

Final

Asthma: diagnosis, monitoring and chronic asthma management (update)

**[M] Evidence reviews for pulmonary function
monitoring in asthma**

BTS/NICE/SIGN collaborative guideline NG245

*Evidence reviews underpinning recommendation 1.5.3 in the
guideline*

November 2024

Final

Developed by BTS, NICE and SIGN

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1. Pulmonary function monitoring

1.1 Review question

In people with asthma, what is the clinical and cost-effectiveness of using measures of pulmonary function assessing asthma control (for example, spirometry and peak expiratory flow) to monitor asthma?

1.1.1 Introduction

It is not clear whether treatment of asthma should be adjusted because of symptoms alone or whether objective measures should also be used. Symptoms are of paramount importance to the person with asthma, but the main symptoms of asthma (cough, breathlessness) can have other causes and there is a danger of overtreatment if dosages are increased too readily. Conversely, some people with asthma do not sense narrowing of their airways until it has become marked, placing them at risk of a severe attack. The purpose of this review is to assess whether regular measurement of airflow obstruction, using either spirometry or peak expiratory flow (PEF), is useful in guiding asthma therapy

1.1.2 Summary of the protocol

For full details see the review protocol in Appendix A.

Table 1: PICO characteristics of review question

| | |
|----------------------|---|
| Population | People with asthma All ages, stratified into the following 2 different groups: <ul style="list-style-type: none">• Children/young people (5-16 years old)• Adults (>17 years old) Exclusions: <ul style="list-style-type: none">• Severe asthma• Children <5 years |
| Interventions | Monitoring lung function using the following tests, and using the outcomes to adjust management/therapy according to physician decision or personalised treatment plan <ul style="list-style-type: none">• Spirometry (FEV1; FEV1/FVC; Flow loop measures)• PEF |
| Comparisons | Comparison of adjustment of asthma therapy based on lung function tests to: <ul style="list-style-type: none">• Usual care: e.g. clinical symptoms according to guidelines (including BTS/SIGN, GINA)• Asthma control or QOL questionnaires Comparison of adjustment of asthma therapy based on: <ul style="list-style-type: none">• Spirometry versus PEF |
| Outcomes | <ul style="list-style-type: none">• Mortality• Unscheduled healthcare utilisation (ED/A&E visit; hospital admissions; GP out of hours or walk-in centre)• Severe asthma exacerbations (defined as asthma exacerbations requiring oral corticosteroid use- dichotomous outcome at ≥ 6 months, latest time point if more than one)• Asthma control (assessed by validated questionnaires (ACT; CACT; ACQ; PACQ; RCP-3; continuous outcome at ≥ 3 months) |

| | |
|---------------------|---|
| | <ul style="list-style-type: none">• Quality of life (QoL assessed via any validated scale including asthma specific questionnaires: AQLQ; pAQLQ; St George’s respiratory questionnaire); (continuous outcome at ≥3 months)• Lung function (FEV1, PEF)• Symptoms (annual symptom free days)• Dose of regular asthma therapy / preventer medication (ICS dose)• Reliever/Rescue medication (SABA use; continuous outcome at ≥3months)• Time off school or work |
| Study design | <ul style="list-style-type: none">• RCTs• SRs of RCTs |

1.1.3 Methods and process

This evidence review was developed using the methods and process described in [Developing NICE guidelines: the manual](#). Methods specific to this review question are described in the review protocol in appendix A and the methods document. Due to the nature of the interventions being assessed in this evidence review, adherence to monitoring strategies within trials has been carefully noted during data extraction; any limitations have been assessed in domain 2b of the Cochrane risk of bias tool.

Declarations of interest were recorded according to [NICE’s conflicts of interest policy](#).

This evidence review is an update of chapter 24 of the previous Asthma guideline [NG80](#).

1.1.4 Effectiveness evidence

1.1.4.1 Included studies

Ten trials were included in the review (Adams, et al., 2001, Buist, et al., 2006, Charlton, et al., 1990, Cote, et al., 1997, Cowie, et al., 1997, Kaya, et al., 2009, Lopez-Vina, et al., 2000, Turner, et al., 1998, Wensley, et al., 2004, Yoos, et al., 2002)all of which focussed on PEF monitoring versus usual care (symptom-based monitoring). Seven studies(Adams et al., 2001, Buist et al., 2006, Cote et al., 1997, Cowie et al., 1997, Kaya et al., 2009, Lopez-Vina et al., 2000) were conducted in adults and two(Wensley et al., 2004, Yoos et al., 2002) were conducted in children and young people; one study (Charlton et al., 1990) was conducted in children and adults. These are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary (Table 3). There was no evidence identified on spirometry monitoring.

All the studies included in this review were included previously in chapter 24 ([NG80](#)); no additional trials have been identified.

See also the study selection flow chart in Appendix C, study evidence tables in Appendix D, forest plots in Appendix E, and GRADE tables in Appendix F.

1.1.4.2 Excluded studies

See the excluded studies list in Appendix I.

1.1.5 Summary of studies included in the effectiveness evidence

Table 2: Summary of studies included in the evidence review

| Study | Intervention and comparison | Population | Outcomes | Comments |
|--------------------------------------|---|--|--|--|
| PEF based monitoring | | | | |
| Adams 2001(Adams et al., 2001) | <p>PEF monitoring (self-management plan activated by a fall in PEF).</p> <p>Usual care (self-management plans activated by increase in symptoms)</p> | <p>Adults aged 16-70 years with moderate-severe asthma (not defined).</p> <p>N=134</p> <p>Ethnicity: not reported</p> <p>Education level: not reported</p> <p>Language: English</p> <p>Australia</p> | <p>Unscheduled healthcare utilisation (emergency department visit, hospital admissions)</p> <p>Lung function (FEV₁)</p> <p>Time off work</p> <p>12 months follow-up</p> | <p>Understanding of self-management protocols was 76-78%</p> <p>Population indirectness: participants described as moderate-severe asthma; baseline characteristics suggestive of severe</p> |
| Buist 2006(Buist et al., 2006) | <p>PEF monitoring (twice daily or as-needed) plus education including inhaler technique and asthma action plan.</p> <p>Usual care (symptom based monitoring, plus education including inhaler technique and asthma action plan)</p> | <p>Adults aged 50-92 years using medication suggestive of moderate-severe asthma</p> <p>N=296</p> <p>Ethnicity: not reported</p> <p>Education level: not reported.</p> <p>Language: English</p> <p>USA</p> | <p>Unscheduled healthcare utilisation (rate of acute asthma care: hospital, ED, other acute care)</p> <p>6, 24 months follow-up</p> | <p>Population indirectness: participants described as moderate-severe asthma</p> |
| Charlton 1990(Charlton et al., 1990) | <p>PEF monitoring (self-management plan activated by PEF)</p> <p>Usual care (symptom based self-management action plan)</p> | <p>Children and adults attending an asthma clinic (no baseline characteristics)</p> <p>N=115 (46 children and 69 adults)</p> <p>Ethnicity: not reported</p> | <p>Severe asthma exacerbations (needing oral steroids) (adults and children outcomes reported separately)</p> <p>12 month follow-up</p> | <p>No baseline characteristics</p> |

| Study | Intervention and comparison | Population | Outcomes | Comments |
|--------------------------------|--|--|--|----------|
| | | <p>Education level: not reported</p> <p>Language: English</p> <p>England</p> | | |
| Cote 1997(Cote et al., 1997) | <p>PEF monitoring (twice per day and reviewed at follow-up visits, with PEF-directed 4 step self-action plan.</p> <p>Usual care (symptom based self-management plan)</p> | <p>Adults with moderate to severe asthma, aged ≥16 y, and taking daily anti-inflammatory agent</p> <p>N=95</p> <p>Ethnicity: not reported</p> <p>Education level: not reported</p> <p>Language: English</p> <p>Canada</p> | <p>Unscheduled healthcare utilisation (hospital admissions, emergency room visit)</p> <p>Time off school/work (days lost from work/school)</p> <p>12 months follow-up</p> | |
| Cowie 1997(Cowie et al., 1997) | <p>PEF monitoring (PEF-based action plan)</p> <p>Usual care (symptom based action plan)</p> | <p>Adults and adolescents who had received urgent treatment at the emergency department for asthma exacerbations in the preceding 12 months and used asthma medication</p> <p>Mean (SD) age in years =39.1 (14.41); 36.8 (16.50)</p> <p>N=91 (completed and included in analysis)</p> <p>Ethnicity: not reported</p> | <p>Unscheduled healthcare utilisation [number of people attending for urgent treatment of asthma; hospital admissions (total number of admissions for asthma)]</p> <p>6 months follow-up</p> | |

| Study | Intervention and comparison | Population | Outcomes | Comments |
|---|---|--|---|---|
| | | <p>Education level: not reported</p> <p>Language: English</p> <p>Canada</p> | | |
| Kaya 2009(Kaya et al., 2009) | <p>PEF monitoring (PEF-based action plan)</p> <p>Usual care (symptom based self-management)</p> | <p>Adults, mean age=43 years (SD 10.48)</p> <p>According to GINA guidelines, 14.3% of the patients were classified as mild (n = 9), 47.6% (n = 30) as moderate, and 38.1% (n = 24) as severe persistent asthmatics.</p> <p>N=63</p> <p>Ethnicity: not reported</p> <p>Education level: mixed</p> <p>Language: not reported</p> <p>Turkey</p> | <p>Health related QoL (SF-36)</p> <p>Lung function (FEV₁ predicted)</p> <p>3, 6 months follow-up</p> | <p>Followed up for 12 months but compliance decreased after 6 months, no 12 months outcomes reported</p> <p>Population indirectness: downgraded because 38.1% severe asthma</p> |
| Lopez-Vina 2000 (Lopez-Vina et al., 2000) | <p>PEF monitoring (PEF-based self-management plan)</p> <p>Usual care (symptom based self-management plan)</p> | <p>Adults aged 17 to 65 years who had required emergency asthma treatment in previous 18 months.</p> <p>N= 100</p> <p>Ethnicity: not reported</p> <p>Education level: not reported</p> <p>Language: not reported</p> | <p>Unscheduled healthcare utilisation (hospital admissions, visits to emergency ward)</p> <p>Lung function (FEV₁% predicted)</p> <p>Time off school/work (absenteeism from work/school)</p> <p>12 months follow-up</p> | |


| Study | Intervention and comparison | Population | Outcomes | Comments |
|------------------------------------|---|--|--|--|
| | | Spain | | |
| Turner 1998(Turner et al., 1998) | PEF monitoring (self-management plan based on PEF monitoring) Usual care (self-management plan based on symptom monitoring) | Adults aged 18-55 years. N=92 Ethnicity: mixed Education level: not reported Language: English Canada | Unscheduled healthcare utilisation (hospitalisation, emergency department visits, unscheduled doctor visits) Severe asthma exacerbations (prednisone treatments) Time off school or work (days lost school/work) 6 months follow-up | |
| Wensley 2004(Wensley et al., 2004) | PEF monitoring (PEF-based action plan plus symptom monitoring) Usual care (symptom based management) | Children aged 7 to 14 (median 11, 12 years) N=90 Ethnicity: not reported Education level: not reported Language: not reported England | Unscheduled healthcare utilisation (hospital admissions, attendance at A&E, emergency GP visits) Time off school or work (absent from school) 12 weeks follow-up | |
| Yoos 2002(Yoos et al., 2002) | PEF monitoring (Twice daily PEF monitoring and symptom-time PEF monitoring in two arms) with personal action plan zones based on symptoms and PEF. Usual care , with personal action | Children and adolescents aged 6-19 years N=168 Ethnicity: mixed Education level: mixed | Lung function (FEV ₁ % predicted) 3 months follow-up | Proportion of people aged 17-19 years not reported, no mean (SD) for age given |

| Study | Intervention and comparison | Population | Outcomes | Comments |
|-------|-----------------------------|---------------------------------|----------|----------|
| | plan based on symptoms only | Language: English USA | | |

See Appendix D for full evidence tables.

1.1.6 Summary of the effectiveness evidence

Table 3: Clinical evidence summary: PEF monitoring versus usual care (symptom monitoring) in adults

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|---|--|---|--------------------------|---|---|--|
| | | | | Risk with symptoms monitoring: adults | Risk difference with PEF | Comments |
| Unscheduled healthcare utilisation (total asthma-related, lower is better, 24 months) | 294 (1 RCT) |  Low ^{a,b} | - | The mean unscheduled healthcare utilisation (total asthma-related health care utilisation, lower is better, 24 months) was 1.5 | MD 0.11 lower (0.59 lower to 0.37 higher) No clinical difference | MID=1.23 (calculated as baseline SD of both arms/2) |

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|--|--|-----------------------------------|----------------------------------|---------------------------------------|---|---|
| | | | | Risk with symptoms monitoring: adults | Risk difference with PEF | Comments |
| Unscheduled healthcare utilisation (urgent asthma treatment, lower is better, 6 months) | 91 (1 RCT) | ⊕⊕○○ Low ^{c,d} | RR 0.35 (0.14 to 0.89) | 311 per 1,000 | 202 fewer per 1,000 (268 fewer to 34 fewer) Clinically important benefit of PEF | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |
| Unscheduled healthcare utilisation (hospital admissions, events, lower is better, 6-12 months) | 417 (4 RCTs) | ⊕○○○ Very low ^{b,e,f} | RR 0.80 (0.35 to 1.83) | 51 per 1,000 | 10 fewer per 1,000 (50 fewer to 30 more) No clinical difference | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|---|--|-----------------------------------|----------------------------------|--|---|---|
| | | | | Risk with symptoms monitoring: adults | Risk difference with PEF | Comments |
| Unscheduled healthcare utilisation (mean hospital admissions over 1 year, lower is better, 12 months) | 95 (1 RCT) | ⊕○○○ Very low ^{g,h} | - | The mean unscheduled healthcare utilisation (mean hospital admissions over 1 year, lower is better, 12 months) was 0.09 | MD 0.05 lower (0.16 lower to 0.06 higher) No clinical difference | MID = 0.138 (SDs of both arms at follow-up/2) |
| Unscheduled healthcare utilisation (ED visits, lower is better, 6-12 months) | 326 (3 RCTs) | ⊕○○○ Very low ^{f,i,j} | RR 1.63 (0.39 to 6.77) | 59 per 1,000 | 37 more per 1,000 (36 fewer to 339 more) Clinically important benefit of symptom monitoring | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|---|--|-----------------------------------|----------------------------------|---|--|--|
| | | | | Risk with symptoms monitoring: adults | Risk difference with PEF | Comments |
| Unscheduled healthcare utilisation (mean number of ED visits, lower is better, 12 months) | 95 (1 RCT) | ⊕⊕○○ Low ^g | - | The mean unscheduled healthcare utilisation (mean number of ED visits, lower is better, 12 months) was 0.7 | MD 0 (0.54 lower to 0.54 higher) No clinical difference | MID=0.675 (SDs of both arms at follow-up/2) |
| Unscheduled healthcare utilisation (unscheduled doctor visits, lower is better, 6 months) | 92 (1 RCT) | ⊕○○○ Very low ^{d,k} | RR 1.55 (0.84 to 2.86) | 250 per 1,000 | 138 more per 1,000 (40 fewer to 465 more) Clinically important benefit of symptom monitoring | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 100 per 1000 |

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|---|--|-----------------------------------|----------------------------------|--|--|---|
| | | | | Risk with symptoms monitoring: adults | Risk difference with PEF | Comments |
| Severe asthma exacerbations (taking oral steroids, lower is better, 6 months) | 152 (2 RCTs) | ⊕○○○ Very low ^{f,i,m} | RR 1.28 (0.29 to 5.57) | 160 per 1,000 | 45 more per 1,000 (114 fewer to 733 more) Clinically important benefit of symptom monitoring | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |
| Quality of life (SF-36, range 0-100, higher is better, 6 months) - Physical total score | 63 (1 RCT) | ⊕○○○ Very low ^{n,o,p} | - | The mean quality of life (SF-36, range 0-100, higher is better, 6 months) - Physical total score was 65.3 | MD 6.49 lower (17.18 lower to 4.2 higher) Clinically important benefit of symptom monitoring | MID=2 (published MID) |

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|---|--|-----------------------------------|--------------------------|---|--|---|
| | | | | Risk with symptoms monitoring: adults | Risk difference with PEF | Comments |
| Quality of life (SF-36, range 0-100, higher is better, 6 months) - Mental total score | 63 (1 RCT) | ⊕○○○ Very low ^{n,o} | - | The mean quality of life (SF-36, range 0-100, higher is better, 6 months) - Mental total score was 74.17 | MD 11.78 lower (20.39 lower to 3.17 lower) Clinically important benefit of symptom monitoring | MID=3 (published MID) |
| Lung function (FEV1 % predicted, higher is better, 6-12 months) | 163 (2 RCTs) | ⊕⊕○○ Low ^q | - | The mean lung function (FEV1 % predicted, higher is better, 6-12 months) was 84.07 | MD 0.1 higher (0.92 lower to 1.12 higher) No clinical difference | MID=5.846 (baseline SDs of both arms/2) |

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|---|--|-----------------------------------|----------------------------------|---|--|--|
| | | | | Risk with symptoms monitoring: adults | Risk difference with PEF | Comments |
| Lung function (FEV1, L, higher is better, 12 months) | 88 (1 RCT) | ⊕○○○ Very low ^{b,e,r} | - | The mean lung function (FEV1, L, higher is better, 12 months) was 2.71 | MD 0.26 lower (0.61 lower to 0.09 higher) Clinically important benefit of symptom monitoring | MID=0.23 (published MID) |
| Time off school/work (mean days off work, lower is better, 12 months) | 183 (2 RCTs) | ⊕○○○ Very low ^{b,e} | - | The mean time off school/work (mean days off work, lower is better, 12 months) was 2.6 | MD 2.5 higher (1.27 higher to 3.74 higher) No clinical difference | MID=3.8 (SDs of both arms at follow-up/2) |
| Time off school/work (time off work events, lower is better, 6-12 months) | 192 (2 RCTs) | ⊕○○○ Very low ^{f,k} | RR 1.41 (0.62 to 3.21) | 87 per 1,000 | 40 more per 1,000 (50 fewer to 120 more) No clinical difference | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 100 per 1000 |

- a. Downgraded by one increment for risk of bias due to some concerns about low adherence to intervention.
- b. Downgraded by one increment for population indirectness (moderate-severe asthma population)
- c. Downgraded by one increment for risk of bias due to some concerns about: lack of information on adherence to intervention; outcome self-reported via questionnaire and study unblinded.
- d. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (0.8-1.25)
- e. Downgraded by two increments because the evidence is at high risk of bias (per protocol analysis, missing data, unblinded and low adherence to intervention)
- f. Downgraded by two increments for imprecision because the 95% confidence interval crosses both MIDs (0.8-1.25)
- g. Downgraded by two increments because the study is at high risk of bias (no information on randomisation process or adherence; analysis method unclear; only drop out information at the time of randomisation, not at follow-up)

- h. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (MID calculated as follow-up SD of both groups/2=0.138)
- i. Downgraded by two increments because the evidence is at high risk of bias (no information on randomisation, issues with adherence, missing data or analysis)
- j. Downgraded by one increment for inconsistency (I squared = 53%)
- k. Downgraded by two increments because the evidence is at high risk of bias (poor adherence to interventions and unclear how handled in analysis; differential in missing data across arms, and related to compliance with intervention)
- l. Downgraded by two increments because the majority of evidence is at high risk of bias (no information about allocation concealment, adherence or baseline characteristics; missing data without reasons reported; unblinded to outcome assessors)
- m. Downgraded by one increment for inconsistency (I squared = 74%)
- n. Downgraded by two increments because the evidence is at high risk of bias (no randomisation information; poor adherence to interventions and not clear how handled in analysis; self-reported outcome and unblinded)
- o. Downgraded by one increment for population indirectness (38.1% severe asthma)
- p. Downgraded by two increments for imprecision because the 95% confidence interval crosses both MIDs (published MID=2)
- q. Downgraded by two increments because the majority of evidence was at high risk of bias (no information on randomisation, adherence or analysis; 50/150 missing data with no reasons given)
- r. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (published MID=0.23 L)

Table 4: Clinical evidence summary: PEF monitoring versus usual care (symptom monitoring) in children

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|--|--|-----------------------------------|---|---|--|---|
| | | | | Risk with symptoms monitoring: children | Risk difference with PEF | Comments |
| Unscheduled healthcare utilisation (hospital admissions, lower better, 12 weeks) | 89 (1 RCT) | ⊕○○○ Very low ^{a,b} | Peto OR 7.56 (0.15 to 381.04) | 0 per 1,000 | 20 more per 1,000 (40 fewer to 80 more) No clinical difference | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |
| Unscheduled healthcare utilisation (attendance at A&E, lower is better, 12 weeks) | 89 (1 RCT) | ⊕○○○ Very low ^{a,b} | Peto OR 7.56 (0.15 to 381.04) | 0 per 1,000 | 20 fewer per 1,000 (40 fewer to 80 more) No clinical difference | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |
| Unscheduled healthcare utilisation (emergency GP visit, lower is better, 12 weeks) | 89 (1 RCT) | ⊕○○○ Very low ^{a,b} | RR 0.93 (0.44 to 1.97) | 244 per 1,000 | 17 fewer per 1,000 (137 fewer to 237 more) No clinical difference | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|--|--|-----------------------------------|---|---|--|--|
| | | | | Risk with symptoms monitoring: children | Risk difference with PEF | Comments |
| Severe asthma exacerbations (needing oral corticosteroids, lower is better, 12 months) | 46 (1 RCT) | ⊕○○○ Very low ^{b,c} | Peto OR 16.34 (3.25 to 82.24) | 0 per 1,000 | 370 more per 1,000 (150 more to 590 more) Clinically important benefit of symptom monitoring | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 30 per 1000 |
| Lung function (FEV1 % predicted, higher is better, 3 months) | 113 (1 RCT) | ⊕⊕○○ Low ^d | - | The mean lung function (FEV1 % predicted, higher is better, 3 months) was 90 | MD 2 lower (9.67 lower to 5.67 higher) No clinical difference | MID=10.4 (SD at follow-up for both arms/2) |
| Time off school (absent from school, events, lower is better, 12 weeks) | 89 (1 RCT) | ⊕○○○ Very low ^{a,b} | RR 1.18 (0.64 to 2.18) | 289 per 1,000 | 52 more per 1,000 (104 fewer to 341 more) No clinical difference | MID (imprecision) = 0.8 – 1.25 MID (clinical importance) = 100 per 1000 |

- a. Downgraded by two increments because the study was at high risk of bias (some concerns on multiple domains: no information about randomisation, some issues with adherence to interventions and self-reported outcome/unblinded)
- b. Downgraded by two increments for imprecision because the 95% confidence interval crosses both MIDs (0.8-1.25)
- c. Downgraded by two increments because the study is at high risk of bias (no information about allocation concealment or adherence; no baseline characteristics reported; unblinded to outcome assessors)
- d. Downgraded by two increments because the study was at high risk of bias (lack of information on randomisation, baseline characteristics or adherence to intervention; missing data unclear)

Table 5: Clinical evidence summary: PEF monitoring at symptom-time versus symptom monitoring in children

| Outcomes | No of participants (studies) Follow-up | Certainty of the evidence (GRADE) | Relative effect (95% CI) | Anticipated absolute effects | | |
|--|--|-----------------------------------|--------------------------|--|---|---|
| | | | | Risk with symptoms monitoring: children | Risk difference with PEF monitoring at symptom-time | Comments |
| Lung function (FEV1% predicted, higher is better, 3 months) | 111 (1 RCT) | ⊕○○○ Very low ^{a,b} | - | The mean lung function (FEV1% predicted, higher is better, 3 months) was 90 | MD 4 higher (3.67 lower to 11.67 higher) No clinical difference | MID=10.27 (SD at follow-up for both arms/2) |

- a. Downgraded by two increments because the study is at high risk of bias (no information on randomisation, baseline characteristics, or adherence; missing data unclear)
- b. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (calculated as FUP SD of both arms/2=10.27)

See Appendix F for full GRADE tables

1.1.7 Economic evidence

1.1.7.1 Included studies

No health economic studies were included.

