Effectiveness of pictorial based self-management among adult with asthma in a suburban primary care health clinic: a randomised controlled trial

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ABSTRACT

Introduction: Self-management asthma education is important in a good asthma model of care. However, its delivery should be simple and easily comprehensible for successful utilisation. Pictograms have been shown to assist the understanding of asthma self-management. The objective of this study is to determine the effectiveness of a pictorial based asthma self-management towards asthma control. **Material and Methods:** This was a open label single centre randomised trial. Sixty-two adults with asthma attending a primary care clinic in suburban Selangor, Malaysia and taking preventive inhaled corticosteroids were randomised into two groups; pictorial based self-management or conventional care. The pictorial based group received a 10 minute individualised session on pictorial asthma action plan. The main outcome measures were improvement in asthma control test (ACT) scores, number of hospitalisations, unscheduled health care visits and absenteeism after three months of follow up. **Results:** A total of 62 participants were analysed. Both groups had improvement of asthma control within the follow-up period. However, there was no significant difference in the asthma control (ACT score changes) between the intervention and control group with their mean ACT score: 21.3 ± 3.2 vs 20.5 ± 3.8, p=0.39, respectively. The mean difference of ACT score from baseline were 2.2 ± 3.2 vs 1.3 ± 4.6 p=0.35, respectively. No significant statistical differences were observed in the number of unscheduled healthcare visits, hospitalisations and absenteeism among the two groups. **Conclusions:** Pictorial based self-management did not offer any advantage over the conventional care among relatively well controlled asthma, middle to lower socioeconomic and low education background population.

Key words: Asthma, education, management, control, self-management

INTRODUCTION

Self-management asthma education is advocated as a major component in asthma management. [1] With a more customised care, asthmatic patients would be empowered to self-manage their medications and intervene appropriately. Hence, exacerbations can be controlled early and this will lead to better asthma outcomes. Previous studies on practice self-management have shown a more positive outcome in their asthma control. [2]

However, despite its huge benefits [2] and strongly recommended by most major guidelines including the Global Initiative For

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Asthma (GINA) and National Heart, Lung and Blood Institute guidelines, [1, 3] this self-management education is still under-utilised regularly by both patients and physicians. [4, 5] The reasons for these could be due to patient's low confidence, understanding and knowledge, low health literacy, poor patient-physician relationship and lack of time and confidence by physicians to generate asthma action plan. [6, 7] One important way to overcome this problem is to ensure asthmatic patients can comprehend self-management plan taught to them. Hence, a simple and comprehensible method of delivery of self-management education needs to be put into place.

Low health literacy has been linked to poor asthma outcomes [8] and it has been recommended that for better understanding and compliance, patient's education materials should be short, clear and include pictures and illustrations. [9] Pictorial representative have been shown to be an effective educational tool in a clinical setting. [10] In this regard, pictorial based self-management education is one option to address this issue. Very often in clinical practice, it is difficult to identify who is or is not functionally literate and having low health literacy. Current asthma action plans unfortunately do not take literacy into account because most educational materials are in written words. Pictorial asthma action (PAA) plan can improve comprehension and clarity and thus will boost patients' confidence in utilising this plan. [11] The concept of "simplified version" in a form of pictogram will overcome the complexity of cultural barriers, low health literacy and improve knowledge and encourage good health seeking behaviour.[10] This method of delivery is more universal and can be applied to various levels of health literacy and educational level which is normally a representative of patients in a primary care clinic.

To date, there has not been any study done in Malaysia looking into the effectiveness of the PAA plans compared to the conventional based asthma plans. For this main reason, we conducted a study in a typical semi-urban health clinic in Malaysia to determine the effectiveness of pictorial based asthma self-management towards asthma control.

MATERIALS AND METHODS

Patient population: The study was conducted at Telok Panglima Garang Health Clinic (KK TPG), a semi urban primary care health clinic located in the district of Kuala Langat, Selangor, Malaysia. The clinic caters to a population of 75,112 people comprising of all major local races. The participants need to be under the clinic follow up for at least 3 months and on inhaled preventive corticosteroids to be eligible for recruitment. We excluded those having significant comorbidities and conditions that affect lung function and those having hearing or visual deficit or mental/ psychiatric disorder that may interfere with the understanding of the study protocol. This study has been approved by Research and Ethics Committee Universiti Kebangsaan Malaysia and Ministry of Health Research and Ethics Committee (MREC) (ID:NMRR-13-240-14823).

