Bull. Pharm. Sci., Assiut University, Vol. 47, Issue 2, 2024, pp. 1163-1175.

Bulletin of Pharmaceutical Sciences
Assiut University
Website: http://bpsa.journals.ekb.eg/

BULL. PHARM. SCI. Assiut Univ.

ENHANCING COMPLIANCE AND ADHERENCE OF INHALATION DEVICES AMONG ASTHMATIC PATIENTS: A COMPREHENSIVE REVIEW AND META-ANALYSIS OF INTERVENTIONS

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Background: *Potentially increased admissions to hospitals and morbidity may be associated with poor asthma care plans and treatment. Adolescents and children with asthma have been the target of numerous initiatives aimed at improving or maintaining treatment adherence.* ***Objective:*** *The purpose of this research was to examine the effect of various interventions on patients' compliance with using asthma controller inhalers.* ***Methods:*** *Studies published up until August 2022 were thoroughly searched for in four databases: Embase, Web of Science, the Cochrane Central Register of Controlled Trials, and PubMed. The data was collected and examined.* ***Results****: The analysis comprised an overall of 39 studies. Asthma educational training sessions, texting reminders, and electronic feedback were among the many interventions found. A minor but significant impact size of 0.37 [95%CI, 0.20, 0.55, P-value <0.001] was produced by the overall effectiveness of the therapies in comparison to the control group. With a cumulative effect size of 0.75 [95% CI, 0.43, 1.06, P-value<0.001], electronic surveillance was statistically significantly better than both pharmacy refills and self-reporting.* ***Conclusions****: Promotional programs aimed at adherence are successful among adolescents diagnosed with asthma. The use of electronic monitoring methods has shown to be superior and successful in enhancing patient compliance with asthma inhalers. Further longitudinal research is required to assess cost-efficiency and quantify a more accurate estimate of the effectiveness of the interventional approach employed over time.*

Keywords*: asthmatic patients, inhalers, compliance, adherence, interventions*

INTRODUCTION

Asthma is a persistent inflammatory respiratory condition that frequently affects children, resulting in severe health consequences, as well as significant morbidity and impairment. Approximately 18% of the global population suffers from symptoms of asthma. The presenting clinical manifestations encompass coughing, dyspnea, constriction, and wheezing[1]. The primary objectives of asthma management are as follows: symptom control, minimization of episodes and exacerbations, maintenance of regular daily activities, reduction of drug adverse effects, and prevention of disease progression in later life [2]. Effective management of asthma relies heavily on the adherence to asthma drugs, which refers to the degree of conforming to the recommendations and following the instructions provided by healthcare providers [3]. Currently, asthma management entails the use of acute-exacerbation drugs for short-term comfort and preventive therapy medications for long-term control. Primary preventive drugs include inhaled corticosteroids (ICS) and β2-agonists (long-acting agents)[3,4].

Improving asthmatics' commitment to long-term conservative medication has resulted in better asthma control and reduced morbidity. However, overall, average adherence remains unsatisfactory. Researchers have linked suboptimal compliance to a decline in pulmonary health, recurring flare-ups,

Received : 13/7/2024 & Accepted : 24/9/2024

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emergency department admissions, steroid use, reduced efficiency, and quality of life [5]. Episodes of asthma and poor management have greatly increased the strain on the healthcare system and expenses. Furthermore, asthma patients regard it as one of the leading causes of mortality [6,7]. Experts predict a recommended degree of adherence for good asthma control to be greater than 80%; however, children typically adhere at around 50 percent, and adults adhere at less than 30 percent. Confusion and ignorance about medication regimens may contribute to suboptimal adherence. High costs, difficulty remembering multiple-dose treatment plans, and a bad taste of the drug may all result in inadequate compliance with inhalation medications [8].

These poor rates of adherence indicate an immediate need for effective interventions to enhance adherence rates and reduce the burden of the condition [9]. Current strategies, such as inhaler reminders, switching from twice to once-daily controller medications, and various other personally adapted methods, are effective in enhancing patient adherence. Hence, the primary aims of the current systematic examination are as follows: The objectives of this study are: 1) to analyze the impact of various strategies on patients' compliance to asthma controller inhalation devices; 2) to identify the distinct categories and investigate the variations in effect sizes among the interventions; and 3) to examine the potential for bias across the implemented interventions.