1.1.7.2 Excluded studies

No relevant health economic studies were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in Appendix G.

1.1.8 Summary of included economic evidence

None.

1.1.9 Economic model

This area was not prioritised for new cost-effectiveness analysis.

1.1.10 Unit costs

Relevant unit costs are provided below to aid consideration of cost effectiveness.

Table 5: PEF per-test cost

| Resource | Quantity | Unit costs | Total cost | Source |
|----------------------------------|--------------------------------|---------------------|------------------------|---|
| Adult mini-wright peak flowmeter | 1 | £4.65 per flowmeter | £4.65 | NHS Supply Chain Catalogue(NHS Supply Chain Catalogue., 2022) |
| Low range mini-wright paediatric | 1 | £4.75 per flowmeter | £4.75 | NHS Supply Chain Catalogue(NHS Supply Chain Catalogue., 2022) |
| Time of practice nurse | 10 – 20 minutes ^(a) | £63.38 per hour | £10.57 - £21.13 | PSSRU 2022(Jones, et al.) |
| Total cost – adults | | | £15.22 - £25.78 | |
| Total cost – children | | | £15.32 - £25.88 | |

Note: all prices are VAT exclusive

(a) 20 minutes assumed in the base case scenario

1.1.11 Evidence statements

1.1.11.1 Economic

- No relevant economic evaluations were identified.

1.2 The committee's discussion and interpretation of the evidence

1.2.1 The outcomes that matter most

The committee considered the outcomes of mortality, unscheduled healthcare utilisation, severe asthma exacerbations, quality of life, asthma control, lung function, dose of regular asthma therapy/preventer medication, symptoms, reliever/rescue medication and time off school/work. For the purposes of decision making, all outcomes were considered equally important and were rated as critical.

For this review there was no outcome data for mortality, symptoms or asthma control based on the recommended questionnaires (ACT; CACT; ACQ; PACQ; RCP-3).

1.2.2 The quality of the evidence

There were 10 RCTs included in the clinical evidence of this review, all of which investigated the effectiveness of PEF-based monitoring versus symptom-based monitoring of asthma. The review was stratified by population age: adults (>16years) and children/young people (5-16 years). No evidence was identified on the value of measuring spirometry at regular intervals.

The quality of the outcomes varied from low to very low quality. Outcomes were downgraded based on the presence of imprecision or concerns about risk of bias due to, for example, lack of randomisation information, low compliance to the intervention and/or missing data.

1.2.3 Benefits and harms

When assessing the clinically significant impact of the evidence included, the GC agreed an approach for use of MIDs. For continuous outcomes, published MIDs were applied for SF-36 (MID =2 for physical total score, 3 for mental total score) and FEV1 (L) (0.23). In the absence of published MIDs, default calculations for MID were applied based on baseline SD (where available) for the rest of the continuous outcomes. For dichotomous outcomes a threshold of 100/1000 people for changes in absolute effects was applied when assessing the following outcomes: unscheduled visits to doctors, emergency GP visits and time off school/work. A threshold of 30/1000 people for changes in absolute effects was applied when assessing the following outcomes: asthma exacerbations; emergency department visits; and hospital admissions; this is because the committee considered small differences between the intervention and comparison groups likely to be important.

Adults

In the adult population there was a clinically significant benefit of PEF-based monitoring seen for one outcome, unscheduled healthcare utilisation (urgent asthma treatment), based on one RCT. However, the certainty of the evidence was low. The remainder of the RCTs demonstrated a clinical benefit favouring symptoms-based monitoring for several outcomes: unscheduled healthcare utilisation (ED visits and unscheduled doctor visits), severe asthma exacerbations, quality of life (SF-36 physical total score and mental total score) and lung function (FEV, L). The GC considered that PEF monitoring helps to identify exacerbations at an earlier stage and the increase in healthcare utilisation may therefore not necessarily be a detrimental finding. The lower quality of life measurement with PEF monitoring was

unexpected but it was noted that some people might become anxious if their PEF level is not consistently at its best, and that regular recording of PEF measurements is an imposition, either of which may explain the finding. The committee were mindful that these outcomes were all taken from small studies of low to very low quality due to imprecision and risk of bias.

The remaining outcomes showed no clinically significant difference between PEF and symptom-based monitoring, including various measures of asthma related healthcare utilisation (mean ER visits and mean hospital admissions, hospital admissions as events and total asthma-related health-care utilisation) lung function (FEV1% predicted) and time off work.

Children

A clinically significant difference favouring symptom-based monitoring was found for: severe asthma exacerbations only (very low certainty evidence). The GC noted that PEF monitoring may be helping identify exacerbations at an earlier stage, although it is equally plausible that PEF monitoring is causing over-anxiety about symptoms in some people and leading to unnecessary treatment. There were no clinically significant differences seen for any other outcome: unscheduled healthcare utilisation, lung function, and time off school (low to very low quality).

The committee acknowledged that PEF monitoring is embedded in healthcare, with routine use in clinics, emergency departments and as part of asthma action plans. This, however, was not necessarily indicative of its effectiveness. They agreed that there was insufficient evidence of benefit to make a recommendation favouring the routine use of PEF-monitoring.

1.2.4 Cost effectiveness and resource use

No relevant published health economic analyses were identified for this review. The unit cost of PEF was presented to aid committee consideration of cost effectiveness. The unit cost of undertaking PEF for diagnostic purposes was £25.78 for adults and £25.88 for children. This included the health care professional time for instructing people on home testing and interpreting the result (£21.13) as well as the flowmeter (£4.65/£4.75 for adults/paediatrics respectively).

The committee discussed the clinical evidence and agreed that it was insufficient to make a positive recommendation, so they recommended against using PEF for monitoring asthma. The committee acknowledged that PEF is typically used in current practice, so the recommendation represents a significant change. The recommendations are expected to reduce the use of PEF for monitoring in favour of using an asthma control questionnaire and FeNO. Given the lack of benefits identified in this review, this is not expected to cause harm to people and could save resource for the NHS that could be reinvested in a more effective monitoring plan.

1.2.5 Other factors the committee took into account

The committee were mindful that some people's symptoms do not correlate well with their lung function measurements. This may result in an underappreciation of the severity of an exacerbation, or conversely in over-sensitivity where symptoms associated with very little change in lung function are perceived as severe. In such people PEF monitoring can be helpful. The committee were therefore reluctant to make a recommendation advising against regular PEF monitoring in all circumstances. However, as the evidence showed no overall benefit for the majority of people with asthma they recommended against its routine use.

No evidence was available on the use of spirometry for monitoring. The GC noted that it has been suggested to be a useful routine measurement but they noted that it is time-consuming and in their experience is unlikely to provide helpful information in the absence of changes in symptoms or other measurements. They therefore made no recommendation on the routine use of spirometry.

1.2.6 Recommendations supported by this evidence review

This evidence review supports recommendation 1.5.3.

1.3 References

- Adams RJ, Boath K, Homan S, et al. (2001) A randomized trial of peak-flow and symptom-based action plans in adults with moderate-to-severe asthma *Respirology* 6 (4): 297-304.
- Buist AS, Vollmer WM, Wilson SR, et al. (2006) A Randomized Clinical Trial of Peak Flow versus Symptom Monitoring in Older Adults with Asthma *American Journal of Respiratory and Critical Care Medicine* 174 (10): 1077-1087.
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- Cote J, Cartier A, Robichaud P, et al. (1997) Influence on asthma morbidity of asthma education programs based on self-management plans following treatment optimization *American Journal of Respiratory and Critical Care Medicine* 155 (5): 1509-1514.
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- Kaya Z, Erkan F, Ozkan M, et al. (2009) Self-Management Plans for Asthma Control and Predictors of Patient Compliance *Journal of Asthma* 46 (3): 270-275.
- Lopez-Vina A, Del Castillo-Arevalo F (2000) Influence of peak expiratory flow monitoring on an asthma self-management education programme *Respiratory Medicine* 94 (8): 760-766.
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- Wensley D, Silverman M (2004) Peak Flow Monitoring for Guided Self-management in Childhood Asthma *American Journal of Respiratory and Critical Care Medicine* 170 (6): 606-612.
- Yoos HL, Kitzman H, McMullen A, et al. (2002) Symptom monitoring in childhood asthma: a randomized clinical trial comparing peak expiratory flow rate with symptom monitoring *Annals of Allergy, Asthma & Immunology* 88 (3): 283-291.

Appendices

Appendix A Review protocols

Review protocol for pulmonary function tests for Asthma

| ID | Field | Content |
|----|------------------------------|---|
| 0. | PROSPERO registration number | CRD42023443062 |
| 1. | Review title | Pulmonary function: spirometry or peak expiratory flow |
| 2. | Review question | In people with asthma, what is the clinical and cost-effectiveness of using measures of pulmonary function assessing asthma control (for example, spirometry and peak expiratory flow) to monitor asthma? |
| 3. | Objective | To evaluate the clinical and cost-effectiveness of using measures of pulmonary function assessing asthma control (for example, spirometry and peak expiratory flow) to monitor asthma. |
| 4. | Searches | <p>The following databases will be searched:</p> <ul style="list-style-type: none">• Cochrane Central Register of Controlled Trials (CENTRAL)• Cochrane Database of Systematic Reviews (CDSR)• Embase• MEDLINE• Epistemonikos <p>Searches will be restricted by:</p> <ul style="list-style-type: none">• English language studies• Human studies |

| | | |
|----|-----------------------------------|--|
| | | <p>•Date: year 2014 onwards as same protocol was used in previous NICE guideline covering studies up to 2014; hence relevant studies before that date will be identified from the existing work.</p> <p>Other searches:</p> <ul style="list-style-type: none"> • Inclusion lists of systematic reviews <p>The searches may be re-run 6 weeks before the final committee meeting and further studies retrieved for inclusion if relevant.</p> <p>The full search strategies will be published in the final review.</p> <p>MEDLINE search strategy to be quality assured using the PRESS evidence-based checklist (see methods chapter for full details).</p> |
| 5. | Condition or domain being studied | Asthma |
| 6. | Population | <p>People with asthma</p> <p>All ages, stratified into the following 2 different groups:</p> <ul style="list-style-type: none"> • Children/young people (5-16 years old) • Adults (>17 years old) <p>Exclusions:</p> <p>Severe asthma</p> <p>Children <5 years</p> |

| | | |
|-----|--------------------------------------|--|
| 7. | Intervention | Monitoring lung function using the following tests, and using the outcomes to adjust management/therapy according to physician decision or personalised treatment plan <ul style="list-style-type: none"> • Spirometry (FEV1; FEV1/FVC; Flow loop measures) • PEF |
| 8. | Comparator | Comparison of adjustment of asthma therapy based on lung function tests to: <ul style="list-style-type: none"> • Usual care: eg clinical symptoms according to guidelines (including BTS/SIGN, GINA) • Asthma control or QOL questionnaires Comparison of adjustment of asthma therapy based on: <ul style="list-style-type: none"> • Spirometry versus PEF |
| 9. | Types of study to be included | RCTs SRs of RCTs |
| 10. | Other exclusion criteria | <ul style="list-style-type: none"> • Exclude observational cohort studies and NRS unless limited evidence from RCTs • Studies not in English • Occupational asthma /allergens |
| 11. | Context | Primary and secondary care |
| 12. | Primary outcomes (critical outcomes) | All outcomes are considered equally important for decision making and therefore have been rated as critical: <ul style="list-style-type: none"> • Mortality • Unscheduled healthcare utilisation (ED/A&E visit; hospital admissions; GP out of hours or walk-in centre) • Severe asthma exacerbations (defined as asthma exacerbations requiring oral corticosteroid use- dichotomous outcome at ≥ 6 months, latest time point if more than one) • Asthma control (assessed by validated questionnaires (ACT; CACT; ACQ; PACQ; RCP-3; continuous outcome at ≥ 3 months) • Quality of life (QoL assessed via any validated scale including asthma specific questionnaires: AQLQ; pAQLQ; St George's respiratory questionnaire; continuous outcome at ≥ 3 months) • Lung function (FEV1, PEF) • Symptoms (annual symptom free days) |

| | | |
|-----|--|--|
| | | <ul style="list-style-type: none"> • Dose of regular asthma therapy / preventer medication (ICS dose) • Reliever/Rescue medication (SABA use; continuous outcome at ≥3months) • Time off school or work |
| 13. | Data extraction (selection and coding) | <p>All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated.</p> <p>This review will make use of the priority screening functionality within the EPPI-reviewer software.</p> <p>10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.</p> <p>The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above.</p> <p>A standardised form will be used to extract data from studies (see Developing NICE guidelines: the manual section 6.4).</p> <p>10% of all evidence reviews are quality assured by a senior research fellow. This includes checking:</p> <ul style="list-style-type: none"> • papers were included /excluded appropriately • a sample of the data extractions • correct methods are used to synthesise data • a sample of the risk of bias assessments <p>Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.</p> <p>Study investigators may be contacted for missing data where time and resources allow.</p> |
| 14. | Risk of bias (quality) assessment | <p>Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. For Intervention reviews the following checklist will be used according to study design being assessed:</p> <ul style="list-style-type: none"> • Systematic reviews: Risk of Bias in Systematic Reviews (ROBIS) • Randomised Controlled Trial: Cochrane RoB (2.0) |

| | | | | | | | | | | |
|-------------------------------------|-----------------------------|---|-------------------------------------|--------------|--------------------------|------------|--------------------------|------------|--------------------------|-------------|
| | | | | | | | | | | |
| 15. | Strategy for data synthesis | <p>Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). Fixed-effects (Mantel-Haenszel) techniques will be used to calculate risk ratios for the binary outcomes where possible. Continuous outcomes will be analysed using an inverse variance method for pooling weighted mean differences.</p> <p>Heterogeneity between the studies in effect measures will be assessed using the I² statistic and visually inspected. An I² value greater than 50% will be considered indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented pooled using random-effects.</p> <p>GRADEpro will be used to assess the quality of evidence for each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome. Publication bias will be considered with the guideline committee, and if suspected will be tested for when there are more than 5 studies for that outcome.</p> <p>The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/</p> <p>Where meta-analysis is not possible, data will be presented and quality assessed individually per outcome. WinBUGS will be used for network meta-analysis, if possible given the data identified.</p> | | | | | | | | |
| 16. | Analysis of sub-groups | <ul style="list-style-type: none"> • Ethnic groups (e.g. south Asians, African Americans, Hispanics) • Education levels • Language (non-English speaking) | | | | | | | | |
| 17. | Type and method of review | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50px; text-align: center;"><input checked="" type="checkbox"/></td> <td>Intervention</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Diagnostic</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Prognostic</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Qualitative</td> </tr> </table> | <input checked="" type="checkbox"/> | Intervention | <input type="checkbox"/> | Diagnostic | <input type="checkbox"/> | Prognostic | <input type="checkbox"/> | Qualitative |
| <input checked="" type="checkbox"/> | Intervention | | | | | | | | | |
| <input type="checkbox"/> | Diagnostic | | | | | | | | | |
| <input type="checkbox"/> | Prognostic | | | | | | | | | |
| <input type="checkbox"/> | Qualitative | | | | | | | | | |

| | | | | |
|-----|--|---|-------------------------------------|-------------------------------------|
| | | <input type="checkbox"/> | Epidemiologic | |
| | | <input type="checkbox"/> | Service Delivery | |
| | | <input type="checkbox"/> | Other – monitoring | |
| 18. | Language | English | | |
| 19. | Country | England | | |
| 20. | Anticipated or actual start date | | | |
| 21. | Anticipated completion date | 31 July 2024 | | |
| 22. | Stage of review at time of this submission | Review stage | Started | Completed |
| | | Preliminary searches | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| | | Piloting of the study selection process | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Formal screening of search results against eligibility criteria | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Data extraction | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Risk of bias (quality) assessment | <input type="checkbox"/> | <input type="checkbox"/> |
| | | Data analysis | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. | Named contact | 5a. Named contact National Guideline Centre | | |

| | | |
|-----|-------------------------|--|
| | | <p>5b Named contact e-mail</p> <p>asthmachronicmanagement@nice.org.uk</p> <p>5e Organisational affiliation of the review</p> <p>National Institute for Health and Care Excellence (NICE) and National Guideline Centre</p> |
| 24. | Review team members | <p>From the National Guideline Centre:</p> <p>Bernard Higgins</p> <p>Sharon Swain</p> <p>Melina Vasileiou</p> <p>Toby Sands</p> <p>Alfredo Mariani</p> <p>Lina Gulhane</p> <p>Amy Crisp</p> <p>Lisa Miles</p> |
| 25. | Funding sources/sponsor | <p>This systematic review is being completed by the National Guideline Centre which receives funding from NICE.</p> |
| 26. | Conflicts of interest | <p>All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.</p> |

| | | | |
|-----|--|---|--|
| 27. | Collaborators | Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual . Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10186 | |
| 28. | Other registration details | N/A | |
| 29. | Reference/URL for published protocol | | |
| 30. | Dissemination plans | <p>NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:</p> <ul style="list-style-type: none"> • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE. | |
| 31. | Keywords | Asthma | |
| 32. | Details of existing review of same topic by same authors | N/A | |
| 33. | Current review status | <input checked="" type="checkbox"/> | Ongoing |
| | | <input type="checkbox"/> | Completed but not published |
| | | <input type="checkbox"/> | Completed and published |
| | | <input type="checkbox"/> | Completed, published and being updated |
| | | <input type="checkbox"/> | Discontinued |
| 34. | Additional information | N/A | |
| 35. | Details of final publication | www.nice.org.uk | |

Health economic review protocol

Table 6: Health economic review protocol

| Review question | All questions – health economic evidence |
|------------------------|--|
| Objectives | To identify health economic studies relevant to any of the review questions. |
| Search criteria | <ul style="list-style-type: none"> • Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English. |
| Search strategy | A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below. |
| Review strategy | <p>Studies not meeting any of the search criteria above will be excluded. Studies published before 2006, abstract-only studies and studies from non-OECD countries or the USA will also be excluded.</p> <p>Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014). (National Institute for Health and Care Excellence)</p> <p>Inclusion and exclusion criteria</p> <ul style="list-style-type: none"> • If a study is rated as both ‘Directly applicable’ and with ‘Minor limitations’ then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either ‘Not applicable’ or with ‘Very serious limitations’ then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as ‘Partially applicable’, with ‘Potentially serious limitations’ or both then there is discretion over whether it should be included. |

Where there is discretion

The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.

The health economist will be guided by the following hierarchies.

Setting:

- UK NHS (most applicable).
- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

Health economic study type:

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

Year of analysis:

- The more recent the study, the more applicable it will be.
- Studies published in 2006 or later but that depend on unit costs and resource data entirely or predominantly from before 2006 will be rated as ‘Not applicable’.
- Studies published before 2006 be excluded before being assessed for applicability and methodological limitations.

Quality and relevance of effectiveness data used in the health economic analysis:

- The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B Literature search strategies

In people with asthma, what is the clinical and cost-effectiveness of using measures of pulmonary function assessing asthma control (for example, spirometry and peak expiratory flow) to monitor asthma?

