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Impact of repeated patient counseling using different pressurized metered-dose inhalers training devices on inhalation technique, lung function, and asthma control in adult asthmatics

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Abstract

Background: Pressurized metered-dose inhalers (pMDIs) are among the most common devices that asthmatic patients use. The poor pMDI inhalation technique mostly results in poor lung deposition. The present work aimed to compare the impact of introducing two different training devices combined with their related smartphone applications on the proper performance of the inhalation technique and lung function in asthmatic adults.

Methods: A total of 316 patients were allocated to 3 groups, 105 in the control group (normal patient education group), 104 in the group using the Clip-Tone device and its smartphone applications, and 107 in the group using the Flo-Tone and its smartphone applications. Each group had three visits. Their number of inhalation technique mistakes was recorded, their forced expiratory volume in the first second (FEV_1) was measured, and an asthma control test (ACT) was given. Afterward, they had their allocated training. Differences in medians of outcomes among repeated visits per group and different groups per visit were measured. Finally, correlation statistics between FEV_1% of predicted and the correct performance of inhalation technique (as a whole and as separate steps) per visit were conducted to study any associations if existed.

Results: In the short term (after 2 visits), the Clip-Tone group showed significant superiority ($p < 0.01$) to both, the control and Flo-Tone groups, in terms of overall proper technique performance, and FEV_1% of predicted. In the long term (after 3 visits), both interventions have shown significant superiority to the control in terms of correct inhalation technique performance ($p < 0.05$) and FEV_1% of predicted ($p < 0.01$). None of them have shown significant superiority to each other. In terms of ACT scores, the Flo-Tone group showed significant improvement to both the control ($p < 0.01$) and the Clip-Tone ($p < 0.05$) groups in the second visit. In the third visit, both advancement counseling groups showed significant superiority to the control group ($p < 0.01$); However, the difference in medians between both Clip-Tone's and Flo-Tone's ACT scores disappeared. Weak, yet significant (− 0.146, $p < 0.05$) negative correlation existed between the number of mistakes in inhalation technique in the third visit and FEV_1% of predicted. Correct performance of step 7 in the third visit showed a weak significant positive correlation (0.2, $p < 0.01$) with FEV_1% of predicted.

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Conclusion: Introducing new training devices to the normal counseling that provides visual and audial feedback has shown that they could further enhance the inhalation technique performance and subsequently the lung function outcomes and asthma control of asthmatic patients. Yet, larger studies might be required to test the superiority of one to another.

Keywords: Asthma, Patient education, Clip-Tone, Flo-Tone, Inhalation technique, Lung function

1 Background

Asthma is a chronic respiratory condition that is affecting around 350 million patients across the globe and the numbers are increasing [1]. The condition requires long-term management with medications to enhance the quality of life and decrease the frequency of acute attacks [2].

pMDIs containing salbutamol are considered a cornerstone in the management of asthma [1]. Its local fast action and minimal side effects compared to their oral solutions [3], low cost per dose [4], accurate consistent dosing, and portability are behind its wide usage in asthma [5].

Although it is one of the most preferred devices in the management of this condition, one of the toughest challenges that face pMDIs is the poor inhalation technique. Previous studies have shown that around 80–90% of the patients make at least one incorrect step and the majority perform more than 20% of the steps incorrectly [6–8]. One of the most crucial errors in this technique is failing to maintain slow inhalation through the device [8].

One of the main reasons for mishandling pMDIs is the lack of proper patient education and counseling by the health care team before their usage [9]. Regular patient education improves therapy outcomes and asthma control [10–12]. The effects could be monitored by conducting lung function tests and giving the Asthma Control Test (ACT) [13]. Advanced counseling using the latest technologies could be of greater aid to enhance the inhalation technique performance by patients, especially when compared to traditional verbal counseling.

Two advanced training add-on tools were recently developed, the Clip-Tone and the Flo-Tone. Both (along with their mobile applications) operate on a basis of audio-visual inhalation technique monitoring and feedback provision. The study aimed to investigate and compare the impact of repeated patient education using these training add-ons to the pMDI and on the proper performance of the inhalation technique and asthma control. We assumed that repeated patient counseling using add-ons that give audial and visual feedback would enhance the inhalation technique and improve the asthma control over normal verbal counseling.

