THE FORMULATION OF LACTOGENIC BANANA FLOWER BISCUITS (*MUSA X PARADISIACA ABB*) AND ITS EFFICACY TOWARDS EXPRESSED BREASTMILK OF LACTATING WOMEN

BY

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TABLE OF CONTENTS

LIST OF TABLES

ABSTRACT

Lack of breast milk production is the most frequent cause of breastfeeding failure in babies among lactating women. The uses of natural substances called galactagogue may assist the production of breast milk. Banana flower of plantain named *Musa x paradisiaca* ABB or locally known as *Pisang Abu* or *Pisang Nipah* contains galactagogue property which has been proven its effectiveness in an animal study. However, there is no data on its effectiveness on human yet. The aim of this study was to produce lactogenic biscuits made from banana flower of *Pisang Abu* or *Pisang Nipah* and to investigate the efficacy of the biscuits in increasing milk production within three weeks' consumption among lactating women. There are two phases of study. The first phase; the laboratory based experimental, involved the production process of banana flower into flour and biscuits, the sensory evaluation as well as proximate analysis. The banana flower flour was mixed with the wheat flour at a certain ratio to be prepared. Finally, four biscuits formulation were produced; as BFF30 (30% banana flower flour + 70% wheat flour), BFF40 (40% banana flower flour + 60% wheat flour), BFF50 (50% banana flower flour + 50% wheat flour) and BFF60 (60% banana flower flour + 40% wheat flour). All four formulated biscuits were analysed to determine their proximate nutrients and sensory acceptability. The best formulation was chosen as a prototype for the second phase experiment. In the second phase, a human trial was conducted among lactating working women. A total of 58 mother-infant pairs were assigned into two groups. Group I (n=29) consists of mothers who consumed plain biscuits as placebo while Group II (n=29) consumed the lactogenic biscuits which contained banana flower flour. Expressed breast milk, anthropometric indices of mothers and infants were recorded before and after the consumption of the biscuits. Dietary intake information of the respondents was taken to assess the maternal calories intake. The content of ash and fibre in the formulated biscuits were significantly ($p<0.05$) increased with the increased percentage of banana flower flour used whereby no significance difference ($p>0.05$) in terms of carbohydrate and fat content in all formulations. In terms of sensory evaluation, BFF50was the most acceptable formulation ($p<0.05$) and was chosen as the prototype. In second phase, the volume of expressed breast milk in experimental group (437.5±13.1 mL) after consuming lactogenic biscuits was significantly higher ($p<0.05$) compared to placebo group (377.384±13.1 mL). The secondary outcome which are the index of weight-for-age (6.76 ± 0.87 kg), height-for-age (0.64 ± 0.04 m); and BMI-for-age (16.45 ± 1.52 kg/m^2) in Placebo group were not significantly different ($p>0.05$) compare to weight-for-age (6.81±1.01 kg), height-for-age (0.63 ± 0.04 M) and BMI-for-age (17.15 ± 1.40 kg/m^2) in infants of experimental group after the intervention. In conclusion, the consumption of lactogenic biscuits in lactating mothers help to increase the expressed breast milk without any adverse effect. However, even though the second outcomes were not significantly different to placebo, each anthropometry indices showed that all infants were in normal growth. This study successfully showed that banana flower biscuit can induce the production of expressed breast milk among lactating women.

