KAP) of PMVs are grossly poor and insufficient to qualify them to fill the manpower gaps. The aim of this paper is to outline the study protocol of a trial to test the efficacy of malaria knowledge, attitude, and practice training among PMVs. A single blinded, randomized, controlled community trial was conducted at Yobe South Senatorial District among 292 respondent PMVs by comparing an intervention to a placebo-controlled arm. Four assessments were performed using self-administered questionnaires. The primary outcome measured was an expected increase in KAP at follow-up assessments compared to baseline assessments. Analysis of the data was conducted using SPSS version 26. The study tested the efficacy of a randomized controlled trial on malaria KAP involving various health promotion methods. It is hoped that the developed module will offer effective training that could serve as a model to reduce the scourge of malaria in all of sub-Saharan Africa.</p>	<p>Received: 23/08/2022 Accepted: 09/09/2022 Published: 10/09/2022</p> <p>Keywords Patent-Medicine-Vendors; Knowledge; Attitudes; Practices; Malaria Intervention</p> <p>License: CC BY 4.0*</p>  <p>Open Access Article</p>
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1.0 Introduction

Malaria has been considered a global public health and development challenge over the years, and approximately 40% of the world's population, who mostly live in the poorest countries, are at a great risk. Malaria is found throughout the tropical and sub-tropical regions of the world and it causes severe loss of lives and devastation to the economies of the affected communities (Akuse *et al.*, 2010; Abasiattai

et al., 2009). Malaria still remains a public health issue in Sub-Saharan Africa and other parts of the developing world (WHO, 2021; Gay-Andrieu *et al.*, 2005; Pluess *et al.*, 2009), but it is also preventable, treatable, and curable (Yahaya, Hayati, and Faisal, 2017; Sachs and Malaney, 2002), despite a rise in malaria-related cases and deaths in 2020 over the previous year (WHO, 2021).

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Nigeria's geographic location provides a climate conducive to malaria transmission throughout the country and all year round, resulting in the high risk experienced. As a result of this, the country thereby bears up to 25 percent of the malarial disease burden in Africa, which resulted in an overburdening influence on the already-weakened health system, leading to nearly 110 million clinical cases of malaria being diagnosed each year and contributing up to 60 percent of outpatient visits and 30 percent of hospital admissions in the country (NMIS, 2012). The high mortality and morbidity rates due to persistent malaria infection thereby become more difficult to handle primarily due to the shortage of trained health professionals to cover the country's huge population (NMIS, 2010), a situation which urged the WHO and the Nigerian government to empower Patent Medicine Vendors (PMVs) to partake in the fight against malaria (FMH, 2006), hence giving legitimacy to the involvement of PMVs in the treatment of malaria.

PMVs are important, usually informal community-based providers of health care (Okonkwo and Okonkwo, 2010; Aniebue *et al.*, 2010). Many developing countries recognize their role and contribution to ensuring equitable access by the population of essential drugs, and thereby permit them to sell certain over-the-counter (OTC) drugs which includes anti-malaria drugs, and other drugs for treatment of common ailments (Prach *et al.*, 2015; FMH, 2003; Goodman *et al.*, 2007). The activities of PMVs, though poorly regulated and poorly understood (Oyeyemi *et al.*, 2020; Beyeler *et al.*, 2015; FHS, 2007), are usually monitored by some agencies of government (Goodman *et al.*, 2007; Amin and Snow, 2005). In Nigeria, the Pharmacists Council of Nigeria (PCN) regulates PMVs' activities as established in Pharmacy Council of Nigeria Decree 91 of 1992 (PCN, 2022). The PCN usually specifies eligibility criteria for the operation as a PMV and stipulates licensing requirements and gives guidelines for operators to follow (Oyeyemi *et al.*, 2014; PCN, 2022). The PCN thus regulates the activities of PMVs, while drug registration and regulation are within the purview of the National Agency for Food and Drug Administration and Control (NAFDAC) (Oyeyemi *et al.*, 2014; FMH, 2003).