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies as these concepts may not be indexed or described in the title or abstract and are therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 7: Database parameters, filters and limits applied

| Database | Dates searched | Search filter used |
|--|--|---|
| Medline (OVID) | 2014 – 20 Dec 2023 | Randomised controlled trials Systematic review studies Exclusions (animal studies, letters, comments, editorials, case studies/reports) English language |
| Embase (OVID) | 2014 – 20 Dec 2023 | Randomised controlled trials Systematic review studies Exclusions (conference abstracts, animal studies, letters, comments, editorials, case studies/reports) English language |
| The Cochrane Library (Wiley) | Cochrane Reviews 2014 to 2023 Issue 12 of 12 CENTRAL to 2023 Issue 12 of 12 | Exclusions (clinical trials, conference abstracts) |
| Epistemonikos (The Epistemonikos Foundation) | 2014 to 20 Dec 2023 | Exclusions (Cochrane reviews) English language |

Medline (Ovid) search terms

| | |
|----|-------------------------|
| 1. | exp Asthma/ |
| 2. | asthma*.ti,ab,kf. |
| 3. | 1 or 2 |
| 4. | letter/ |
| 5. | editorial/ |
| 6. | news/ |
| 7. | exp historical article/ |
| 8. | Anecdotes as Topic/ |

| | |
|-----|---|
| 9. | comment/ |
| 10. | case reports/ |
| 11. | (letter or comment*).ti. |
| 12. | or/4-11 |
| 13. | randomized controlled trial/ or random*.ti,ab. |
| 14. | 12 not 13 |
| 15. | animals/ not humans/ |
| 16. | exp Animals, Laboratory/ |
| 17. | exp Animal Experimentation/ |
| 18. | exp Models, Animal/ |
| 19. | exp Rodentia/ |
| 20. | (rat or rats or mouse or mice or rodent*).ti. |
| 21. | or/14-20 |
| 22. | 3 not 21 |
| 23. | limit 22 to English language |
| 24. | vital capacity/ |
| 25. | forced expiratory volume/ |
| 26. | (FEV1 or FEV 1 or FVC).ti,ab,kf. |
| 27. | (volume* adj2 (loop* or curve* or graph* or time*)).ti,ab,kf. |
| 28. | (flow* adj2 (volume* or loop*)).ti,ab,kf. |
| 29. | ((function* or vital) adj2 capacit*).ti,ab,kf. |
| 30. | (forced adj2 (expiratory or expiration or exhal* or volume* or expel*)).ti,ab,kf. |
| 31. | ((lung or pulmonary) adj2 function*).ti,ab,kf. |
| 32. | exp Spirometry/ |
| 33. | (spiromet* or spiograph* or spriogram* or pneumotachograph* or bronchspiromet* or microspiromet* or bronchspiograph*).ti,ab,kf. |
| 34. | peak expiratory flow rate/ |
| 35. | (PEFV or PEF or PEFr or PFR).ti,ab,kf. |
| 36. | (peak adj2 flow*).ti,ab,kf. |
| 37. | or/24-36 |
| 38. | monitoring, physiologic/ |
| 39. | monitor*.ti,ab,kf. |
| 40. | self care/ |
| 41. | plan*.ti,ab,kf. |
| 42. | (educat* or "self manag*" or "self care" or "self medicat*" or "manag* program*" or WAP or WAAP).ti,ab,kf. |
| 43. | (deciding or decision*).ti,ab,kf. |
| 44. | or/38-43 |
| 45. | 37 and 44 |
| 46. | 23 and 45 |
| 47. | randomized controlled trial.pt. |
| 48. | controlled clinical trial.pt. |
| 49. | randomi#ed.ab. |
| 50. | placebo.ab. |
| 51. | randomly.ab. |
| 52. | clinical trials as topic.sh. |

| | |
|-----|--|
| 53. | trial.ti. |
| 54. | or/47-53 |
| 55. | Meta-Analysis/ |
| 56. | Meta-Analysis as Topic/ |
| 57. | (meta analy* or metanaly* or metaanaly* or meta regression).ti,ab. |
| 58. | ((systematic* or evidence*) adj3 (review* or overview*)).ti,ab. |
| 59. | (reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab. |
| 60. | (search strategy or search criteria or systematic search or study selection or data extraction).ab. |
| 61. | (search* adj4 literature).ab. |
| 62. | (medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab. |
| 63. | cochrane.jw. |
| 64. | ((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab. |
| 65. | or/55-64 |
| 66. | 46 and (54 or 65) |

Embase (Ovid) search terms

| | |
|-----|--|
| 1. | exp Asthma/ |
| 2. | asthma*.ti,ab. |
| 3. | 1 or 2 |
| 4. | letter.pt. or letter/ |
| 5. | note.pt. |
| 6. | editorial.pt. |
| 7. | case report/ or case study/ |
| 8. | (letter or comment*).ti. |
| 9. | (conference abstract* or conference review or conference paper or conference proceeding).db,pt,su. |
| 10. | or/4-9 |
| 11. | randomized controlled trial/ or random*.ti,ab. |
| 12. | 10 not 11 |
| 13. | animal/ not human/ |
| 14. | nonhuman/ |
| 15. | exp Animal Experiment/ |
| 16. | exp Experimental Animal/ |
| 17. | animal model/ |
| 18. | exp Rodent/ |
| 19. | (rat or rats or mouse or mice or rodent*).ti. |
| 20. | or/12-19 |
| 21. | 3 not 20 |
| 22. | limit 21 to English language |
| 23. | vital capacity/ |
| 24. | forced expiratory volume/ |
| 25. | lung flow volume curve/ |
| 26. | (FEV1 or FEV 1 or FVC).ti,ab,kf. |
| 27. | (volume* adj2 (loop* or curve* or graph* or time*)).ti,ab,kf. |

| | |
|-----|--|
| 28. | (flow* adj2 (volume* or loop*)).ti,ab,kf. |
| 29. | ((forced or time*) adj2 "vital capacit*").ti,ab,kf. |
| 30. | (forced adj2 (expiratory or expiration or exhal* or volume* or expel*)).ti,ab,kf. |
| 31. | ((lung or pulmonary) adj2 function*).ti,ab,kf. |
| 32. | exp Spirometry/ |
| 33. | (spiromet* or spiograph* or spriogram* or pneumotachograph* or bronchspiromet* or microspiromet* or bronchspiograph*).ti,ab,kf. |
| 34. | peak expiratory flow/ |
| 35. | (PEFV or PEF or PEFr or PFR).ti,ab,kf. |
| 36. | (peak adj2 flow*).ti,ab,kf. |
| 37. | or/23-36 |
| 38. | exp monitoring/ |
| 39. | monitor*.ti,ab,kf. |
| 40. | self care/ |
| 41. | plan*.ti,ab,kf. |
| 42. | (educat* or "self manag*" or "self care" or "self medicat*" or "manag* program*" or WAP or WAAP).ti,ab,kf. |
| 43. | (deciding or decision*).ti,ab,kf. |
| 44. | or/38-43 |
| 45. | 37 and 44 |
| 46. | 22 and 45 |
| 47. | random*.ti,ab. |
| 48. | factorial*.ti,ab. |
| 49. | (crossover* or cross over*).ti,ab. |
| 50. | ((doubl* or singl*) adj blind*).ti,ab. |
| 51. | (assign* or allocat* or volunteer* or placebo*).ti,ab. |
| 52. | crossover procedure/ |
| 53. | single blind procedure/ |
| 54. | randomized controlled trial/ |
| 55. | double blind procedure/ |
| 56. | or/47-55 |
| 57. | Systematic Review/ |
| 58. | Meta-Analysis/ |
| 59. | (meta analy* or metanaly* or metaanaly* or meta regression).ti,ab. |
| 60. | ((systematic* or evidence*) adj3 (review* or overview*)).ti,ab. |
| 61. | (reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab. |
| 62. | (search strategy or search criteria or systematic search or study selection or data extraction).ab. |
| 63. | (search* adj4 literature).ab. |
| 64. | (medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab. |
| 65. | cochrane.jw. |
| 66. | ((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab. |
| 67. | or/57-66 |
| 68. | 46 and (56 or 67) |

Cochrane Library (Wiley) search terms

| | |
|------|---|
| #1. | MeSH descriptor: [Asthma] explode all trees |
| #2. | asthma*.ti,ab |
| #3. | #1 or #2 |
| #4. | ((clinicaltrials or trialsearch* or trial-registry or trials-registry or clinicalstudies or trialsregister* or trialregister* or trial-number* or studyregister* or study-register* or controlled-trials-com or current-controlled-trial or AMCTR or ANZCTR or ChiCTR* or CRiS or CTIS or CTRI* or DRKS* or EU-CTR* or EUCTR* or eudract* or ICTRP or IRCT* or JAPIC* or JMCTR* or JRCT or ISRCTN* or LBCTR* or NTR* or ReBec* or REPEC* or RPCEC* or SLCTR or TCTR* or UMIN*):so or (ctgov or ictrp)):an |
| #5. | #3 not #4 |
| #6. | conference:pt |
| #7. | #5 not #6 |
| #8. | MeSH descriptor: [Vital Capacity] explode all trees |
| #9. | MeSH descriptor: [Forced Expiratory Volume] explode all trees |
| #10. | (FEV1 or FEV 1 or FVC):ti,ab |
| #11. | (volume* near/2 (loop* or curve* or graph* or time)):ti,ab |
| #12. | (flow* near/2 (volume* or loop*)):ti,ab |
| #13. | (function* or vital) near/2 capacit*:ti,ab |
| #14. | (forced near/2 (expiratory or expiration or exhal* or volume* or expel*)):ti,ab |
| #15. | (lung or pulmonary) near/2 function*:ti,ab |
| #16. | MeSH descriptor: [Spirometry] explode all trees |
| #17. | (spiromet* or spiograph* or spriogram* or pneumotachograph* or bronchospiromet* or microspiromet* or bronchospirograph*):ti,ab |
| #18. | MeSH descriptor: [Peak Expiratory Flow Rate] explode all trees |
| #19. | (PEFV or PEF or PEFr or PFR):ti,ab |
| #20. | (peak near/2 flow*):ti,ab |
| #21. | (or #8-#20) |
| #22. | MeSH descriptor: [Monitoring, Physiologic] explode all trees |
| #23. | monitor*:ti,ab |
| #24. | MeSH descriptor: [Self Care] explode all trees |
| #25. | plan*:ti,ab |
| #26. | (educat* or self next manag* or self next care or self next medicat* or manag* next program* or WAP or WAAP):ti,ab |
| #27. | (deciding or decision*):ti,ab |
| #28. | (or #22-#27) |
| #29. | #21 and #28 |
| #30. | #7 and #29 with Cochrane Library publication date Between Jan 2014 and Dec 2023 |

Epistemonikos search terms

| | |
|----|---|
| 1. | (title:((function* OR vital) AND capacit*) OR abstract:((function* OR vital) AND capacit*)) OR (title:(forced AND (expiratory OR expiration OR exhal* OR volume* OR expel*)) OR abstract:(forced AND (expiratory OR expiration OR exhal* OR volume* OR expel*))) OR (title:((lung OR pulmonary) AND function*) OR abstract:((lung OR pulmonary) AND function*)) OR (title:(spiromet* OR spiograph* OR spriogram* OR pneumotachograph* OR bronchospiromet* OR microspiromet* OR bronchospirograph*) OR abstract:(spiromet* OR spiograph* OR spriogram* OR pneumotachograph* OR bronchospiromet* OR microspiromet* OR bronchospirograph*)) OR (title:(peak AND flow*) OR abstract:(peak AND flow*)) AND |
|----|---|

| | |
|--|---|
| | (title:(monitor* OR plan* OR educat* OR "self manag*" OR "self care" OR "self medicat*" OR "manag* program*" OR WAP OR WAAP OR deciding OR decision*) OR abstract:(monitor* OR plan* OR educat* OR "self manag*" OR "self care" OR "self medicat*" OR "manag* program*" OR WAP OR WAAP OR deciding OR decision*)) AND (title:(asthma*) OR abstract:(asthma*)) |
|--|---|

B.2 Health economic literature search strategy

Health economic evidence was identified by conducting searches using terms for a broad Asthma population. The following databases were searched: NHS Economic Evaluation Database (NHS EED - this ceased to be updated after 31st March 2015), Health Technology Assessment database (HTA - this ceased to be updated from 31st March 2018) and The International Network of Agencies for Health Technology Assessment (INAHTA). Searches for recent evidence were run on Medline and Embase from 2014 onwards for health economics, and all years for quality-of-life studies and modelling.

Table 8: Database parameters, filters and limits applied

| Database | Dates searched | Search filters and limits applied |
|--|--|--|
| Medline (OVID) | Health Economics 1 January 2014 – 29 Dec 2023 | Health economics studies Quality of life studies Modelling |
| | Quality of Life 1946 – 29 Dec 2023 | Exclusions (animal studies, letters, comments, editorials, case studies/reports) |
| | Modelling 1946 – 29 Dec 2023 | English language |
| Embase (OVID) | Health Economics 1 January 2014 – 29 Dec 2023 | Health economics studies Quality of life studies Modelling |
| | Quality of Life 1974 – 29 Dec 2023 | Exclusions (animal studies, letters, comments, editorials, case studies/reports, conference abstracts) |
| | Modelling 1974 – 29 Dec 2023 | English language |
| NHS Economic Evaluation Database (NHS EED) (Centre for Research and Dissemination - CRD) | Inception – 31 st March 2015 | |
| Health Technology Assessment Database (HTA) (Centre for Research and Dissemination – CRD) | Inception – 31 st March 2018 | |

| Database | Dates searched | Search filters and limits applied |
|---|-------------------------|-----------------------------------|
| The International Network of Agencies for Health Technology Assessment (INAHTA) | Inception - 29 Dec 2023 | English language |

Medline (Ovid) search terms

| | |
|-----|--|
| 1. | exp Asthma/ |
| 2. | asthma*.ti,ab. |
| 3. | 1 or 2 |
| 4. | letter/ |
| 5. | editorial/ |
| 6. | news/ |
| 7. | exp historical article/ |
| 8. | Anecdotes as Topic/ |
| 9. | comment/ |
| 10. | case reports/ |
| 11. | (letter or comment*).ti. |
| 12. | or/4-11 |
| 13. | randomized controlled trial/ or random*.ti,ab. |
| 14. | 12 not 13 |
| 15. | animals/ not humans/ |
| 16. | exp Animals, Laboratory/ |
| 17. | exp Animal Experimentation/ |
| 18. | exp Models, Animal/ |
| 19. | exp Rodentia/ |
| 20. | (rat or rats or mouse or mice or rodent*).ti. |
| 21. | or/14-20 |
| 22. | 3 not 21 |
| 23. | limit 22 to English language |
| 24. | quality-adjusted life years/ |
| 25. | sickness impact profile/ |
| 26. | (quality adj2 (wellbeing or well being)).ti,ab. |
| 27. | sickness impact profile.ti,ab. |
| 28. | disability adjusted life.ti,ab. |
| 29. | (qal* or qtime* or qwb* or daly*).ti,ab. |
| 30. | (euroqol* or eq5d* or eq 5*).ti,ab. |
| 31. | (qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab. |
| 32. | (health utility* or utility score* or disutilit* or utility value*).ti,ab. |
| 33. | (hui or hui1 or hui2 or hui3).ti,ab. |
| 34. | (health* year* equivalent* or hye or hyes).ti,ab. |
| 35. | discrete choice*.ti,ab. |

| | |
|-----|---|
| 36. | rosser.ti,ab. |
| 37. | (willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab. |
| 38. | (sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab. |
| 39. | (sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab. |
| 40. | (sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab. |
| 41. | (sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab. |
| 42. | (sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab. |
| 43. | or/24-42 |
| 44. | exp models, economic/ |
| 45. | *Models, Theoretical/ |
| 46. | *Models, Organizational/ |
| 47. | markov chains/ |
| 48. | monte carlo method/ |
| 49. | exp Decision Theory/ |
| 50. | (markov* or monte carlo).ti,ab. |
| 51. | econom* model*.ti,ab. |
| 52. | (decision* adj2 (tree* or analy* or model*)).ti,ab. |
| 53. | or/44-52 |
| 54. | Economics/ |
| 55. | Value of life/ |
| 56. | exp "Costs and Cost Analysis"/ |
| 57. | exp Economics, Hospital/ |
| 58. | exp Economics, Medical/ |
| 59. | Economics, Nursing/ |
| 60. | Economics, Pharmaceutical/ |
| 61. | exp "Fees and Charges"/ |
| 62. | exp Budgets/ |
| 63. | budget*.ti,ab. |
| 64. | cost*.ti. |
| 65. | (economic* or pharmaco?economic*).ti. |
| 66. | (price* or pricing*).ti,ab. |
| 67. | (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. |
| 68. | (financ* or fee or fees).ti,ab. |
| 69. | (value adj2 (money or monetary)).ti,ab. |
| 70. | or/54-69 |
| 71. | 23 and 43 |
| 72. | 23 and 53 |
| 73. | 23 and 70 |

Embase (Ovid) search terms

| | |
|-----|---|
| 1. | exp Asthma/ |
| 2. | asthma*.ti,ab. |
| 3. | 1 or 2 |
| 4. | letter.pt. or letter/ |
| 5. | note.pt. |
| 6. | editorial.pt. |
| 7. | case report/ or case study/ |
| 8. | (letter or comment*).ti. |
| 9. | (conference abstract or conference paper).pt. |
| 10. | or/4-9 |
| 11. | randomized controlled trial/ or random*.ti,ab. |
| 12. | 10 not 11 |
| 13. | animal/ not human/ |
| 14. | nonhuman/ |
| 15. | exp Animal Experiment/ |
| 16. | exp Experimental Animal/ |
| 17. | animal model/ |
| 18. | exp Rodent/ |
| 19. | (rat or rats or mouse or mice or rodent*).ti. |
| 20. | or/12-19 |
| 21. | 3 not 20 |
| 22. | limit 21 to English language |
| 23. | quality adjusted life year/ |
| 24. | "quality of life index"/ |
| 25. | short form 12/ or short form 20/ or short form 36/ or short form 8/ |
| 26. | sickness impact profile/ |
| 27. | (quality adj2 (wellbeing or well being)).ti,ab. |
| 28. | sickness impact profile.ti,ab. |
| 29. | disability adjusted life.ti,ab. |
| 30. | (qal* or qtime* or qwb* or daly*).ti,ab. |
| 31. | (euroqol* or eq5d* or eq 5*).ti,ab. |
| 32. | (qol* or hqi* or hqol* or h qol* or hrqol* or hr qol*).ti,ab. |
| 33. | (health utility* or utility score* or disutilit* or utility value*).ti,ab. |
| 34. | (hui or hui1 or hui2 or hui3).ti,ab. |
| 35. | (health* year* equivalent* or hye or hyes).ti,ab. |
| 36. | discrete choice*.ti,ab. |
| 37. | rosser.ti,ab. |
| 38. | (willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab. |
| 39. | (sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab. |
| 40. | (sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab. |

| | |
|-----|---|
| 41. | (sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab. |
| 42. | (sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab. |
| 43. | (sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab. |
| 44. | or/23-43 |
| 45. | statistical model/ |
| 46. | exp economic aspect/ |
| 47. | 45 and 46 |
| 48. | *theoretical model/ |
| 49. | *nonbiological model/ |
| 50. | stochastic model/ |
| 51. | decision theory/ |
| 52. | decision tree/ |
| 53. | monte carlo method/ |
| 54. | (markov* or monte carlo).ti,ab. |
| 55. | econom* model*.ti,ab. |
| 56. | (decision* adj2 (tree* or analy* or model*)).ti,ab. |
| 57. | or/47-56 |
| 58. | health economics/ |
| 59. | exp economic evaluation/ |
| 60. | exp health care cost/ |
| 61. | exp fee/ |
| 62. | budget/ |
| 63. | funding/ |
| 64. | budget*.ti,ab. |
| 65. | cost*.ti. |
| 66. | (economic* or pharmaco?economic*).ti. |
| 67. | (price* or pricing*).ti,ab. |
| 68. | (cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab. |
| 69. | (financ* or fee or fees).ti,ab. |
| 70. | (value adj2 (money or monetary)).ti,ab. |
| 71. | or/58-70 |
| 72. | 22 and 44 |
| 73. | 22 and 57 |
| 74. | 22 and 71 |

NHS EED and HTA (CRD) search terms

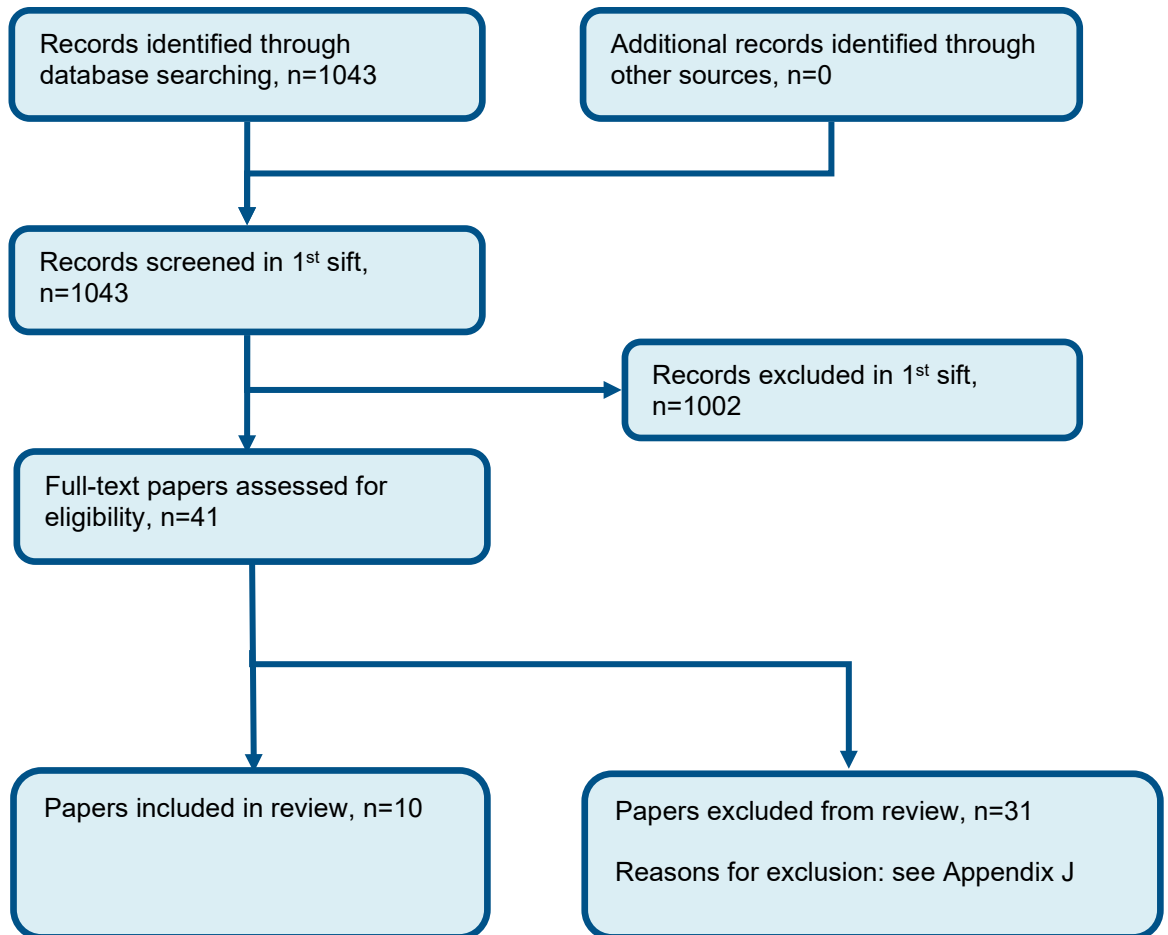
| | |
|-----|--|
| #1. | MeSH DESCRIPTOR Asthma EXPLODE ALL TREES |
| #2. | (asthma*) |
| #3. | #1 OR #2 |

INAHTA search terms

| | |
|----|--|
| 1. | (Asthma)[mh] OR (asthma*)[Title] OR (asthma*)[abs] |
|----|--|

Appendix C Effectiveness evidence study selection

Figure 1: Flow chart of clinical study selection for the review of pulmonary function monitoring for Asthma



Appendix D Effectiveness evidence

ADAMS, 2001

Bibliographic Reference ADAMS, ROBERT J.; BOATH, KAREN; HOMAN, SEAN; CAMPBELL, DONALD A.; RUFFIN, RICHARD E.; A randomized trial of peak-flow and symptom-based action plans in adults with moderate-to-severe asthma; *Respirology*; 2001; vol. 6 (no. 4); 297-304