2 Methods

The prospective interventional study was conducted in Beni-Suef University Hospital chest clinic, and Beni-Suef chest hospital, Beni-Suef, Egypt after the study protocol was approved by the Research Ethical Committee of the Faculty of Pharmacy, Beni-Suef University (REC-H-PhBSU-21032), and following the Declaration of Helsinki. Subjects who agreed to participate provided written informed consent.

2.1 Patients

The exclusion criteria of the study were the inability of the patient to perform lung function tests in a correct manner or the possession of any neurological disorder that can affect the performance of the inhalation technique. The inclusion criteria included adult patients that were diagnosed with asthma (by two pulmonologists through history taking and lung function tests) and were prescribed the short-acting bronchodilator pMDI as a component of their treatment regimen. In this investigational study, as shown in Fig. 1, 316 asthma out-patients (193 females) were recruited and allocated to their groups using simple randomization. A total of 64 females were in the control group, 61 in the first intervention group, and 68 in the second intervention group.

2.2 Study design

The control group received normal verbal patient counseling on the correct usage of pMDI with no spacer resembling the common practice in Egypt. The first intervention group received the normal patient counseling with the addition of a training aid Clip-Tone device to the pMDI and the "Clip-Tone buddy" electronic application on a smartphone. The application only recognizes the tone that comes from the training device only if slow inspiration is maintained. The second intervention group had the same patient counseling but with the substitution of the later device with the training aid, Flo-Tone combined with the "Trainhaler Buddy" electronic smartphone application. The application here recognizes any tone that is produced by the training device despite the speed of inspiration. Figure 2 displays pictures of the two training aids, their orientation, and their respective

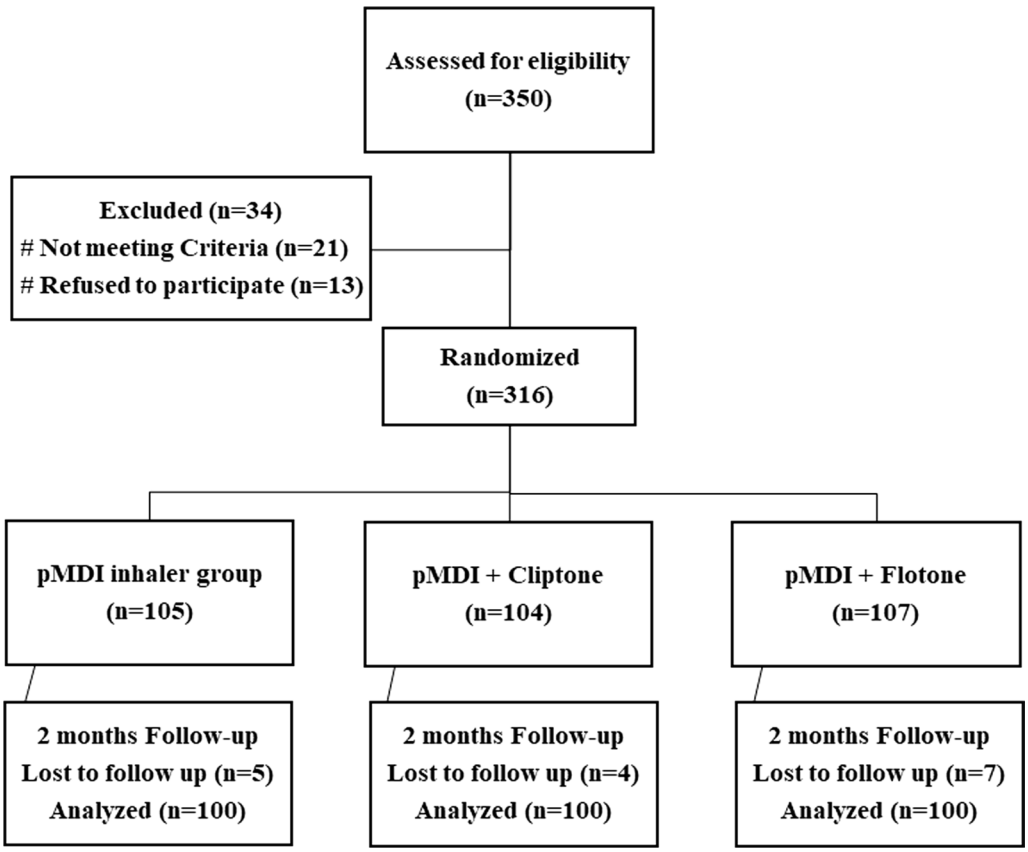

Fig. 1 Flow chart of the study

smartphone application. More details regarding the two interventions will be provided at the end of the methods section.