However, a closer look at PMV dealings and a thorough systematic assessment of the quality of their performance are actually necessary if their role is to be contained within the health system (Berendes *et al.*, 2012). Deficiencies in proper knowledge, attitudes, and practices are the major challenges that have been widely found to characterize the operations of PMVs (Oyeyemi *et al.*, 2020; Akuse *et al.*, 2010; Buabeng *et al.*, 2010; Abuya *et al.*, 2010; Okeke and Uzochukwu, 2009; Livinus *et al.*, 2009). PMVs were reported to practice carelessly, and only less than half of the

PMVs surveyed (41.3%) by Oladepo (2011) were aware of a change in policy regarding the first-line drugs for malaria from chloroquine to the ACT range of antimalarials, and only about 8.5% had the recommended first-line drug in their shops (Oladepo, 2011). Deficiencies in KAP of PMVs could lead to far-reaching consequences such as misdiagnosis, over- and under-treatment with drugs, delayed referrals, and the increased risk of disease progression, toxicity, and the development of drug resistance (Okeke *et al.*, 2006; Goodman *et al.*, 2007). These deficiencies are enough to pose a threat to the PMV's envisaged potential in malaria control as projected by the WHO through the Nigerian government.

Across Africa, it is a fact that millions of people still lack access to the knowledge, skills, and tools they need to prevent and treat malaria (WHO, 2016). Additionally, 60% of the total population in Nigeria prefers consulting PMVs whenever a health problem resembling malaria arises (Okeke and Okeibunor, 2010). The best way forward as to achieving appropriate and effective malaria treatment and prevention accessible to both the urban and especially the rural populace is the organization of comprehensive training sessions for the entire PMV population with regards to their KAP on malaria, so that appropriate knowledge, attitudes, and practices will be attained for the benefit of the entire communities that depend on them for regular treatment. This could be achieved through this intervention that will empower PMVs as a strategy for reaching the bulk of the population. It is therefore the aim of this trial to test the effectiveness of a developed training intervention module to be used in training PMVs on malaria treatment and prevention.

2.0 Research Objectives

2.1 Main Objectives

- To develop, implement and determine the effectiveness of a malaria treatment and prevention training program on knowledge, attitudes and practices among Patent Medicine Vendors in Yobe-South senatorial district, Nigeria.

2.2 Specific Objectives

- To determine the socio-demographic characteristics, the working experience, and the previous training experience of respondent PMVs.
- To determine the knowledge, attitudes, and practices of respondent PMVs on malaria treatment and prevention at baseline.
- To determine the relationship between knowledge, attitudes, and practices of respondent PMVs and their socio-demographic characteristics, working experiences, and previous training experiences.

- To develop a training module and program aimed at improving the knowledge, attitudes, and practices of the PMVs on treatment and prevention of malaria.
- To carry out the malaria education program on the respondents
- To determine the differences in knowledge, attitudes, and practices of respondents within and between the intervention and the wait-list groups at baseline, immediately after the intervention, at three months, and at six months post-intervention.

3.0 Materials and Methods

3.1 Study Design

A two-arm, parallel, single-blind randomized controlled community trial was planned to evaluate the efficacy of a developed educational intervention module on malaria treatment and prevention among PMVs in the study district. This was compared to a placebo-effected control (waitlist) arm from different local councils within the study district. A pre- and post-test, measured at baseline, immediately, 3-months, and 6-months post-intervention, will be used to assess the effectiveness of the program. In order to fulfill the eligibility criteria, PMVs registered with the local association and residents and practitioners within the study district were recruited, and consents to participate in the study were signed.

3.2 Study Setting and Population

The study location, Yobe-South Senatorial District, is largely rural in nature with high commercial and PMV activity all year round. The district consists of four local government councils. PMVs within the district have a registered local association that they belong to, and within the PMV members exist varying characteristics, ranging from members with wide age groups, genders, educational backgrounds, working experiences, training experiences, and some from different job careers not related to the practice.

3.3 Randomization and Allocation Concealment

A simple random sampling technique is used to randomly assign the four local government councils within the study district in a group randomization to form the intervention and wait-list groups, respectively, while a systematic random sampling method is applied to select the participants into the two groups. The assignment of the four local councils to form the intervention and wait-list groups was kept from all the participants. Additionally, all four local councils have short traveling distances between them, a situation that makes contamination minimal in the study.