Study details

| | |
|---|---|
| Secondary publication of another included study- see primary study for details | No additional information |
| Other publications associated with this study included in review | No additional information |
| Trial name / registration number | No additional information |
| Study type | Randomised controlled trial (RCT) |
| Study location | Australia |
| Study setting | Secondary care |
| Study dates | 1991-1993 |
| Sources of funding | Funding was given by The University of Adelaide, The Queen Elizabeth Hospital Research Foundation |

| | |
|--|--|
| Inclusion criteria | <p>Aged 16-70 years</p> <p>Physician's diagnosis of asthma, according to ATS guidelines</p> <p>Demonstrated ability to use a peak flow monitor</p> |
| Exclusion criteria | <p>Previous life-threatening asthma attack</p> <p>Current or previous written asthma plan based on either symptoms or PEF</p> <p>Pregnancy</p> <p>Poor perception of bronchoconstriction during a histamine challenge test</p> <p>FEV1 <1.5 L</p> |
| Recruitment / selection of participants | <p>Recruited from inpatient and outpatient clinics</p> |
| Intervention(s) | <p>All participants were reviewed by a specialist pulmonologist to provide the action plan and to initiate ICS at an appropriate dose, if not already receiving ICS. All participants were instructed to use SABA as needed and were provided with oral corticosteroids to use as-needed according to the individual self-management plan. Self-management plans were based on those recommended by the Australian National Asthma Campaign. All participants were also given asthma education leaflets, containing information as to how to recognise if asthma is getting out of control, diagrams on the use of inhaler technique and spacer use. Leaflets titled 'What is asthma?' and 'What factors will trigger an asthma attack?' were also provided.</p> |

| | |
|---------------------------------|--|
| | <p>Participants randomised to the PEF monitoring group had self-management plans that were activated by a fall in PEF. Each participant's best recorded peak flow was used to determine the values at which aspects of the self-management plan were initiated. The self-management plan was as follows:</p> <ol style="list-style-type: none"> 1. If PEF \geq70% of best: continue usual treatment 2. If PEF <70% of best: double your dose of inhaled steroid for 2 weeks 3. If PEF <50% of best: (i) start oral prednisolone 37.5 mg daily and continue for 1 week; (ii) contact your general practitioner 4. If PEF <30% of best: call ambulance or go directly to the hospital emergency department |
| Population subgroups | No additional information |
| Ethnic Group | Not reported/unclear |
| Education Levels | Not reported/unclear |
| Language of Participants | English |
| Comparator | All participants were reviewed by a specialist pulmonologist to provide the action plan and to initiate ICS at an appropriate dose, if not already receiving ICS. All participants were instructed to use SABA as needed and were provided with oral corticosteroids to use as-needed according to the individual self-management plan. Self-management plans were based on those recommended by the Australian National Asthma Campaign. All participants were also given asthma education leaflets, containing information as to how to recognise if asthma is getting out of control, diagrams on the use of inhaler technique and spacer use. Leaflets titled 'What is asthma?' and 'What factors will trigger an asthma attack?' were also provided. |

| | |
|-------------------------------|---|
| | <p>Participants randomised to the symptom monitoring group had self-management plans that were activated by an increase in symptoms. The self-management plan was as follows:</p> <ol style="list-style-type: none"> 1. If feeling normal: continue usual treatment 2. If waking more than once a night due to asthma or using more bronchodilator: double your dose of inhaled steroids for 2 weeks 3. If waking twice or more at night due to asthma, or using bronchodilator 6 or more times a day: start oral prednisolone 37.5 mg daily for 1 week and contact your general practitioner 4. If needing bronchodilator at least every 2 h: call ambulance or go directly to the hospital emergency department |
| Number of participants | <p>172 randomised, 134 completed</p> <p>73 received and completed PEF monitoring</p> <p>61 received and completed symptom monitoring</p> |
| Duration of follow-up | 12 months |
| Indirectness | None |
| Additional comments | Per protocol - study analysed data from those participants that completed the full 12-month treatment period |

Study arms

PEF monitoring (N = 73)

Self-management plans activated by a decrease in peak expiratory flow

Usual care (N = 61)

Self-management plans activated by an increase in symptoms

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 73) | Usual care (N = 61) |
|--|-------------------------|---------------------|
| % Female | n = 44 ; % = 60 | n = 38 ; % = 62 |
| Sample size | | |
| Mean age (SD) | 37.3 | 35.5 |
| Nominal | | |
| Ethnicity | NR | NR |
| Nominal | | |
| Comorbidities | NR | NR |
| Nominal | | |
| Asthma control >400 mcg per day of bronchodilator | n = 7 ; % = 10 | n = 4 ; % = 7 |
| Sample size | | |

Outcomes

Study timepoints

- Baseline
- 12 month

Continuous Outcomes

| Outcome | PEF monitoring, Baseline, N = 73 | PEF monitoring, 12 month, N = 73 | Usual care, Baseline, N = 61 | Usual care, 12 month, N = 61 |
|---|----------------------------------|----------------------------------|------------------------------|------------------------------|
| Time off work (days) Final values, time off over past 12 months | NA (NA) | 5 (11) | NA (NA) | 2.3 (4) |
| Mean (SD) | | | | |
| Unscheduled healthcare utilisation (ED visits) Final values, average number of events per participant | n = 25 ; % = NR | n = 5 ; % = NR | n = 30 ; % = NR | n = 7 ; % = NR |
| No of events | | | | |
| Unscheduled healthcare utilisation (ED visits) Final values, average number of events per participant | 0.59 (0.6) | 0.11 (0.4) | 0.73 (1) | 0.15 (0.4) |
| Mean (SD) | | | | |
| Unscheduled healthcare utilisation (hospitalisation) Final values, average number of events per participant | n = 22 ; % = NR | n = 4 ; % = NR | n = 20 ; % = NR | n = 3 ; % = NR |
| No of events | | | | |

| Outcome | PEF monitoring, Baseline, N = 73 | PEF monitoring, 12 month, N = 73 | Usual care, Baseline, N = 61 | Usual care, 12 month, N = 61 |
|---|----------------------------------|----------------------------------|------------------------------|------------------------------|
| Unscheduled healthcare utilisation (hospitalisation) Final values, average number of events per participant | 0.58 (0.7) | 0.07 (0.3) | 0.51 (0.6) | 0.1 (0.5) |
| Mean (SD) | | | | |
| Lung Function (FEV1) (Litres) Final values | 2.57 (0.81) | 2.45 (0.82) | 2.71 (0.87) | 2.71 (0.86) |
| Mean (SD) | | | | |

Time off work - Polarity - Lower values are better

Unscheduled healthcare utilisation (ED visits) - Polarity - Lower values are better

Unscheduled healthcare utilisation (hospitalisation) - Polarity - Lower values are better

Lung Function (FEV1) - Polarity - Higher values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Continuous Outcomes - Time off school - Mean SD - PEF monitoring - Usual care - t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Unblinded, issues with adherence, some missing data, per protocol analysis)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

ContinuousOutcomes-Unscheduledhealthcareutilisation(EDvisits)-MeanSD-PEF monitoring-Usual care-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---------------------|
| Overall bias and Directness | Risk of bias judgement | High |
| Overall bias and Directness | Overall Directness | Directly applicable |

ContinuousOutcomes-Unscheduledhealthcareutilisation(hospitalisation)-MeanSD-PEF monitoring-Usual care-t12

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | High (<i>PP analysis and low adherence</i>) |
| Overall bias and Directness | Overall Directness | Directly applicable |

ContinuousOutcomes-LungFunction(FEV1)-MeanSD-PEF monitoring-Usual care-t12

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | High (<i>PP analysis and low adherence</i>) |
| Overall bias and Directness | Overall Directness | Directly applicable |

Buist, 2006

Bibliographic Reference Buist, A. Sonia; Vollmer, William M.; Wilson, Sandra R.; Frazier, E. Ann; Hayward, Arthur D.; A Randomized Clinical Trial of Peak Flow versus Symptom Monitoring in Older Adults with Asthma; American Journal of Respiratory and Critical Care Medicine; 2006; vol. 174 (no. 10); 1077-1087

Study details

| | |
|---|--|
| Secondary publication of another included study- see primary study for details | No additional information |
| Other publications associated with this study included in review | No additional information |
| Trial name / registration number | No additional information |
| Study type | Randomised controlled trial (RCT) |
| Study location | USA |
| Study setting | Community |
| Study dates | No additional information |
| Sources of funding | Supported by the National Heart, Lung, and Blood Institute |
| Inclusion criteria | Aged 50-92 years |

| | |
|--|---|
| | <p>Physician diagnosed asthma</p> <p>Using medication suggestive of moderate-severe asthma</p> <p>Bronchodilator reversibility >8%</p> <p>Demonstrated ability to keep a symptom diary</p> <p>Not currently using a peak flow meter</p> |
| Exclusion criteria | None reported |
| Recruitment / selection of participants | Recruited from a managed-care organisation |
| Intervention(s) | Interventions consisted of four 90-minute small-group classes and included development of a personalised action plan and review of participant's diaries. Participants were coached on proper inhaler technique and were coached using a pre-specified skills checklist, containing items such as shaking the inhaler before use, exhaling fully prior to inhalation and holding breath after inhalation. Coaching continued until the individual had correctly demonstrated at least 7 of the 8 skills on this list, including all 5 linked to maximal deposition of inhaled medication. Interventionists met with participants twice per year to review inhaler and peak flow technique, review daily diaries, and discuss action plans. In between these meetings, participants were phone quarterly to review diaries and answer questions. Participants in the peak flow monitoring were divided into twice daily vs as-needed monitoring, although these were combined for the analysis of the results. |
| Population subgroups | No additional information |
| Ethnic Group | Not reported/unclear |
| Education Levels | Not reported/unclear |
| Language of Participants | English |
| Comparator | Interventions consisted of four 90-minute small-group classes and included development of a personalised action plan and review of participant's diaries. Participants were coached on proper inhaler technique and were coached using a pre- |

| | |
|-------------------------------|--|
| | specified skills checklist, containing items such as shaking the inhaler before use, exhaling fully prior to inhalation and holding breath after inhalation. Coaching continued until the individual had correctly demonstrated at least 7 of the 8 skills on this list, including all 5 linked to maximal deposition of inhaled medication. Interventionists met with participants twice per year to review inhaler technique, review daily diaries, and discuss action plans. In between these meetings, participants were phone quarterly to review diaries and answer questions. |
| Number of participants | 296 randomised 149 received peak flow monitoring 147 received symptom monitoring |
| Duration of follow-up | 24 months |
| Indirectness | None |
| Additional comments | Available case analysis - participants were excluded from analysis at a given time-point if they were missing data from the preceding 6 months |

Study arms

PEF monitoring (N = 149)

Based on peak flow monitoring, twice daily or as-needed, as well as symptoms via diaries

Usual care (N = 147)

Symptom monitoring via diaries

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 149) | Usual care (N = 147) |
|-------------------------|--------------------------|----------------------|
| % Female | n = 77 ; % = 52 | n = 76 ; % = 52 |
| Sample size | | |
| Mean age (SD) | 66 (9.6) | 66 (9.2) |
| Mean (SD) | | |
| Ethnicity | n = 142 ; % = 95 | n = 138 ; % = 94 |
| White/non-Hispanic | | |
| Sample size | | |
| Comorbidities | 1 (0 to 5) | 1 (0 to 4) |
| Number of comorbidities | | |
| Median (IQR) | | |

Outcomes

Study timepoints

- Baseline
- 6 month
- 24 month

Continuous Outcomes

| Outcome | PEF monitoring, Baseline, N = 149 | PEF monitoring, 6 month, N = NA | PEF monitoring, 24 month, N = 148 | Usual care, Baseline, N = 147 | Usual care, 6 month, N = NA | Usual care, 24 month, N = 146 |
|--|-----------------------------------|---------------------------------|-----------------------------------|-------------------------------|-----------------------------|-------------------------------|
| Unscheduled healthcare utilisation (Number of events per person-year of follow-up) Final values, rate of total acute asthma care use (hospital, ED, other acute care) Mean (SD) | 1.46 (2.53) | NR (NR) | 1.39 (1.98) | 1.3 (2.39) | NR (NR) | 1.5 (2.23) |

Unscheduled healthcare utilisation - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

ContinuousOutcomes-Unscheduledhealthcareutilisation-MeanSD-PEF monitoring-Usual care-t24

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | Some concerns (<i>Low adherence to intervention</i>) |
| Overall bias and Directness | Overall Directness | Partially applicable (<i>Population indirectness - participants described as moderate-severe asthma using NAEPP 1997 definition</i>) |

Charlton, 1990

Bibliographic Reference Charlton, I; Charlton, G; Broomfield, J; Mullee, M A; Evaluation of peak flow and symptoms only self management plans for control of asthma in general practice.; British Medical Journal; 1990; vol. 301 (no. 6765); 1355

Study details

| | |
|---|--|
| Secondary publication of another included study- see primary study for details | Not stated |
| Other publications associated with this study included in review | None stated |
| Trial name / registration number | Not stated |
| Study location | England |
| Study setting | Nurse ran asthma clinic in a GP practice |
| Study dates | 1990 |
| Sources of funding | Clare Wand fund, the Scientific Foundation of the Royal College of General Practitioners, and Vitalograph |
| Inclusion criteria | People with asthma who were having prophylactic treatment for asthma and attending a nurse run asthma clinic. |
| Exclusion criteria | Patients who required maintenance treatment with steroids or nebulised salbutamol during the study were not included in the relevant analyses. |

| | |
|--|--|
| Recruitment / selection of participants | Patients on the repeat prescribing register who were receiving prophylactic treatment for asthma were invited. |
| Intervention(s) | <p>Peak flow self management plan:</p> <ul style="list-style-type: none"> • If peak flow greater than 70% of normal Continue maintenance treatment: (a) Bronchodilator two times a day or when needed (b) Inhaled steroid two times a day • If peak flow less than 70% of normal (1) Double dose of inhaled steroid for number of days required to achieve previous baseline (2) Continue on this increased dose for same number of days (3) Return to previous dose of maintenance treatment • If peak flow less than 50% of normal (1) Start oral prednisolone 40 mg daily (20 mg daily for children) and contact general practitioner (2) Continue on this dose for the number of days required to achieve previous baseline (3) Reduce oral prednisolone to 20 mg daily (10 mg daily for children) for same number of days (4) Stop prednisolone • If peak flow less than 30% (1) Contact general practitioner urgently or, if unavailable, (2) Contact ambulance or, if unavailable, (3) Go directly to hospital <p>The nurse instructed each patient in the methods to be used in carrying out the two self management plans. The first interview usually took 45 minutes. One week later the patients were reviewed by the nurse for a further 15 minutes, when spirometry was again performed and inhaler technique checked. Progress with self monitoring and self management were checked and treatment altered, if necessary, after discussion with the patient's general practitioner. Topics such as smoking, holidays, provoking factors, and emergency treatments were discussed in the course of the follow up visits. All the patients were reviewed every eight weeks by the nurse or more often if she considered it necessary.</p> |
| Population subgroups | |
| Ethnic Group | Not reported/unclear |
| Education Levels | Not reported/unclear |
| Language of Participants | Not reported/unclear |

| | |
|-------------------------------|--|
| Comparator | <p>Self-management plan:</p> <ul style="list-style-type: none"> • When you feel normal Continue maintenance treatment: (a) Bronchodilator two times a day or when needed (b) Inhaled steroid two times a day • If you get a cold or start to feel tight Use your bronchodilator two puffs every four hours • If you wake with wheezing at night or have a persistent cough (1) Double dose of inhaled steroid for number of days it takes you to return to normal (2) Use bronchodilator two puffs every four hours • If your bronchodilator only lasts two hours and you find doing your normal activities makes you short of breath (1) Start oral prednisolone 40 mg daily (20 mg daily for children) and contact general practitioner (2) Continue to use this dose for the number of days required to return you to normal (3) Reduce oral prednisolone to 20 mg daily (10 mg daily for children) for same number of days (4) Stop prednisolone • If your bronchodilator lasts only 30 minutes or you have difficulty talking call the doctor immediately <p>The nurse instructed each patient in the methods to be used in carrying out the two self management plans. The first interview usually took 45 minutes. One week later the patients were reviewed by the nurse for a further 15 minutes, when spirometry was again performed and inhaler technique checked. Progress with self monitoring and self management were checked and treatment altered, if necessary, after discussion with the patient's general practitioner. Topics such as smoking, holidays, provoking factors, and emergency treatments were discussed in the course of the follow up visits. All the patients were reviewed every eight weeks by the nurse or more often if she considered it necessary.</p> |
| Number of participants | 115 |
| Duration of follow-up | 12 months |
| Indirectness | None |

Study arms

PEF monitoring (N = 51)

PEF-based self-management plan

Usual care (N = 64)

Symptom-based self management action plan

Characteristics**Study-level characteristics**

| Characteristic | Study (N = 115) |
|-----------------------|------------------------|
| % Female | NR |
| Nominal | |
| Ethnicity | NR |
| Nominal | |
| Comorbidities | NR |
| Nominal | |
| Asthma control | NR |
| Nominal | |

Arm-level characteristics

| Characteristic | PEF monitoring (N = 51) | Usual care (N = 64) |
|-----------------------|--------------------------------|----------------------------|
| Mean age (SD) | 19 children | 27 children |

| Characteristic | PEF monitoring (N = 51) | Usual care (N = 64) |
|----------------|-------------------------|---------------------|
| Custom value | | |

Outcomes

Study timepoints

- Baseline
- 12 month

Dichotomous outcomes

| Outcome | PEF monitoring, Baseline, N = 51 | PEF monitoring, 12 month, N = 51 | Usual care, Baseline, N = 64 | Usual care, 12 month, N = 64 |
|---|----------------------------------|----------------------------------|------------------------------|------------------------------|
| Severe asthma exacerbations (needing oral steroids) (number of people) | n = NA ; % = NA | n = NA ; % = NA | n = NA ; % = NA | n = NA ; % = NA |
| No of events | | | | |
| Severe asthma exacerbations (needing oral steroids) (number of people) | n = NA ; % = NA | n = NA ; % = NA | n = NA ; % = NA | n = NA ; % = NA |
| Sample size | | | | |
| Adults | n = 22 ; % = 81 | n = 13 ; % = 48 | n = 21 ; % = 63 | n = 7 ; % = 21 |
| No description | | | | |
| No of events | | | | |

| Outcome | PEF monitoring, Baseline, N = 51 | PEF monitoring, 12 month, N = 51 | Usual care, Baseline, N = 64 | Usual care, 12 month, N = 64 |
|-----------------------------------|----------------------------------|----------------------------------|------------------------------|------------------------------|
| Adults No description | n = 27 ; % = NA | n = 27 ; % = NA | n = 33 ; % = NA | n = 33 ; % = NA |
| Sample size | | | | |
| Children No description | n = 12 ; % = 63 | n = 7 ; % = 37 | n = 11 ; % = 41 | n = 0 ; % = 0 |
| No of events | | | | |
| Children No description | n = 19 ; % = NA | n = 19 ; % = NA | n = 27 ; % = NA | n = 27 ; % = NA |
| Sample size | | | | |

Severe asthma exacerbations (needing oral steroids) - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Dichotomous outcomes - Needing oral steroids - Adults - No Of Events - PEF monitoring - Self management - t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information about allocation concealment or adherence ; no baseline characteristics reported; missing data without reasons reported; unblinded to outcome assessors)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomous outcomes-Needing oral steroids-Children-No Of Events-PEF monitoring-Self management-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High (No information about allocation concealment or adherence ; no baseline characteristics reported; unblinded to outcome assessors) |
| Overall bias and Directness | Overall Directness | Directly applicable |

Coté, 1997

Bibliographic Reference Coté, J; Cartier, A; Robichaud, P; Boutin, H; Malo, J L; Rouleau, M; Fillion, A; Lavallée, M; Krusky, M; Boulet, L P; Influence on asthma morbidity of asthma education programs based on self-management plans following treatment optimization.; American Journal of Respiratory and Critical Care Medicine; 1997; vol. 155 (no. 5); 1509-1514

Study details

| | |
|---|------------|
| Secondary publication of another included study- see primary study for details | Not stated |
| Other publications associated with this study included in review | Not stated |

| | |
|--|--|
| Trial name / registration number | Not stated |
| Study location | Canada |
| Study setting | Tertiary care |
| Study dates | 1997 |
| Sources of funding | Glaxo Canada, Mississauga (Ontario) |
| Inclusion criteria | Eligibility criteria included the presence of moderate to severe asthma, age of 16 yr or older, and the need to take daily anti-inflammatory agent (inhaled corticosteroids, cromoglycate, or nedocromil). The diagnosis of asthma had to be confirmed by either a documented reversibility greater than 15% in FEV1 or a PC20 methacholine \leq 8 mg/ml when determined by the method described by Cockcroft and coworkers. The study protocol was approved by the local ethics committees of the three participating hospitals, and all subjects signed informed consent forms. |
| Exclusion criteria | We excluded all current or ex-smokers 40 yr of age or older in whom the best FEV1 after salbutamol was <80% of predicted patients with significant concurrent diseases, those requiring >7.5 mg/d of prednisone to control asthma symptoms, and finally those having taken part in an asthma educational program. |
| Recruitment / selection of participants | From three tertiary care hospitals at the time of their hospitalization or visit to the clinic between April and December 1993. |
| Intervention(s) | <p>A run-in period of 2 to 6 weeks covered medication adjustment according to the International Consensus on asthma therapy. In patients receiving budesonide, this medication was replaced by an equivalent dose of inhaled beclomethasone dipropionate (BDP). All subjects were instructed on the correct use of inhalers and mini-Wright peak-flow meters. Spirometry was done and physicians analysed PEF values. Stable patients were randomized.</p> <p>The subjects in this group received instructions from their pulmonologists regarding (1) medication use, and (2) influence of allergenic and nonallergenic triggers. They were taught how to use their inhaler properly by the educator. A verbal action plan could be given by the physician. Individual counseling with the specialized educator during a 1 -h session. The following issues were covered: brief information on pathophysiology of asthma, role of medication and side effects, allergenic and nonallergenic triggers, symptoms indicating the beginning of a flare-up, and, finally, role of self-action plans;</p> |

| | |
|---------------------------------|---|
| | <p>emphasis was placed on those issues that seemed most relevant to the patient's needs. A book entitled Understand and Control Your Asthma was given at no charge to all participants. Additional educational visits were scheduled if necessary.</p> <p>PEF monitoring: These patients were asked to continue measuring PEF twice a day and to keep a diary of the results which was reviewed at every follow-up visit.</p> <p>Self-action plan: Step 1: (green zone): morning prebronchodilator PEF values are $\geq 85\%$ of the PBV (personal best value): continue the same maintenance treatment. STEP 2 (yellow zone): for the past 24 h, PEF values have been between 60 and 85% of the PBV: increase the dose of BDP to four puffs twice a day (2,000 $\mu\text{g}/\text{d}$) for a minimum of 10 d and the time required to return to PBV, then progressively reduce the dose of BDP to the initial level over 2 wk. If 48 h after increasing the dose of BDP, there is no increase in PEF values, proceed to STEP 3. For patients with a maintenance dose of BDP $>1,000 \mu\text{g}$ per day, the action plan was modified as follows: the dose of BDP was increased as much as four puffs three times a day (3,000 $\mu\text{g}/\text{d}$). STEP 3 (red zone): for the previous 12 h, PEF values have been $<60\%$ of the PBV: advise personal physician and start using oral prednisone 30 mg/d for 5 days, then reduce prednisone by 5 mg/d every day. STEP 4 (red extra zone): PEF values are $<50\%$ of your PBV: visit your physician promptly or go directly to an emergency room.</p> |
| Population subgroups | None |
| Ethnic Group | Not reported/unclear |
| Education Levels | Not reported/unclear |
| Language of Participants | Not reported/unclear |
| Comparator | <p>A run-in period of 2 to 6 weeks covered medication adjustment according to the International Consensus on asthma therapy. In patients receiving budesonide, this medication was replaced by an equivalent dose of inhaled beclomethasone dipropionate (BDP). All subjects were instructed on the correct use of inhalers and mini-Wright peak-flow meters. Spirometry was done and physicians analysed PEF values. Stable patients were randomized</p> <p>The subjects in this group received instructions from their pulmonologists regarding (1) medication use, and (2) influence of allergenic and nonallergenic triggers. They were taught how to use their inhaler properly by the educator. A verbal action</p> |

| | |
|-------------------------------|---|
| | <p>plan could be given by the physician. Individual counseling with the specialized educator during a 1 -h session. The following issues were covered: brief information on pathophysiology of asthma, role of medication and side effects, allergenic and nonallergenic triggers, symptoms indicating the beginning of a flare-up, and, finally, role of self-action plans; emphasis was placed on those issues that seemed most relevant to the patient's needs. A book entitled Understand and Control Your Asthma was given at no charge to all participants. Additional educational visits were scheduled if necessary.</p> <p>Self-management plan: Step 1 (green zone): not awakened at night by asthma, using the usual dose of beta2-agonist, able to perform usual activities without becoming short of breath: continue the same treatment. STEP 2 (yellow zone): for the previous 24 h, using twice as much beta2-agonist or awakening at night because of asthma, moderate exercise induces unusual breathlessness, beta2-agonist relieves respiratory symptoms for less than 4 h: increase the dose of BDP as described above for patients in Group P. STEP 3 (red zone): for the previous 24 h, (3 2-agonist has been relieving the asthma symptoms for less than 4 h, or using more than 10 puffs of (32-agonist a day, or daily life activities cause shortness of breath, or breathlessness is present at rest: contact personal physician and start using oral prednisone 30 mg as described above for Group P. STEP 4 (extra red): difficulty talking, the beta2-agonist relieves the symptoms for 2 h or less: advise personal physician if possible and go directly to an emergency clinic.</p> |
| Number of participants | 188 recruited, 50 randomised to PEF arm and 45 to self-management arm |
| Duration of follow-up | 12 months |
| Indirectness | None |
| Additional comments | None |

