

**THE EFFECTIVENESS OF WRITTEN
ASTHMA ACTION PLAN ON ASTHMA
CONTROL AND QUALITY OF LIFE AMONG
PAEDIATRIC ASTHMATIC PATIENTS**

BY:

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ABBREVIATIONS

ACQ – Asthma Control Questionnaire

ANOVA – Analysis of Variance

GINA - Global Initiative for Asthma

HSNZ – Hospital Sultanah Nur Zahirah, Kuala Terengganu

MDI – Metered dose inhaler

PAQLQ – Paediatric Asthma Quality of Life Questionnaire

PEFR – Peak Expiratory Flow Rate

QoL – Quality of Life

RM ANOVA – Repeated measure analysis of variance

SPSS – Statistical Package for Social Sciences

USA – United States of America

WAAP – Written Asthma Action Plan

ABSTRAK

KEBERKESANAN PELAN TINDAKAN ASMA BERTULIS TERHADAP KAWALAN ASMA DAN KUALITI HIDUP DI KALANGAN KANAK-KANAK YANG MEMPUNYAI ASMA

Latar belakang kajian: Bronkial asma adalah penyakit kronik yang menjejaskan penduduk di seluruh dunia termasuk kanak-kanak. Matlamat pengurusan penyakit asma di kalangan kanak-kanak adalah untuk mencapai kawalan asma yang baik supaya mereka dapat menjalani kehidupan yang lebih sihat.

Objektif: Untuk mengkaji keberkesanan Pelan Tindakan Asma Bertulis (WAAP) terhadap kawalan asma dan kualiti hidup di kalangan kanak-kanak yang menghidap asma.

Kaedah: Satu kajian intervensi telah dijalankan bermula Februari sehingga Jun 2016 yang melibatkan 120 peserta, terdiri daripada kanak-kanak berusia dari 6 hingga 12 tahun yang mempunyai kawalan asma separa terkawal dan tidak terkawal. 61 kanak-kanak berada di dalam kumpulan intervensi yang mendapat pendedahan mengenai pelan tindakan asma, diberi WAAP dan pendidikan asma yang standard manakala 59 kanak-kanak di dalam kumpulan kawalan yang hanya diberi pendidikan asma yang standard. Tahap kawalan asma dan kualiti hidup dinilai menggunakan Soalan Kawalan Asma (ACQ) dan Soalan Kualiti Hidup Asma Pediatrik (PAQLQ) yang diambil pada temujanji pertama dan tiga bulan selepas itu. Skor min daripada kedua-dua kumpulan telah dianalisis dengan menggunakan ukuran berulang ANOVA.

Keputusan: Terdapat peningkatan yang ketara dalam kawalan asma dan kualiti hidup selepas tiga bulan. Analisis skor min ACQ pada awal kajian tidak menunjukkan skor min ACQ yang berbeza antara kedua-dua kumpulan, [F(df) = 1.17(1,119), P = 0.282].

Walaupun bagaimanapun, pada rawatan susulan selepas tiga bulan diikuti menunjukkan skor min yang berbeza antara kedua-dua kumpulan, [F(df) = 7.32(1,119), P = 0.008] di mana skor min (SD) dalam kumpulan intervensi adalah 0.96(0.53) dan dalam kumpulan kawalan adalah 1.21(0.49). Analisis interaksi waktu dan kumpulan menggunakan RM ANOVA menunjukkan perbezaan yang signifikan pada perubahan skor min [F(df) = 5.03(1,116), P = 0.027] ACQ di mana skor min yang lebih rendah dilihat dalam kumpulan intervensi yang menunjukkan kawalan asma yang lebih baik berbanding kumpulan kawalan. Analisis skor min PAQLQ menunjukkan kedua-dua kumpulan mempunyai skor min yang sama pada awal kajian. Walaubagaimanapun, terdapat perbezaan skor PAQLQ yang ketara [F(df) = 10.9(1,119), P = 0.001] pada rawatan susulan selepas tiga bulan di mana pesakit di dalam kumpulan intervensi mendapat skor min(SD) 6.19(0.45), dan kumpulan kawalan adalah 5.94(0.38). Analisis interaksi waktu-kumpulan menggunakan RM ANOVA menunjukkan perubahan ketara skor min [F(df) = 11.55(1,116), P = 0.001] di mana skor yang lebih tinggi dilihat dalam kumpulan intervensi menunjukkan kualiti hidup yang lebih baik.

Kesimpulan: Dalam kajian ini, WAAP dapat meningkatkan kawalan asma dan kualiti hidup di kalangan pesakit asma pediatrik. Oleh itu, adalah digalakkan pendidikan asma diberi bersama WAAP sebagai sebahagian daripada pengurusan asma pada kanak-kanak.

ABSTRACT

THE EFFECTIVENESS OF WRITTEN ASTHMA ACTION PLAN ON ASTHMA CONTROL AND QUALITY OF LIFE AMONG PAEDIATRIC ASTHMATIC PATIENTS

Background: Bronchial asthma is a chronic disease affecting worldwide population including children. The goal of paediatric asthma management is to achieve good asthma control for the children to live a healthier life.

Objectives: To study the effect of Written Asthma Action Plan (WAAP) on the asthma control and quality of life among paediatric asthmatic patients.