All patients included in the study were asked to come for 2 clinic visits in addition to the first one that established their baseline characteristics. The difference between each visit was a month. Starting from the first visit, every patient performed the lung function tests and the best of 3 readings of FEV_1 was recorded and FEV_1% of predicted was calculated. This was followed by asking the patient to demonstrate his/her inhalation technique of using the pMDI while we assessed their technique using the 11-steps guidelines as shown in Table 1. Step 10 in Table 1 was verbally communicated by the patients as it was not applicable in the chest clinic. According to the ERS/ISAM task force report suggestions, this separation of steps may help subjects in improving their inhalation technique as it makes the pMDI counseling more operative and permits us to easily notice the hard steps [14]. After their demonstration, we recorded the mistakes made and pointed them out to them along with a live demonstration of the correct inhalation technique. An additional step was added to the two intervention groups which was adding the training devices to the pMDI and training them to maintain slow inhalation as much as they can while visually monitoring their inspiration performance on the smartphone application. The inhalation through the pMDIs while using the training devices creates continuous whistle sounds which were detected by the smartphone applications, a bar corresponding to the sound goes up counting the number of seconds of slow inspiration they maintained, and a final number of seconds is displayed once they stop inspiration. A final step in the visit was asking the patients to complete the ACT, a self-administered 5-items questionnaire that assesses asthma control. The questionnaire asks about frequency of symptoms, effects on daily activities and sleep, the use of rescue medications, and overall assessment of asthma. The patients were scoring each item on a scale out of 5; 1 means not controlled at all and 5 means completely controlled. An ACT score is the sum of scores of the 5 items. A score greater than 19 indicates well-controlled asthma [15, 16]. The ACT was used to evaluate asthma control between each monthly visit. All the previous procedure was repeated in the 2 upcoming clinic visits. The two training devices (interventions) were used on spot with

Fig. 2 Clip-Tone and Flo-Tone training devices with their respective smartphone applications. **A** Clip-Tone device **B** Clip-tone placement on pMDI **C** "Clip-Tone Buddy" smartphone application (in-application screenshot). **D** Flo-Tone Device **E** Flo-Tone placement on pMDI **F** "Trainhaler Buddy", Flo-tone's smartphone application (in-application screenshot)

Table 1 Steps of correct pMDI inhalation technique

pMDI inhalation technique steps
Step 1. Remove the pMDI protective cap
Step 2. Shake the pMDI before use
Step 3. Exhale smoothly as far as comfortable
Step 4. Put the mouthpiece of the pMDI between your teeth and cover it with lips
Step 5. Ensure that your tongue does not block the pMDI mouthpiece
Step 6. Press the inhaler at the start of inhalation to emit the dose
Step 7. Maintain a slow inhalation rate until your lungs are filled
Step 8. Remove the pMDI from your mouth and hold your breath for 5–10 s
Step 9. Wait for 30 s before taking another aerosol dose, if more than a single dose is needed
Step 10. Rinse your mouth and brush your teeth
Step 11. Replace the cap on the pMDI

Table 2 Outcomes of patient education per intervention and visit

Intervention	Control			Flo-Tone CR			Clip-Tone		
Visit	1st visit	2nd visit	3rd visit	1st visit	2nd visit	3rd visit	1st visit	2nd visit	3rd visit
Number of mistakes	7 (1.75)	2 (1.75)	1 (1)	7 (2)	2 (1)	0 (1)	8 (5)	1 (3)	0 (0)
FEV_1% of predicted	57.5 (10.75)	61 (12.75)	71 (8)	56 (9)	62.5 (12.5)	81 (14)	59.75 (7.88)	68.7 (7.72)	77.7 (7.63)
Asthma control test scores	16 (3.75)	18 (2.75)	19 (1)	15.5 (4)	19 (5)	20 (4)	16 (3.75)	19 (3)	20 (2)

Outcomes of subjects are reported as median (Interquartile range)

the patients. They were not used in-between visits. Not all patients have the luxury of using smartphones or dealing with advanced technology.

