



Effectiveness of written action plans for acute asthma: A systematic review

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TITLE: Effectiveness of written action plans for acute asthma: A systematic review.

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Self-management, education, emergency department, relapse, exacerbation, discharge.

ABSTRACT

Objective: Self-management is an essential part of achieving asthma control and improving long-term outcomes. While guidelines recommend the provision of written asthma action plans (AAPs), few patients presenting to emergency departments (ED) have one. This systematic review examined if individualized written AAPs reduce relapses in adults following an ED visit for acute asthma.

Data Sources: Comprehensive searches of seven electronic databases and grey literature were conducted.

Study Selections: Randomized controlled trials (RCTs) examining the effectiveness of individualized written AAPs to reduce relapses after ED visits for acute asthma were included. Study quality was determined using the Cochrane Risk of Bias (RoB) tool; intervention fidelity was assessed.

Results: From 695 potentially relevant studies, three RCTs were included. The RoB was low in two studies and high in one study; description of intervention fidelity varied across studies. The provision of individualized written AAPs in adults following an ED visit for acute asthma did not reduce the risk of relapse after ED discharge (risk ratio [RR]= 0.66;

95% confidence intervals [CI]: 0.36, 1.23; $I^2 = 40\%$). There was a 49% reduction in the risk of relapse after ED discharge when only studies with low RoB were pooled (RR= 0.51; 95% CI: 0.31, 0.83; $I^2 = 0\%$).

Conclusion: This review didn't provide conclusive evidence to support the consideration of individualized written AAPs for the reduction of relapses after an ED visit; however, the low frequency of events, small number of studies and samples and their methodological quality might play an important role in this overall finding.

INTRODUCTION

In theory, Emergency Department (ED) presentations for acute asthma should result from clinical conditions in which asthma control is lost despite appropriately guided self-management and escalating therapeutic approaches.(1) Much evidence exists to suggest that the reality is remote from this situation. For example, in Canada many patients with asthma do not have a family physician or primary care provider (PCP) providing routine asthma assessment and guidance on self-management care.(2) Second, for those who report having a PCP, sub-optimal assessment of preventive actions (including the provision of written asthma action plans [AAPs] has been documented;(3) these gaps in care could be influencing the poor asthma control and the excess healthcare utilization described among patients treated in primary care.(4) While clinical practice guidelines recommend the provision of written AAPs to maintain asthma control, facilitate early detection of change in signs and symptoms, and self-direct management to mitigate the severity of exacerbations,(5) they are rarely provided to patients or employed by patients effectively. A study revealed that 22% of Canadian physicians (both primary care providers and specialists) reported to provide written AAPs to patients with asthma;

however, only 11% of the patients reported receiving them.(3) The uptake of written AAPs was lower (3%) among patients treated and discharged from the ED for acute asthma.(2) Moreover, patients having *any* AAP (either verbal or written) used ineffective strategies to mitigate the severity of the symptoms that prompted their ED visit.

The most effective setting for the delivery of self-management interventions for asthma remains unclear.(6) Since the majority of patients presenting to Canadian EDs with acute asthma improve and are safely discharged,(7) the ED represents a potentially valuable setting for the promotion of asthma education, including the provision of guidance on self-management,(6) particularly to those patients without a formal linkage to a PCP.(8-10)

The effectiveness of individualized written AAPs provided along with education and regular monitoring has been previously evaluated in a variety of settings;(11) however, the effectiveness of their provision after an ED visit for acute asthma on the reduction of relapses has not been specifically assessed in the adult population. **The research question addressed in this systematic review according to the population-intervention-comparison-outcome-study design (PICO-D) structure was: In adults presenting to EDs with asthma exacerbations (P) will ED-directed educational interventions involving the provision of individualized AAPs (I), when compared to usual care (C), reduce the proportion of asthma relapses after an asthma exacerbation (O)? - only randomized controlled trials were considered (D).**

METHODS

The objective of this review was to examine if the provision of individualized written AAPs reduces relapses in adults following an ED visit for acute asthma.

A review protocol was developed *a priori* defining objectives, search strategy, eligibility criteria and outcomes of interest. The processes for extracting information from eligible studies, and the methods for data analysis and synthesis were outlined. The systematic review conforms to PRISMA guidelines. No ethics approval was required.