METHODS

This meta-analysis was designed using the accepted principles outlined in the recommended reporting items for systematic reviews and meta-analyses (PRISMA).

Search strategies and sources of literature

We conducted a thorough search on electronic databases such as PubMed, Google Scholar, Cochrane library, and Web of Science (WOS) between January 2021 and August 2022. A manual scan of the references list for the included research revealed additional articles. A thorough approach for doing a literature search was established by combining combinations of Mesh phrases, including asthma, intervention, compliance, adherence, and following up. We referenced and compiled all obtained articles into an EndNote file to screen for duplicates and omissions. We excluded articles that we deemed irrelevant based on their abstract or full text.

Studies selection and eligibility

Inclusion of the retrieved studies was contingent upon their conformity to the following criteria: 1) Empirically assessed the impact of interventions on adherence to asthma controller drugs (e.g., ICS); 2) Thoroughly designed randomized controlled trials (RCTs) and non-RCTs; 3) Clearly defined the data on average adherence outcomes and the standard deviation, or SD, to determine the overall magnitude of the intervention's effect. We used the following criteria to exclude studies: (1) Studies published with a purpose other than quantitatively assessing the impact of an intervention on adhering to asthma treatment as the main outcome; 2) Case reports, review articles, abstracts, and editorials; 3) Studies lacking data or insufficient to estimate the overall effect size (e.g., binary outcomes).Two writers conducted separate screenings and evaluations of the titles and abstracts to determine their initial eligibility, followed by a critical examination of the complete text of the obtained studies. The search methodology and study selection process are detailed in **Fig. 1**. We examined multiple publications to identify any instances of duplication. We resolved disputes about study quality or eligibility for inclusion through deliberation and agreement.

Data extraction

Using a pre-made framework form, we extracted the following information: the name of the first author, the location, the time period, the year of publication, the age group, study approach, the total number of individuals, the demographics, the strategy used, and the adherence results. We directly obtained the data from the selected studies, without reaching out to the authors to fill in any missing information. The obtained results comprised continuous variables that were indicative of adherence to asthma drugs, as well as other mechanisms of adherence assessment such as pharmacy refills, monitoring via electronic modalities, and self-reports. In order to evaluate the extent of the contribution of the

intervention to adherence, we eliminated binary variables related to adherence that indicated the proportion of those who participated with adherence exceeding the predetermined threshold.

Quality assessment

After extracting the data, the authors evaluated the quality of the chosen studies using the Cochrane Collaboration tool[10]. The eligible studies were assigned a bias grade on a scale of low to high risk of bias. The assessment of bias risk was conducted by considering the allocation concealment strategy employed, blinding of the findings of the evaluation, missing information, attrition bias, and potential selective reporting. Any discrepancies or disputes were settled by a secondary examination of the original article.

Statistical analysis

Effect size estimates and graphical representations of interventions were generated using the Reviewer Manager (RevMan) software version 5.3 developed by The Cochrane Collaboration in Denmark. The statistical measure employed was the standardized mean difference (SMD) together with a 95% confidence interval (95%CI). A positive SMD suggests that the intervention group performed better in terms of adherence as opposed to the control group. The random or fixed-effect model was used, and the Chi-square test was employed to assess heterogeneity. The I^2 index was calculated to measure heterogeneity and varied from 0% to 100%. A value of 0% for the I^2 index indicated no heterogeneity, 25% indicated low heterogeneity, and 50% and 75% indicated moderate and extensive heterogeneity, respectively [11]. For values of I^2 above 50%, we used the random-effect model; for values below 50%, we used the fixed-effect model [12]. A subgroup analysis was conducted for every category of adherence evaluation by stratifying the original calculation according to the outcome category. A *P*-value below 0.05 indicates statistical significance for differences between subgroups. A quantitative bias evaluation was conducted using the Egger test, where bias was considered present if the P-value was less than 0.05. Qualitative assessment of bias was conducted by visually examining funnel plots of SMD against the standard errors (SE).