Study arms

PEF monitoring (N = 50)

Twice daily and reviewed at follow-up visits, with PEF self-management plan, plus education

Usual care (N = 45)

Symptom-based self-management plan, plus education

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 50) | Usual care (N = 45) |
|-----------------------------|-------------------------|---------------------|
| % Female (Number of female) | 22 | 15 |
| Nominal | | |
| Mean age (SD) (Mean (SEM)) | 37 (2) | 39 (2) |
| Mean (SE) | | |
| Duration of asthma (years) | 14 (2) | 14 (2) |
| Standardised Mean (SE) | | |

Outcomes

Study timepoints

- 12 month

Morbidity outcomes

| Outcome | PEF monitoring, 12 month, N = 50 | Usual care, 12 month, N = 45 |
|--|----------------------------------|------------------------------|
| Unscheduled health utilisation (hospitalisation) (Number of visits) | 0.04 (0.04) | 0.09 (0.04) |
| Mean (SE) | | |
| Unscheduled healthcare utilisation (emergency room visit) Number of visits | 0.7 (0.2) | 0.7 (0.2) |
| Mean (SE) | | |
| Time off school or work (days lost from work/school) | 2.2 (1.8) | 2.9 (1.9) |
| Mean (SE) | | |

Unscheduled health utilisation (hospitalisation) - Polarity - Lower values are better

Unscheduled healthcare utilisation (emergency room visit) - Polarity - Lower values are better

Time off school or work (days lost from work/school) - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Morbidityoutcomes-Hospitalisation-MeanSE-PEF monitoring-Self-management of symptoms-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information on randomisation process, adherence and analysis method unclear; only drop out information at the time of randomisation, not at follow-up)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Morbidityoutcomes-Emergencyroomvisit-MeanSE-PEF monitoring-Self-management of symptoms-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information on randomisation process, adherence and analysis method unclear; only drop out information at the time of randomisation, not at follow-up)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Morbidityoutcomes-Dayslostfromwork/school-MeanSE-PEF monitoring-Self-management of symptoms-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information on randomisation process, adherence and analysis method unclear; only drop out information at the time of randomisation, not at follow-up)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Cowie, 1997

Bibliographic Reference

Cowie, Robert L.; Revitt, Shirley G.; Underwood, Margot F.; Field, Stephen K.; The Effect of a Peak Flow-Based Action Plan in the Prevention of Exacerbations of Asthma; CHEST; 1997; vol. 112 (no. 6); 1534-1538

Study details

| | |
|---|--|
| Secondary publication of another included study- see primary study for details | Not stated |
| Other publications associated with this study included in review | No information given |
| Trial name / registration number | Not stated |
| Study location | Canada |
| Study setting | University hospital asthma clinical |
| Study dates | 1997 |
| Sources of funding | Grant from Foothills Hospital, Calgary |
| Inclusion criteria | Adult and adolescent patients who had received urgent treatment at the emergency department for asthma exacerbations in the preceding 12 months and used asthma medication |
| Exclusion criteria | People with written asthma management plans |
| Recruitment / selection of participants | Subjects were recruited by contacting those who had been treated for an exacerbation of asthma in an emergency department in one of the teaching hospitals in the city of Calgary. Subjects were also recruited from those attending a university asthma clinic when they gave a history of having received urgent treatment for their asthma in the previous 12 months. |
| Intervention(s) | All participants had an interview about their asthma, assessed with spirometry before and after a beta2-agonist and given personalised instruction from an asthma nurse regarding the nature of their asthma (triggers, medication), correct use of inhalation devices were checked education was given regarding asthma medication dosages. |

| | |
|---------------------------------|---|
| | <p>Patients were given a peak flowmeter and brief instructions in its use and in recording the data. Their action plan included peak flow measurements that were estimated from their measured and predicted peak expiratory flows. Peak flow readings at or below which each step should be initiated were written into each subject's action plan. Doubling of their inhaled corticosteroid was recommended when the peak expiratory flow was <70% of their estimated best reading or when the diurnal variation was >20%. Initiation of the third step (prednisone) was advised at <50%, and the fourth step (urgent treatment in an emergency department) at <30% of their estimated best peak expiratory flow</p> |
| Population subgroups | None |
| Ethnic Group | Not reported/unclear |
| Education Levels | Not reported/unclear |
| Language of Participants | Not reported/unclear |
| Comparator | <p>All participants had an interview about their asthma, assessed with spirometry before and after a beta2-agonist and given personalised instruction from an asthma nurse regarding the nature of their asthma (triggers, medication), correct use of inhalation devices were checked education was given regarding asthma medication dosages.</p> <p>The instructions for the symptom-based plan listed common symptoms of asthma, including waking at night or a persistent cough and Clinical evidence tables Asthma © NICE 2017. All rights reserved. Subject to Notice of rights. 302 symptoms of a common cold as indications for doubling their inhaled corticosteroid. The third step required the introduction of prednisone if their relief following the use of a bronchodilator lasted <2 h or if they became short of breath doing their normal daily activities. The fourth step required them to seek urgent treatment if their bronchodilator provided relief for <30 min or if their breathing made it difficult for them to speak.</p> |
| Number of participants | 115 overall recruited |
| Duration of follow-up | 6 months |
| Indirectness | None |

| | |
|----------------------------|------|
| Additional comments | None |
|----------------------------|------|

Study arms

PEF monitoring (N = 48)

Peak flow based action plan

Usual care (N = 50)

Symptom based action plan

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 48) | Usual care (N = 50) |
|----------------|---|--|
| % Female | 29/46 of those who completed the study | 25/45 of those who completed the study |
| Custom value | | |
| Mean age (SD) | 38.1 (14.41) Age (SD) for those who completed the study | 36.8 (16.5) Age (SD) for those who completed the study |
| Custom value | | |

Outcomes

Study timepoints

- 6 month

Dichotomous outcomes

| Outcome | PEF monitoring, 6 month, N = 46 | Usual care, 6 month, N = 45 |
|---|---------------------------------|-----------------------------|
| Unscheduled healthcare utilisation (number of people attending for urgent treatment of asthma) Number of people | n = 5 ; % = 10.9 | n = 14 ; % = 31.1 |
| No of events | | |
| Unscheduled healthcare utilisation (hospital admissions, total number of admissions for asthma) No of events | n = 2 ; % = 4.3 | n = 2 ; % = 13.3 |

Unscheduled healthcare utilisation (number of people attending for urgent treatment of asthma) - Polarity - Lower values are better

Unscheduled healthcare utilisation (hospital admissions, total number of admissions for asthma) - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Dichotomous outcomes-Number of people attending for urgent treatment of asthma-No Of Events-PEF monitoring-Self-management-t6

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | Some concerns <i>(No information on adherence to intervention; outcome self-reported via questionnaire and study unblinded)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomous outcomes-Total number of admissions for asthma-No Of Events-PEF monitoring-Self-management-t6

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | Some concerns <i>(No information on adherence to intervention; outcome self-reported via questionnaire and study unblinded)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Kaya, 2009

Bibliographic Reference

Kaya, Zuleyha; Erkan, Feyza; Ozkan, Mine; Ozkan, Sedat; Kocaman, Nazmiye; Ertekin, Banu Aslantas; Direk, Nese; Self-Management Plans for Asthma Control and Predictors of Patient Compliance; Journal of Asthma; 2009; vol. 46 (no. 3); 270-275

Study details

| | |
|---|--|
| Secondary publication of another included study- see primary study for details | Not stated |
| Other publications associated with this study included in review | Not stated |
| Trial name / registration number | Not stated |
| Study location | Turkey |
| Study setting | Asthma outpatients |
| Study dates | 2009 |
| Sources of funding | No information given |
| Inclusion criteria | People with the persistent asthma during their routine visits, receiving follow-up care for at least 1 year in a specific asthma clinic |
| Exclusion criteria | People with handicaps such as illiteracy, hearing and visual defects, mental retardation, and psychotic disorders |
| Recruitment / selection of participants | The study sample consisted of 63 patients with persistent asthma outpatients |
| Intervention(s) | Asthma history taken, psychiatric evaluation taken using various scales (BDI, STAI, SCID-1, SF-36). A standard education program on asthma self-management that was prepared according to GINA recommendations was given directly to the patients along with a booklet for keeping daily records of symptoms and PEFs. People were given PFM-based written self-management education programs with 45 minutes training time. The physicians' telephone numbers were made available to the subjects for need-based access during the study duration. The PFMs were provided free of charge. |

| | |
|---------------------------------|--|
| Ethnic Group | Not reported/unclear |
| Education Levels | Mixed |
| Language of Participants | Not reported/unclear |
| Comparator | Asthma history taken, psychiatric evaluation taken using various scales (BDI, STAI, SCID-1, SF-36). A standard education program on asthma self-management that was prepared according to GINA recommendations was given directly to the patients along with a booklet for keeping daily records of symptoms. People were given symptom-based written self-management education programs with 45 minutes training time. The physicians' telephone numbers were made available to the subjects for need-based access during the study duration. |
| Number of participants | 63 |
| Duration of follow-up | 12 months |
| Indirectness | According to GINA guidelines, 14.3% of the patients were classified as mild (n = 9), 47.6% (n = 30) as moderate, and 38.1% (n = 24) as severe persistent asthmatics. |

Study arms

PEF monitoring (N = 31)

PEF-based action plan

Usual care (N = 32)

Symptom based self-management

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 31) | Usual care (N = 32) |
|-------------------------|-------------------------|---------------------|
| % Female | n = 25 ; % = 80.6 | n = 25 ; % = 78.1 |
| Sample size | | |
| Mean age (SD) | 44.16 (10.67) | 42.5 (10.39) |
| Mean (SD) | | |
| Asthma duration (years) | 11.32 (8.94) | 9.11 (7.76) |
| Mean (SD) | | |

Outcomes

Study timepoints

- Baseline
- 3 month
- 6 month

Quality of life (SF-36)

| Outcome | PEF monitoring, Baseline, N = 31 | PEF monitoring, 3 month, N = 31 | PEF monitoring, 6 month, N = 31 | Usual care, Baseline, N = 32 | Usual care, 3 month, N = 32 | Usual care, 6 month, N = 32 |
|--|----------------------------------|---------------------------------|---------------------------------|------------------------------|-----------------------------|-----------------------------|
| Quality of life, SF-36, Physical total score Range 0-100 | 53.63 (21.67) | 58.81 (21.98) | NA (NA) | 62.85 (22.08) | 65.3 (21.31) | NA (NA) |
| Mean (SD) | | | | | | |
| Quality of life (SF-36, Mental total score) Range 0-100 | 46.43 (13.08) | 62.39 (19.1) | NA (NA) | 50.49 (16.24) | 74.17 (15.51) | NA (NA) |
| Mean (SD) | | | | | | |

Quality of life, SF-36, Physical total score) - Polarity - Higher values are better

Quality of life (SF-36, Mental total score) - Polarity - Higher values are better

Pulmonary function

| Outcome | PEF monitoring, Baseline, N = 31 | PEF monitoring, 3 month, N = 31 | PEF monitoring, 6 month, N = 31 | Usual care, Baseline, N = 32 | Usual care, 3 month, N = 32 | Usual care, 6 month, N = 32 |
|---|----------------------------------|---------------------------------|---------------------------------|------------------------------|-----------------------------|-----------------------------|
| Lung function (FEV1 % predicted) | 85.7 (21.05) | NA (NA) | 87.74 (19.02) | 87.74 (19.02) | NA (NA) | 87.35 (21.25) |
| Mean (SD) | | | | | | |

Lung function (FEV1 % predicted) - Polarity - Higher values are better

FEV1 %

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Qualityoflife(SF-36)-Physicaltotalscore-MeanSD-PEF monitoring-Symptom monitoring -t3

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | High <i>(No randomisation information; poor adherence to interventions and not clear how handled in analysis; Self-reported outcome and unblinded.)</i> |
| Overall bias and Directness | Overall Directness | Partially applicable <i>(Population indirectness: 38.1% severe asthma)</i> |

Qualityoflife(SF-36)-Mentaltotalscore-MeanSD-PEF monitoring-Symptom monitoring -t3

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | High <i>(No randomisation information; poor adherence to interventions and not clear how handled in analysis; Self-reported outcome and unblinded.)</i> |
| Overall bias and Directness | Overall Directness | Partially applicable <i>(Population indirectness: 38.1% severe asthma)</i> |

Pulmonaryfunction-FEV1%-MeanSD-PEF monitoring-Symptom monitoring -t6

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No randomisation information; poor adherence to interventions and not clear how handled in analysis.)</i> |
| Overall bias and Directness | Overall Directness | Partially applicable <i>(Population indirectness: 38.1% severe asthma)</i> |

LÓPEZ-VIÑA, 2000

Bibliographic Reference LÓPEZ-VIÑA, A.; DEL CASTILLO-ARÉVALO, F.; Influence of peak expiratory flow monitoring on an asthma self-management education programme; Respiratory Medicine; 2000; vol. 94 (no. 8); 760-766

Study details

| | |
|---|---|
| Secondary publication of another included study- see primary study for details | Not stated |
| Other publications associated with this study included in review | Not stated |
| Trial name / registration number | Not stated |
| Study location | Spain |
| Study setting | secondary care (people requiring to visit emergency departments due to asthma) |
| Study dates | 2000 |
| Sources of funding | Supported in part by grant FISS 92/372 |
| Inclusion criteria | 17±65 years of age, symptomatic disease during the previous year and voluntary participation in the study. Each patient satisfied the American Thoracic Society (ATS) definition of asthma, with symptoms of episodic wheezing, cough and shortness of breath responding to bronchodilators, and reversible airflow obstruction documented on at least one previous |

| | |
|--|---|
| | pulmonary function study. Reversibility was defined as a >20% increase in the forced expiratory volume in 1 sec (FEV1) or peak expiratory flow following inhalation of salbutamol (0.2 mg). In patients with normal spirometric data at the initial assessment (before randomization) and lack of functional demonstration of asthma before their visit to the emergency department, a methacholine challenge test was required. The challenge was terminated when FEV1 fell by more than 20% from baseline value (PD20). |
| Exclusion criteria | Patients with concurrent chronic diseases that may affect the interpretation of results (COPD, emphysema, cystic fibrosis, severe rheumatoid arthritis, neoplasia, etc.) were excluded. |
| Recruitment / selection of participants | All consecutive patients who required treatment in an emergency department of acute-care hospitals in the area of Gijon, Asturias (Spain) over an 18-month period because of an episode of acute asthma exacerbation were recruited. |
| Intervention(s) | Patients in the experimental group received personal instruction on general concepts and management of asthma (e.g., chronic disease, difference between inflammation and bronchoconstriction, clinical manifestations, mechanism of action of anti-asthmatic drugs, need to take medication daily, adverse effects, etc. and were taught by a nurse to acquire skills in self-management. Patients also received a self-management plan with a card of colour codes and diary cards (with top marks at 80%, 60% and 40% of the best patient's value) in which symptoms, medication and PEFr values had to be registered. |
| Population subgroups | None |
| Ethnic Group | Not reported/unclear |
| Education Levels | Not reported/unclear |
| Language of Participants | Not reported/unclear |
| Comparator | Patients in the control group received the same education programme except for informative pamphlets; diary cards for symptoms, medication and PEFr; and self-management plan with a card of colour codes. The education programme included adherence enhancing strategies for all patients. |
| Number of participants | 150 |
| Duration of follow-up | 12 months |
| Indirectness | None |

Study arms

PEF monitoring (N = 56)

PEF-based self-management

Usual care (N = 44)

Symptom-based self-management

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 56) | Usual care (N = 44) |
|---|---|---|
| % Female Number of people | n = 26 ; % = 46.4 | n = 25 ; % = 56.8 |
| No of events | | |
| Mean age (SD) Custom value | aged 17-34: 24 people; 35-65: 32 people | aged 17-34: 18 people; 35-65: 26 people |
| Asthma control (number of people) Asthma severity: mild, moderate, severity Custom value | mild: 4; moderate: 31; Severe: 21 | mild: 4; moderate: 29; severe: 11 |

Outcomes

Study timepoints

- Baseline
- 12 month

dichotomous outcomes

| Outcome | PEF monitoring, Baseline, N = 56 | PEF monitoring, 12 month, N = 56 | Usual care, Baseline, N = 44 | Usual care, 12 month, N = 44 |
|--|----------------------------------|----------------------------------|------------------------------|------------------------------|
| Time off school/work (absenteeism from school/work) (number of people) | n = 19 ; % = 33.9 | n = 2 ; % = 3.5 | n = 18 ; % = 40.9 | n = 0 ; % = 0 |
| No of events | | | | |
| Unscheduled healthcare utilisations (visits to emergency ward) (number of people) | n = 50 ; % = 89.2 | n = 3 ; % = 5.3 | n = 35 ; % = 79.5 | n = 0 ; % = 0 |
| No of events | | | | |
| Unscheduled healthcare utilisation (hospital admissions) (number of people) | n = 17 ; % = 30.3 | n = 2 ; % = 3.9 | n = 10 ; % = 22.7 | n = 0 ; % = 0 |
| No of events | | | | |

Time off school/work (absenteeism from school/work) - Polarity - Lower values are better

Unscheduled healthcare utilisations (visits to emergency ward) - Polarity - Lower values are better

Unscheduled healthcare utilisation (hospital admissions) - Polarity - Lower values are better

Note: number of people calculated from percentages given

Continuous outcome

| Outcome | PEF monitoring, Baseline, N = 56 | PEF monitoring, 12 month, N = 56 | Usual care, Baseline, N = 44 | Usual care, 12 month, N = 44 |
|---|----------------------------------|----------------------------------|------------------------------|------------------------------|
| Lung function (FEV1 % predicted) | 75.1 (3.2) | 80.9 (2.3) | 79.5 (3.5) | 80.8 (2.8) |
| Mean (SD) | | | | |

Lung function (FEV1 % predicted) - Polarity - Higher values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

dichotomousoutcomes-Absenteeisnfromschool/work-NoOfEvents-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information on randomisation, adherence or analysis; 50/150 missing data with no reasons given; self-reported outcome and unblinded.)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

dichotomousoutcomes-Visitstoemergencyward-NoOfEvents-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information on randomisation, adherence or analysis; 50/150 missing data with no reasons given.)</i> |

| Section | Question | Answer |
|-----------------------------|--------------------|---------------------|
| Overall bias and Directness | Overall Directness | Directly applicable |

dichotomousoutcomes-Hospitaladmission-NoOfEvents-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information on randomisation, adherence or analysis; 50/150 missing data with no reasons given.)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Continuousoutcome-FED1%predicted-MeanSD-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(No information on randomisation, adherence or analysis; 50/150 missing data with no reasons given.)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

TURNER, 1998

Bibliographic Reference TURNER, MARK O.; TAYLOR, DARLENE; BENNETT, RON; FITZGERALD, J. MARK; A Randomized Trial Comparing Peak Expiratory Flow and Symptom Self-management Plans for Patients with Asthma Attending a Primary Care Clinic; American Journal of Respiratory and Critical Care Medicine; 1998; vol. 157 (no. 2); 540-546