Methods: An interventional study was conducted from February to June 2016 involving 120 participants, aged from 6 to 12 years old who had partly controlled and uncontrolled asthma. 61 children were allocated to the intervention group that received WAAP with standard asthma education while 59 children were in control group who were only given standard asthma education. The asthma control and quality of life scored using Asthma Control Questionnaire (ACQ) and Paediatric Asthma Quality of Life Questionnaire (PAQLQ) was assessed at baseline and at three months. Repeated measure analysis of variance (ANOVA) was used to analyse mean score difference of both groups after the intervention.

Results: There was a significant improvement in asthma control and quality of life after three months follow up. For the analysis of ACQ, there was no significant difference of mean score for asthma control at baseline in between groups, [F(df)=1.17(1,119), P=0.282]. However, at three months, there was a significant different of mean score

between groups, [F(df)=7.32(1,119), P=0.008]. The mean score (SD) in the interventional group was 0.96(0.53) and in control group was 1.21(0.49). Time-group interaction analysis using RM ANOVA showed significant different of mean score changes [F(df)=5.03(1,116), P=0.027] where lower mean score was seen in the interventional group indicating better asthma control.

For analysis of PAQLQ, there was no significant difference of mean score for quality of life baseline for both groups. Again, there was a significant mean score changes for the quality of life [F(df)=10.9(1,119), P=0.001] at three months follow up where those in interventional group scored mean (SD) score of 6.19 (0.45), and control group was 5.94(0.38). Time-group interaction using RM ANOVA showed significant mean score changes [F(df)=11.55(1,116), P=0.001] where higher score was seen in interventional group indicating better quality of life.

Conclusions: Written asthma action plan (WAAP) resulted in greater improvement of asthma control and quality of life among asthmatic children. Thus, it is advocated to be given along with standard asthma education as a part of the management of asthma in children.

CHAPTER 1 INTRODUCTION

Asthma is one of the health burden affecting adults in every country including children (Global Initiative for Asthma, 2017). Globally, it was estimated that asthma accounted for 250,000 deaths per year where more asthma death was seen in countries where essential medications of asthma are not easily accessible (World Health Organization, 2007). Worldwide prevalence of asthma in 2007 as reported by the World Health Organisation was 300 million people. It was estimated that there will be 100 million of newly diagnose asthma in the next decade (World Health Organization, 2007). As reported by United States National Health Interview Survey in 2014, it showed that the prevalence of bronchial asthma was increasing in trend particularly among paediatric and adolescent age groups. The prevalence of asthma of those under 18 years old in the United States in 2015 was 6.2 million of population (United States Department of Health and Human Services, 2015). According to International Study of Asthma and Allergies in Childhood (ISAAC) III, even though overall difference in prevalence of asthma worldwide is reducing particularly in western countries, but the prevalence of younger children age of 6-7 years old to be diagnosed with asthma is increased (Neil Pearce, 2007).

In Malaysia, the prevalence of childhood asthma in 1995 was about 10% as per survey conducted by ISAAC phase I study (The Global Asthma Network, 2014). However, this may not be a true representative of the burden of childhood asthma in Malaysia as the survey was only conducted in three centres in Malaysia. Better reflection on the prevalence of childhood asthma in Malaysia can be obtained from 2006 National Health Morbidity Survey (NHMS III), where it showed that the prevalence of childhood asthma was 7.1% (Institute Public Health, 2008). The prevalence of asthma in younger age group was higher among male and adolescent

age group and it was associated with living in an urban or rural area (Institute Public Health, 2008). For example, a study conducted in Selangor which is an urban area in 2010 revealed that the prevalence of childhood asthma is 24%, which is higher among Malays compared to Indians and Chinese population (Roslan *et al.*, 2011). However, different study conducted among aborigines in rural Pahang in 2007 till 2009 showed that the prevalence of childhood bronchial asthma is only 1.5% (Nguai *et al.*, 2011).

Although the prevalence of childhood asthma in Malaysia was about 7% to 24% depending on the different areas of the country, the control was not optimised. Among paediatric asthmatic patients, 65.2% of them were having persistent asthma symptoms (Institute Public Health, 2008). They posed poorer morbidity due to asthma compared to those in the US. For example, about 53% of Malaysian asthmatic children will miss school due to asthma attack, with average day loss of 3.6 days as compared to those in US which was 48% (Institute Public Health, 2008; Prevention, 2013). The unscheduled doctor visit due to exacerbation of asthma was about 82%, in which about one-third of them visit emergency department for acute exacerbation of asthma. More than one-fifth of them reported limitation of physical activity due to the illness (Institute Public Health, 2008). Data published by World Health Organisation in May 2014 showed the Malaysia's prevalence of mortality due to overall asthma was 1.3% of total deaths even though it is a preventable cause of death.

Bronchial asthma is a heterogenous disease, caused by chronic reversible airway obstruction. The mechanism is a rather complex process where it involves airway inflammation and bronchial hyper-responsiveness leading to intermittent airflow obstruction, dyspnoea, chest tightness, wheezing, and cough (Global Initiative for Asthma, 2017). The asthmatic attack among paediatric age group usually triggered

by respiratory tract infection. Other triggering factors are cold temperature, exercise, emotional liability, allergens, and air born irritants such as mould, animal fur, pollen, smoke and house dust mites (Clancy and Blake, 2013). Predictors of development of asthma in paediatric include family history of asthma, personal history of allergy, and associated comorbidities such as allergic rhinitis, sinusitis, adenoidal hypertrophy, and urticaria. (Dan *et al.*, 2016).