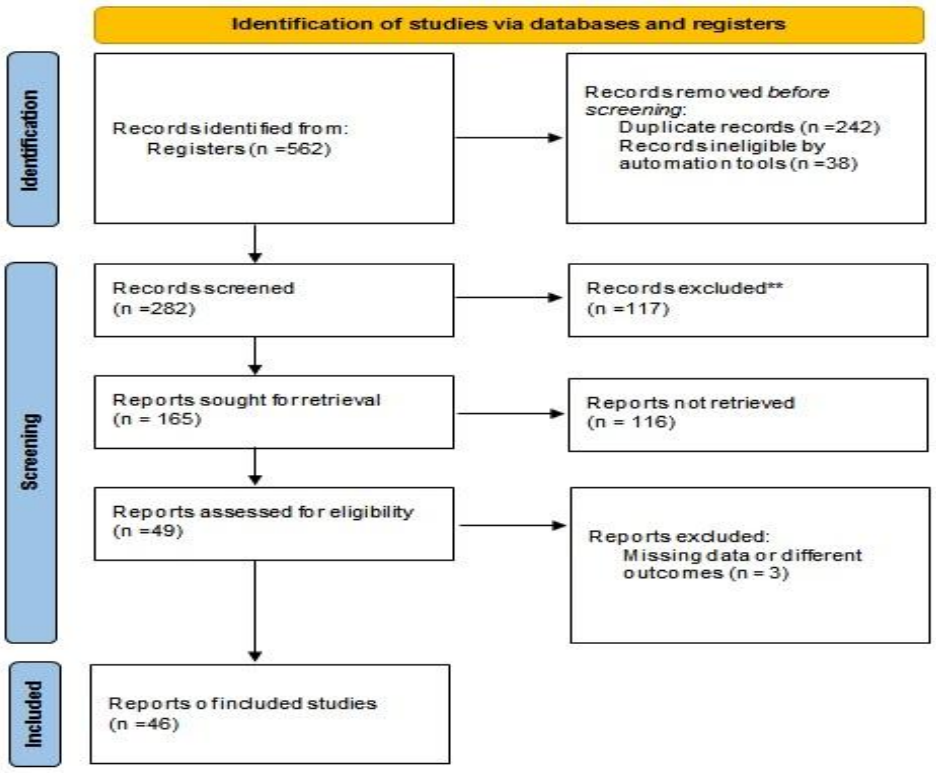

Fig. 1: Procedure flowchart for the research.

RESULTS AND DISCUSSION

Results

Interventions and studies key features

After eliminating duplicate entries, a thorough search of databases produced 562 matches. After applying the inclusion and exclusion criteria, a total of 51 papers met the requirements for full-text review and evaluation. The final, thorough qualitative and quantitative study selected 49 papers out of the total. Out of the chosen publications, 3 studies were not included in the quantitative analysis because of the inconsistency in the provided results, such as the dichotomous adherence measure or the failure to provide the mean adherence value and its standard deviation in the study groups. The included studies encompassed a combined total of 17,545 asthma patients in pediatric and adolescent populations[13–58]. The study included 41 RCTs out of 46 total studies included. There was a wide difference in the original sample sizes of the studies, ranging between 8 in Garbut et al., 2015[39] and 8,517 patients with asthma in Vollmer et al., 2011[24] study. **Table 1** displays the key features of the publications that were included. The average age in the majority of research was between six and twelve years old.

Table 1: Included studies main characteristics.

Study ID	Study design	No. of patients	Follow-up duration	Intervention description
Van ES et al., 2001 [13]	RCT	86	2 months	Sessions with asthma nurse individually or in groups for social support and motivation
Chan et al., 2003 [14]	RCT	10	24 weeks	Internet based monitoring and asthma education
Farber and Oliveria, 2004 [15]	RCT	50	Single session	Asthma education of basics and self-control plan
Hederos et al., 2005[16]	RCT	60	24 weeks	Parent support group
Butz et al., 2006 [17]	RCT	181	6 months	Asthma education in home including appropriate practice and symptoms identification
Charles et al., 2007 [18]	RCT	110		Audio-visual reminders with EM
Jan et al., 2007 [19]	RCT	153	12 weeks	Internet-based monitoring and educational system for asthma control
Petkova et al., 2008 [20]	RCT	50	4 months	Educational plan for patients
Saini et al., 2008 [21]	Non-RCT	90	24 weeks	Educational plan for asthmatic patients
Otsuki et al., 2009 [22]	RCT	167	About 45 minutes home visits	Asthma education in home visits and feedback for adherence
Bender et al., 2010 [23]	RCT	50	10 weeks	Interactive phone calls and EM
Burgess et al., 2010 [24]	RCT	26	4 months	Smart inhaler device send feedback to parents and physicians
Butz et al., 2010 [25]	RCT	156	6 months	Asthma management skill education
Chen et al., 2010[26]	RCT	60	10 months	Support group and action plan tailored for patients
Strandbygaard et al., 2010 [27]	RCT	26	12 weeks	Text messages

Table 1: Continued.