Study details

| | |
|---|---|
| Secondary publication of another included study- see primary study for details | Not stated |
| Other publications associated with this study included in review | Not stated |
| Trial name / registration number | Not stated |
| Study location | Canada |
| Study setting | Primary care |
| Study dates | 1998 |
| Sources of funding | Supported in part by a grant from Glaxo Wellcome Canada Inc. |
| Inclusion criteria | People with a diagnosis of asthma defined by the American Thoracic Society were enrolled from a primary care clinic in Vancouver, British Columbia, Canada. Aged between 18 and 55 years of age with moderate to moderately severe asthma. We defined asthma severity by including only patients with a baseline PC20 methacholine <8 mg/ml and a daily requirement for inhaled corticosteroids to manage their asthma symptoms. People were either newly prescribed inhaled corticosteroids independently by their family physician or were currently using inhaled corticosteroids. |

| | |
|--|--|
| Exclusion criteria | Comorbid conditions that would impact on quality of life measurements, current use of a peak flow meter, inability to use peak flow meters, inability to communicate in English. |
| Recruitment / selection of participants | Potential study patients were identified from the clinic computer database, and the clinic physicians were encouraged to refer patients meeting study criteria. |
| Intervention(s) | <p>The asthma nurse reviewed patients monthly for 6 months after the initial visit (seven total visits). Patients who completed at least five visits were included in the final analysis. The initial visit included a history of asthma control and health care utilisation for the previous 6 months, spirometry, methacholine challenge testing, skin prick testing for common allergens, quality of life, and instruction in the use of daily diary cards. The self-management plans and use of a PFM were reviewed in detail after randomisation. Monthly visits documented morbidity outcomes, reinforced and evaluated use of the self-management plan, and provided ongoing education. Patients were asked to contact their physician if action points requiring prednisone were reached.</p> <p>Self Management Plan for PFM Group:</p> <ol style="list-style-type: none"> 1. If PEF \geq70% predicted, continue maintenance treatment: (1) bronchodilators as needed, (2) inhaled steroid twice daily. 2. If PEF <70% predicted: (1) double dose of inhaled steroid for number of days required to reach baseline PEF, (2) continue this increased dose for the same number of days needed to achieve baseline before, (3) returning to previous dose of maintenance treatment. 3. If PEF falls to <50% predicted: (1) start oral prednisone 40 mg daily after consulting with your family physician, (2) continue on this dose for the number of days required to achieve previous baseline for at least 1 week, then (3) reduce oral prednisone by 5 mg daily until off. 4. If PEF <30% predicted: (1) contact family physician immediately or, if physician unavailable, (2) call ambulance (dial 911) or (3) go directly to hospital emergency department. |

| | |
|---------------------------------|---|
| | Education was provided to each patient who participated in the study. It was individualized, but the general format was based on disease characteristics, triggers for airway obstruction, and treatment objectives. |
| Population subgroups | Not stated |
| Ethnic Group | Mixed Caucasian %: PFM group 93%, Symptom group 87% |
| Education Levels | Not reported/unclear |
| Language of Participants | English |
| Comparator | <p>The asthma nurse reviewed patients monthly for 6 months after the initial visit (seven total visits). Patients who completed at least five visits were included in the final analysis. The initial visit included a history of asthma control and health care utilisation for the previous 6 months, spirometry, methacholine challenge testing, skin prick testing for common allergens, quality of life, and instruction in the use of daily diary cards. The self-management plans were reviewed in detail after randomisation. Monthly visits documented morbidity outcomes, reinforced and evaluated use of the self-management plan, and provided ongoing education. Patients were asked to contact their physician if action points requiring prednisone were reached.</p> <p>Self Management Plan for Symptoms Group</p> <ol style="list-style-type: none"> 1. When you feel normal continue maintenance treatment with: (1) bronchodilators as needed, (2) inhaled steroid twice daily. 2. If you catch a cold or start to feel tight or awake at night with wheezing or have a persistent cough: (1) double the dose of inhaled steroid for the number of days it takes for you to return to normal, then reduce to maintenance dose of inhaled steroids after same number of days, (2) use bronchodilators two puffs every 4 h as needed. |

| | |
|-------------------------------|---|
| | <p>3. If the effect of your bronchodilators lasts only 2 h and you find doing your normal activities makes you short of breath (1) start oral prednisone 40 mg daily after consulting with your family physician, (2) continue to use this dose for at least 1 week, or until symptoms have normalised, then reduce prednisone dose by 5 mg daily until off.</p> <p>4. If the effect of your bronchodilators lasts only 30 min or you have difficulty talking: (1) contact family physician immediately, or, if physician unavailable, (2) call ambulance (dial 911) or (3) go directly to hospital emergency department.</p> <p>Education was provided to each patient who participated in the study. It was individualized, but the general format was based on disease characteristics, triggers for airway obstruction, and treatment objectives.</p> |
| Number of participants | At randomisation: PFM group 44, Symptom group 48 |
| Duration of follow-up | 6 months |
| Indirectness | None |
| Additional comments | |

Study arms

PEF monitoring (N = 44)

Self-management plan based on peak expiratory flow (PEF) monitoring

Usual care (N = 48)

Self-management plan based on symptom monitoring

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 44) | Usual care (N = 48) |
|--|-------------------------|---------------------|
| % Female | 22 | 27 |
| Nominal | | |
| Mean age (SD) | 34.1 (10.5) | 34.1 (9.4) |
| Mean (SD) | | |
| Ethnicity | Caucasian 93% | Caucasian 87% |
| Custom value | | |
| Asthma control (years) Asthma duration | 17.9 (14) | 17.2 (13.5) |
| Mean (SD) | | |
| FEV1 L (geometric mean) | 2.84 (0.86) | 2.86 (0.88) |
| Mean (SD) | | |

Outcomes

Study timepoints

- Baseline
- 6 month

Dichotomous outcomes

| Outcome | PEF monitoring, Baseline, N = 44 | PEF monitoring, 6 month, N = 44 | Usual care, Baseline, N = 48 | Usual care, 6 month, N = 48 |
|---|----------------------------------|---------------------------------|------------------------------|-----------------------------|
| Unscheduled healthcare utilisation (hospitalisations) Nominal | 0 | 0 | 0 | 1 |
| Unscheduled healthcare utilisation (emergency department visits) (number of people) Nominal | 8 | 6 | 3 | 2 |
| Time off school/work (days lost work/school) (number of people) Nominal | 9 | 9 | 10 | 8 |
| Severe asthma exacerbations (prednisone treatments) (Number of Events) Nominal | 5 | 4 | 3 | 6 |
| Unscheduled healthcare utilisation (unscheduled doctor visits) (Number of Events) Nominal | 31 | 17 | 29 | 12 |

Unscheduled healthcare utilisation (hospitalisations) - Polarity - Lower values are better

Unscheduled healthcare utilisation (emergency department visits) - Polarity - Lower values are better

Time off school/work (days lost work/school) - Polarity - Lower values are better

Severe asthma exacerbations (prednisone treatments) - Polarity - Lower values are better

Unscheduled healthcare utilisation (unscheduled doctor visits) - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Dichotomousoutcomes-Hospitalisations-Nominal-PEF monitoring-Self symptom monitoring-t6

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Poor adherence to interventions and unclear how handled in analysis; Differential in missing data across arms, and related to compliance with intervention)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomousoutcomes-Emergencydepartmentvisits-Nominal-PEF monitoring-Self symptom monitoring-t6

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Poor adherence to interventions and unclear how handled in analysis; Differential in missing data across arms, and related to compliance with intervention)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomousoutcomes-Dayslostwork/school-Nominal-PEF monitoring-Self symptom monitoring-t6

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Poor adherence to interventions and unclear how handled in analysis; Differential in missing data across arms, and related to compliance with intervention)</i> |

| Section | Question | Answer |
|-----------------------------|--------------------|---------------------|
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomousoutcomes-Prednisonetreatments-Nominal-PEF monitoring-Self symptom monitoring-t6

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Poor adherence to interventions and unclear how handled in analysis; Differential in missing data across arms, and related to compliance with intervention)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomousoutcomes-Unscheduleddoctorvisits-Nominal-PEF monitoring-Self symptom monitoring-t6

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Poor adherence to interventions and unclear how handled in analysis; Differential in missing data across arms, and related to compliance with intervention)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Wensley, 2004

Bibliographic Reference

Wensley, Diane; Silverman, Mike; Peak Flow Monitoring for Guided Self-management in Childhood Asthma; American Journal of Respiratory and Critical Care Medicine; 2004; vol. 170 (no. 6); 606-612

Study details

| | |
|---|---|
| Secondary publication of another included study- see primary study for details | Not stated |
| Other publications associated with this study included in review | Not stated |
| Trial name / registration number | Not stated |
| Study location | England |
| Study setting | Primary and Secondary care |
| Study dates | 2004 |
| Sources of funding | United Kingdom National Asthma Campaign and from Glaxo SmithKline, United Kingdom. |
| Inclusion criteria | Children: (1) age 7–14 years, (2) physician-diagnosed asthma, (3) at least step 2 of the British Thoracic Society Guidelines for Asthma Management (regular inhaled corticosteroid therapy) (18), (4) stable treatment for 1 month, (5) no other respiratory problem, (6) competent at spirometry, and (7) a successful 4-week run-in period. |
| Exclusion criteria | Not stated |

| | |
|--|--|
| Recruitment / selection of participants | In primary and secondary care for physician diagnosed asthma in children. At recruitment, demographic data were collected, and the QoL questionnaires were completed. Children performed twice daily spirometry (Vitalograph DSS; Vitalograph, Buckinghamshire, UK) to American Thoracic Society (1987) criteria. |
| Intervention(s) | The child and the main caregiver were taught self-management at a training session, which also included training in spirometry and symptom recording and which lasted 30–90 minutes according to need. A printed plan incorporating the child’s own medication regime was color coded: green, PEF more than 70%, few symptoms (carry on as usual); yellow, PEF 50–70% after beta2 agonist (double-inhaled corticosteroid as well as taking additional beta2-agonist therapy); and red, PEF less than 50% after taking additional inhaled beta2 agonist, severe symptoms (commence oral prednisolone and/or seek medical help). The PEF levels for action were based on the child’s best previous PEF. A written symptom diary was completed each morning, and spirometry was performed twice daily. Children were visited approximately monthly to download spirometric data, exchange the written diary for a new one, and complete QoL and Use of Health Services Questionnaires. Spirometric performance was checked, questions answered, and treatment changes incorporated into the plan. |
| Population subgroups | None stated |
| Ethnic Group | Not reported/unclear |
| Education Levels | Not reported/unclear |
| Language of Participants | Not reported/unclear |
| Comparator | Assuming same as intervention arm minus the PEF readings. |
| Number of participants | 90 randomised |
| Duration of follow-up | 12 weeks |
| Indirectness | Population indirectness as at least 25% of participants are age 14 years |
| Additional comments | |

Study arms

PEF monitoring (N = 44)

PEF-based action plan plus symptoms monitoring. Measure PEF twice daily

Usual care (N = 46)

Symptom-based management

Characteristics

Arm-level characteristics

| Characteristic | PEF monitoring (N = 44) | Usual care (N = 46) |
|--------------------------------------|-------------------------|---------------------|
| % Female | 32 | 61 |
| Nominal | | |
| Mean age (SD) | 11 (7 to 14) | 12 (7 to 14) |
| Median (IQR) | | |
| Asthma severity (%) BTS >2 | 30 | 20 |
| Nominal | | |
| Quality of life | 4.89 (0.2) | 5.09 (0.19) |
| Mean (SE) | | |

Outcomes

Study timepoints

- 12 week

Dichotomous outcomes

| Outcome | PEF monitoring, 12 week, N = 44 | Usual care, 12 week, N = 45 |
|---|---------------------------------|-----------------------------|
| Unscheduled healthcare utilisation (hospital admissions) (Number of children) Nominal | 1 | 0 |
| Unscheduled healthcare utilisation (attendance at A&E) (number of people) Nominal | 1 | 0 |
| Unscheduled healthcare utilisation (emergency GP visits) (Number of children) Nominal | 10 | 11 |
| Time off school or work (absent from school) (Number of children) Nominal | 15 | 13 |

Unscheduled healthcare utilisation (hospital admissions) - Polarity - Lower values are better

Unscheduled healthcare utilisation (attendance at A&E) - Polarity - Lower values are better

Unscheduled healthcare utilisation (emergency GP visits) - Polarity - Lower values are better

Time off school or work (absent from school) - Polarity - Lower values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Dichotomousoutcomes-Hospitaladmissions-Nominal-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Some concerns on multiple domains (no information about randomisation, some issues with adherence to interventions and self-reported outcome/unblinded.))</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomousoutcomes-AttendanceatA&E-Nominal-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Some concerns on multiple domains (no information about randomisation, some issues with adherence to interventions and self-reported outcome/unblinded.))</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomousoutcomes-EmergencyGpvisits-Nominal-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Some concerns on multiple domains (no information about randomisation, some issues with adherence to interventions and self-reported outcome/unblinded.))</i> |

| Section | Question | Answer |
|-----------------------------|--------------------|---------------------|
| Overall bias and Directness | Overall Directness | Directly applicable |

Dichotomous outcomes-Absent from school-Nominal-PEF monitoring-Self symptom monitoring-t12

| Section | Question | Answer |
|-----------------------------|------------------------|---|
| Overall bias and Directness | Risk of bias judgement | High <i>(Some concerns on multiple domains (no information about randomisation, some issues with adherence to interventions and self-reported outcome/unblinded.))</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Yoos, 2002

Bibliographic Reference Yoos, H.L.; Kitzman, Harriet; McMullen, Ann; Henderson, Charles; Sidora, Kimberly; Symptom monitoring in childhood asthma: a randomized clinical trial comparing peak expiratory flow rate with symptom monitoring; Annals of Allergy, Asthma & Immunology; 2002; vol. 88 (no. 3); 283-291

Study details

| | |
|---|------------|
| Secondary publication of another included | Not stated |
|---|------------|

| | |
|---|--|
| study- see primary study for details | |
| Other publications associated with this study included in review | Not stated |
| Trial name / registration number | Not stated |
| Study location | USA |
| Study setting | Primary care |
| Study dates | 2002 |
| Sources of funding | This work was supported by NIH grants NR04351– 03 and NR04351– 02S1 |
| Inclusion criteria | Subjects based on age (6 to 19 years) and severity (more than three asthma-related visits in the previous 12 months) were asked to participate in the study if they met two additional criteria: 1) the family was English-speaking; and 2) the child had not used a PFM in the previous 6-month period, and the family could not identify personal zones for the child. |
| Exclusion criteria | Children who had mild asthma and were only rarely symptomatic. |
| Recruitment / selection of participants | 11 primary care settings, school aged children and adolescents diagnosed with asthma. |
| Intervention(s) | All families received asthma education related to the pathophysiology of asthma, triggers, medications, and treatment goals as well as written materials reinforcing this information. They also received training in asthma symptom recognition, early and late symptoms that indicate inadequate asthma control, and symptom management. Families were referred to their primary care providers if the medication regimen appeared to be suboptimal (based on their current level of symptoms) or if treatment questions arose. Each group then received further training in their symptom-monitoring strategy as specified by group assignment. |

| | |
|---------------------------------|---|
| | <p>Intervention 1: Twice daily PEF monitoring and symptom monitoring. Personal action plan zones based on symptoms and PEF. Green zone, yellow zone (rescue medication) and red zone (contact healthcare provider).</p> <p>Intervention 2: Symptom-time PEF monitoring and symptom monitoring. Personal action plan zones based on symptoms and PEF. Green zone, yellow zone (rescue medication) and red zone (contact healthcare provider).</p> |
| Population subgroups | None stated |
| Ethnic Group | Mixed |
| Education Levels | Mixed |
| Language of Participants | English |
| Comparator | <p>All families received asthma education related to the pathophysiology of asthma, triggers, medications, and treatment goals as well as written materials reinforcing this information. They also received training in asthma symptom recognition, early and late symptoms that indicate inadequate asthma control, and symptom management. Families were referred to their primary care providers if the medication regimen appeared to be suboptimal (based on their current level of symptoms) or if treatment questions arose. Each group then received further training in their symptom-monitoring strategy as specified by group assignment.</p> <p>Intervention: Personal action plan zones based on symptoms only. Green zone, yellow zone (rescue medication) and red zone (contact healthcare provider).</p> |
| Number of participants | <p>PEF monitoring (twice daily) arm: 57</p> <p>PEF monitoring (symptom-time) arm: 55</p> <p>Symptom only monitoring arm: 56</p> |
| Duration of follow-up | 3 months |

| | |
|---------------------|--|
| Indirectness | children and adolescents (aged 6-19 years) |
|---------------------|--|

Study arms

PEF monitoring (twice daily) (N = 57)

Twice daily PEF monitoring and symptom monitoring. Personal action plan zones based on symptoms and PEF.

Usual care (N = 56)

Personal action plan zones based on symptoms only.

PEF monitoring (symptom-time) (N = 55)

Symptom-time PEF monitoring. Personal action plan zones based on symptoms and PEF

Characteristics

Study-level characteristics

| Characteristic | Study (N = 186) |
|----------------------------------|------------------------------------|
| % Female | 66 |
| Nominal | |
| Mean age (SD) (number of people) | school children 125, adolescent 43 |
| Custom value | |

| Characteristic | Study (N = 186) |
|-----------------------|------------------------|
| Ethnicity | NA |
| Nominal | |
| White % | 66 |
| Nominal | |
| Black % | 24 |
| Nominal | |
| Other | 10 |
| Nominal | |

Outcomes

Study timepoints

- Baseline
- 3 month

Continuous outcomes

| Outcome | PEF monitoring (twice daily), Baseline, N = 57 | PEF monitoring (twice daily), 3 month, N = NR | Usual care, Baseline, N = 56 | Usual care, 3 month, N = NR | PEF monitoring (symptom-time), Baseline, N = 55 | PEF monitoring (symptom-time), 3 month, N = NR |
|---|--|---|------------------------------|-----------------------------|---|--|
| Lung function (FEV1 % predicted) | 83 (2.62) | 88 (2.73) | 88 (2.74) | 90 (2.81) | 87 (2.64) | 94 (2.72) |
| Mean (SE) | | | | | | |

Lung function (FEV1 % predicted) - Polarity - Higher values are better

Critical appraisal - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Continuous outcomes - FEV1 % predicted - Mean SE - PEF monitoring - Self symptom monitoring - t3

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | High <i>(Lack of randomisation information or baseline characteristics, lack of adherence at 3 months information, lack of clarity on missing data)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Continuous outcomes-Lung function(FEV1%predicted)-Mean SE-PEF monitoring (twice daily)-Usual care-PEF monitoring (symptom-time)-t3

| Section | Question | Answer |
|-----------------------------|------------------------|--|
| Overall bias and Directness | Risk of bias judgement | High <i>(Lack of randomisation information or baseline characteristics, lack of adherence at 3 months information, lack of clarity on missing data)</i> |
| Overall bias and Directness | Overall Directness | Directly applicable |

Appendix E Forest plots

PEF vs symptom monitoring

Adults

Figure 2: Unscheduled healthcare utilisation (total asthma-related, lower is better, 24 months)

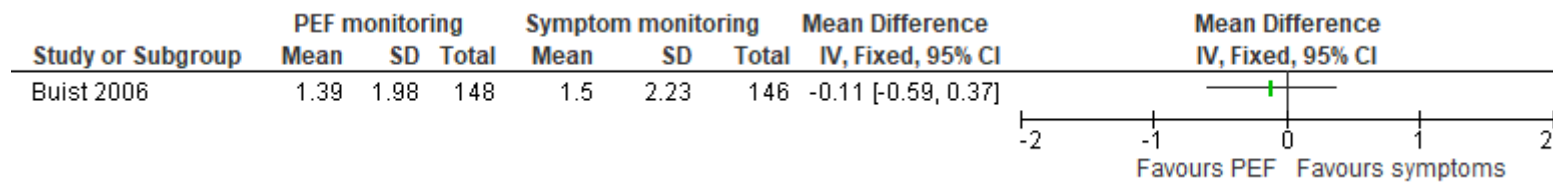


Figure 3: Unscheduled healthcare utilisation (urgent asthma treatment, lower is better, 6 months)

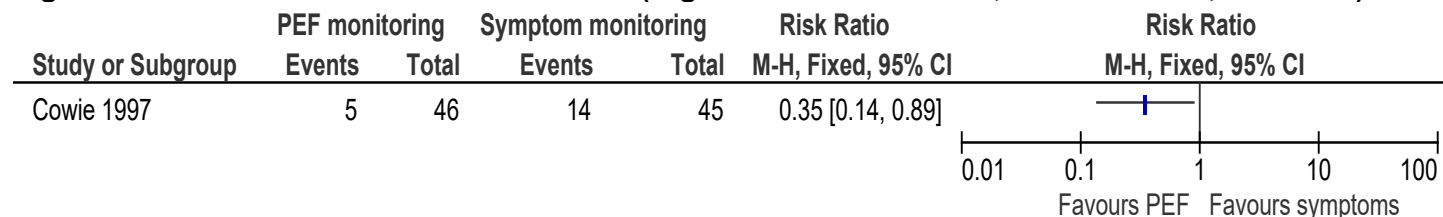


Figure 4: Unscheduled healthcare utilisation (hospital admissions, events, lower is better, 6-12 months)

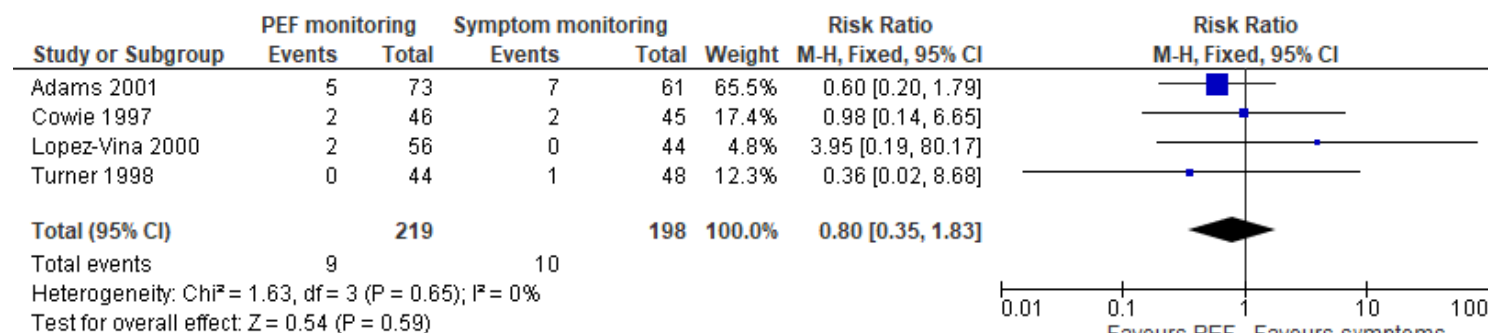


Figure 5: Unscheduled healthcare utilisation (mean hospital admissions, lower is better, 12 months)

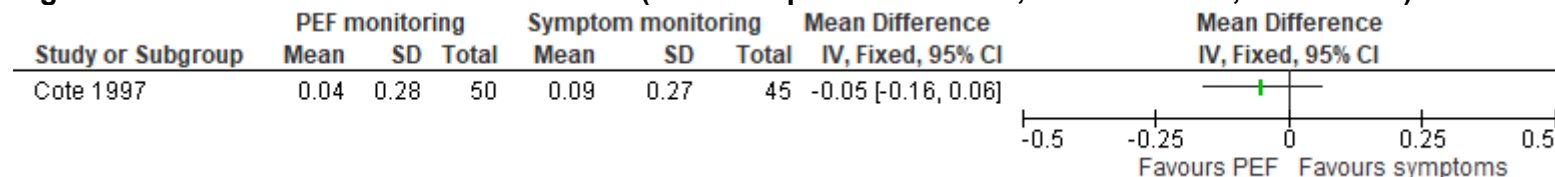


Figure 6: Unscheduled healthcare utilisation (ED visits, lower is better, 6-12 months)

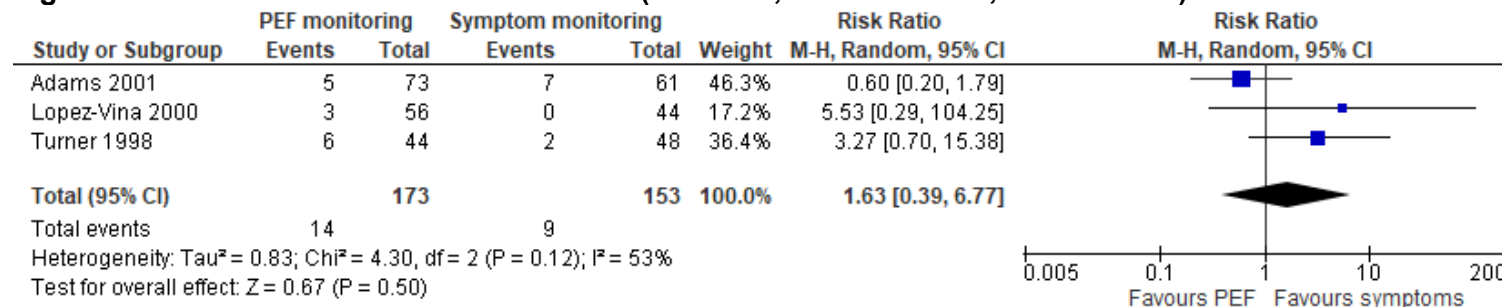


Figure 7: Unscheduled healthcare utilisation (mean number of ED visits, lower is better, 12 months)