Data sources and searches: Comprehensive searches of seven electronic databases (Medline, EMBASE, Cochrane Library, CINAHL, SCOPUS, ERIC, and ProQuest Dissertations and Theses Database) were conducted from database inception to March 2016. An information specialist designed the search strategy, which comprised both controlled vocabulary and keywords adapted to each database (**Appendix 1** includes Medline search strategies; the complete search strategy is available upon request).

References were manually selected from the first ten pages of Google Scholar results. Proceedings from the 2004-2015 Canadian (Canadian Association of Emergency Physicians) and United States (Society for Academic Emergency Medicine) conferences were hand-searched. No other limits were applied.

Study selection: Studies were included in the review if they were randomised controlled trials (RCTs) assessing any educational intervention involving the provision of individualized AAPs (either oral or written) directed from the ED (or equivalent settings) and targeting adults (or adults and children with $\geq 80\%$ of the study population being ≥ 16 years of age) who were seen for an asthma exacerbation. The comparison group was the provision of usual care following the ED presentation. The primary outcome of interest

was the **proportion** of relapses after an asthma exacerbation. Relapses were defined as any unscheduled visit to a PCP, ED or equivalent setting (e.g., emergency rooms in outpatient clinics) for asthma care. Primary care providers may have included family physicians, general practitioners, general internists and/or nurses. Secondary outcomes of interest were the number of ED visits and time to first relapse.

Two reviewers (BV and TN) independently screened the titles and abstracts of studies identified in the literature searches. Eligibility was determined based on the independent review (BV and TN) of full text of articles deemed relevant. Disagreements were discussed and resolved with a third party adjudicator (CVR or BHR).

Data extraction and risk of bias assessment: Information on patients, methods, interventions and outcomes was extracted by a single reviewer (BV) from the original reports onto standardized data collection forms and verified by a second reviewer (CVR). Authors were contacted to clarify study methods and to obtain non-published original data as needed.

Two reviewers (BV and TN) independently assessed the included trials using the Cochrane Risk of Bias (RoB) tool; which includes an evaluation of random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias.(12) Disagreements were discussed and resolved with a third party (CVR).

Methodological strategies to monitor and enhance the reliability and validity of behavioural interventions(13) were assessed using the five domains of the Treatment Fidelity Assessment Grid (CVR):(14) congruence with theory (i.e., did the intervention include the relevant “active ingredients” based on the proposed fidelity theory?); provider

training (i.e., were the providers capable of delivering the intervention as designed?; intervention implementation (i.e., did the providers actually implement the intervention as it was designed?); intervention receipt (i.e., did the participants receive the relevant “active ingredients” as intended?) and intervention enactment (i.e., did the participants put new skills or behaviours into practice?).

Data synthesis and analysis: Data from individual studies were summarized in evidence tables. Pooled risk ratios (RR) with 95% confidence intervals (CI) were calculated using a random effects model. Heterogeneity was tested using the I^2 statistic with I^2 values of 25, 50, and 75% representing low, moderate, and high degrees of heterogeneity, respectively.(15) Sub-group analyses based on sex, age, and asthma severity were originally planned, as well as sensitivity analyses based on different pooling methods (random vs. fixed effects model), measures of association (odds ratio [OR] vs. risk difference [RD]), and risk of bias (high vs. low). Analyses were conducted using Review Manager (RevMan) software, version 5.2 (IMS Inc, Nordic Cochrane Centre, Copenhagen, Denmark).

RESULTS

Search results: The literature search strategy identified 698 citations. After removing duplicates, screening of titles and abstracts, and reviewing the full text of articles, three studies satisfied the eligibility criteria for the review. Fifty-two manuscripts were excluded for the following main reasons: not RCT study designs (n=23); not ED based studies (n=10), no AAP provision (n=7), no control group (n=5); no outcome on relapses (n=1); other reasons for exclusion (n=6) were paediatric population, mixed **co-existing diagnoses (e.g., asthma and chronic obstructive pulmonary disease)** and protocol status (**Figure 1**). The complete list of excluded studies is available upon request.