When an asthmatic patient is exposed to triggering factors such as dust, smokes, cold weather, or viral infection of the respiratory tract, it will trigger the inflammatory cells infiltration to the airways which includes eosinophils, neutrophils, lymphocytes and mast cells (National Heart, 2007). These inflammatory cells will release inflammatory mediators causing bronchial smooth muscle constriction causing bronchial airway narrowing and subsequently airflow limitation which causing cough and wheezing. As the inflammatory process becomes more persistent and progressive, there will be remodelling of the airway causing permanent change in the airway, for example, thickening of sub-basement membrane, sub-epithelial fibrosis, airway smooth muscle hypertrophy, blood vessel proliferation and mucous gland hyperplasia and hypersecretion (National Heart, 2007).

Environmental factors play important role in asthma trigger and exacerbation. It was hypothesized that ‘Western’ environment is a precipitating risk factor for development of asthma, indicating urbanisation and reduction of childhood exposure to ‘good’ microorganism that is protective against allergies and asthma (Chung, 2016). A local study conducted in Universiti Kebangsaan Malaysia Medical Centre (UKMMC), Kuala Lumpur in 2015 showed there was an increased risk of bronchial asthma in those who exposed to lorry fume, congested roads and indoor carpet indicating environmental factors contributing to development of asthma (Idris *et al.*,

2016). This reflected why the burden of asthma is higher in more urbanised and industrialised area as compared to rural areas (Institute Public Health, 2008).

Asthma is diagnosed mainly from the history of variable respiratory symptoms and confirmation of airflow limitation (Global Initiative for Asthma, 2017). The respiratory symptoms include wheeze, shortness of breath, chest tightness and cough. In paediatric asthma case, investigations such as spirometry, exhaled nitrite oxide and skin prick test are not usually carried out. If the airflow limitation is to be confirmed, the response to bronchodilator therapy is taken as improvement of FEV1 of more than 12% or improvement of PEFr of 20%. However, the changes may not be seen in mild asthmatics (Ministry of Health Malaysia, 2014).

Goals of asthma therapy in children are to maintain their normal activities including participation in exercise and sports events, prevent absentees from school, no visit to emergency department and hospitalisation due to exacerbation of asthma, no side effects of the medications, hence to improve morbidity and mortality (Ministry of Health Malaysia, 2014). This goal can be achieved by compliance with medical care and follow ups. This is a difficult tasks to be accomplished by health care providers as NHMS III showed that 69% of asthma patients did not have proper follow ups (Institute Public Health, 2008). Asthmatic status among the patients need to be monitored in term of control and compliance. Both care takers and patients should be educated during the follow ups (Ministry of Health Malaysia, 2014). Thus, the importance of compliance to the medications and follow ups among asthmatic patients should be emphasized to the care takers.

Management of asthma should be individualised. Pharmacological management of asthma basically divided into two which are anti-inflammatory and

bronchodilator (Global Initiative for Asthma, 2017; Ministry of Health Malaysia, 2014). Anti-inflammatory medication used in asthma mainly corticosteroid and leukotriene inhibitors. Based on the asthma control, the pharmacological management can be either step up or step down according to the stepwise approach of medication adjustment as proposed by Global Initiative of Asthma (GINA) (Global Initiative for Asthma, 2017). However, the problem with the use of corticosteroid in paediatric asthmatic patients is reduction of the rate of growth in children (Philip, 2014). The growth rate reduction depends on the dose and the type of inhaled corticosteroid (ICS) molecules used (Philip, 2014). However, the slower growth rate was not cumulative beyond the first year of using ICS, thus the use of ICS outweighs the harm to achieve good asthma control (Zhang *et al.*, 2014). Thus, every asthmatic child who use inhaled corticosteroid, it is a good routine by physician to monitor the growth of the children.

Other than pharmacotherapy, asthma education is also vital in controlling asthma and reducing the severity of an exacerbation. It empowers patients and caretakers in active management of asthma. Asthma education includes education on how to recognise sign and symptoms of asthma, avoid the triggering factors, education on physical activities, information on the medications and individualised written asthma action plan (Ministry of Health Malaysia, 2014).

Asthma action plan is introduced as an integral part of asthma self-care management (Global Initiative for Asthma, 2017; Ministry of Health Malaysia, 2014). It is an individualised plan that divides the asthma severity based on the symptoms. By symptoms recognition, caretakers can initiate the rescue therapy at home if needed. It empowers patients and caretakers in initiating acute asthmatic attack at home (Khan *et al.*, 2014). It improves caregivers' understanding on the use of inhalers during exacerbation before coming to emergency department for treatment. A study in

Singapore showed that the understanding of the asthma and the use of devices are better among those educated with asthma action plan, and the decision to visit the physician does not change (Ngiap Chuan Tan, 2013)

1.1 Justification of Study

Many asthmatic children in Malaysia had persistent asthma symptoms despite availability of the treatment (Institute Public Health, 2008). Poor compliance and poor knowledge are among the contributory factors leading to persistent symptoms (Rakhee Yadav, 2014). Asthma control as stated by many literatures can be achieved by adherence to medications and asthma education. The use of asthma action plan improved parental knowledge and confidence in managing their children with asthma attack (Ngiap Chuan Tan, 2013). Both parties (patients and parents) can recognise the early exacerbation episodes at home and prompt initial management at home can be commenced, thus reducing and improving the severity and morbidity of the illness.