3.4 Sample size calculation

The randomized control trial formula described by Rosner (2010) is used to calculate the appropriate sample size of participants for each of the two groups, as shown below:

$$N1 = [Z\alpha \sqrt{pq} (1+1/k) + Z\beta \sqrt{p1 q1 + p2 q2 /k}]^2 / \Delta^2$$

(Rosner, 2010).

An additional 30% of samples are to be added to the sample size obtained to cover attrition rates due to estimated loss considered at follow-ups during three- and six-month post-intervention assessments (Mary *et al.*, 2013). This gives a total figure of 292 respondents, with 146 each for the intervention and wait-list groups.

3.5 Procedure

All the selected PMVs were invited to participate in the study, and a meeting was scheduled between the research team and the selected PMVs at separate instances through their association officials where consent forms were filled out and a schedule of training was agreed upon. The malaria training was then conducted for the intervention arm, and a placebo-effected training was concurrently conducted for the wait-list arm, as seen in the flow chart of the study (Figure 1).

3.6 Intervention/Training Module

The developed training program consists of five modules spread within five days of training at two and a half hours per day. The training module was aimed at improving PMVs' knowledge, attitudes, and practices towards malaria, its treatment, and its prevention, and this was conceptualized via the information motivation and behavioral skills (IMB) model. The training's informational constructs provided behavior-specific and disease-specific information about malaria infection via posters, pamphlets, and lectures via power point presentations, group discussions, and demonstration exercises. Activities that encourage personal and collective motivations could help to develop a positive attitude and feelings in respondents regarding their attitudinal changes that relate to malaria. Motivational interviewing techniques, social motivation, and empathy sessions were strategically used, as were group discussions, dramas, working through case studies together, and the facilitator's or respondent's participation in role plays. On the behavioral construct aspect, objective skills, perceived self-efficacy, drama presentations, and a teach-back behavior strategy were used to impact behavioral changes on respondent PMVs. It was believed that all these theorist strategies have produced an outstanding improvement in the outcome measure immediately, three months later, and six months later as compared to the baseline or wait-list group that has not been impacted by the training. The module was developed in English and was meant to be systematically delivered by the facilitators and monitored by the researchers. At precisely three months after the training, a booster session was organized and delivered to the intervention group. This session is meant to reinforce the knowledge gained on the training days and to improve the participant's motivation for the envisaged impact.