2.3 Data analysis

The study was investigational to compare two recently developed add-on tools. The recommended sample size for the pilot study assuming very small effect size was 75 per group as per whitehead et al. [17]. The analyses in this study were per protocol. Normality tests were done using the Shapiro–Wilk test showing the abnormal distribution of data. Therefore, nonparametric statistical tests were used. Friedman test was used to measure differences in the medians of the number of mistakes, FEV_1% of predicted and ACT scores through the repeated visits. Should any differences occur, paired Wilcoxon test was used. This was done in general and in segregation for each of the 3 groups. Kruskal–Wallis H test was used to measure differences in the medians of the number of mistakes, FEV_1% of predicted and ACT scores among the 3 groups in each visit. It was followed by post-hoc Mann–Whitney test if significance was detected. Finally, Spearman correlation was used to measure associations between the number of mistakes and FEV1% of predicted in each visit in general. All analyses were conducted using Statistical Product and Service Solutions (SPSS), the 22nd version, and Microsoft Excel version 365. The graphical representation was done using SigmaPlot version 14.5.

3 Results

The average ages ± standard deviation overall was 46.5 ± 13.2 y, 43 ± 13.21 in the control group, 48.8 ± 12.36 y in the Clip-Tone group, and 47.8 ± 13.42 y in the Flo-Tone group.

The median values for the number of mistakes, lung function (FEV_1% of predicted), and ACT scores per visit and group are shown in Table 2 and visually presented in Figs. 3, 4 and 5. In terms of the number of mistakes, FEV_1% of predicted, and ACT scores, repeated visits, in general, have shown a significant improvement ($p < 0.001$) between any visit and the one that followed it. The Clip-Tone group showed significant improvement in the second visit compared to the control group. In the third visit, both interventions showed significant improvement compared to the control group in terms of the (inhalation technique) number of mistakes.

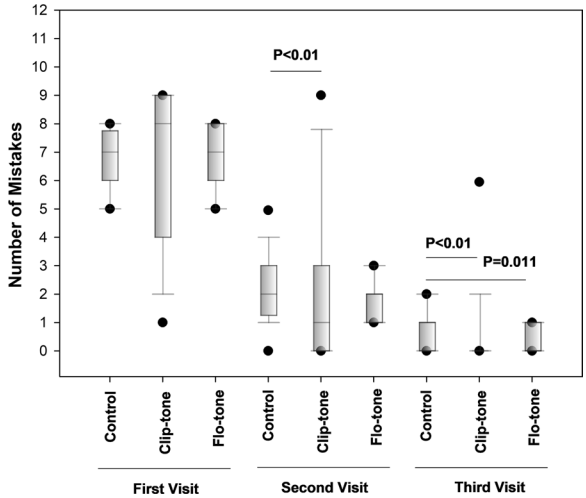

Fig. 3 Comparing medians of number of mistakes of different interventions per visit

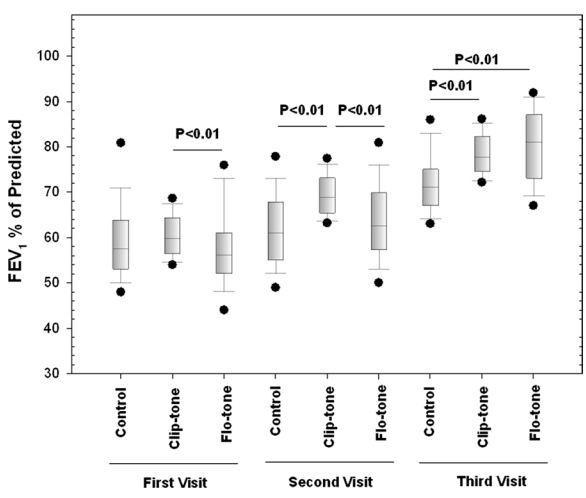

Fig. 4 Comparing medians of FEV1% of predicted of different interventions per visit

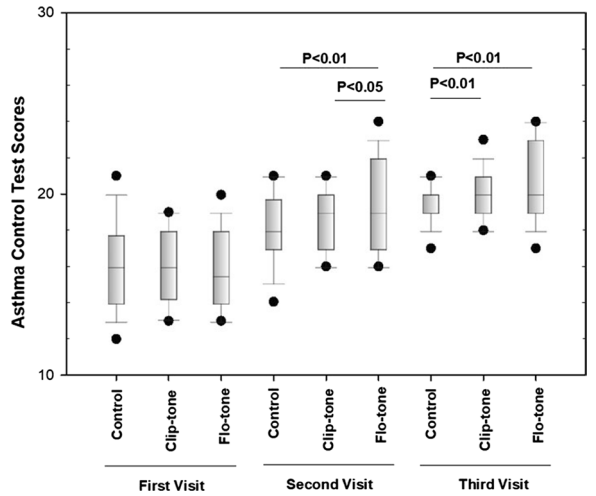

Fig. 5 Comparing medians of asthma control test scores of different Interventions per visit