خلاصةالبحث

يعد نقص إنتاج حليب الثدي السبب الأكثر شيوعًا لفشل عملية الرضاعة في الأطفال بين النساء المرضعات، وقد يساعد استخدام المادة الطبيعية المسماة كالاكتاقوق في إنتاج حليب الثدي. تحتوي زهرة موز الجنة (Musa x paradisiaca ABB) أو المعروفة محليًا باسم موز أبو أو موز نيباه على خاصية الكالاكتاقوق والتي أثبتت فعاليتها في دراسة أجريت على الحيوانات، ولكن لا توجد هناك بيانات عن فعاليتها على الإنسان حتى الآن. ولذا فالهدف من هذه الدراسة هو إنتاج بسكويت لاكتوجيني مصنوع من زهرة موز أبو أو زهرة موز نيباه والتحقق من فعالية البسكويت في زيادة إنتاج الحليب خلال ثلاثة أسابيع من الاستهلاك من قبل النساء المرضعات. تكونت الدراسة من مرحلتين، المرحلة الأولى تضمنت التجارب المخبرية لعملية إنتاج وتحويل زهرة الموز إلى دقيق وبسكويت، والتقييم الحسي، والتحليل التقريبي، وتم خلط دقيق زهرة الموز مع دقيق القمح بنسبة معينة. وفي النهاية تم إنتاج أربعة أنواع من البسكويت وهي: BFF30 (30٪ طحين زهرة الموز + 70٪ دقيق القمح)، BFF40 (40٪ طحين زهرة الموز + 60٪ دقيق القمح)، BFF50 (50٪ طحين زهرة الموز + 50٪ دقيق القمح)، وأخيرا BFF60 (60٪ طحين زهرة الموز + 40٪ دقيق القمح) حيث تم تحليل أنواع البسكويت الأربعة المصنّعة لتحديد مغذياتها التقريبية ومقبوليتها الحسية وتم اختيار الصيغة الأفضل كنموذج أولي للمرحلة الثانية من التجربة. في المرحلة الثانية أجريت تجارب بشرية بين النساء العاملات المرضعات. تم تقسيم 58 زوجًا مكونا من أم ورضيعها إلى مجموعتين. الأمهات في المجموعة الأولى (ن = 29) تناولن البسكويت العادي كعلاج وهمي، بينما الأمهات في المجموعة الثانية (ن = 29) تناولن البسكويت اللاكتوجيني المحتوي على دقيق زهرة الموز، وتم تسجيل كمية حليب الأم المسحوب ومؤشرات القياسات البشرية للأمهات والأطفال قبل وبعد تناول البسكويت في حين تم أخذ معلومات المدخول الغذائي للمشاركات لتقييم تناول السعرات الحرارية للأمهات وزاد محتوى الرماد والألياف في البسكويت المحضر ($P<0.05$) مع زيادة نسبة دقيق زهرة الموز المستخدم، حيث لم يكن هناك فرق ملحوظ ($P<0.05$) من حيث محتوى الكربوهيدرات والدهون في جميع التركيبات. على حسب التقييم الحسي كانت الصيغة BFF50 الأكثر تقبلًا ($P<0.05$) وتم اختيارها كنموذج أولي. في المرحلة الثانية ، كانت كمية حليب الثدي المنتج في المجموعة التجريبية (437.5 ± 13.1 مل) بعد تناول البسكويت اللاكتوجيني أعلى بكثير ($P<0.05$) مقارنة بمجموعة العلاج الوهمي (377.384 ± 13.1 مل). وبناء على ذلك، فالنتائج الثانوية وهي مؤشر الوزن بالنسبة للعمر (6.76 ± 0.87 كجم) والطول مقابل العمر (0.64 ± 0.04 م) ومؤشر كتلة الجسم للعمر (16.45 ± 1.52 كجم / م^2) في حين مجموعة العلاج الوهمي لم تختلف اختلافًا كبيرًا ($P<0.05$)مقارنة بالوزن بالنسبة للعمر (6.81 ± 1.01 كجم) والطول مقابل العمر (0.63 ± 0.04 م) ومؤشر كتلة الجسم للعمر (17.15 ± 1.40 كجم / م^2) عند الرضع في المجموعة التجريبية بعد عملية التدخل. في الختام، اثبت أن استهلاك البسكويت اللاكتوجيني لدى الأمهات المرضعات قد ساعد على زيادة حليب الثدي المنتج دون أي آثار سلبية وعلى الرغم من أن النتائج الثانوية لم تكن مختلفة بشكل كبير عن نتائج العلاج الوهمي فإن كل مؤشرات القياسات البشرية أظهرت أن الرضع كانوا في نمو طبيعي وأظهرت هذه الدراسة بنجاح أنه بإمكان بسكويت زهرة الموز أن يحفز إنتاج حليب الثدي المنتج بين النساء المرضعات.

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APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a thesis for the degree of Master of Health Sciences.

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DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

Zahariah bt Mohd Nordin

Signature ..... Date .....

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LIST OF FIGURES

LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
ANCOVA	Analysis of Co-Variance
BFF	Banana Flower Flour
BMI	Body Mass Index
FAO	Food and Agriculture Organisation
GH	Growth Hormone
LFPR	Labour of Female Participation Rate
MANS	Malaysian Adult Nutrient Survey
NHMS	National Health Morbidity Survey
PRL	Prolactin
RNI	Recommended Nutrient Intake
TRH	Thyrotropin Releasing Hormone
WHO	World Health Organisation
ABB	Genomic Group of Plantain
AAP	American Academy of Paediatrics