Williams et al., 2010[28]	RCT	2,968	12 months	Patient adherence monitoring and feedback
Ducharme et al., 2011[29]	Single blinded RCT	309	Single session	Written action plan for asthma during acute visits
Petrie et al., 2011 [30]	RCT	216	9 months	Text messages
Riekert et al., 2011 [31]	Pre and post intervention	37	About 45 minutes home visits	Home visits for motivational interviews based on asthma self-control program
Vollmer et al., 2011[32]	RCT	8,517	18 months	Interactive voice calls
Feldman et al., 2012[33]	Non-randomized controlled trial	85	6 weeks	Comparison of children predicted PEF and actual values.
Gustafson et al., 2012[34]	RCT	259	12 months	Phone calls from healthcare practitioner integrated eHealth program
Armour et al., 2013 [35]	RCT	398	6 months	Educational program for patients and follow-up for 6 months
Duncan et al., 2013 [36]	RCT	29	8 weeks	Youth and parent teamwork for targeted asthma control
Mosnaim et al., 2013[37]	RCT	46	10-week duration	Support group for asthma and recorded messages for motivation
Rohan et al., 2013 [38]	RCT	11	2-3 sessions	Electronic problem solving and feedback
Butz et al., 2014 [39]	RCT	274	16 weeks	Home visits for asthma education with feedback letter to clinician
Foster et al., 2014 [40]	RCT	78	26 weeks	Digital education and follow-up for asthmatic patients
Naar-king et al., 2014[41]	RCT	167	24 weeks	Therapy-healthcare intervention
Abramson et al., 2015[42]	RCT	72	12 weeks	4 visits in 1 year with reports and medical review
Bender et al., 2015 [43]	RCT	899	24 weeks	Phone call for inhaler refill
Chan et al., 2015 [44]	RCT	220	6 months	Audio-visual reminders
Garbutt et al., 2015 [45]	Pre and post intervention	8	24 weeks	Skill training and education for targeted asthma management
Koufopolous et al., 2015 [46]	RCT	103	9 weeks	Internet-based support group and social media
Wiecha et al., 2015 [47]	RCT	30	6 months	Educational website for adherence promotion and teamwork with family members
Horner et al., 2016 [48]	RCT	173	Single day	Day camp for asthma followed by plan for patients
Johnson et al., 2016[49]	RCT	65	3 weeks	Text messages at pre-determined medication administration times

Table 1: Continued.

Vasbinder et al., 2016[50]	RCT	209	12 months	Text messages as reminders for medication
Britto et al., 2017 [51]	Cross-over study	22	3 months	Text messages for asthma management reminder for 3 months
Morton et al., 2017 [52]	RCT	77	12 weeks	Electronic monitoring with daily reminders
Pool et al., 2017 [53]	RCT	407	52 weeks	Online tool for patients queries about asthma symptoms and medication use
Harrington et al., 2018[54]	RCT	46	8 weeks	Morning inhaler use guided by school nurse
Kenyon et al., 2019 [55]	RCT	32	4 weeks	Text messages as a reminder for inhaler use
Kosse et al., 2019 [56]	RCT	234	24 weeks	Smartphone application for education, reminder and pharmacist chat
Koumpagioti et al., 2020 [57]	RCT	78	Single session	Educational program for asthma care
Rodrigues et al., 2021[58]	Cluster RCT	201	6 months	Education of patients about proper inhalation devices techniques

*RCT: randomized controlled trials, PEF: Peak expiratory flow, EM: electronic monitoring.