In terms of lung function (FEV_1% of predicted), the Clip-Tone group showed significant improvement ($p < 0.01$) compared to the other groups in the second visit, where this difference disappeared in the third visit between the two interventions, the Clip-Tone, and the Flo-Tone groups. However, both showed significant superiority to the control group ($p < 0.01$).

Demonstrating the inhalation technique in a more detailed structure, in Table 3 we present the percentage of mistakes per step in all groups and visits. Step 7 (maintaining slow inhalation) is one of the steps that showed the highest percentage of mistakes in performing it correctly by the patients in all groups. Both interventions at the third visit showed noted better results compared to the control group.

Reflecting on the asthma control between visits, the Flo-Tone showed significant improvement compared to both, the control group and the Clip-Tone group ($p < 0.01$ and $p < 0.05$), respectively. This difference disappeared between both advanced interventions in the third visit.

Studying associations between the number of mistakes in the inhalation technique and the lung function (FEV_1% of predicted), we found a weak negative correlation between inhalation technique and the lung function in each visit, though significant in the third visit. They were as follows, an (−0.003) association between the number of mistakes in the first visit and the FEV_1% of predicted, an (−0.103) association in the second visit, and an [−0.146, $P < 0.05$)] in the third one. Measuring them in a detailed structure, associations between the correct performance of each step (especially the steps that is directly involved or may affect the inhalation technique, step 2–step 8) and the lung function in each visit are shown in Table 4, correct performance of step 6 in the second visit (coordination of actuation–inhalation step) showed a weak significant positive correlation with FEV_1% of predicted ($p < 0.05$). Correct performance of step 7 (maintaining slow inhalation) in the third visit showed a weak significant positive correlation ($p < 0.01$) with FEV_1% of predicted.

4 Discussion

Patient counseling regarding the correct performance of the inhalation technique remains a critical factor in reaching better lung function outcomes [18–21]. In our study, we have witnessed patients that used to put almost half the pMDI in their mouth, did not seal the mouthpiece with their lips, or have all the components of the puff coming out of their nostrils. Our study has shown that counseling patients through repeated visits,

Table 3 Percentage of subjects making mistakes in each inhalation technique step per intervention and visit

Intervention	Control			Flo-Tone			Clip-Tone		
Visit	1st visit	2nd visit	3rd visit	1st visit	2nd visit	3rd visit	1st visit	2nd visit	3rd visit
Step 1	0	0	0	0	0	0	0	0	0
Step 2	43	16	2	49	4	2	54	13	5
Step 3	86	40	17	91	40	14	88	41	16
Step 4	77	17	0	73	10	0	76	11	3
Step 5	59	11	0	64	9	0	57	15	6
Step 6	93	36	9	88	28	4	67	21	4
Step 7	100	48	26	100	31	8	97	26	7
Step 8	63	8	0	69	4	0	75	18	3
Step 9	62	13	2	48	5	1	51	10	8
Step 10	83	39	14	88	51	11	82	50	18
Step 11	0	0	0	0	0	0	0	0	0

Table 4 Correlation table between correct performance of a step with FEV1% of predicted

Step Number	*r* with FEV1% of predicted (Visit 1)	*r* with FEV1% of predicted (Visit 2)	*r* with FEV1% of predicted (Visit 3)
Step 1	0	0	0
Step 2	0.016	0.015	−0.032
Step 3	0.024	0.040	−0.045
Step 4	0.107	0.035	−0.051
Step 5	0.026	−0.029	−0.035
Step 6	0.091	0.137*	−0.002
Step 7	−0.031	0.104	0.2**
Step 8	−0.075	−0.094	0.047
Step 9	−0.035	−0.052	−0.002
Step 10	−0.016	−0.136*	0.07
Step 11	0	0	0

*Significant at the 0.05 level; **Significant at the 0.01 level

even without training aids, would correct their inhalation technique performance which means that continuous feedback is important till patients become natural performers. This confirms what has been reported in previous studies [10, 22].