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND OF THE STUDY

Breastfeeding provides the best food for infants and cannot be denied as an optimal way of feeding a baby. According to a statement from the World Health Organisation (WHO), breastfeeding is a preventive intervention on mortality among children below the age of five years, especially in developing and undeveloped countries. WHO recommends mothers worldwide to exclusively breastfeed their infants for the first six months to achieve optimal growth, development, and health. Thereafter, they should be given nutritious complementary foods and continue breastfeeding up to the age of two years or beyond (WHO, 2011). In 2012, WHO held the World Health Assembly Resolution 65.6, whereby a comprehensive implementation plan on maternal, infant and young child nutrition was endorsed. There are six global nutrition targets for the year of 2025 which specifically highlight the increment of rate of exclusive breastfeeding in the first 6 months up to at least 50% (WHO/UNICEF, 2014). However, only 38% of infants aged up to six months were exclusively breastfed globally (WHO, 2013). Whereby in Malaysia, referring to National Health Morbidity Survey in 2016 (NHMS 2016), it was reported that only 47.1% of infants up to the age of six months were exclusively breastfed (Aris *et al*., 2016).

The workforce in public and private sector in Malaysia were mostly consists of women. According to the statistic by Employment and Labour Department, Ministry of Human Resources, Malaysia, there were 2.7 million out of 6.7 million (39%) are women employees in the reproductive age (15 to 39 years) (Kementerian Sumber Manusia, 2012). They are subjected to Circular No. 14 of 2010 Maternity Leave Public Service

Employees Government of Malaysia or the Employment Act 1955 (Act 265), which provide paid maternity leave for 60 days, depending on the employment sector whether public or private. Related to that, a study done in Selangor found that, 51% of employed mothers were not breastfeeding their children (Amin et al., 2011). The statement was also supported by NHMS 2016 report (Jai *et al*., 2016) which stated that only 46% of working women in public sectors succeeded in breastfeeding their infants exclusively up to six months.

Besides that, a study about health-related behaviours done in United States of America (USA), quoted that returning to work had been one of the underlying factors which contribute to mother's decision to discontinue breastfeeding (Bai, Middlestadt, Peng, & Fly, 2009). Most working women discontinued breastfeeding upon returning to work because of physiological, psychological as well as social factors (Win, Binns, Zhao, Scott, & Oddy, 2006). The most common reason for breastfeeding discontinuation among women is insufficient or low milk supply which related to physiological and psychological factors (Rozga, Kerver, & Olson, 2015).The discontinuation of breastfeeding among lactating women might get even worst with the perception of inadequate supply which lead them to the use of formula milk (Hernández & Vásquez, 2010).

Insufficient supply of breast milk can happen due to several factors such as infrequent milk removal, deficient mammary gland tissue and maternal hormone imbalances. Therefore, lactating women should practice breast milk expression during confinement to encourage continuous milk production in preparation to return to work. The three months postnatal period was the time that breast milk expression should be more frequent as to maintain adequate milk production (Slusser, Lange, Dickson, Hawkes, & Cohen, 2004). In addition to physiological factors such as the frequency of

breast milk expression external factors such as consuming of galactagogue also have an impact on breast milk production. Lactating women experiencing breast milk supply problem found that complementary or alternative food or medicine interventions is beneficial for increasing milk supply (Demirci, Bare, Cohen, & Bogen, 2016). In other words, the study demonstrated the importance of galactagogue supplement in improving breast milk supply. A galactagogue in the form of banana flower biscuits may support the achievement of 70% targeted exclusive breastfeeding rates among lactating mothers for more than 6 months (Razak, & Divisions, 2016).

1.2 PROBLEM STATEMENT

Almost 38% of the work sector comprise of women, either mothers or future mothers. As discussed earlier, breast milk is the best food for infants. The Ministry of Health Malaysia has implemented a breastfeeding policy to encourage all mothers to breastfeed their child during the first six months. This is to ensure that their infants are at optimal health level. By helping mothers who contribute to 38% of workers in Malaysia, the targeted 70% women in Malaysia to fully breastfeed until six months can be achieved. When the rate of exclusive breastfeeding is increased significantly in Malaysia, it will also indirectly improve the health status of our children. However, there is a high rate of breastfeeding discontinuation among working mothers as they start to work. Since they are unable to breastfeed their child directly, milk expression is a strategy to help them to continue breastfeeding and provide precious of breast milk to their infants. They also face a problem in ensuring that the volume of expressed breast milk was enough to meet the daily requirements of the baby. Many studies stated that galactagogue is among the alternatives to assist milk production and is also the preferred choice among women.

Currently, there are no natural milk boosters of plants or herbs origin produced locally in the forms of ready to use food in the Malaysian market.