Even though asthma action plan is advocated in many guidelines, the positive effect on it is not well established. A study in Trinidad comparing paediatric asthmatic patients receiving standard asthma care versus asthma action plan did not find significant improvement of the asthma outcomes in term of asthma symptoms and morbidity (Khan *et al.*, 2014). A local study in a tertiary centre in Kuala Lumpur unable to demonstrate a significant impact of asthma action plan on the asthma control, quality of life and unscheduled doctors visit among paediatric asthmatic patients (Wong *et al.*, 2013). However, the study was done among elder paediatric asthmatic patients, with mean age group was 12 years old. The study included all

asthmatic patients regardless of the severity of asthma where many of their patients had controlled asthma at baseline of study.

Since there was conflicting of evidence on the use of written asthma action plan (WAAP), thus this study was conducted to assess and promote on the effectiveness of WAAP in achieving better asthma control and improving quality of life among partly controlled and uncontrolled bronchial asthma among younger age children.

CHAPTER 2 LITERATURE REVIEW

2.1 Asthma Control

2.1.1 Definition of Asthma Control

Asthma control is assessed by symptoms, peak expiratory flow meter and assessing the future exacerbation (Global Initiative for Asthma, 2017). Predictors of uncontrolled asthma include female sex, reduce forced expiratory volume (FEV1) reading and history of exacerbations (Corrado *et al.*, 2013). The control needs to be assessed using standard evaluation as the pharmacological management of an asthmatic patient is tailored by the asthma control status.

Many tools developed to assess asthma control. For instant, ‘Royal College of Physician Three Questions’ tool, GINA symptom control box, as well as written questionnaires that have been developed to assess the control of asthma including Asthma Control Test (ACT) and Asthma Control Questionnaires (ACQ) (E.F. Juniper, 1999; Global Initiative for Asthma, 2017). Different tools have different scores to determine the control state of asthma.

Predictors of good asthma control include adherence to medications and good knowledge on asthma (Global Initiative for Asthma, 2017). Other than that, parents with higher literacy and greater perceived self-efficacy with patient-physician interactions were associated with higher satisfaction and asthma control (Pranav K Ghandi, 2013). In the other hand, poor asthma control was associated with working mothers, crowded home environment, and family history of asthma, concomitant rhinitis, smoking, obesity and poor inhaler technique (Gordon Bloomberg, 2009; John Haughney, 2008; Kim L. Lavoie, 2006).

2.1.2 Factors Affecting Asthma Control

Many factors were identified from studies that predict the asthma control among paediatric patients. Among the risk factors studied that related to asthma control were ongoing exposure to triggering allergens such as smoking and dust, presence of concomitant rhinitis, obesity, adherence to medications and poor socioeconomic status.

2.1.2.1 Ongoing exposure to allergen

A child who is a passive smoker will have poorer asthma control compared to non-smoking exposure child (Groot *et al.*, 2015). This is because, the smokes induces neutrophils infiltration to the airway, unlike the pathophysiology of asthma which involved eosinophil infiltration that is sensitive to corticosteroids (John Haughney, 2008). Thus, the role of corticosteroid as controller is limited in those exposed to cigarette smoke, making the efforts in controlling asthma is greater in this population.

Maternal smoking is also an independent risk factor for poor asthma control among children as early exposure to the smoking is related to poor lung function (Zacharasiewicz, 2016). However, once the exposure to the cigarette smoke was diminished, better asthma control can be achieved. An interventional study done in intention to eliminate the exposure to environmental tobacco smoke showed reduced unscheduled visit to health care provider in interventional groups over twelve months study (Rao and Phipatanakul, 2011).

Those in urban area will experience poorer asthma control due to smoke from vehicles and dust. A local study showed an increased risk of childhood asthma was seen in those living near congested roads, exposure to lorry fumes, and indoor carpets

(Idris *et al.*, 2016). For example, presence of in-house allergen due to indoor carpet contributes to two times higher risk of developing asthma (Idris *et al.*, 2016). Thus, in managing asthma, patients and care takers should be educated to minimise the exposure to reversible cause of allergen such as smoke, dust, house dust mites and moulds at home (Hsu *et al.*, 2016)

2.1.2.2 Concomitant Medical Illness and Obesity

Poor asthma control was also related to concomitant co-morbidities for example presence of nasal symptoms, atopy, and gastroesophageal reflux disease (Manuel Ferreira-Magalhaes, 2015). Many studies showed presence of nasal symptoms or allergic rhinitis symptoms gave more negative impact on the asthma control. Even though the fact has been established, it was observed that the symptoms was not well recognised and undertreated (Groot *et al.*, 2015). Asthma and allergic rhinitis correlates which each other because both disease manifestation is triggered by allergens, and presence of rhinitis symptoms increases risk of asthma (Khan, 2014). Thus, treating allergic rhinitis symptoms in accordance to the Allergic Rhinitis and its Impact on Asthma (ARIA) severity classification will improve asthma outcome as per suggested by Cochrane review (Taramarcaz P, 2003).

Obesity is related to poor control of asthma (Seiler and Sarver, 2016). Asthma seems to be more severe in obese children compared to lean children (Lang, 2012). Researchers found that there was a reduction of inhaled corticosteroid efficacy in obese children making the controller medications less effective in this population (Forno *et al.*, 2011; Jensen *et al.*, 2012). This may be due to reduce peripheral lung deposition or absorption of inhaled corticosteroid (Anderson WJ, 2012).