Interventions Effectiveness

The therapies comprised asthma teaching workshops, text-message reminders, and technological feedback. The compliance with asthma inhalers was assessed using digital tracking (n=21), pharmacy refill tracking (n=15), and self-reporting (n=10). The comparison of interventions with the control showed a modest but statistically significant effect size (SMD: 0.37, 95%CI: 0.20, 0.55, P <0.001). The studies showed a high level of heterogeneity (I^2 = 95%), indicating the existence of possible factors that may moderate the impact of the interventions. These findings can be examined in **Fig. 2.** A subgroup analysis was conducted based on the specific type of adherence measurement. A statistically significant difference was observed between the subgroups (P-value=0.002). The collective effect size of studies that used pharmacy refill data was not statistically significant, with a standardized mean difference (SMD) of 0.09 (95% CI: -0.18, 0.37, P-value = 0.51). However, for self-report intervention, a significant difference was found, with an SMD of 0.08 (95% CI: -0.13 - 0.55, P=0.45). Nevertheless, we noted a significant degree of variation in the use of pharmacy refills (I^2=97%) and a modest divergence (I^2=74%) in the implementation of self-report adherence measures. Electronic monitoring yielded a greater combined effect size than pharmacy refill and self-report, and this difference was statistically significant with a standardized mean difference (SMD) of 0.75 (95% confidence interval from 0.43 to 1.06, P<0.001). Indeed, the level of heterogeneity was notably high (I^2=92%).

The conducted sensitivity analyses by removing William et al., 2010[20] and Chan et al., 2015 [38] in which the intervention involved physicians instead of patients or the use of different settings. The cumulative effect size changed to SMD (95%CI) of 0.33 (0.21 to 0.45), P<0.001 and heterogeneity level (I^2) of 85%.