In addition, most lactating women preferred natural products rather than pharmaceutical ones due to the side effects concerned. Thus, this research is aimed towards the use of banana flower of Musa x *Paradisiaca* ABB or *pisang Abu/Nipah* as a galactagogue, whereby the consumption is facilitated by making them into biscuits. Previously, there were no data which supports its efficacy as a natural milk booster, except for a study on rats. A study on galactagogue effects of *Musa x paradisiaca* ABB flower extract on lactating rats proved that it helps in increasing milk production(Mahmood, Omar, & Ngah, 2012). Based on this, it is expected that the formulated products of *Musa x paradisiaca* ABB flower will also give the same effect as well.

1.3 PURPOSE OF THE STUDY

The flower of banana plantain has been used for generations in the Malay community to help lactating women who experienced low breast milk production. Therefore, to overcome the problem of low milk production among lactating women, this research focused on mammary glands tissue functions, by using galactagogues. This study is conducted to provide local and natural galactagogue as an alternative for lactating women to augment expressed breast milk production and supply, instead of using drugs as a milk booster. Banana flower is known to provide macronutrients functional, and fibre as an alternative in management of insufficient breast milk among lactating working women and is also a contributing factor in improving their health. Besides that, the output that would be expected from this research is the utilisation of local galactagogue product from banana flower. At present, there are several products

available in the market, which claim to boost breast milk production. Most of the products are sold in the form of nutritional supplement, which are not originally local herbs or plants origin. Despite, the fact that banana flower was proven as a galactagogue, only a few lactating women can accept its astringent taste. Therefore, to solve this, the banana flower should be prepared in a simple form, tasty and ready to eat. Developing a preserved product from the banana flower would eliminate such difficulties and offer benefits such as prolonged shelf life and convenient preparation, hence biscuits are the best choice. A study on food consumption pattern among Malaysian adults in 2003 found out that biscuits were one of the top ten food items consumed daily by this group (Norimah *et al*., 2008)**.** There is an increasing trend in the consumption of convenience food, which is ready-made such as bread, biscuits, and cakes in Malaysia. It could be inferred that biscuits are among the popular food item in Malaysia. Some of the reasons for such popularity are affordable cost compared to other processed foods, availability in different flavours, readiness to eat, storage and longer shelf life (Hooda & Jood, 2005). Apart from that, working women in Malaysia have a busy lifestyle, thus biscuits constitute a food that can be consumed anywhere and anytime without too much hassle. Nowadays, public awareness on health issues has led Malaysians to become more concerned about healthier food. In response to this awareness and demands, biscuits made from banana flower were selected as foodstuff in this study to find out the effect of galactagogue. By producing lactogenic biscuits from *Musa x paradisiaca* flower, it will not only benefit our lactating mothers, but also plantain farmers increasing their profit.

1.4 RESEARCH OBJECTIVES

1.4.1 General Objective

The general objective of this study is to investigate the potential of banana flower as a galactagogue in the form of biscuits which could help augmenting the production of expressed breast milk among lactating women.

1.4.2 Specific Objectives

The specific objectives are:

1. To formulate lactogenic biscuits from banana flower (*Musa x paradisiaca* ABB flower).
2. To assess the acceptability of lactogenic biscuits and to choose the best formulation by sensory evaluation.
3. To evaluate the proximate analysis of four different formulations of lactogenic biscuits.
4. To assess the effectiveness of formulated lactogenic biscuits on breast milk production among lactating working women.

1.5 RESEARCH HYPOTHESES

The null hypotheses and their alternatives are:

i. H_o1 = There is no significant difference ($P<0.05$) of mean values for each acceptability criteria of the four bananas (Musa *x paradisiaca* ABB) flower biscuit formulations.

   H_a1= There is at least one significant difference ($P<0.05$) of mean values for each acceptability criteria of the four bananas (Musa *x paradisiaca* ABB) flower biscuit formulations.

ii. H_o2 = There is no significant difference ($P<0.05$) of mean values for each physicochemical property of the four banana (*Musa x paradisiaca* ABB) flower biscuit formulations.

H_a2= There is at least one significant difference ($P<0.05$) of mean values for each physicochemical property of the four banana (Musa *x paradisiaca*) flower biscuit formulations.

iii. H_o3 = There is no significant differences ($P<0.05$) of mean amount of breastmilk production which influenced by lactogenic biscuit as compared to the influence by other lactogenic products.

H_a3= There is at least one significant difference ($P<0.05$) of mean amount of breastmilk production which influenced by lactogenic biscuit as compared to the placebo influence.

iv. H_o4 = There is no significant difference ($P<0.05$) of mean weight, height, and BMI for age of infants in experimental group compared to placebo group.

H_a4 = There is at least one significant difference ($P<0.05$) of mean weight, height, and BMI for age of infants in experimental group compare to placebo group.