Randomisation, concealment, allocation and blinding: The subjects were centrally randomised to control or intervention group using a computer generated permuted block design to ensure an equal number of intervention and control participants. The random allocation sequence was generated by a clerk who was independent of the allocation concealment and the recruitment process. The sequences were written in individualized sealed envelopes by the clerk, which were only opened by nurse (independent of the recruitment process) after collection of the baseline data. We collected baseline data on patient socio-demographic, clinical characteristics and asthma control test (ACT) scores

prior to the allocation.

Each eligible and consented participant was given a serial number accordingly as the participants were recruited. The allocation to the control/intervention group was made by matching the participants' serial number to the computer generated sequence. Allocation took place after collection of the baseline data, ensuring concealment of allocation. The subjects were followed up for three months.

Treatment regime: The control group received the standard usual clinic care, which consisted of basic education on asthma and its pathophysiology, asthma medications, inhaler technique, asthma diary and written asthma action plan.

The intervention group also received the standardised usual clinic care in addition to the Pictorial Asthma Action (PAA) plan (Appendix). This PAA plan was developed and was shown to be easily comprehensible among three different groups of asthma patients including Malaysians living in Seremban. [12] We modified and pre-tested the PAA plan to be locally and culturally accepted. This was done among 10 patients in whom all of them reported that they could understand the flow and instructions. This plan was individualised according to the patient's severity of asthma and his/her current medications. The intervention was delivered by a single person with standardised script lasting 10 minutes (Appendix). At the end of the 10-minute session, the participants will be asked whether they understood the plan. They were allowed to be retaught regarding the pictorial asthma action plan upon request within the three months follow-up.

Outcome assessment: The primary clinical outcome measure was asthma control which was measured pre and post three months of follow up using Asthma Control Test (ACT) which is a validated self-administered questionnaire to determine asthma control. [13, 14] The summed up score for 5 items in that test would yield a score ranging from 5 to 25. Cut-off point of >19 was used for well controlled asthma. [14] A difference of 3 points in mean ACT score between the two groups or in an individual patient over time (minimal important difference, MID) were considered clinically significant. [15] Secondary outcomes included number of hospitalisations, unscheduled health care visits, absenteeism from work/college three months post initiation of the study. Outcome assessors were blinded to the intervention allocation.

Statistical analysis: The sample size was calculated based on a previous similar study conducted by Pur Ozyigit *et al*., which used the similar intervention tool. [16] Based on their estimated effect size with a two-sided 5% significance level, power of 80% and accounting for 30% drop out rate, a sample size of 31 subjects per group was calculated. Although the minimal important difference (MID) for ACT is 3, this value was not used for estimated effect size as the sample would be relatively small and there was the need to consider the secondary outcomes (number of emergency department visits, number of hospitalisations) which requires a larger sample size. Therefore, sample size was calculated to ensure the ability to assess both primary and secondary outcomes.

Statistical analysis was done using SPSS version 22.0. All analysis was done on an intention-to-treat. Descriptive statistics was computed for the socio-demographic and clinical characteristics for both groups. Analysis of any differences in the baseline characteristics, changes in the primary and secondary outcomes and differences in the changes among the two groups were done by using Chi Square test, Yates correction and independent t-test. Significant level is defined as $p < 0.05$.

RESULTS

Figure 1 shows the CONSORT flow diagram of the study. All participants completed the study and were included in the analyses. The baseline characteristics of the participants did not differ significantly among the two groups (Tables 1 and 2). The mean age (years) of the participants of the intervention and control arms were 50.0 ± 13.9 and 50.4 ± 11.5 respectively. Majority of the participants in this study were females (82%), married (77%), not working (66%), obtained lower education (92%) and came from low-income group (93%).

Both groups were relatively similar in their asthma background history on enrolment. This includes duration, severity and medication. Two participants form the intervention group had previously been admitted to intensive care unit. Majority of the participants from both groups were on moderate to

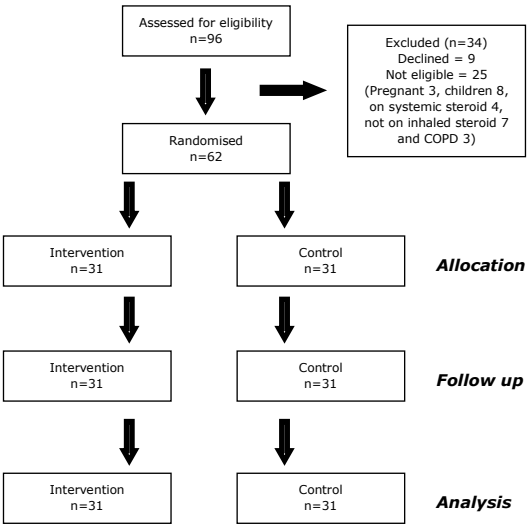


Fig. 1: The CONSORT flow diagram of the study.