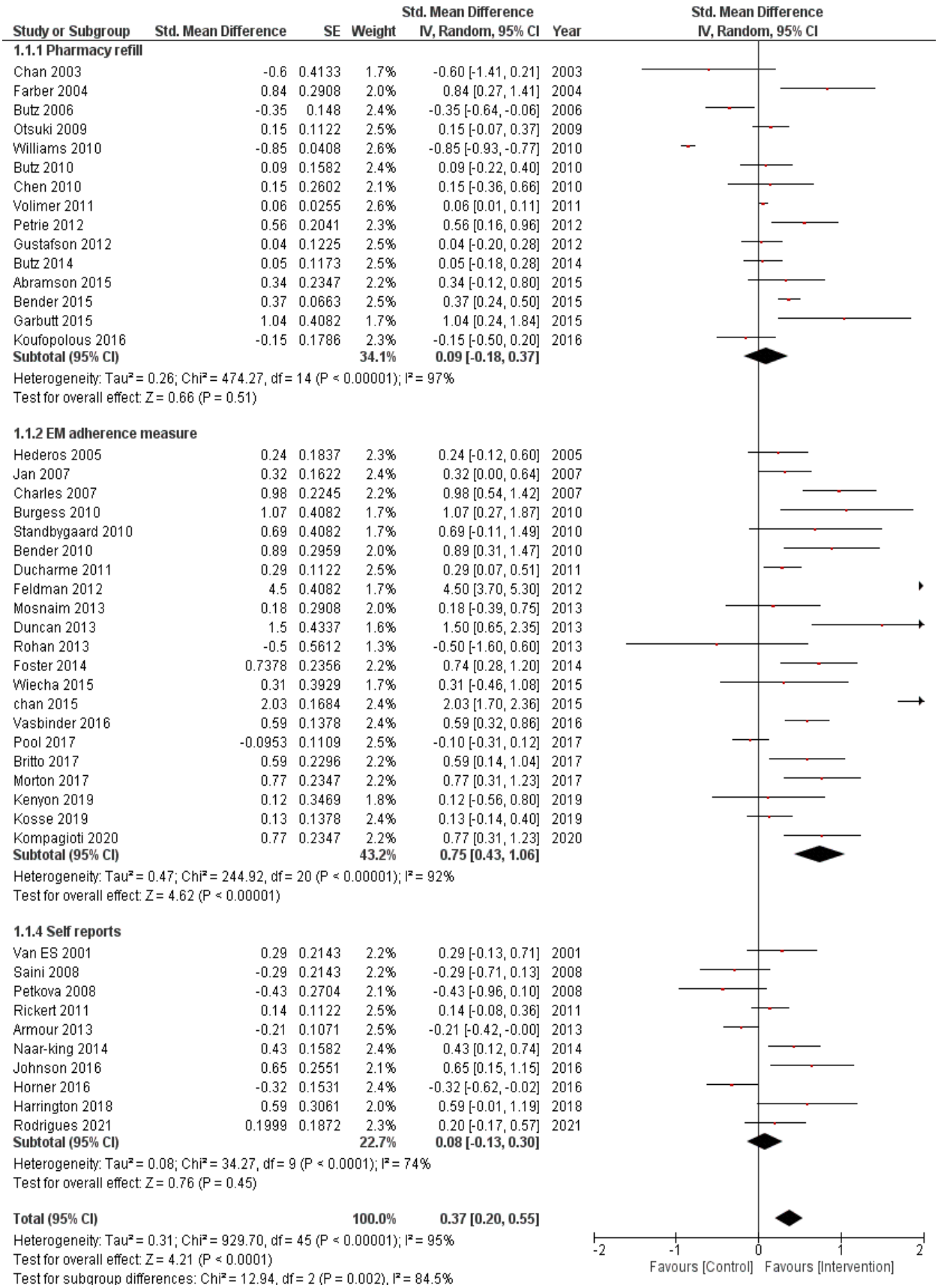

Fig. 2: Post-interventional pooled impact estimates for adherence in comparison to the control forest plot.

Risk of bias

All qualifying trials underwent an evaluation of bias risk using the Cochrane Collaboration methodology. Seven studies were deemed to have a high RoB in at least one domain. The majority of trials are classified as high risk due to insufficient blinding protocols, randomization, and concealment description. Only two researches sufficiently explained the mechanism of blinding for both investigators and participants. Results from the Egger regression analysis indicated absence of publication bias (P-value = 0.741), which was also seen in the symmetry of the funnel plots.

Discussion

Clinical practitioners could overestimate the degree of severity of asthma if they neglect to assess adherence, therefore establishing a mutually influencing connection between severe asthma and adherence. Furthermore, if not treated properly, insufficient adherence to the prescribed regimen may lead to the onset of severe asthma [59]. The primary aim of this meta-analysis investigation was to evaluate the degree to which treatments can enhance compliance with inhalers for asthma among children and adolescents. Pooling the effect size after the intervention from the 46 trials considered showed a modest yet statistically significant increase in compliance to inhalation devices with the implemented treatments. Due to its ability to offer objective and precise data, electronic monitoring is considered the gold standard method for assessing asthma adherence. The findings of our study indicated that the utilized methodology in measuring adherence had an influence on the observed impact of the intervention. Electronic monitoring for adherence measurement yielded a cumulative effect size of [SMD: 0.75, 95%CI, 0.43, 1.06, P-value<0.001], which is approximately double the combined effect size derived from the various types of adherence metrics. The results of our study indicate that those who utilized electronic monitoring tools for adherence were more inclined to adhere to their inhalers as opposed to the control group.

The effect size observed when self-reported adherence evaluation was used was modest and did not reach statistical significance. This can be ascribed to the variations in the methods of self-report used in the research articles reviewed, which ranged from telephone calls or single-item questionnaires to a standardized compliance questionnaires [60]. In contrast to the self-reported and digital monitoring measures, the cumulative estimate for pharmacy refills was the lowest and surprisingly favored the control group over the interventions. This conclusion may be attributed to the physician-based strategy that had been analyzed. Nevertheless, the omission of this research in the conducted sensitivity analysis resulted in a significant rise in the cumulative effect of pharmacy refill sub-category, favoring the interventional study groups SMD (95%CI) of (0.14; 0.01 to 0.28, P-value =0.040).

Various studies in this review had different populations and methods of measuring adherence, which likely contributed to the heterogeneity. These factors included different intervention recipients' sociodemographics, the age of groups of the included population, and the methods used to measure adherence.

Consistent with other systematic reviews and meta-analyses [61,62], the findings of this meta-analysis indicate the positive role of interventions in enhancing adherence to asthma inhalers among asthma patients [63]. Among the analyzed research studies, about 13% (n=6) evaluated adherence after a long follow-up period. It is noteworthy that the substantial magnitude of the overall impact of the intervention decreased during the period of follow-up, indicating that the interventions didn’t lead to long-term improvements in inhaler adherence. The research articles included in the analysis examined the impact of various interventions aimed at improving adherence. These interventions included home and audio-taped visits, customized treatment plans, digital monitoring devices, education programs, and text messages that served as reminders for individuals to take their prescribed medication doses [64]. Further investigation is necessary to determine the optimal time period for monitoring in order to confirm the long-lasting effects of digital adherence devices for monitoring.