1.6 SIGNIFICANCE OF STUDY

There has never been a study on banana flower to support its effectiveness in augmenting breast milk among lactating women except a research previously done on lactating rats by Mahmood *et al*., (2012). It should be strongly proposed to be tested on lactating working women because of high percentage breastfeeding discontinuation among them due to insufficient of breast milk. In addition, enhanced expressed breast milk production among lactating working women is an alternative way to increase the

prevalence of exclusive breastfeeding until six months and up to two years. It is in line with the suggestion by Ministry of Health in Malaysia and WHO to encourage the practice of exclusive breastfeeding. Besides that, this study gives an alternative to increase production of breast milk instead of using drugs which also had side effects to women's health (Havnen, Smestad Paulsen, & Nordeng, 2004). Consequently, the health status of our children could improve and benefit the country from the economical context by reducing the cost of ailment treatment with the said being done

1.7 CHAPTER SUMMARY

This chapter presented and discussed the background of the study. It explained the importance of breastfeeding to human and its impact to the nation in terms of economics and social. In this study, the highlighted concern was given to career women who also contribute to the development of a country and at the same time were breastfeeding their babies. The main obstacle is to continue breastfeeding for up to six months; otherwise these working mothers should opt for formula feeding. The Malaysian government under the Ministry of Health had setup a breastfeeding policy to promote the implementation of breastfeeding programs throughout the country. In this regard, human physiological and emotional factors play important roles in ensuring the continuity of breastfeeding for up to two years. The proposed approach was through the usage of plant galactagogue. Hence, this study was aimed at assessing the efficacy of galactagogue plants, the banana flower which may have the potential to increase breast milk production. The significance of the study highlighted how this study fills the gap in research literature on the usage of plant galactagogue.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

The study aims to recognize the role of banana flower as a galactagogue that helps women who practice breastfeeding. The subjects to be discussed are the speciality of breast milk, feeding physiology and the current situation of breastfeeding practices. Several literature reviews address the association of breastfeeding and galactagogue in terms of definition and explanation. The selection of banana flower of *Musa x paradisiaca* ABB as a study material and followed by its modifications to a more convenient form during the study also being explained clearly.

2.2 UNIQUENESS OF BREASTMILK

UNICEF and WHO (WHO 2001) recommend that infants should be exclusively breastfed for the first six months of life which means that they should be only fed with breastmilk and no other liquids added including water or food. Similarly, The American Academy of Paediatrics (AAP), also recommended that exclusive breastfeeding during the first six months of life and continuation of breastfeeding for the second 6 months as optimum nutrition in infancy(Ackerman, 2011). Based on the statement, it can be concluded that, exclusive breastfeeding to the age of six months is the most important and protective way to decrease the risk of infectious diseases and reduce mortality in infancy. Research from developing and less developing countries proved that undernutrition, including retarded foetal growth, stunting, wasting, deficiencies of vitamin and mineral along with suboptimum breastfeeding resulted in an increased risk for mortality in the first two years of life. These problems had caused 3.1 million child deaths annually or 45% of all child deaths in 2011.

Consistently with the results of random effect meta-analyses of eighteen studies which revealed that, without breastfeeding practices would resulted in a high risk of diarrhoea mortality compared to exclusive breastfeeding among infants 0-5 months of age (Lamberti, Fischer Walker, Noiman, Victora, & Black, 2011). On top of that, the most important thing is, breast milk could save the lives of infants and children, especially caused by neonatal disease such as pneumonia and diarrhoea. As it is known, diarrhoea is the most infectious disease determinant in mortality among infants, where it could be prevented by breastfeeding. It was stated that, 63% of deaths of children under five years old could be overcome, if 90% of the infants were given breast milk exclusively for six months to eleven months(Coutinho, De Lira, De Carvalho Lima, & Ashworth, 2005). Therefore, the speciality of breast milk is highlighted, as the content of it, was the first immunization to all babies. It is because of the unique characteristic, consists of bound components which are immunology factors, enzymes, growth factors and anti-inflammatory agent(Field, 2005).

However, the replacement of breast milk by formula milk still could not prevail the advantages of it in terms of the impact to the health. Generally, the protein content in human milk which is approximately 70% whey and 30% casein, compare to bovine milk which is 18% whey and 82% casein, makes the breast milk easily digests and facilitate absorption and utilization (Picciano, 2001). In addition, component of whey protein consists of alpha-lactalbumin, lactoferrin, lysozyme, and secretory immunoglobulin *A* plays an important role in host defence, that could be excreted in human milk when exposed to foreign antigens (Ackerman, 2011). All these bioactive components improve immunity system development and cognitive as well as growth development. Cohort studies done on exclusive breastfeeding babies provide strong