Table 1: Sociodemographic characteristics of the intervention and control groups.

	Intervention (n=31)	Control (n=31)	*p* value
Age			
Mean age (years) ± SD	50.0 ± 13.9	50.4 ± 11.5	0.789
Range (years)	(19, 75)	(30, 71)	
	n (%)	n (%)	
Gender			
Male	6 (19)	5 (16)	0.740
Female	25 (81)	26 (84)	
Ethnic			
Malay	12 (39)	13 (42)	0.796
Non-Malay	19(61)	18 (58)	
Marital status			
Married	24 (77)	24 (77)	1.000
Unmarried	7 (23)	7 (23)	
Employment			
Working	11 (35)	10 (32)	0.788
Not working	20 (65)	21 (68)	
Education level			
Lower	27 (87)	30 (97)	0.351*
Higher	4 (13)	1 (3)	
Income level			
Low	28 (90)	30 (97)	0.605*
Medium/high	3 (10)	1 (3)	
Smoking status			
Current/former smoker	5 (16)	3 (10)	0.705*
Non-smoker	26 (84)	28 (90)	

***** Yates correction

to intensive care unit. Majority of the participants from both groups were on moderate to high dose of inhaled corticosteroids with a median dose of 800µg with less than 15% of the participants on combined β_2-agonist and corticosteroid. Majority of them do not have any concomitant atopy diseases which usually exist together with asthma.

Both groups had similar cardiovascular background risk such as diabetes mellitus and hypertension with some already having end organ complications (Table 2).

Primary outcomes: Asthma control: The ACT mean score at baseline were similar in both control and intervention group (19.2 ± 4.2 vs. 19.1 ± 3.8, *p=0.4*, respectively) (Table 3). Both groups had improvement of asthma control within the follow up period. However, there was no significant difference in the asthma control (ACT mean score) between the two groups (20.5 ± 3.8 vs. 21.3 ± 3.2, *p=0.7*) (Table 3). The mean difference of ACT scores after three months were 1.3 ± 4.6 in control group and 2.2 ± 3.2 in the intervention group but they were not statistically significant. (*p=0.4*) (Table 3). The mean difference of ACT score from baseline to three

Table 2: Clinical characteristics for intervention and control groups.

	Intervention (n=31)	Control (n=31)	*p* value
Mean asthma duration in years ± SD (Range)	24.7 ± 15.3 (3, 51)	28.6 ± 14.3 (6, 52)	0.310
Previous severe attack of asthma, n (%)			
Yes	18 (58)	13 (42)	0.204
No	13 (42)	18 (58)	
Admission to intensive care unit, n (%)			
Yes	2 (6)	0 (0)	0.472*
No	39 (94)	31 (100)	
Median dose of ICS (µg)	800	800	
(IQR)	(300)	(0)	0.219†
(Range)	(400, 800)	(320, 1000)	
Strength of ICS, n (%)			
Low dose	0 (0)	1 (3)	1.000*
Moderate and high dose	31 (100)	30 (97)	
Asthma medications, n (%)			
Inhaled ICS ‡	27 (87)	26 (84)	1.000*
Combined β_2-agonist & CS §	4 (13)	5 (16)	1.000*
Theophylline SR	8 (26)	7 (23)	0.767
Leukotriene inhibitors	1 (3)	1 (3)	1.000*
Comorbidities, n (%)			
Yes	12 (39)	18 (58)	0.127
No	19 (61)	13 (42)	
Presence of atopy, n (%)			
Yes	6 (19)	11 (35)	0.155
No	25 (81)	20 (65)	
BMI, n (%)			
Underweight & normal	7 (22)	6 (19)	0.584
Overweight	12 (39)	9 (29)	
Obese	12 (39)	16 (52)	
ACT mean score baseline (SD)	19.1 ± 3.8	19.2 ± 4.2	0.899

*Yates Correction, † Mann-Whitney test,
IQR: Interquartile range; ICS: inhaled corticosteroid; CS: corticosteroid; SR: slow release; BMI: body mass index

months for both groups also did not achieve the MID of three.