Study characteristics: Two studies provided individualized written AAPs at the ED visit: one trial compared *usual care* versus a) *limited education (LE)*: teaching of inhaler techniques plus *self-action plan* provided by the on-call physician, and b) *LE plus a structured educational program* emphasizing self-capacity to manage asthma exacerbations.(16) The other trial compared *usual care* (including the provision of standardized paper-based education materials) versus a *standard written AAP*.(17) One study evaluated and educated patients who had received urgent treatment for asthma in the preceding 12 months and randomly allocated them to receive a) *no AAP*, b) *symptom-based AAP* and c) *peak expiratory flow (PEF) meter and PEF based AAP*.(18) Characteristics of the three included studies are summarized in **Table 1**.

Risk of bias assessment: The risk of bias was low in two trials.(17, 18) One trial that used a non-random sequence generation and failed to describe allocation concealment and blinding of outcome assessors was rated as at high risk of bias.(16)

Fidelity of the interventions: One of the trials reported that the “active ingredients” of the intervention were based on a theoretical framework.(16) While all studies reported who delivered the interventions (*providers*), there was no description of their skills and training protocols. *Intervention implementation* was described in all the included studies and the provision of standard delivery materials was the most common method to ensure that the intervention was implemented as designed. *Intervention receipt and enactment* were not reported in any of the included studies (**Table 2**). Fidelity assessment of one of the included studies(17) **relied on an unpublished manuscript draft provided by the corresponding author.**

Primary outcome: All the included studies (n=317 participants in total) reported the percentage of relapses after an ED visit for an asthma exacerbation; six months was the most common follow-up period (**Table 1**). A combination of outcome data was considered in one study;(18) outcome data from one intervention arm was excluded from the analyses due to the subjects’ participation in a structured educational program.(16) A meta-analysis of the three trials with moderate heterogeneity showed that the provision of individualized written AAPs in adults following an ED visit for acute asthma failed to reduce the risk of relapses within the first six months of ED discharge (RR= 0.66; 95% CI: 0.36, 1.23; I^2 = 40%) (**Figure 2**).

Secondary outcomes and subgroup analyses: Inconsistent reporting precluded our planned analyses on the number of ED visits and time to first relapse. Sub-group analyses based on sex, age, asthma severity were not performed for the same reason.

Sensitivity analyses: No statistically significant difference in the percentage of relapses was observed between the groups that received individualized written AAPs

compared to usual care when considering other measures of association (OR= 0.56; 95% CI: 0.25, 1.25; I^2 = 38% and RD= -0.11; 95% CI: -0.22, 0.01; I^2 = 27%). There was a significant reduction in **the risk of relapse within the first 6 months of an ED visit for acute asthma**, however, when a fixed-effects model was used (RR= 0.64; 95% CI: 0.42, 0.97; I^2 = 40%). **In addition**, no statistical heterogeneity **was observed** when limiting the pooling to studies assessed as having low risk of bias (RR= 0.51; 95% CI: 0.31, 0.83; I^2 = 0%).

DISCUSSION

Despite the positive impact derived from the use of written AAP on symptoms, health care utilization, absenteeism and quality of life,(11) a major gap between what is currently recommended in asthma guidelines and what is implemented in clinical practice has been previously identified.(19) Using high-quality methods to minimize the risk of selection and publication bias, this systematic review identified three trials involving 317 patients, which examined the effectiveness of providing AAPs to adults following an ED visit for acute asthma. The review didn't provide conclusive evidence to support the consideration of this specific intervention for the reduction of relapses after an ED visit. The low frequency of events, the small number of trials, the small sample sizes of the included studies and the methodological quality likely play an important role in this overall finding.

Despite revealing a clinically relevant effect (a 34% reduction in relapses), statistical imprecision (**based on the confidence interval**, from as much as a **64% reduction** to a possible 23% **increase** in relapses) precluded a definitive interpretation of our pooled estimate. Variations across the included studies **in their target population (e.g., patients with different levels of asthma control and medication use) and co-interventions (e.g., prescription for prednisone and/or ICS at ED discharge and sending letters to the PCP) could have influenced their effect estimates; differences** in the characteristics (e.g., visual design, usability, content and recommended actions) **and time of provision** of the written AAPs that were tested might **also** affect their uptake and explain the moderate statistical heterogeneity observed in the meta-analysis.(20) Interestingly, the sensitivity analyses revealed significant changes in the magnitude and

precision of the pooled treatment effect when excluding the trial at high risk of bias, and with different analytic assumptions. The specific dimensions of methodological quality that were considered inadequate in this study have been associated with biased estimates of effectiveness.(21) Nonetheless, these results highlight the need for further and rigorous research in this setting, and in other countries.