Other than that, sedentary lifestyle that is related to obesity plays role in severity of asthma. Exercise seems to improve asthma outcomes as it provides 'respiratory endurance' to the asthmatic patients. For example, when a child goes out playing, he will have hyperventilation, thus exercising his airway smooth muscles. This will make the airway smooth muscle more stretchable resulting in increasing airway calibre, thus increases lung volume (Lang, 2012). That is why exercise is a protective mechanism towards better control of asthma.

2.1.2.3 Adherence

Good adherence to medication especially inhaled corticosteroid and other controller medications is important in achieving good asthma control. A study in tertiary teaching hospital has found significant correlation between poor adherence and persistent asthma control (Adyani Md Redzuan, 2014). Other than that, non-adherence was related to increase risk of hospital admission and mortality due to asthma (Scott Burgess, 2011). Non-adherence is a loss to health care system (John Haughney, 2008) which will lead to increase cost of disease management (Scott Burgess, 2011). However, non-adherence is not commonly assessed during follow-up by physicians, in addition to patients' refusal to admit it, leading to unnecessary adjustment of controller medications, thus increasing the cost of asthma management.

Many factors identified that can lead to non-adherence to asthmatic medications. The barriers can be due to social factors, patients' or caretakers' belief, and poor understanding of the illness. A study conducted showed that caretakers' difficulty in getting time off work is a barrier in bringing the children for follow-up (Cindy A. Trent, 2015). Poor family development and relationship also affects the

compliance. It was made known that family dysfunction, conflict family, and children with behavioural problem resulting in poor adherence to medication, thus the control of asthma was also affected (Scott Burgess, 2011). It was found that higher maternal educational level was related to non-adherence to inhaled corticosteroid, as they were afraid of the side effects of the medication including stomatitis, and taste at the throat (Dan *et al.*, 2016). Parental underestimation of the illness also plays a role in causing non-adherence among the affected children in which they reduce the frequency or the dose of the control medications by themselves (John Haughney, 2008). However, medication adherence seems to be good in asthmatic patients with concomitant comorbidities (Adyani Md Redzuan, 2014).

Poor inhaler technique was also found to cause uncontrolled asthma as medication effects would not take place as expected. Children who had poor coordination to inhalers are advised to use chamber device for better delivery of medication. However, the use of handheld chambers does not improve the adherence among patients. Thus, to improve adherence, it was proposed that the caretakers and affected children are involved directly in the discussion of the treatment decision making by the physician (Scott Burgess, 2011). Specific educational program to the patient and the caretakers is also seemed to improve the compliance to the medication.

2.1.2.4 Socioeconomic factors

There are other factors that negatively impacts asthma control which are lower socioeconomic status and educational background (Hallit *et al.*, 2017). Asthmatic outcomes seem to be worse in poorer population (World Health Organization, 2007). This is because of inaccessibility of those from lower income group to controller medications (Gong *et al.*, 2014) and the policy of certain countries making the target

group could not go to seek proper treatment and follow up due to limited health insurance policy coverage (Manuel Ferreira-Magalhaes, 2015). Other than no health insurance coverage, family structure also plays role in the outcome of management of childhood asthma. A study showed that Medicaid receivers had poorer asthma control compared to other general population and it was an independent predictor (Gordon Bloomberg, 2009). Medicaid is a health coverage incentives given to poor and disabled population in the United States.

2.2 Asthma Education

Asthma education undeniably plays an important role in management of bronchial asthma. Even though Cochrane review unable to find consistent findings on the impact of asthma education on the asthma outcome (Welsh EJ, 2011), but many international guidelines advocate on the use of asthma education to improve the asthma control and thus the quality of life among affected children. Every asthmatic patient and the caretakers should have higher health literacy on asthma as to reduce risk of exacerbation. Thus, good physician and patient-care givers partnership should be developed and good communications is found to be the key in achieving it. Family empowerment was found to be effective in achieving asthma control in term of improving the lung function and reducing the parental stress (Yeh *et al.*, 2016). For example, they will avoid the environmental factors that trigger exacerbation of asthma as one of the strategies in reducing the severity of exacerbation and asthma control.

Asthma education can reduce the gap of managing asthma in poor countries due to inaccessibility of asthma medications in such countries. They found that that integration of correct medications, partnership between caretakers and health

providers, and asthma education through meetings gave a significant improvement in the outcome of asthma in terms of hospital admissions and emergency department visits (Fischer and Camargos, 2002).

According to Malaysian Clinical Practice Guidelines on Management of Childhood Asthma (Ministry of Health Malaysia, 2014), asthma education should include explanation on nature of disease, symptoms of asthma, and triggering factors, medications, MDI technique and asthma action plan. The education on the correct use of metered-dose inhaler (MDI) gives positive impact on the asthma symptoms and control significantly (Türkeli *et al.*, 2016). For children, the correct use of MDI is difficult to be achieved as per coordination of the hand movement and inhalation technique. If during assessment, the child has poor coordination and technique, health care provider can try another device that suits child's need for example to change to 'easyhaler' or use of chambers to optimise medications delivery. On the training of MDI use method, a recent study showed that both verbal counselling and 'trainhaler' use improved device technique and asthma outcome among paediatric asthmatic patients (Ammari *et al.*, 2017). Thus, it was fair to use verbal counselling during this study.