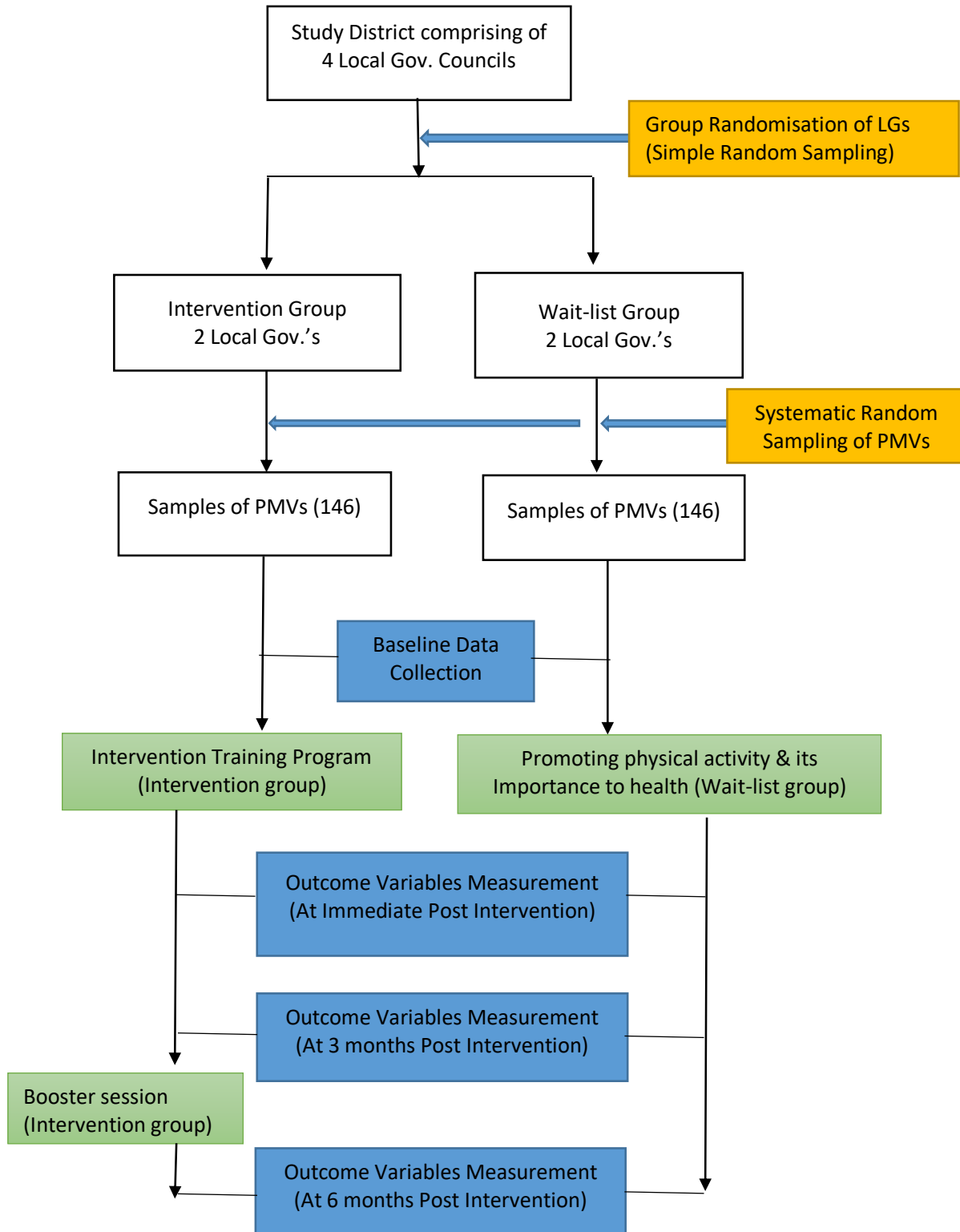


Figure 1: Flow Chart of the Study

The additional booster session helped to re-direct individuals with peculiar needs and further solve problems or issues that may arise during practice within the three months post-intervention. During the content validity testing, a team of experts determined that the contents of the intervention module were commensurate with the standards of the PMV respondents.

3.7 Intervention delivery

The training has been conducted in the local council (LC) secretariat offices of each of the four LCs. The training was done by two malariologists who had earlier studied the modules. Four sub-groups of 36 and 37 PMVs each were formed out of the intervention group (146); this serves to have smaller groups convenient for learning and interaction. By this arrangement, each of the two LCs in the intervention group has two sub-groups.

The booster session was organized after three months of the intervention, and participants from the intervention group attended the two-and-a-half-hour session to review the training, reinforce learning and behavior, and also to discuss problems encountered in real-life practice within the period. The booster session was similar in content to the original training.

3.8 Wait-list arm training

The Wait-list group received a two-session lecture on malaria epidemiology, promoting physical activity, and the importance of physical activity in improving health. This was delivered by two facilitators, one of whom is an expert in the field of physical and health education in a public school. The lecture was based on an already developed module recommended by the World Health Organization, and it was given in parallel to the intervention group lecture. However, the wait-list groups had the malaria training program after all the assessments had been conducted at the end of the study, so as not to deny their local communities the benefits of the intervention.

3.9 Assessment of Respondents

To determine the knowledge pertaining to malaria treatment and prevention, twenty-six questions were provided. The questions were answered: true or false. A correct answer had a score of one mark, and no mark was awarded for an incorrect answer. The participants were classified as having good knowledge of malaria if they answered half of the questions correctly. Conversely, twenty-two questions were used to measure respondent's attitudes on malaria, but here, a 5-point Likert scale ranging from "truly disagree" to "truly agree" was used to assess the respondents. On the attitude questions, marks were given from 5 to 1, and the sum of the total scores was calculated. Furthermore, the practices of respondents were assessed by twenty-four questions, and the questions were answered yes or no. In addition, each question was awarded a mark for a correct answer, and based

on the twenty-four questions, the total score was calculated. The researcher and study assistants also conduct the three and six month follow up assessment using same questionnaires to both arms of the study.