Similar to a previous review focused on educational trials in acute asthma, there was a poor description of intervention fidelity.(22) Measures to monitor participants' acquisition of knowledge, development of new skills and change in practices were fidelity factors infrequently reported in individual studies. Standardized descriptions of intervention fidelity could promote research on novel predictors of effectiveness (e.g., impact of intervention characteristics on individual and pooled estimates of effectiveness); consideration of key confounders during the analytic phases could facilitate the interpretability and applicability of research results.(23)

While the lack of standardized reporting precluded further analyses (e.g., focused on secondary outcomes, subgroups), a few important **potentially** relevant **implications** to **clinical practice** arose from individual studies. In the study conducted by *Cowie et al*,(18) the implementation of AAP based on PEF monitoring was associated with the lowest proportion of visits for urgent treatment among the comparison groups ($p=0.002$). This finding could support the provision of this type of AAPs (over the symptom-based ones) to **adolescent and adult** patients in whom a lack of awareness of their asthma severity is identified.(24, 25) **In two of the studies included in this review that showed a statistically significant and clinically relevant reduction in the proportion of relapses within the first six months of ED discharge a co-intervention accompanied**

the written AAPs. (17, 18) PCPs **were notified** about their patients' ED visit **via** individualized letters with details of patients' ED management, and recommendations for medication adjustment and post-ED follow-up. Potential intermediate effects derived from this **specific action** over usual discharge instructions (e.g., promotion of **earlier** patient-PCP post ED follow-up **and of evidence-based management in ambulatory care settings**) were not explored in depth **in the included studies. Important patient, health provider and system factors that potentially confound the association between the provision of written AAPs after an ED visit for acute asthma and relapse occurrence (e.g., medication adherence, evidence-based post-ED management, access to medication and prevention programs)(8) should be explored in future trials.**(26)

Limitations: The review has several limitations. The inclusion criteria were restricted to RCTs based on our interest in summarizing the highest quality evidence and adding value to current guideline recommendations. We were unable to formally assess the potential for publication bias due to the small number of studies for each comparison;(27) however, a comprehensive search of the published and grey literature was conducted without restrictions on publication status or language of publication. In addition, two independent reviewers identified potentially relevant studies and the authors are confident that the studies that were excluded were done so for consistent and appropriate reasons. Therefore, the risk of publication and selection bias should be low.

The generalizability of our results could be limited to ED settings with non evidence-based management approaches and different health care resources (e.g., countries with limited access to medications and with no usual linkage between patients and

PCPs). Finally, only one of the included studies reported on quality of life with a non-significant improvement between the ED visit and the follow-up at 12-months.(16)

Details on this and other important outcomes such as symptoms improvement and pulmonary function were not the focus of this review.

ACCEPTED MANUSCRIPT

CONCLUSION

Whilst there is general agreement that recommendations for self-management should include patient education and regular medical review; its is still unclear whether or not directing the provision of written AAPs from the ED is effective in reducing relapses after discharge. Additional research in the ED setting and in other countries is needed to provide robust evidence to emergency physicians for its adoption. Future primary research should use rigorous research methods and standardize the reporting of intervention fidelity, study outcomes and key confounders.

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Cristina Villa-Roel (CVR) takes responsibility for the content of this manuscript, including the data and data analysis. Cristina Villa-Roel and Brian H. Rowe wrote the study protocol and were responsible for the general coordination of the study; Britt Voaklander and Taylor Nikel contributed to study selection, data abstraction and quality assessment; Maria Ospina participated in the analysis/interpretation of data and CVR drafted the final manuscript; Sandra Campbell designed the search strategy, conducted the literature search and made substantial contributions to the final manuscript.