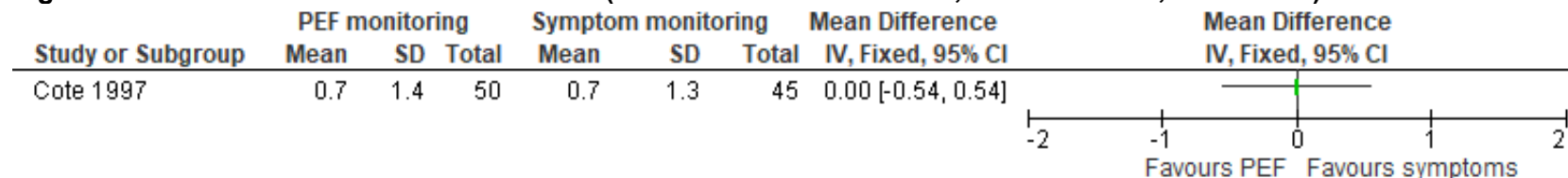


Figure 8: Unscheduled healthcare utilisation (unscheduled doctor visits, lower is better, 6 months)

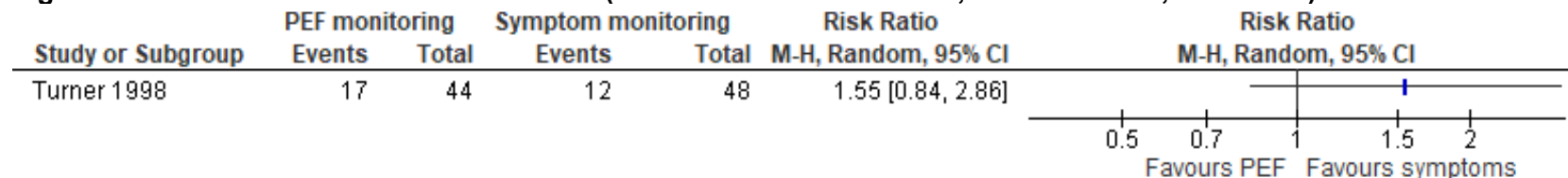


Figure 9: Severe exacerbations (taking oral steroids, lower is better, 6 months)

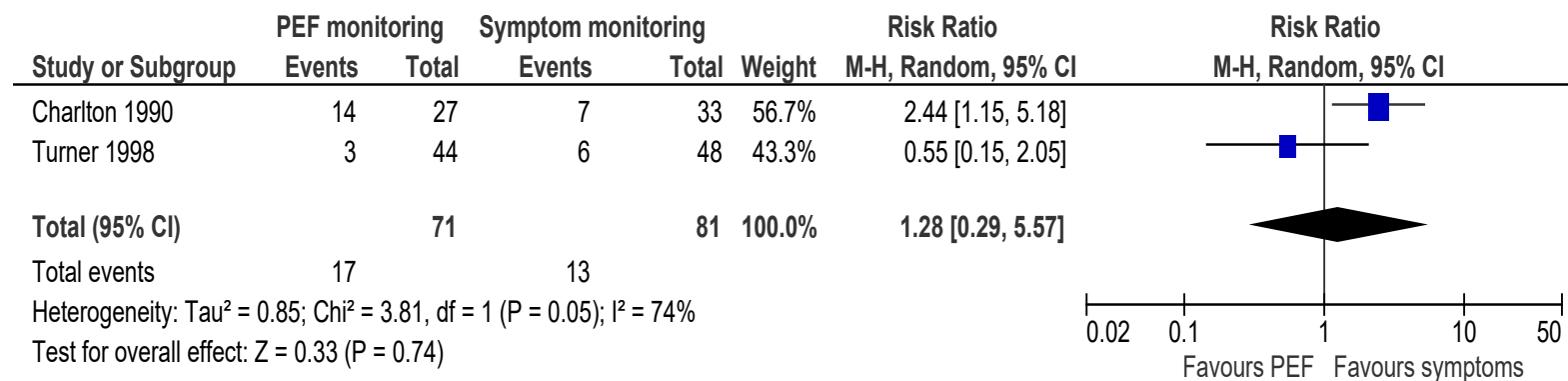


Figure 10: Quality of life (SF-36, range 0-100, higher is better, 6 months)

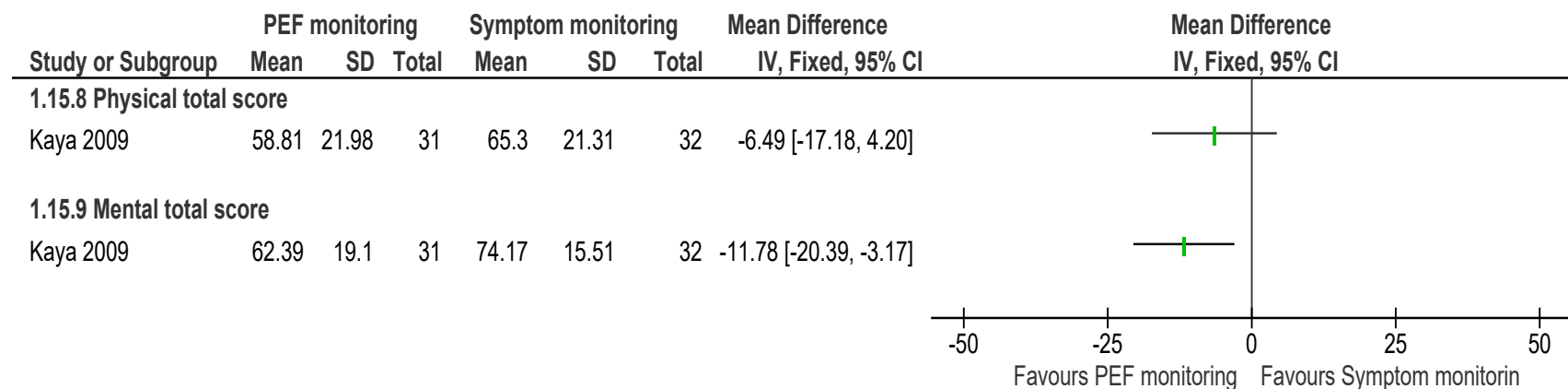


Figure 11: Lung function (FEV1 % predicted, higher is better, 6-12 months)

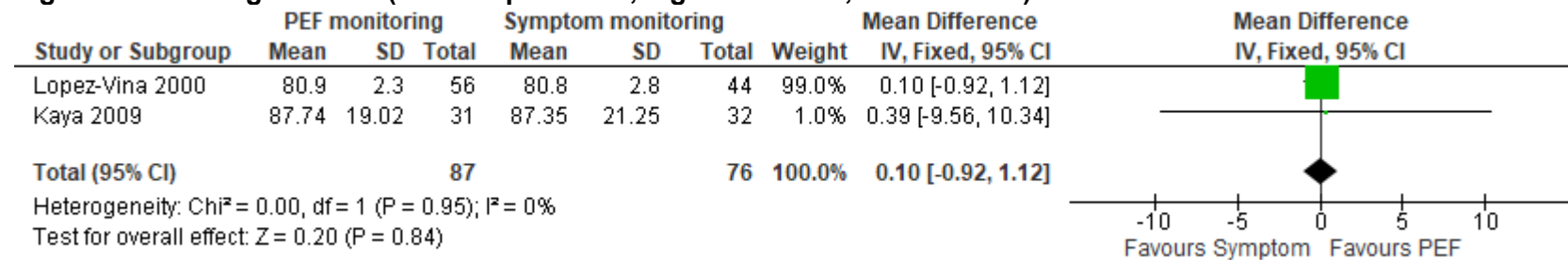


Figure 12: Lung function (FEV₁ L, higher is better, 12 months)

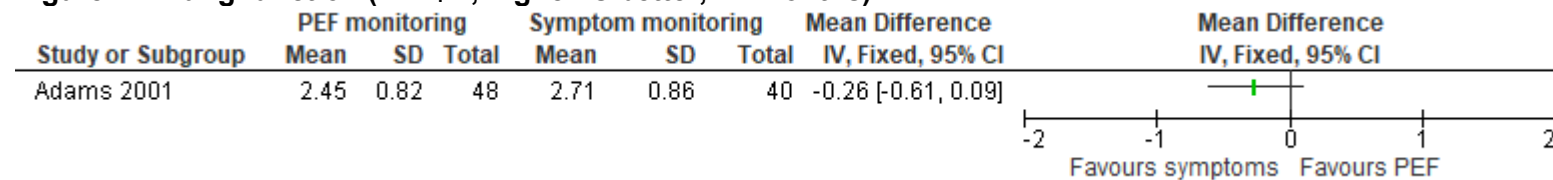


Figure 13: Time off school/work (time off work events, lower is better, 6-12 months)

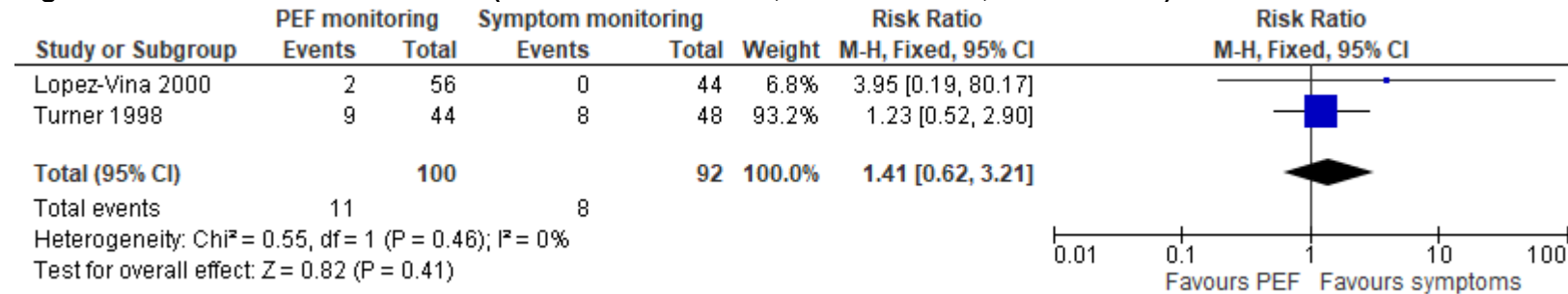
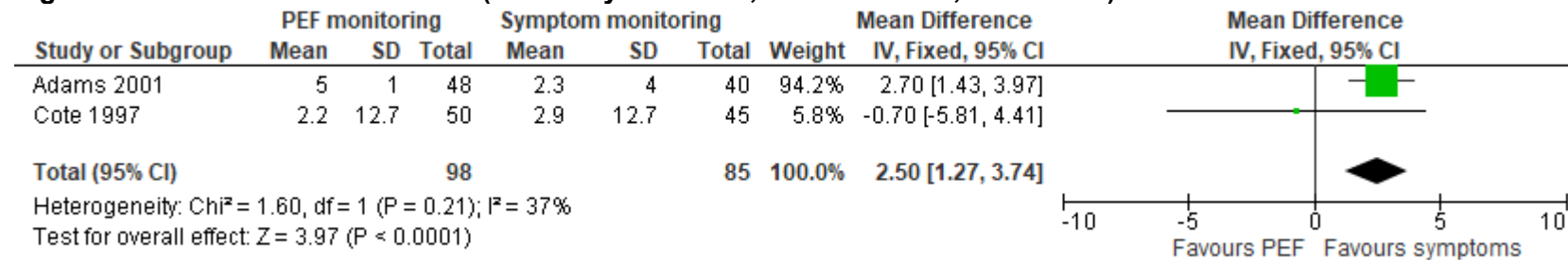


Figure 14: Time off school/work (mean days off work, lower is better, 12 months)



Children

Figure 15: Unscheduled healthcare utilisation (hospital admissions, lower is better, 12 weeks)

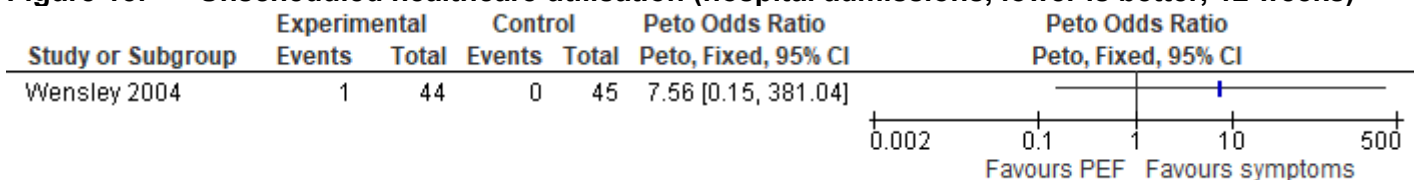


Figure 16: Unscheduled healthcare utilisation (attendance at A&E, lower is better, 12 weeks)

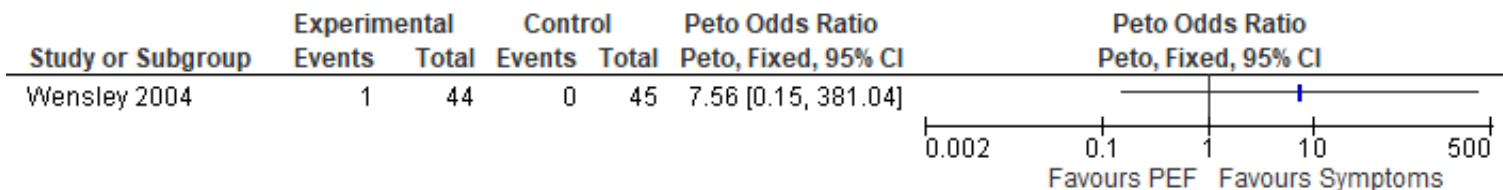


Figure 17: Unscheduled healthcare utilisation (emergency GP visit, lower is better, 12 weeks)

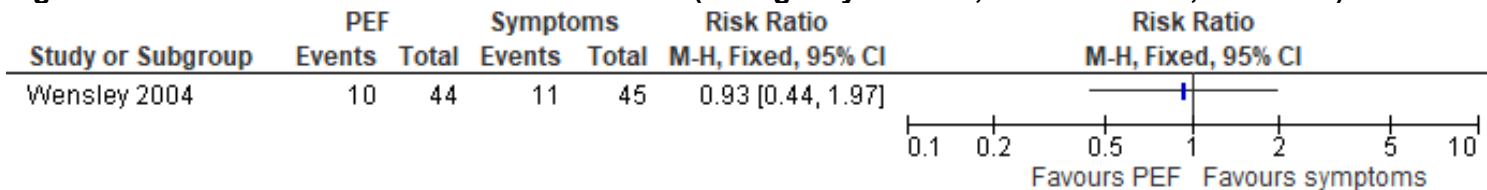


Figure 18: Severe exacerbations (needing oral corticosteroids, lower is better, 12 months)



Figure 19: Lung function (FEV₁ % predicted, higher is better, 3 months)

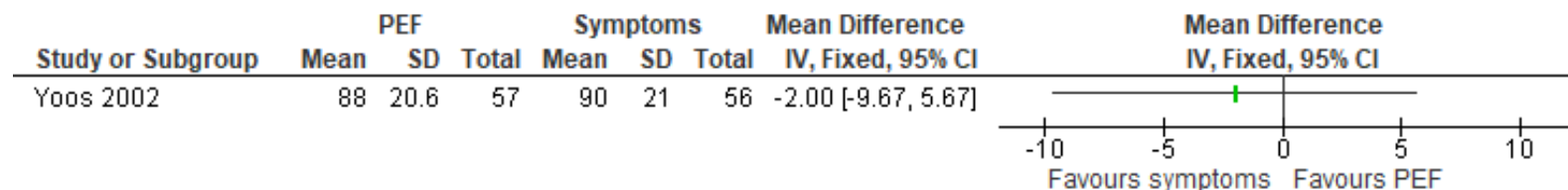
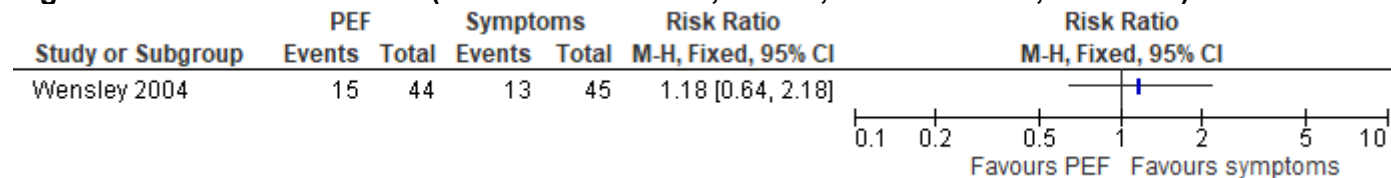


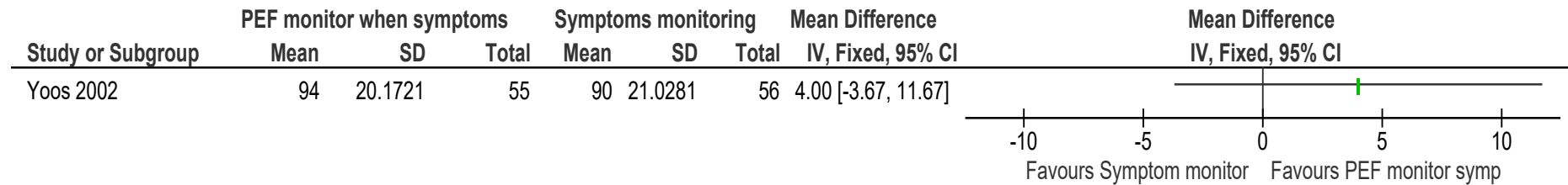
Figure 20: Time off school (absent from school, events, lower is better, 12 weeks)



PEF at symptom time vs usual care (symptom monitoring)

E.2.1 Children

Figure 21: Lung function (FEV1% predicted, higher is better, 3 months)




Appendix F GRADE tables


Table 9: Clinical evidence profile: PEF monitoring versus usual care (symptom monitoring) in adults

| Certainty assessment | | | | | | | № of patients | | Effect | | Certainty | Importance |
|--|-------------------|---------------------------|---------------|----------------------|---------------------------|----------------------|---------------|-----------------------------|------------------------|--|------------------|------------|
| № of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | PEF | symptoms monitoring: adults | Relative (95% CI) | Absolute (95% CI) | | |
| Unscheduled healthcare utilisation (total asthma-related, lower is better, 24 months) | | | | | | | | | | | | |
| 1 | randomised trials | serious ^a | not serious | serious ^b | not serious | none | 148 | 146 | - | MD 0.11 lower (0.59 lower to 0.37 higher) | ⊕⊕○○ Low | CRITICAL |
| Unscheduled healthcare utilisation (urgent asthma treatment, lower is better, 6 months) | | | | | | | | | | | | |
| 1 | randomised trials | serious ^c | not serious | not serious | serious ^d | none | 5/46 (10.9%) | 14/45 (31.1%) | RR 0.35 (0.14 to 0.89) | 202 fewer per 1,000 (from 268 fewer to 34 fewer) | ⊕⊕○○ Low | CRITICAL |
| Unscheduled healthcare utilisation (hospital admissions, events, lower is better, 6-12 months) | | | | | | | | | | | | |
| 4 | randomised trials | very serious ^e | not serious | serious ^b | very serious ^f | none | 9/219 (4.1%) | 10/198 (5.1%) | RR 0.80 (0.35 to 1.83) | 10 fewer per 1,000 (from 50 fewer to 30 more) ^g | ⊕○○○ Very low | CRITICAL |
| Unscheduled healthcare utilisation (mean hospital admissions over 1 year, lower is better, 12 months) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ^h | not serious | not serious | serious ⁱ | none | 50 | 45 | - | MD 0.05 lower (0.16 lower to 0.06 higher) | ⊕○○○ Very low | CRITICAL |


Unscheduled healthcare utilisation (ED visits, lower is better, 6-12 months)

| Certainty assessment | | | | | | | No of patients | | Effect | | Certainty | Importance |
|----------------------|-------------------|---------------------------|----------------------|--------------|---------------------------|----------------------|----------------|-----------------------------|----------------------------------|---|---|------------|
| No of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | PEF | symptoms monitoring: adults | Relative (95% CI) | Absolute (95% CI) | | |
| 3 | randomised trials | very serious ^j | serious ^k | not serious | very serious ^l | none | 14/173 (8.1%) | 9/153 (5.9%) | RR 1.63 (0.39 to 6.77) | 37 more per 1,000 (from 36 fewer to 339 more) |  Very low | |


Unscheduled healthcare utilisation (mean number of ED visits, lower is better, 12 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|-------------|-------------|------|----|----|---|--|--|----------|
| 1 | randomised trials | very serious ^h | not serious | not serious | not serious | none | 50 | 45 | - | MD 0 (0.54 lower to 0.54 higher) |  Low | CRITICAL |
|---|-------------------|---------------------------|-------------|-------------|-------------|------|----|----|---|--|--|----------|


Unscheduled healthcare utilisation (unscheduled doctor visits, lower is better, 6 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|-------------|----------------------|------|---------------|---------------|----------------------------------|--|---|----------|
| 1 | randomised trials | very serious ⁱ | not serious | not serious | serious ^d | none | 17/44 (38.6%) | 12/48 (25.0%) | RR 1.55 (0.84 to 2.86) | 138 more per 1,000 (from 40 fewer to 465 more) |  Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|-------------|----------------------|------|---------------|---------------|----------------------------------|--|---|----------|


Severe asthma exacerbations (taking oral steroids, lower is better, 6 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|----------------------|-------------|---------------------------|------|---------------|---------------|----------------------------------|--|--|----------|
| 2 | randomised trials | very serious ^m | serious ⁿ | not serious | very serious ^f | none | 17/71 (23.9%) | 13/81 (16.0%) | RR 1.28 (0.29 to 5.57) | 45 more per 1,000 (from 114 fewer to 733 more) |  Very low | CRITICAL |
|---|-------------------|---------------------------|----------------------|-------------|---------------------------|------|---------------|---------------|----------------------------------|--|--|----------|

Quality of life (SF-36, range 0-100, higher is better, 6 months) - Physical total score

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|----------------------|---------------------------|------|----|----|---|---|---|----------|
| 1 | randomised trials | very serious ^o | not serious | serious ^p | very serious ^q | none | 31 | 32 | - | MD 6.49 lower (17.18 lower to 4.2 higher) |  Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|----------------------|---------------------------|------|----|----|---|---|---|----------|

Quality of life (SF-36, range 0-100, higher is better, 6 months) - Mental total score

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|----------------------|-------------|------|----|----|---|--|---|----------|
| 1 | randomised trials | very serious ^o | not serious | serious ^p | not serious | none | 31 | 32 | - | MD 11.78 lower (20.39 lower to 3.17 lower) |  Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|----------------------|-------------|------|----|----|---|--|---|----------|