In our study, we wanted to compare the impacts of two different training aids that have been added to the patient counseling on the proper performance of the inhalation technique. Though they differ in the design and the orientation on the pMDI, as shown in Fig. 2, both give audial and visual feedback. In our study, both interventions eventually (after 3 visits) showed superiority to the control in terms of the number of mistakes in the technique, FEV_1% of predicted, and the ACT scores. This could be attributed to the fact that both interventions engaged the patients more than the control group providing more visual and audial feedback to them. Patients can follow up regularly and try to outperform their technique. The Clip-Tone showed swift superiority to both groups in the second visit. That improvement was less with the Flo-Tone compared to Clip-Tone in the third visit. This could be explained by the orientation of the training aid (Fig. 2). The Clip-Tone is placed upwards distant from the patients' mouth not interrupting their technique which might make it easier to adapt to it and more reasonable for swifter impact. On the other hand, the Flo-Tone is placed directly on the mouthpiece and might require a longer time to adapt since it comes in direct contact with the patients' mouth.

In our study, we found that repeated visits, despite the intervention used, had an impact on decreasing the number of mistakes done while performing the inhalation technique, and this might be an important factor in improving lung function outcomes. This was in concordance with the results of previous studies [10, 23].

Since asthma control is concerned with reducing the symptoms associated with this disease and preventing risks of exacerbations [13], it was important to monitor the effectiveness of both tools on ACT scores which gives an indication of how well the asthma is controlled [15, 16]. It was evident that repetitive counseling improved the ACT scores in all intervention groups, the traditional and the advanced educational groups. The pattern was repeated in the third visit, which showed that both advanced tools were both superior to the traditional verbal counseling. However, no advanced tool showed superiority to the other in terms of controlling the disease. Our results are in concordance with the outcome of previous studies in aspect of improving disease control using advanced training such as smartphone applications [24, 25].

Based on our results, we believe that better lung function outcomes could be associated with almost mastering the inhalation technique which usually happens after frequent counseling with patients [8]. Better performance in step 7 specifically which is concerned with maintaining slow inhalation (the main focus of our study) might be one of the most important factors in the inhalation technique that could impact lung function [26]. Combining this with the results of different interventions used on the lung function and the fact that these training aids' main focus is the maintenance of slow inhalation, we would suggest that the direct involvement of these devices with step 7 has impacted the lung function performance in asthmatic patients. Of course, there were other steps in the inhalation technique that did not affect the lung function performance even remotely because they are mandatory steps such as steps 1 and 11 which are opening and closing the cap respectively. This indeed was similar to what was reported by Haitham et al. in their Flo-Tone study [27]. Though in the short term, the Clip-Tone device showed superiority to the Flo-Tone, in the long term, both of them showed similar results that better resulted than that of traditional patient counseling. [28, 29].

5 Limitations

Our study had some limitations. The lung function baseline characteristics in the Flo-Tone group were slightly lower than both the traditional verbal counseling and the Clip-Tone group. Significant superiority of one advanced counseling group to another (Clip-Tone or Flo-tone) in the long run could have required larger sample size. The impact of advanced counseling on the inhalation

technique, lung function outcomes, and asthma control beyond 3 visits is yet to be tested.

6 Conclusion

Based on our results, we would emphasize the role that regular patient education through repeated visits. This would enhance lung function outcomes. Every visit had an impact on the inhalation technique and the lung function outcome despite the intervention used. Inserting new technologies such as training devices with their smartphone applications engaged patients more, improved their technique compared to the traditional counseling, and provided better outcomes in asthmatic patients. Working on step 7 (maintaining slow inhalation) using the advanced technologies could be critical to enhancing lung function. Although both devices showed better outcomes compared to the traditional counseling, the superiority of one add-on tool training device to the other over time requires conducting a study with a larger sample size.

Abbreviations

pMDIs: Pressurized metered-dose inhalers; FEV_1: Forced expiratory volume in the first second; ACT: Asthma control test.

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Author contributions

MA. Administrative support: AS. Provision of study materials: HR. Collection and assembly of data: FS. Data analysis and interpretation: MH. Manuscript writing: AS. Final approval of manuscript: MA. All authors have read and approved the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Research Ethical Committee of the Faculty of Pharmacy, Beni-Suef University (REC-H-PhBSU-21032). Subjects who agreed to participate provided written informed consent.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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