2.3 Written Asthma Action Plan

Asthma action plan is an individualised written instruction to the patient on how to monitor the asthma control, adherence to medications, avoidance of allergens, and to recognise exacerbations thus prompt action can be taken when asthmatic attack occurs. It is recommended to be delivered to those who has partly controlled asthma, uncontrolled asthma and those who had history of severe asthma (Ministry of Health

Malaysia, 2014). The physician can also discuss with the patients on how to adjust medications in certain situation, and when to seek early medical attention.

Since it is an individualised plan which practically planned by doctors, it consists of types and doses of different medications needed daily by the children in controlling asthma. Ideally, patients need to document their peak expiratory flow rate (PEFR) daily to give idea on the patency of the airways. Later, it teaches caretakers in recognising early symptoms of exacerbation of asthma, thus, child's medications particularly reliever medication can be gradually increased to reduce the symptoms. The caretakers also taught on when and how to seek medical treatment after initial plan taken at home has not taken better effect, for example, what to do during the travel to the nearest health facilities, and important numbers to contact in case of emergency situations.

In an interventional local study conducted in University Malaya Medical Centre showed that there was a reduction in asthmatic exacerbation when using written asthma action plan even it did not reach statistical significance (Wong Su Sien, 2010). An interventional study conducted in Delhi, India comparing standard treatment guidelines group and another group with standard treatment guidelines with asthma education produced several statistical significant in improving asthma control (Anita Kotwani, 2012). Since patient and caregiver is taught how to increase the medications and when to seek medical attention, asthma action plan can decrease hospitalisation for and death from asthma (British Thoracic Society, 2016). It is concluded that children symptoms-based written plan is effective in reducing emergency consultation for asthma (British Thoracic Society, 2016).

2.4 Quality of Life

Quality of life is an evaluation of the positive and negative aspect of life. It involves the view of oneself of the disease to the social, psychological and medical services (Centres for Disease Control and Prevention, 2016). Thus, improving quality of life is an aim in the management of chronic illness such as in this asthma study. Many studies concluded that asthma control is correlated with improved quality of life among asthmatic patient. For example, good asthma control reduced daytime sleepiness thus mediated the quality of life (Zheng Li, 2013).

A systematic review of fourteen literatures showed that uncontrolled asthma is correlated with poor quality of life. Children whose asthma symptoms were not well managed were likely to experience impairments in quality of life such as school absentee, daytime sleepiness, and limitation of exercise capacity (Li *et al.*, 2013; Robin S. Everhart, 2009).

Good asthma control among asthmatic children improved quality of life among caretakers in term of reduction number of sick leave and hospitalisation, reduction level of stress and health care cost (Ayfer Ekim, 2016; Gordon Bloomberg, 2009). Parental coping strategies in dealing children with asthma also contributes to the quality of life of care-takers. Less disease burden was seen among care takers with good asthma control children (Neuza Silva, 2015).

2.5 Written Asthma Action Plan on the Asthma Control and Quality of Life

In a two year prospective study done among 229 asthmatic children concluded that asthma control was proportionate to the quality of life (Li *et al.*, 2016). However, there are conflicting evidences on the use of asthma action plan in improving the

quality of life and asthma control among sufferers. A study in an urban area in Malaysia has not found significant result on asthma action plan and asthma control and quality of life in term of unscheduled doctor visit (Wong *et al.*, 2013). They also found that those with WAAP had increased rate of hospitalisation among paediatric asthmatic patients (Kelso, 2016). A different study among sub-speciality clinic attendees over 1 year also did not find the superiority of WAAP compared to other standard asthma care (Sheares *et al.*, 2015).

Nevertheless, there were also positive finding of WAAP on asthma control and quality of life seen. A study conducted in Singapore concluded that parents had better understanding and confidence on the illness (Ngiap Chuan Tan, 2013) and the use of WAAP may play a useful role in asthma management (Khan *et al.*, 2014). Doctors who practised giving WAAP gave positive impact on the adherence to inhaled corticosteroid and overall asthma outcome (Smita Shah, 2011).

2.6 Delivering Asthma Education and Asthma Action Plan

Continuous education on asthma to patient and caretakers is always suggested in literatures as a tool to achieve better asthma control. The methods varied from individual basis, group intervention or interactive methods (Liu and Feekery, 2001). Medical professionals should spend time in educating children and care-takers on bronchial asthma to achieve better compliance and asthma control. Face-to-face asthma education by medical doctor improved knowledge on asthma, asthma control and satisfaction among patients (Anita Kotwani, 2012; Liu and Feekery, 2001). It was also found that the time spent by the physician was not significantly increase when delivering face-to-face asthma education to the patients.

However, those from lower socioeconomic status might not have good chance in assessing health support and service providers, resulting in lacking information shared to them (Stewart *et al.*, 2016). It is proposed that the task of educating publics can be done by non-medical personnel to improve the asthma control as well as to reduce the severity of the disease. For example, an intervention at school by teachers to the caretakers showed positive outcome of the asthma frequency and severity among primary school children (Neuharth-Pritchett and Getch, 2016). A systematic review on the school-based education to the teachers, caretakers and children on asthma showed positive impacts on improvement of knowledge, asthma control and exacerbation, unscheduled doctor visit and quality of life (Carvalho Coelho *et al.*, 2016; Walter *et al.*, 2016). Peer education among adolescent age group also is an effective way in delivering the message on asthma as peers are recognised influential factor among adolescent.