4.0 Data Analysis

The data was entered into SPSS statistical package version 26.0. The categorical variables including gender, age group, level of education, training as PMV, training on malaria, and training on ACTs were described using frequencies and proportions. The quantitative variables (malaria knowledge scores, malaria attitude scores, and malaria practice scores) were subjected to a test for normality and were summarized using means and standard deviations. The outcome variables were then assessed for violations of the assumptions of ANOVA, including the normality test, the sphericity test, and the homogeneity of variances test, and the correlation matrix was computed.

Associating between socio-demographic variables, working experience, and training experience was assessed by a chi-square test, and the group equivalences between the intervention and the control group variables were tested at baseline for all the categorical variables; a t-test was used to test for all continuous variables.

The primary tools for the analysis were the paired samples t-test, the one-way ANOVA, and the mixed-design ANOVA. A paired samples t-test was run to compare groups separately at baseline, immediately post-intervention, three months, and six months post-intervention within the intervention group and then within the wait-list group, while a one-way ANOVA was used to compare the differences in means of the two groups at the various levels of assessments, the baseline levels, immediately post-intervention, 3-months post-intervention, and 6-month post-intervention. Finally, a split-plot (mixed-design) ANOVA was used to investigate the main effect of group, time, and group x time interactions.

5.0 Outcomes

5.1 Primary outcomes

The expected immediate outcomes of this study were a significant improvement in good knowledge, positive attitudes, and good practices regarding malaria treatment and prevention among respondent PMVs in the intervention group at the end of the training program. The primary outcome was assessed at immediate postintervention, three months, and six months postintervention.

5.2 Secondary outcomes

There was a direct benefit to the study communities in the form of improved malaria treatment and prevention, which had a positive impact on the high mortality and morbidity rates for the over one million

people residents within the study location who suffer direct consequences of poor PMV's KAP. Furthermore, the study provided information on the level of KAP of PMVs within the study location, giving an indication of the extent to which standard practices are employed or not. Furthermore, the developed module and study program served as a source of information on malaria to other PMVs, other healthcare professionals, and organized training programs.

6.0 Discussion

The study was a description and the design of a randomized controlled trial regarding the efficacy of a malaria training to increase the knowledge, attitudes and practices among selected PMVs within the study location.

The realization of the fact that participants lack proper and adequate KAP in malaria basic knowledge, its diagnosis, referrals, treatment and prevention, and also lacking is the motivational zeal to practice appropriately. This realization greatly underscores the need for the training and also the need to imbibe the contents of the training in a manner that participants will find worthy of giving full attention, good attendance, and a maximum zeal to learn from the developed training module. Consideration is also given to the fact that PMV membership spans a group of people with very diverse socio-demographic factors such as highly contrasting age groups, educational levels, background professions, and a total lack of training in some cases. These reasons informed the decision to develop a training based on the IMB theory, where, in addition to the knowledge and skills to be imparted, participants will be greatly motivated to act according to the government-approved guidelines. This is the first documented controlled trial testing the efficacy of malaria intervention among PMVs that involves the use of this theoretical approach in the training of participants.

This training program will further equip the PMVs to face the challenges ahead in their new role of assisting in the war against malaria as outlined by the WHO and implemented by the various affected governments. In the long run, the PMVs are expected to impact the cases of morbidity and mortality recorded within the study location and thereby contribute towards scaling up the burden within the sub-region.

7.0 Conclusion

Given that the malaria intervention training was effective, and provided a simple, attractive, and cost-effective model using the IMB theory to increase the knowledge, attitude and practice of PMVs on malaria and also provided an avenue to reduce the devastations due to malaria in the study location which will impact on the mortality and morbidity rates in Nigeria and

globally. Furthermore, the program could be easily disseminated through PMV associations or upheld as a format by regulatory government agencies to train PMVs and other healthcare professionals nationwide. In addition, its contents could be disseminated during national prevention campaigns, and internationally it could be useful to other endemic countries.

Declarations

Ethics approval and consent to participate

Not Applicable

Consent for publication

All authors have read and consented to the submission of the manuscript.

Availability of data and material

Not Applicable.

Competing interests

All authors declare no competing interests.

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