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DECLARATION OF INTEREST

The authors have no conflicts of interest to declare related to this topic. Brian H. Rowe was the principal investigator of one included trial; however, he was excluded from the selection of potentially eligible manuscripts and final inclusion/exclusion decisions. Within the past 2 years, Dr. Rowe has received research funding from the following respiratory companies as a site principal investigator for multi-centred trials (CEMPRA: Chapel Hill, NC, USA) and investigator-initiated research (Merck, Inc.: Montreal, Quebec, Canada). All payments were made to the University of Alberta.

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Data from this study were presented at the following scientific meeting: Canadian Association of Emergency Physicians Annual Scientific Meeting, Edmonton, AB, Canada; June 3, 2015.

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Table 1. Characteristics of included studies

Authors	Year	Country	Sample size	Age (years)	Timing of the intervention	Follow-up period	Primary Outcome (% Relapses at six months)
Cowie et al. ¹⁸	1997	Canada	139	Adults and adolescents	Within the first 12 months of the ED visit	6 months	C: 39.6% I: 20.9%
Cote et al. ¹⁶	2001	Canada	98	> 18 years old	At the time of the ED visit	2 weeks, 6 & 12 months	C: 25.7% I: 30%
Rowe et al. ¹⁷	2006	Canada	64	16-60	At the time of the ED visit	30 and 90 days	C:18.2% I: 6.5%

Note: ED= emergency department; C= control group; I= intervention group.

Table 2. Fidelity assessment of studies' interventions

Study	Domains	Steps taken to ensure fidelity
		How was fidelity assessed?
Cowie et al 1997. ¹⁸	Theory congruence	No theoretical framework. Non applicable (N/A)
	Provider Training	Nurse clinicians. Not mentioned.
	Intervention Implementation	* Standardized educational session to all participants . Control: ED-discharge instructions and reminder of the importance of corticosteroid's dose adjustment. Intervention: Individualized and adapted written asthma action plans (AAP; either symptom- or peak flow-based) following a step-up approach + prescription for Prednisone. Letter sent to the subject's family doctor including advice on inhaled corticosteroid medication and a copy of the AAPs. Standard delivery materials were used; no delivery methods are detailed. No measures of provider monitoring or strategies to prevent contamination are described.
	Intervention Receipt	Not mentioned. N/A
	Intervention Enactment	Not mentioned. N/A
Cote et al. 2001. ¹⁶	Theory congruence	Structured education program based on the PRECEDE model and self-efficacy theory of Bandura. ¹⁹ Not mentioned.
	Provider Training	On call physician; respiratory therapists, study nurses. Not mentioned.
	Intervention Implementation	Control: Usual discharge instructions and provision of inhaler techniques if the on call physician was willing (C). Intervention: <i>Limited educational intervention (LE):</i> care provided in C + traffic light colors self-action plan explained by a physician. Patients chose between a peak flow-based and a symptom-based AAP. <i>Structured educational intervention (SE):</i> Care provided in C and LE + participation in a small-groups educational program focused on self-management.
		Standard delivery materials were used and delivery

		methods detailed. No measures of provider monitoring or strategies to prevent contamination are described.
	Intervention Receipt	Not mentioned. N/A
	Intervention Enactment	Not mentioned. N/A
Rowe et al. 2006.¹⁷	Theory congruence	No theoretical framework. N/A
	Provider Training	Research nurses. Not mentioned.
	Intervention Implementation	* Standardized discharge package given to all participants. Control: Usual discharge instructions. Intervention: Written AAP from the Canadian Thoracic Society provided and encouragement to visit and review the AAP with family doctor. Letter faxed to the family doctor outlining the need for follow-up and gaps in care identified during the ED visit. Standard delivery materials were used; no delivery methods are detailed. No measures of provider monitoring or strategies to prevent contamination are described.
	Intervention Receipt	Not mentioned. N/A
	Intervention Enactment	Not mentioned. N/A

¹⁷ Adapted from Beasley et al. Thorax 1989; 44:200-04 and Charlton et al. BMJ 1990; 301:1355-59. ¹⁸ Green, L & Kreuter, M. Health promotion planning: an educational and environmental approach. 2nd edition. Mountain View, CA. Mayfield Publishing; 1991 and Bandura, A. Social foundations of thoughts and action. Englewood Cliffs, NJ: Prentice-Hall: 1986.