Interactive computer programmed asthma education can be an alternative method in educating the asthmatic children even in emergency setting (Joshi *et al.*, 2007) and at classrooms setting (Greer *et al.*, 2017). In older children, peer education along with interactive computer asthma education to improve knowledge and attitude on asthma was found to be feasible and effective (Ando *et al.*). Both improved child's knowledge of asthma. The positive impact of asthma education was seen in up to twelve-month post intervention (Liu and Feekery, 2001). Thus, long term plan in asthma management should include continuous asthma education including personalised action plan at every follow-up in conjunction with improvement of health delivery system (Barthwal MS, 2009; Pinnock, 2015).

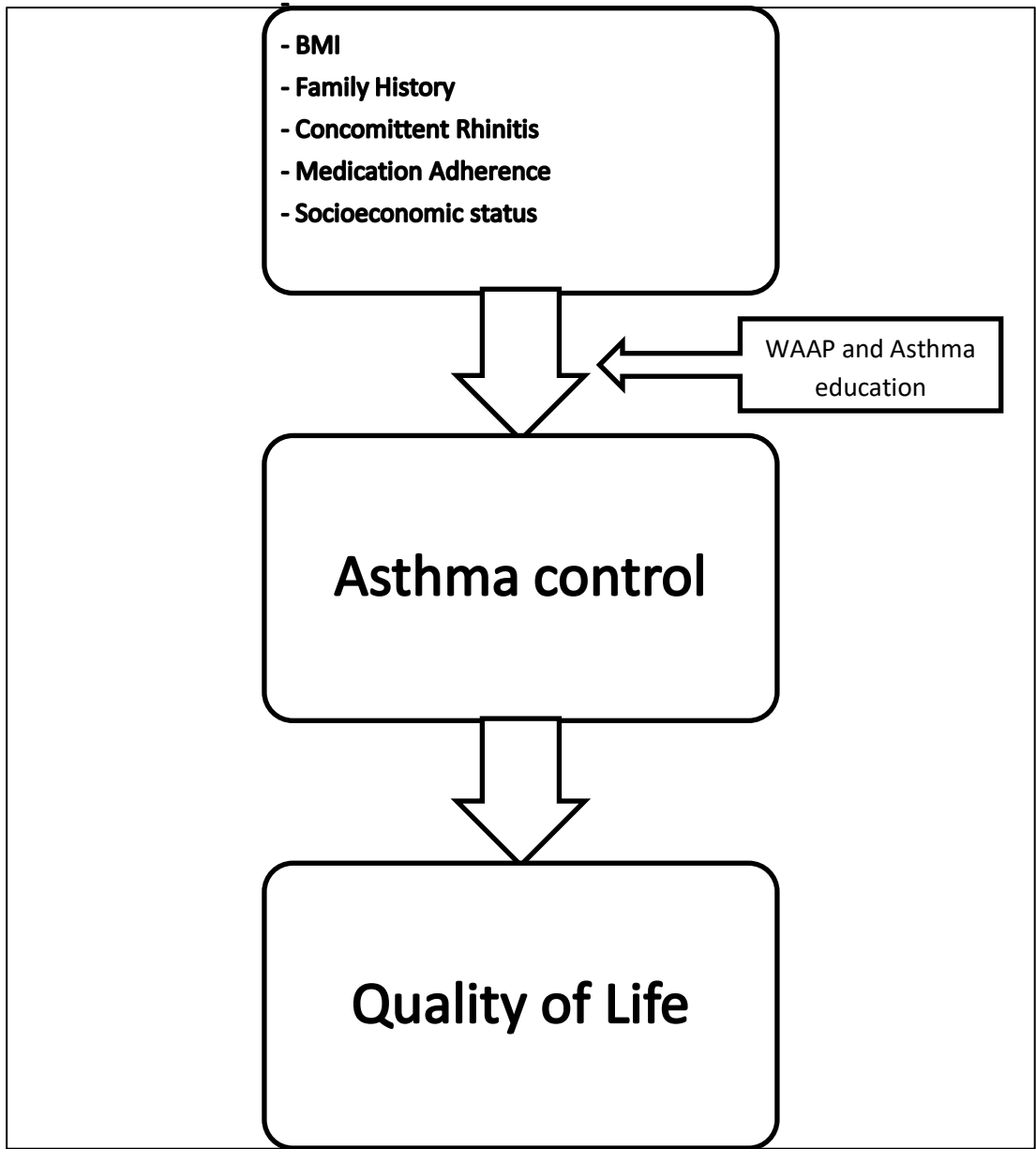


Figure 2. 1 Conceptual Framework

CHAPTER 3 OBJECTIVES

3.1 General objective

To determine the effectiveness of Written Asthma Action Plan (WAAP) on asthma control and quality of life at baseline and follow up among paediatric age groups attending Paediatric Clinic, Hospital Sultanah Nur Zahirah, Kuala Terengganu.