Lung function (FEV1 % predicted, higher is better, 6-12 months)

| Certainty assessment | | | | | | | No of patients | | Effect | | Certainty | Importance |
|----------------------|-------------------|---------------------------|---------------|--------------|-------------|----------------------|----------------|-----------------------------|-------------------|---|-------------|------------|
| No of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | PEF | symptoms monitoring: adults | Relative (95% CI) | Absolute (95% CI) | | |
| 2 | randomised trials | very serious ^f | not serious | not serious | not serious | none | 87 | 76 | - | MD 0.1 higher (0.92 lower to 1.12 higher) | ⊕⊕○○ Low | CRITICAL |

Lung function (FEV1, L, higher is better, 12 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|----------------------|----------------------|------|----|----|---|---|------------------|----------|
| 1 | randomised trials | very serious ^a | not serious | serious ^b | serious ^a | none | 48 | 40 | - | MD 0.26 lower (0.61 lower to 0.09 higher) | ⊕○○○ Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|----------------------|----------------------|------|----|----|---|---|------------------|----------|

Time off school/work (mean days off work, lower is better, 12 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|----------------------|-------------|------|----|----|---|--|------------------|----------|
| 2 | randomised trials | very serious ^a | not serious | serious ^b | not serious | none | 98 | 85 | - | MD 2.5 higher (1.27 higher to 3.74 higher) | ⊕○○○ Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|----------------------|-------------|------|----|----|---|--|------------------|----------|


Time off school/work (time off work events, lower is better, 6-12 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|----------------|-------------|------------------------|--|------------------|----------|
| 2 | randomised trials | very serious ^f | not serious | not serious | very serious ^f | none | 11/100 (11.0%) | 8/92 (8.7%) | RR 1.41 (0.62 to 3.21) | 40 more per 1,000 (from 50 fewer to 120 more) ^g | ⊕○○○ Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|----------------|-------------|------------------------|--|------------------|----------|

- a. Downgraded by one increment for risk of bias due to some concerns about low adherence to intervention.
- b. Downgraded by one increment for population indirectness (moderate-severe asthma population)
- c. Downgraded by one increment for risk of bias due to some concerns about: lack of information on adherence to intervention; outcome self-reported via questionnaire and study unblinded.
- d. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (0.8-1.25)
- e. Downgraded by two increments because the evidence is at high risk of bias (per protocol analysis, missing data, unblinded and low adherence to intervention)
- f. Downgraded by two increments for imprecision because the 95% confidence interval crosses both MIDs (0.8-1.25)
- g. Absolute effect based on RD (zero events)

- h. Downgraded by two increments because the study is at high risk of bias (no information on randomisation process or adherence; analysis method unclear; only drop out information at the time of randomisation, not at follow-up)
- i. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (MID calculated as follow-up SD of both groups/2=0.138)
- j. downgraded by two increments because the evidence is at high risk of bias (no information on randomisation, issues with adherence, missing data or analysis)
- k. Downgraded by one increment for inconsistency (I squared = 53%)
- l. Downgraded by two increments because the evidence is at high risk of bias (poor adherence to interventions and unclear how handled in analysis; differential in missing data across arms, and related to compliance with intervention)
- m. downgraded by two increments because the majority of evidence is at high risk of bias (no information about allocation concealment, adherence or baseline characteristics; missing data without reasons reported; unblinded to outcome assessors)
- n. Downgraded by one increment for inconsistency (I squared = 74%)
- o. Downgraded by two increments because the evidence is at high risk of bias (no randomisation information; poor adherence to interventions and not clear how handled in analysis; self-reported outcome and unblinded)
- p. Downgraded by one increment for population indirectness (38.1% severe asthma)
- q. Downgraded by two increments for imprecision because the 95% confidence interval crosses both MIDs (published MID=2)
- r. Downgraded by two increments because the majority of evidence was at high risk of bias (no information on randomisation, adherence or analysis; 50/150 missing data with no reasons given)
- s. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (published MID=0.23 L)

Table 10: Clinical evidence profile: PEF monitoring versus usual care (symptom monitoring) in children.

| Certainty assessment | | | | | | | № of patients | | Effect | | Certainty | Importance |
|---|-------------------|---------------------------|---------------|--------------|---------------------------|----------------------|---------------|-------------------------------|--------------------------|--|---|------------|
| № of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | PEF | symptoms monitoring: children | Relative (95% CI) | Absolute (95% CI) | | |
| Unscheduled healthcare utilisation (hospital admissions, lower better, 12 weeks) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ^a | not serious | not serious | very serious ^b | none | 1/44 (2.3%) | 0/45 (0.0%) | OR 7.56 (0.15 to 381.04) | 20 more per 1,000 (from 40 fewer to 80 more) ^c |  Very low | CRITICAL |

Unscheduled healthcare utilisation (attendance at A&E, lower is better, 12 weeks)

| Certainty assessment | | | | | | | No of patients | | Effect | | Certainty | Importance |
|----------------------|-------------------|---------------------------|---------------|--------------|---------------------------|----------------------|----------------|-------------------------------|--------------------------|--|------------------|------------|
| No of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | PEF | symptoms monitoring: children | Relative (95% CI) | Absolute (95% CI) | | |
| 1 | randomised trials | very serious ^a | not serious | not serious | very serious ^b | none | 1/44 (2.3%) | 0/45 (0.0%) | OR 7.56 (0.15 to 381.04) | 20 more per 1,000 (from 40 fewer to 80 more) ^c | ⊕○○○ Very low | CRITICAL |

Unscheduled healthcare utilisation (emergency GP visit, lower is better, 12 weeks)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|---------------|---------------|------------------------|--|------------------|----------|
| 1 | randomised trials | very serious ^a | not serious | not serious | very serious ^b | none | 10/44 (22.7%) | 11/45 (24.4%) | RR 0.93 (0.44 to 1.97) | 17 fewer per 1,000 (from 137 fewer to 237 more) | ⊕○○○ Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|---------------|---------------|------------------------|--|------------------|----------|

Severe asthma exacerbations (needing oral corticosteroids, lower is better, 12 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|--------------|-------------|--------------------------|--|------------------|----------|
| 1 | randomised trials | very serious ^d | not serious | not serious | very serious ^b | none | 7/19 (36.8%) | 0/27 (0.0%) | OR 16.34 (3.25 to 82.24) | 370 more per 1,000 (from 150 more to 590 more) ^c | ⊕○○○ Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|--------------|-------------|--------------------------|--|------------------|----------|

Lung function (FEV1 % predicted, higher is better, 3 months)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|-------------|-------------|------|----|----|---|---|-------------|----------|
| 1 | randomised trials | very serious ^a | not serious | not serious | not serious | none | 57 | 56 | - | MD 2 lower (9.67 lower to 5.67 higher) | ⊕⊕○○ Low | CRITICAL |
|---|-------------------|---------------------------|-------------|-------------|-------------|------|----|----|---|---|-------------|----------|

Time off school (absent from school, events, lower is better, 12 weeks)

| | | | | | | | | | | | | |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|---------------|---------------|------------------------|---|------------------|----------|
| 1 | randomised trials | very serious ^a | not serious | not serious | very serious ^b | none | 15/44 (34.1%) | 13/45 (28.9%) | RR 1.18 (0.64 to 2.18) | 52 more per 1,000 (from 104 fewer to 341 more) | ⊕○○○ Very low | CRITICAL |
|---|-------------------|---------------------------|-------------|-------------|---------------------------|------|---------------|---------------|------------------------|---|------------------|----------|

a. Downgraded by two increments because the study was at high risk of bias (some concerns on multiple domains: no information about randomisation, some issues with adherence to interventions and self-reported outcome/unblinded)

b. Downgraded by two increments for imprecision because the 95% confidence interval crosses both MIDs (0.8-1.25)

c. Absolute effect based on RD (zero events)

d. Downgraded by two increments because the study is at high risk of bias (no information about allocation concealment or adherence; no baseline characteristics reported; unblinded to outcome assessors)

e. Downgraded by two increments because the study was at high risk of bias (lack of information on randomisation, baseline characteristics or adherence to intervention; missing data unclear)

Table 9: Clinical evidence profile: PEF monitoring at symptom-time versus usual care (symptom monitoring) in children.

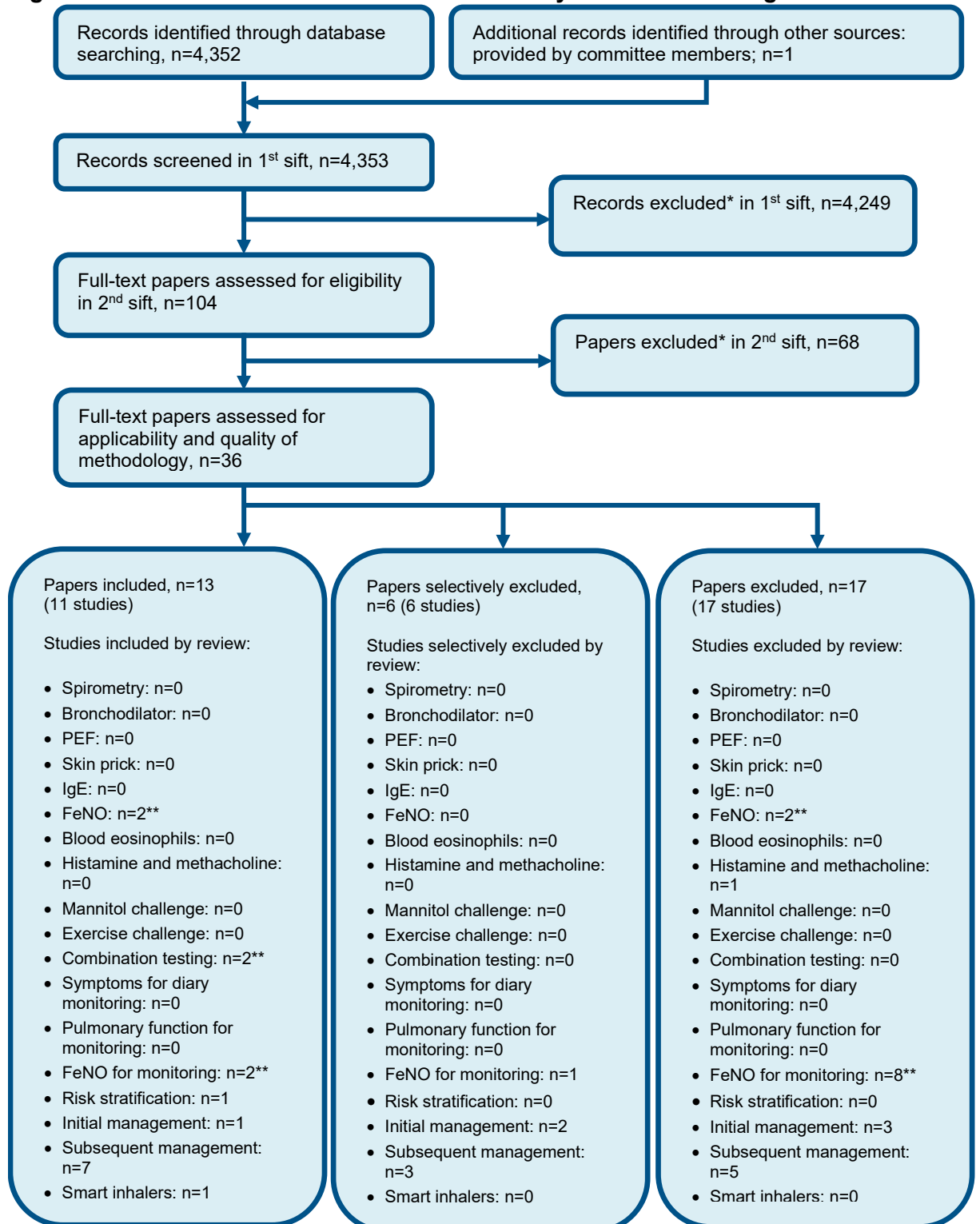
| Certainty assessment | | | | | | | No of patients | | Effect | | Certainty | Importance |
|--|-------------------|---------------------------|---------------|--------------|----------------------|----------------------|--------------------------------|-------------------------------|-------------------|--|------------------|------------|
| No of studies | Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | PEF monitoring at symptom-time | symptoms monitoring: children | Relative (95% CI) | Absolute (95% CI) | | |
| Lung function (FEV1% predicted, higher is better, 3 months) | | | | | | | | | | | | |
| 1 | randomised trials | very serious ^a | not serious | not serious | serious ^b | none | 55 | 56 | - | MD 4 higher (3.67 lower to 11.67 higher) | ⊕○○○ Very low | CRITICAL |

a. Downgraded by two increments because the study is at high risk of bias (no information on randomisation, baseline characteristics, or adherence; missing data unclear)

b. Downgraded by one increment for imprecision because the 95% confidence interval crosses one MID (calculated as FUP SD of both arms/2=10.27)

Appendix G Economic evidence study selection

Figure 22: Flow chart of health economic study selection for the guideline



* Non-relevant population, intervention, comparison, design or setting; non-English language

** Includes studies that are in multiple reviews

Appendix H Economic evidence tables

None.

Appendix I Excluded studies

Clinical studies

Table 11: Studies excluded from the clinical review

Excluded studies

| Study | Exclusion reason |
|---|--|
| Abramson, Michael J, Schattner, Rosa L, Holton, Christine et al. (2015) Spirometry and regular follow-up do not improve quality of life in children or adolescents with asthma: Cluster randomized controlled trials. Pediatric pulmonology 50(10): 947-54 | - Study does not contain an intervention relevant to this review protocol <i>the participants attended clinical for spirometry however there is no mention of consequential treatment adjustment.</i> |
| Barnes, Camilla Boslev and Ulrik, Charlotte Suppli (2015) Asthma and adherence to inhaled corticosteroids: current status and future perspectives. Respiratory care 60(3): 455-68 | - Systematic review used as source of primary studies <i>Review examining methods to improve medication adherence, not specifically pulmonary monitoring</i> |
| Bateman, E., Reddel, H.K., O'Byrne, P.M. et al. (2018) Severe exacerbations and inhaled corticosteroid load with as-needed budesonide/formoterol vs maintenance budesonide in mild asthma. American Journal of Respiratory and Critical Care Medicine 197(meetingabstracts) | - Conference abstract |
| Bindler, R., Haverkamp, H.C., O'Flanagan, H. et al. (2022) Feasibility and acceptability of home monitoring with portable spirometry in young adults with asthma. Journal of Asthma | - Study design not relevant to this review protocol <i>Not randomised and no comparator</i> |
| Bookser, M., Drennen, C., Leonard, E. et al. (2018) Pharmacist-led medication intervention for patients with asthma and COPD within a primary care setting. Journal of the American Pharmacists Association 58(3): e24 | - Conference abstract |
| Boonjindasup, Wicharn, Chang, Anne B, McElrea, Margaret S et al. (2022) Does the routine use of spirometry improve clinical outcomes in children?-A systematic review. Pediatric pulmonology 57(10): 2390-2397 | - Systematic review used as source of primary studies <i>Review identified one relevant study, included in this review</i> |
| Burkhart, PV (1996) Effect of contingency management on adherence to peak flow | - Study design not relevant to this review protocol |

| Study | Exclusion reason |
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| monitoring in school-age children with asthma. Dissertation/ thesis: 276p | |
| Celler, Branko, Argha, Ahmadreza, Varnfield, Marlien et al. (2018) Patient Adherence to Scheduled Vital Sign Measurements During Home Telemonitoring: Analysis of the Intervention Arm in a Before and After Trial. JMIR medical informatics 6(2): e15 | <p>- Study design not relevant to this review protocol</p> <p><i>Before and after trial that included many chronic conditions, not just asthma</i></p> |
| Choi, B., Lee, S., Jung, J. et al. (2017) Impact of patient education on medication on health outcomes and adherence in patients with asthma. Allergy: European Journal of Allergy and Clinical Immunology 72(supplement103): 380-381 | <p>- Conference abstract</p> |
| Ferrés, Cristina Subirana (2018) La utilidad de los medidores de flujo espiratorio máximo en el diagnóstico de la gravedad del asma. Metas de Enfermería 21(10): 57-65 | <p>- Systematic review does not contain factors of interest</p> <p><i>based on diagnosing asthma</i></p> |
| Fielding, Shona, Pijnenburg, Marielle, de Jongste, Johan C et al. (2019) Change in FEV1 and Feno Measurements as Predictors of Future Asthma Outcomes in Children. Chest 155(2): 331-341 | <p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Study examined measurement of spirometry or FeNO as risk-prediction tools, not methods of monitoring</i></p> |
| Hale, Elaine Mac, Greene, Garrett, Mulvey, Christopher et al. (2023) Use of digital measurement of medication adherence and lung function to guide the management of uncontrolled asthma (INCA Sun): a multicentre, single-blinded, randomised clinical trial. The Lancet. Respiratory medicine | <p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>focused on increasing treatment adherence</i></p> |
| Kim, M.-A., Ye, Y.-M., Park, J.-W. et al. (2014) A computerized asthma-specific quality of life: A novel tool for reflecting asthma control and predicting exacerbation on behalf of the premier researchers aiming new era in asthma and allergic diseases (PRANA) study group. International Archives of Allergy and Immunology 163(1): 36-42 | <p>- Study design not relevant to this review protocol</p> <p><i>Observational study aiming to validate asthma control tool</i></p> |
| Kohlbrenner, Dario, Clarenbach, Christian F, Ivankay, Adam et al. (2022) Multisensory Home-Monitoring in Individuals With Stable Chronic Obstructive Pulmonary Disease and Asthma: Usability Study of the CAir-Desk. JMIR human factors 9(1): e31448 | <p>- Study design not relevant to this review protocol</p> <p><i>Observational study examining the utility of a home-monitoring device</i></p> |

| Study | Exclusion reason |
|---|---|
| <p>Lake, C.; Wong, K.; Brannan, J. (2020) Monitoring Asthma Control with Inhaled Corticosteroids (ICS) Using Airway Hyperresponsiveness (AHR) to Mannitol Compared to Routine Spirometry in A Pulmonary Function Laboratory (PFL). Respirology 25: 5</p> | <p>- Conference abstract</p> |
| <p>Letz, K.L.; Schlie, A.R.; Smits, W.L. (2004) A Randomized Trial Comparing Peak Expiratory Flow Versus Symptom Self-Management Plans for Children with Persistent Asthma. Pediatric Asthma, Allergy & Immunology 17(3): 177-190</p> | <p>- No outcomes relevant to protocol</p> |
| <p>Letz, K and Smits, W (2004) A randomized trial comparing peak expiratory flow versus symptom self-management plans for children with persistent asthma. Journal of allergy and clinical immunology 113(suppl2): 286</p> | <p>- Conference abstract</p> |
| <p>Moeller, Alexander, Carlsen, Kai-Hakon, Sly, Peter D et al. (2015) Monitoring asthma in childhood: lung function, bronchial responsiveness and inflammation. European respiratory review : an official journal of the European Respiratory Society 24(136): 204-15</p> | <p>- Review article but not a systematic review</p> |
| <p>Patel, P.J., Abou Baker, N., Travis, R. et al. (2015) Assessing subjective and objective measures of asthma control in an inner city pediatric and adolescent population. Annals of Allergy, Asthma and Immunology 115(5suppl1): a22</p> | <p>- Conference abstract</p> |
| <p>Perry, T.T., Halterman, J.S., Brown, R.H. et al. (2015) Breath connection: A school-based telemedicine program for rural children with asthma. Journal of Allergy and Clinical Immunology 135(2suppl1): ab169</p> | <p>- Conference abstract</p> |
| <p>Portnoy, Jay M, Waller, Morgan, De Lurgio, Stephen et al. (2016) Telemedicine is as effective as in-person visits for patients with asthma. Annals of allergy, asthma & immunology : official publication of the American College of Allergy, Asthma, & Immunology 117(3): 241-5</p> | <p>- Study design not relevant to this review protocol</p> <p><i>non-randomised comparison between telemonitoring and in-person monitoring for children with asthma</i></p> |
| <p>Thomas, RP, Rani, NV, Kannan, G et al. (2015) Impact of pharmacist-led continuous education on the knowledge of inhalation technique in</p> | <p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>assessing inhalor techniques</i></p> |

| Study | Exclusion reason |
|---|--|
| <p>asthma and COPD patients. International journal of medical and health sciences 4: 40-46</p> | |
| <p>Tolnai, J., Petak, F., Sudy, R. et al. (2021) Remote monitoring of lung function in asthmatic children with telespirometry. European Respiratory Journal 58(suppl65)</p> | <p>- Conference abstract</p> |
| <p>Turner, S.W. (2019) The uncertain role of spirometry in managing childhood asthma in the UK 2019. Thorax 74(supplement2): a126-a127</p> | <p>- Conference abstract</p> |
| <p>Van Vliet, D, Van Horck, M, Van De Kant, K et al. (2014) Electronic monitoring of symptoms and lung function to assess asthma control in children. Annals of allergy, asthma and immunology 113(3): 257-262</p> | <p>- Study design not relevant to this review protocol</p> <p><i>Observational</i></p> |
| <p>Wallace-Farquharson, Tanya, Rhee, Hyekyun, Oguntoye, Anne O et al. (2023) Adolescents' practical knowledge of asthma self-management and experiences in the context of acute asthma: a qualitative content analysis. The Journal of asthma : official journal of the Association for the Care of Asthma 60(2): 277-287</p> | <p>- Full text paper not available</p> <p><i>Full paper due to release in February 2024</i></p> |
| <p>Wang, L, Zheng, S, Wang, Q et al. (2023) emergency nursing based on PEWS can improve the condition of children with acute asthma. Alternative therapies in health and medicine. http://alternative-therapies.com/oa/index.html?fid=9854</p> | <p>- Study does not contain an intervention relevant to this protocol</p> <p>Intervention does not involve PEF or spirometry. Also an emergency setting context, patients in hospital with acute asthma episode.</p> |
| <p>Wen, Tzu-Ning, Lin, Hsueh-Chun, Yeh, Kuo-Wei et al. (2022) Effectiveness of eAsthmaCare on Symptoms, Childhood Asthma Control Test, and Lung Function among Asthmatic Children. Journal of medical systems 46(11): 71</p> | <p>- Study does not contain an intervention relevant to this review protocol</p> <p><i>Comparing e-asthma care programme to usual care</i></p> |
| <p>Zhang, Olivier; Minku, Leandro L; Gonem, Sherif (2021) Detecting asthma exacerbations using daily home monitoring and machine learning. The Journal of asthma : official journal of the Association for the Care of Asthma 58(11): 1518-1527</p> | <p>- Study design not relevant to this review protocol</p> <p><i>Secondary analysis of SAKURA trial - participants were randomised to treatments, not monitoring strategies</i></p> |

Health economic studies

Published health economic studies that met the inclusion criteria (relevant population, comparators, economic study design, published 2006 or later and not from non-OECD country or USA) but that were excluded following appraisal of applicability and methodological quality are listed below. See the health economic protocol for more details.

None.