Secondary outcomes: There were one hospitalisation, four unscheduled health care visits and two cases of absenteeism in the control group whereas no hospitalisation, five unscheduled health care visits and no absenteeism in the intervention group over the three-month period. No significant statistical differences were observed in all the secondary outcomes among the two groups (Table 4).

Table 3: Overall mean ACT scores and at baseline and 3 months for intervention and control groups.

	Intervention group (n=31)	Control group (n=31)	*t* statistic (df)	*p* value □
Baseline	19.1 ± 3.8	19.2 ± 4.2	0.127	0.388
3 months	21.3 ± 3.2	20.5 ± 3.8	0.902	0.657
Mean difference (SD)	2.2 ± 3.2	1.3 ± 4.6	0.934	0.354

□ Independent t- test

DISCUSSION

Previous studies has reported that asthma education supported with pictorial based plans significantly improved patients' comprehension and therefore self-empowered to manage their own asthma, resulting in improvement in asthma control. [10, 16] Our study evaluated the effectiveness of adding PAA plan to standard asthma management plan in comparison with standard asthma management plan along in our local population. Both control and intervention group showed moderate improvement in asthma control from baseline which although did not achieved statistical significance but suggested that our standard asthma management plan does work in educating our patients to self-manage their own asthma. The addition of PAA plan to standard asthma management plan did not make any significant difference to standard asthma management plan alone in our study

Table 4: Asthma control parameters between the intervention and control groups.

Parameters	Intervention group (N=31) n (%)	Control group (N=31) n (%)	*p* value
Unscheduled health care visits			
Yes	5 (16)	4 (13)	1.000*
No	26 (84)	27 (87)	
Hospitalisations			
Yes	0	1 (3)	1.000*
No	31 (100)	30 (97)	
Absenteeism			
Yes	0	2 (7)	0.472*
No	31 (100)	29 (93)	

***** Yates correction

groups, which was different from the Turkish study, the latter which demonstrated the significant benefit of using the PAA plan. [16] Possible reasons for the differences could be due to the fact that the mean baseline ACT scores of our study groups were much higher than that reported by the Turkish study (19 vs. 13). Hence our study groups consisted of patients who already had well-controlled asthma at baseline or are of low risk category and hence significant improvement from using the PAA plan could not be achieved as a result. Perhaps a group with poorly controlled asthma at baseline or higher risk group may benefit more from the addition of PAA plan to standard asthma management plan.

Majority of our patients are from low educational level and low-income background, which is representative of a population where such PAA plan would have been beneficial as an educational aid. The high baseline ACT scores, besides indicating a low risk group could also perhaps suggest that the standard asthma management education provided by our Healthcare clinics were effective in empowering the patients to self-manage their asthma better. This is a positive point for our Healthcare clinics, considering over 90% of our patients are of low education level back grounds as well as low income backgrounds.

Besides that, almost 80% of participants from the Turkish study had difficulty seeking healthcare services. [16] This may have indirectly motivated the participants to manage their own disease, which could have translated to better adherence to the asthma action plan. It has been shown that highly perceived personal benefits of an asthma self-management program will motivate oneself to be more likely to participate in such programme. [17]

There were also no significant differences between these two groups in our study in terms of secondary endpoints achieved. These findings again, could be explained by the high baseline ACT scores in our study groups indicating that their asthma were well controlled at baseline and hence they are unlikely to require hospitalisation or make unscheduled healthcare visits. This again was different from the Turkish study, where they reported higher lower secondary outcomes in the intervention group. [16]

Another point to note is that there could be Hawthorne effect, which could potentially improve the asthma control indirectly and dilute the effect of the intervention. Both groups perhaps modified or improved their aspect of behaviour in response to their awareness of being observed. This is reflected in the results whereby the level of asthma control for both groups was relatively good after three months, hence the benefit of the intervention does not appear.