3.2 Specific objectives:

3.2.1 To determine asthma control between those receiving and not receiving Written Asthma Action Plan (WAAP).

3.2.2 To determine quality of life between those receiving and not receiving Written Asthma Action Plan (WAAP).

3.3 Research Questions

3.3.1 What is the effect of Written Asthma Action Plan (WAAP) on asthma control among asthmatic paediatric patient?

3.3.2 What is the effect of Written Asthma Action Plan (WAAP) on the quality of life among asthmatic paediatric patient?

3.4 Research Hypothesis

3.4.1 Paediatric asthma patient receiving Written Asthma Action Plan has better asthma control

3.4.2. Paediatric asthma patient receiving Written Asthma Action Plan has better quality of life.

3.5 Operational Definition

3.5.1 Asthma Control

Asthma control is assessed based on the symptoms, activity limitation, usage of reliever, exacerbation and peak expiratory flow meter rate change. A few methods available to assess the control for example Asthma Control Questionnaire (ACQ) which consisted of seven questions. Figure below showed the characteristic of asthma control status based on Global Initiative for Asthma (GINA) guidelines.

A. Asthma symptom control		Level of asthma symptom control		
In the past 4 weeks, has the patient had:		Well controlled	Partly controlled	Uncontrolled
• Daytime asthma symptoms more than twice/week?	Yes <input type="checkbox"/> No <input type="checkbox"/>	None of these	1-2 of these	3-4 of these
• Any night waking due to asthma?	Yes <input type="checkbox"/> No <input type="checkbox"/>			
• Reliever needed for symptoms* more than twice/week?	Yes <input type="checkbox"/> No <input type="checkbox"/>			
• Any activity limitation due to asthma?	Yes <input type="checkbox"/> No <input type="checkbox"/>			

Figure 3. 1 Asthma control assessment (Global Initiative for Asthma, 2017)

3.5.2 Quality of Life

Quality of life is defined as individual's perception of their position in life in the context of the culture and value systems in which they live in relation to their goals, expectations, standards and concern (World Health Organization). In this study, quality of life will be assessed using Paediatric Asthma Quality of Life Questionnaire (PAQLQ).

CHAPTER 4 METHODOLOGY

4.1 Trial Design

This was a single blinded, parallel, hospital based, randomized control trial study.

4.2 Participants

4.2.1 Study populations and Eligibility

The source of populations were asthmatic children receiving treatment and follow up at Paediatric Clinic, Hospital Sultanah Nur Zahirah, Kuala Terengganu. Eligible participants were all pediatric asthmatic patients aged 6-12 years old who attended the clinic from February till March 2016 who had partly controlled and uncontrolled asthma control status. Exclusion criteria were those who had asthma exacerbation who warranted prompt treatment, had concomitant cardiopulmonary disease, unable to answer the questionnaire and unable to perform peak expiratory flow meter. They were followed up in three-month time.

4.2.2 Study setting

The study was conducted at Paediatric Clinic, Hospital Sultanah Nur Zahirah Kuala Terengganu from February till June 2016. It is a multidisciplinary specialist clinic catering various paediatric cases, including uncontrolled and partly controlled bronchial asthma mainly who was referred from Kuala Terengganu and surrounding districts. Kuala Terengganu district is a semi-urban area in Terengganu. The clinic is run by paediatricians and medical officers. The asthmatic patients will be seen every Wednesday and Thursday.

4.3 Interventions

Consented participants allocated into interventional group or control group by computer-based simple randomisation. Both group then assessed on baseline asthma control and quality of life using Asthma Control Questionnaire (ACQ) and Paediatric Asthma Quality of Life Questionnaire (PAQLQ). The researcher interviewed the patient on ACQ and PAQLQ directly while the caretaker waited outside the interview room. After completing the questionnaires, subjects subjected to do Peak Expiratory Flow Rate (PEFR) for three times, and the highest reading was taken.

Those who were in interventional group, researcher explained on the standard asthma education and individualized asthma action plan to the patients and caretakers at first visit. The Written Asthma Action Plan (WAAP) was brought home and advised to be used as a guidance when patients had asthmatic exacerbation. Three-month follow-up appointment date was given. Post-interventional assessment of ACQ and PAQLQ sought back during the follow-up visit.

As comparison, control group received the asthma education and verbal asthma action plan at first visit. 3 month follow up appointment date given where ACQ and PAQLQ reassessed.

4.4 Sample size

To measure the effectiveness of WAAP on the asthma control using ACQ score, determination of sample size was based on an interventional trial done in India (Anita Kotwani, 2012) which stated the mean score different (δ) of morning symptoms between control and experimental group was 0.28 with standard deviation (σ) 0.35.

Taking the power of study as 90%, and type I error, α as 0.01, thus 48 subjects per group needed. As 20% was taken as drop-out rate, 58 subjects needed in both control and interventional group.

To determine the effectiveness of WAAP on the quality of life among patients using PAQLQ score, determination of sample size was based on an interventional study conducted in Iran (Zahra Payroovee, 2014) which stated mean score different (δ) of PAQLQ between interventional and control group was 0.87 with standard deviation (σ) of 0.75. Taking the power of study as 90%, and type I error, α as 0.01, thus 24 subjects needed for each study group. As drop-out samples taken as 20%, thus this study needed 29 subjects in each interventional and control group.

Based on both calculations, the larger sample size was obtained from calculation yielded from initial objective which was to determine the effectiveness of WAAP on the asthma control based on ACQ score. Thus, the minimum sample size taken as 58 subjects per group.

4.5 Randomisation

Allocation of samples into interventional and control group was made by computer generated simple randomization.