LEGENDS FOR FIGURES

Figure 1. Literature search for systematic review of the effectiveness of written asthma action plans on improving outcomes after ED discharge for acute asthma

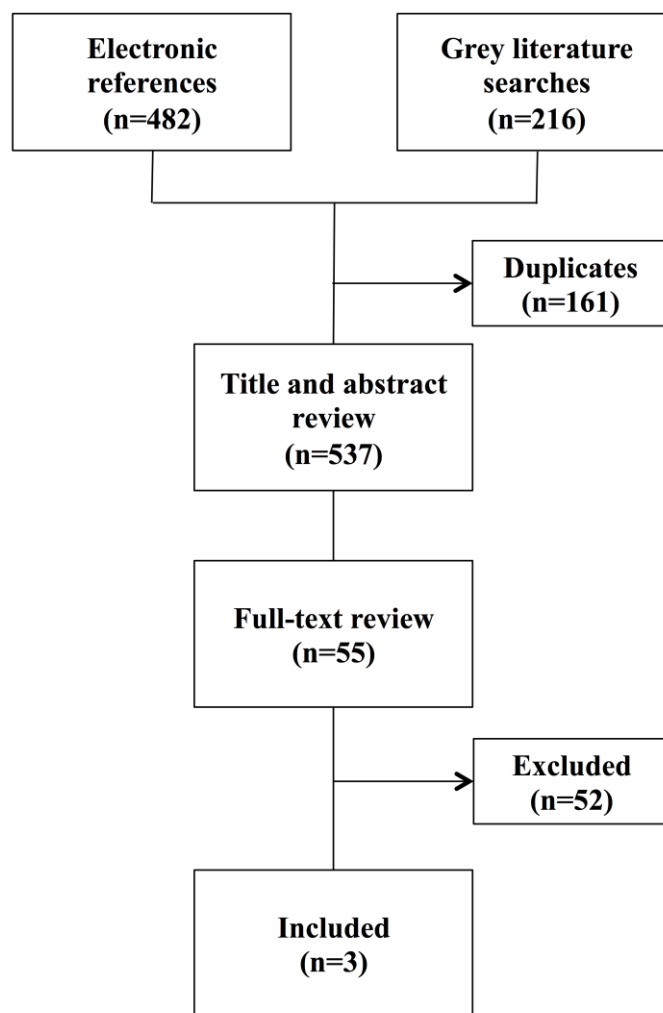
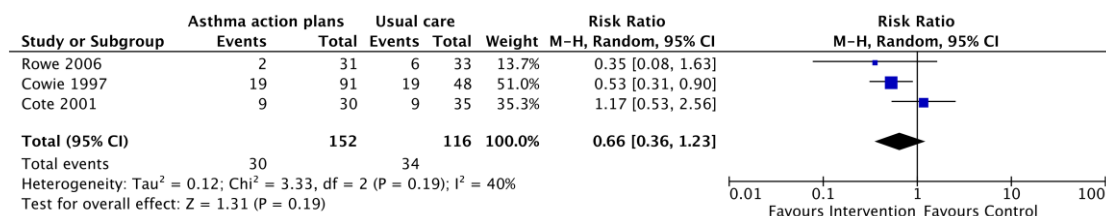


Figure 2. Effectiveness of written asthma action plans on the percentage of relapses after asthma exacerbations in adult patients



Appendix 1. Medline search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>
Searched March 24, 2016

- 1 exp Patient Education as Topic/ or exp Self Care/ or exp Patient Care Planning/ (151860)
- 2 asthma action plan.mp. (150)
- 3 *"Asthma"/th [Therapy] (8896)
- 4 (plan or plans).ti,ab. (105379)
- 5 3 and 4 (501)
- 6 Emergency Treatment/ or Emergency Medicine/ or emergency medical services/ or emergency service, hospital/ or trauma centers/ or triage/ or exp Evidence-Based Emergency Medicine/ or exp Emergency Nursing/ or Emergencies/ or emergicent*.mp. or ((emergenc* or ED) adj1 (room* or accident or ward or wards or unit or units or department* or physician* or doctor* or nurs* or treatment* or visit*)).mp. or (triage or critical care or (trauma adj1 (cent* or care))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (201293)
- 7 5 and 6 (155)
- 8 limit 7 to clinical trial, all (41)