There are several limitations of note in our study. Firstly, our study group consisted of patients with well-controlled asthma, which may have attenuated the benefit of the PAA plan. Choosing a study population with poor asthma control like the Turkish study may provide a more positive outcome for the study. Secondly, the study was carried out only in one health clinic and in a suburban area. Therefore, the results cannot be gener-

alised to other population. Thirdly, although the sample size was calculated based on the Turkish study, but our recruitment of patients with well controlled asthma may have required a much larger sample size than calculated. Fourthly, the duration period of this study was relatively short which was three months but this was designed based on a similar study in which the duration of the follow up was also three months. [13] There were other studies which had duration ranging from six to twelve months and a longer period of follow up may have a different outcome by allowing for repeated reinforcement of the pictorial based self-management education through multiple follow ups. [16, 18] Behavioural changes cannot be successful at one visit and longer duration with repetitive reinforcement is needed to see the effects. [19] Our study unfortunately did not include the perspectives of asthmatics on the usage of self-management plans, which would be useful for future studies when customising PAA plans.

Although our study did not show significant clinical outcomes, this study, to the knowledge of the authors is the first of its kind in Malaysia to compare clinical effectiveness of pictorial based self-management with the usual care towards asthma outcomes. Since it was conducted in primary care, a setting for most asthmatics seeking for help, it provided insight into the feasibility of the utilisation of this plan at primary care level. Most of the usual care self-management are written based. On top of that, this study also demonstrated improvement of the mean ACT score within three months and the minimal important difference (MID) almost reach three in the intervention group (MID=2.2).

In conclusions, our study showed that among low to middle socioeconomic and low education background population with well-controlled asthma, the addition of pictorial based self-management education to standard asthma management education plan did not offer any significant advantage in better asthma control over the standard asthma management education plan alone (written based self-management education). Further study is required to establish its education role in a similar local population group but with poorer asthma controlled and lower ACT score.

ACKNOWLEDGEMENT

The authors would like to thank the Director of Health Malaysia for permission to publish the paper, Selangor Health Department for their permission to conduct the study in the selected clinic and the Dean and Director of UKMMC for their support and permission to conduct the study. We also like to express our gratitude to Professor Martyn Partridge, Professor Loh Li-Cher, Ms Nicola J. Roberts and Ms Wong Pei-Se for allowing us to use the pictorial asthma action plan.

REFERENCES

1: Global Initiative For Asthma. Global strategy for asthma management and prevention [Internet]. 2011 Available from: http://www.ginaasthma.org

2: Gibson P, Powell H, Wilson A, et al. Self-management education and regular practitioner review for adults with asthma. The Cochrane Library. 2001;

3: National Asthma Education and Prevention Program. Expert panel report 3: guidelines for the diagnosis and management of asthma—summary report 2007. J Allergy Clin Immunol. 2007; 120:S94-138.

4: Ahmad N, Chan M, Hiew F, et al. Disease impact and patient insight--a study on a local population of asthmatics. Med J Malaysia. 2003; 58:526-32.

5: Zainudin B, Kai Wei Lai C, Soriano J, Jia-Horng W, De Guia T. Asthma control in adults in Asia-Pacific. Respirology. 2005; 10:579-86.

6: Douglass J, Aroni R, Goeman D, et al. A qualitative study of action plans for asthma. BMJ 2002; 324:1003-5.

7: Partridge MR. Written asthma action plans. Thorax. 2004; 59:87-8.

8: Mancuso CA, Rincon M. Impact of health literacy on longitudinal asthma outcomes. J Gen Int Med. 2006; 21:813-7.

9: Safeer R, Keenan J. Health literacy: the gap between physicians and patients. Am Fam Physician. 2005; 72:463-8.

10: Houts PS, Doak CC, Doak LG, Loscalzo MJ. The role of pictures in improving health communication: a review of research on attention, comprehension,

recall, and adherence. Patient Educ Couns. 2006; 61:173-90.

11: Ring N, Jepson R, Hoskins G, et al. Understanding what helps or hinders asthma action plan use: a systematic review and synthesis of the qualitative literature. Patient Educ Couns. 2011; 85:e131-43.

12: Roberts NJ, Mohamed Z, Wong PS, Johnson M, Loh LC, Partridge MR. The development and comprehensibility of a pictorial asthma action plan. Patient Educ Couns. 2009; 74:12-8.

13: Urek MC, Tudorić N, Plavec D, Urek R, Koprivc-Milenović T, Stojić M. Effect of educational programs on asthma control and quality of life in adult asthma patients. Patient Educ Couns. 2005; 58:47-54.

14: Schatz M, Sorkness CA, Li JT, et al. Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. J Allergy Clin Immunol. 2006; 117:549-56.

specialists. J Allergy Clin Immunol. 2006; 117:549-56.