Limitations

Several limitations, including the general quality of the research analyzed, should be

considered when interpreting this meta-analysis. Some studies' methodology was flawed due to issues such as inadequate randomization, improper blinding for the findings assessors, a large number of the participants dropping out, or poor adherence data. Most interventions had a high or uncertain risk of bias in at least one area, and often a large risk. While it's common knowledge that participants' knowledge of treatment instructions can cause performance distortion and impact behavioral outcomes, particularly adherence, it's crucial to acknowledge that blinding doesn't apply to all behavioral therapies. Additional limitations pertain to the applied criteria for exclusion and the generalizability of the findings.

Conclusions

Our objective in doing this review was to synthesize the strongest evidence from a number of studies by employing a meta-analysis approach that was strict, systematic, and analytical. This comprehensive review emphasizes the crucial role that digital devices for adherence tracking and evaluation play in asthmatic care, particularly in improving inhaler usage compliance. To apply the results to a larger population of asthmatic patients, further studies using well-constructed trials with larger samples are required. Digital adherence monitoring equipment, capable of recording both actuation and inhalation actions, is increasingly necessary to ensure medication inhalation, particularly in relation to adherence responses and the involvement of caregivers and healthcare professionals in asthma symptom management.

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Bull. Pharm. Sci., Assiut University, Vol. 47, Issue 2, 2024, pp. 1163-1175.

نشرة العلوم الصيدليـــة
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BULL. PHARM. SCI. Assiut Univ.

التدخلات لتحسين الالتزام ومراقبة أجهزة الاستنشاق بين مرضى الربو: مراجعة منهجية وتحليل تلوي

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الخلفية: الرعاية غير الكافية للربو كانت متورطة في ارتفاع معدلات دخول المستشفى والمراضة. تم تطوير مجموعة واسعة من التدخلات لدعم وتعزيز الالتزام بالعلاج بين الأطفال والمراهقين المصابين بالربو.

الهدف: تهدف الدراسة الحالية إلى تقييم تأثير التدخلات المختلفة على التزام المريض بأجهزة الاستنشاق للتحكم في الربو.

الطرق: أجريت هذه الدراسة وفقًا لإرشادات PRISMA (عناصر إعداد التقارير المفضلة للمراجعات المنهجية وامتداد التحليلات الوصفية). تم البحث بشكل منهجي في أربع قواعد بيانات (PubMed، وسجل كوكرين المركزي للتجارب ذات الشواهد، وWeb of Science، وEmbase) عن الدراسات المنشورة حتى أغسطس ٢٠٢٢. وتم استخراج البيانات وتحليلها.

النتائج: تم تضمين ما مجموعه ٣٩ دراسة في التحليل. تم تحديد مجموعة واسعة من التدخلات، بما في ذلك الدورات التعليمية حول الربو، والتذكير بالرسائل النصية وردود الفعل على التكنولوجيا. أدت الفعالية الإجمالية للتدخلات مقابل التحكم إلى حجم تأثير صغير، ولكنه مهم بمتوسط فرق (SMD) قدره ٠.٣٧ [٩٥% CI: ٠.٢٠ إلى ٠.٥٥، P <٠.٠٠١]. حققت المراقبة الإلكترونية حجم تأثير مجمع أعلى مقارنة بإعادة تعبئة الصيدلية والتقرير الذاتي وكانت ذات دلالة إحصائية مع متوسط متوسط قدره ٠.٣٧ [٩٥% CI: ٠.٤٣ إلى ١.٠٦، P<٠.٠٠١].

الاستنتاجات: تدخلات تعزيز الالتزام فعالة بين الشباب المصابين بالربو. وكانت طرائق المراقبة الإلكترونية متفوقة وفعالة في تحسين التزام المريض باستنشاق الربو. هناك حاجة إلى دراسات بحثية طولية إضافية لتقييم فعالية التكلفة وتحديد مقياس أكثر دقة لفعالية التدخل مع مرور الوقت.