15: Schatz M, Kosinski M, Yarlas AS, Hanlon J, Watson ME, Jhingran P. The minimally important difference of the Asthma Control Test. J Allergy Clin Immunol. 2009; 124:719-23.e1.

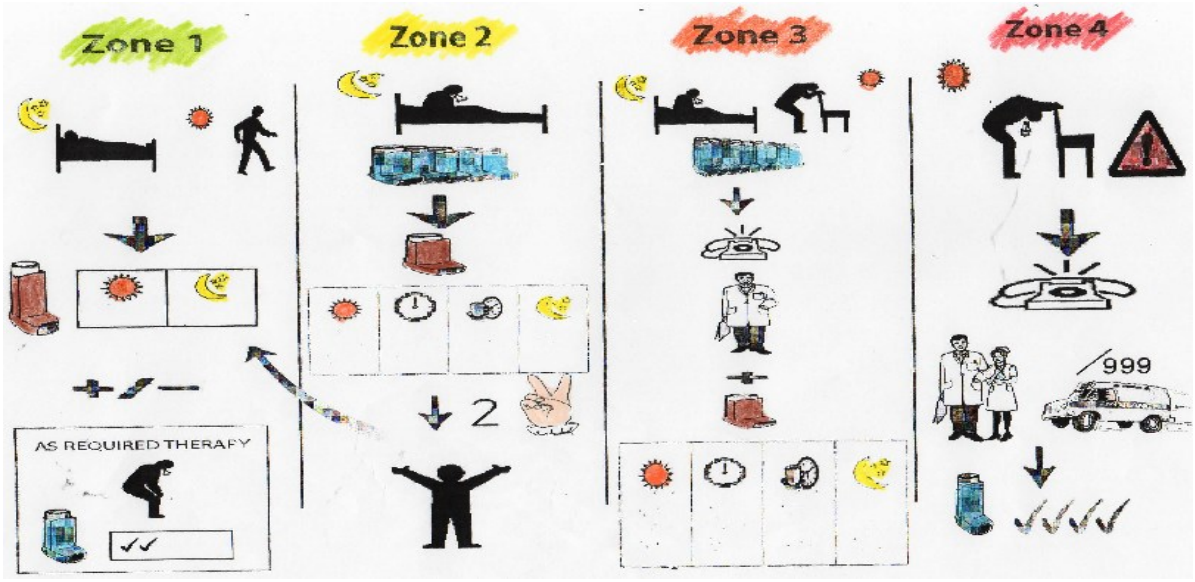
16: Pur Ozyigit L, Ozcelik B, Ozcan Ciloglu S, Erkan F. The effectiveness of a pictorial asthma action plan for improving asthma control and the quality of life in illiterate women. J Asthma. 2014; 51:423-8.

17: Lemaigre V, Van den Bergh O, Van Hasselt K, De Peuter S, Victoir A, Verleden G. Understanding participation in an asthma self-management program. Chest. 2005; 128:3133-9.

18: Van der Meer V, Bakker M, Van den Hout W, et al. Internet-based self-management plus education compared with usual care in asthma: a randomized trial. Ann Intern Med. 2009; 151:110-20.

19: Kaya Z, Erkan F, Ozkan M, et al. Self-management plans for asthma control and predictors of patient compliance. J Asthma. 2009; 46:270-5.

Pictorial Asthma Plan (PAA).



Zones and colour coding is asthma control.

ZONES	COLOUR CODING	INSTRUCTIONS
ZONE 1	GREEN	If you are feeling well, you should take _ puffs of your budesonide/beclomethasone inhaler __ per day. Use your blue inhaler for unexpected coughing, wheezing or breathlessness
ZONE 2	YELLOW	If you are woken at night by coughing, chest tightness or breathlessness or need to use your blue reliever inhaler often (2-3 times) you should increase your routine therapy to: __ puffs of your budesonide/beclomethasone inhaler _ times per day. When you feel better for at least 48 hours you can go back to your normal maintenance therapy (Zone 1)
ZONE 3	ORANGE	If you are becoming increasingly breathlessness and using your blue reliever inhaler every 4-6 hours or more, (≥ 4 times) you should let your doctor know within 24-36 hours so that the doctor can start you on prednisolone tablets.
ZONE 4	RED	It is a medical emergency if your symptoms continue to get worse. Get help immediately by dialling 999. Use the blue reliever inhaler every 5-10 minutes until you have received medical assistance.