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**EDIFIP study: Evaluation of the Impact of Patient Information Leaflets on doctor-patient communication, satisfaction and global adherence for 6 acute pathologies (medical and traumatic), in 2 emergency departments.
A prospective multicentric before-after study**

Marisa Tissot, Julie Tyrant

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UNIVERSITE JOSEPH FOURIER
FACULTE DE MEDECINE DE GRENOBLE

Année : 2015

Etude EDIFIP : Evaluation De l'Impact des Fiches Information Patient sur la communication médecin malade, la satisfaction et l'adhérence globale pour 6 pathologies aiguës infectieuses et traumatique dans 2 services d'urgence.

Etude interventionnelle multicentrique avant-après.

THESE
PRESENTEE POUR L'OBTENTION DU DOCTORAT EN MEDECINE
DIPLOME D'ETAT

Marisa TISSOT

et

Julie TYRANT

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Serment d'Hippocrate

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List of Abbreviations

DPC: Doctor Patient Communication

PIL(s): Patient Information Leaflet(s)

TPE: Therapeutic Patient Education

WHO: World Health Organization

ED: Emergency Department

FNAH: French National Authority for Health

GA: Global Adherence

RCT: Randomised Controlled Trial

CECIC: Comité d’Ethique des Centres d’Investigation Clinique

AP: Acute Pathology

ABSTRACT

« EDIFIP study: Evaluation of the Impact of Patient Information Leaflets on doctor-patient communication, satisfaction and global adherence for 6 acute pathologies (medical and traumatic), in 2 emergency departments. A prospective multicentric before-after study »

Background

Doctor-Patient Communication (DPC) is an essential part of the relationship between the doctor and his patient. Patient Information Leaflets (PILs) created for the management of acute pathologies aim at improving the quality of information given to the patient. Our before-after study explored the role of written information in the management of 6 acute pathologies (medical and traumatic), in an emergency ward, as a means of improving doctor-patient communication, satisfaction and global adherence.

Methods

In this prospective multicenter study, patients consulting in 2 emergency departments (Grenoble and Chambéry) for an acute pathology (medical or traumatic) were included. Seven to 10 days later, they were contacted by phone and answered questionnaires. We used 3 validated scales (doctor-patient communication, satisfaction and global adherence scales) in a "before-after" study to ensure comparability.

Results

Analysis of 168 patients (14,2 % were lost to follow-up) showed that PILs improved DPC (p -value = 0,002). In phase 2, DPC score's median was 46 [42-49]. In phase 1, the median was 44 [38-48]. Our analysis also showed that with leaflets, there were almost twice as many patients (10,3 % in phase 1 and 18 % in phase 2) who found that DPC was very good (DPC score > 50). Furthermore, we observed half as many

patients (20 % in phase 1 and 8,4 % in phase 2) who thought that DPC was insufficient (DPC score \leq 35).

Conclusion

Written information is a precious tool for patients and doctors. The use of PILs modifies the behavior of patients and doctors, leading to better healthcare.

Keywords

Communication, pamphlet, acute disease, patient satisfaction, adherence, physician patient relations

RESUME

« Etude EDIFIP : Evaluation De l'Impact des Fiches Information Patient sur la communication médecin malade, la satisfaction et l'adhérence globale pour 6 pathologies aiguës infectieuses et traumatique dans 2 services d'urgence. Etude interventionnelle multicentrique avant-après »

Introduction

La communication médecin malade (CMM) est un élément essentiel de la relation entre un médecin et son patient. Les fiches information patient (FIP) pour des pathologies aiguës ont été créées dans le but d'améliorer la qualité de l'information donnée au patient. Cette étude avant-après a étudié l'impact des FIP sur la communication médecin malade, la satisfaction et l'adhérence globale au cours de la prise en charge de 6 pathologies aiguës (infectieuses et traumatique), dans un service de médecine d'urgence.

Méthode

Dans cette étude prospective multicentrique, les patients consultant dans 2 services de médecine d'urgence (Grenoble et Chambéry) pour une des 6 pathologies aiguës étudiées ont été inclus. Sept à 10 jours plus tard, la collecte des données se faisait par questionnaire téléphonique. Trois échelles génériques validées ont été utilisées (échelles de communication médecin malade, de satisfaction et d'adhérence globale) dans une étude avant-après afin d'assurer la comparabilité.

Résultats

L'analyse des 168 patients (14,2 % de perdus de vue) a montré que les FIP amélioraient la CMM (p -value = 0,002). Dans la phase 2, la médiane du score de CMM était de 46 [42-49]. Dans la phase 1, la médiane était de 44 [38-48]. L'analyse a aussi montré qu'avec les FIP, quasiment 2 fois plus de patients (10,3 % dans la phase 1 et 18 % dans la phase 2) ont trouvé la CMM très bonne (score CMM > 50).

Deux fois moins de patients (20 % dans la phase 1 et 8,4 % dans la phase 2) ont trouvé la CMM insuffisante (score CMM \leq 35).

Conclusion

Les FIP sont un outil précieux pour les patients et les médecins. Leur utilisation modifie à la fois le comportement des patients et des médecins.

Mots-clés

Communication, fiche information patient, pathologie aigue, satisfaction du patient, adhérence, relation médecin malade

INTRODUCTION

Delivering information to patients is a duty and every patient has a right to be informed about his health condition (1,2). Healthcare is not seen any more as a paternalistic relationship, where the doctor takes decisions and the patient obeys without questioning diagnosis or treatment, but it has evolved into the process of shared decision making (3). In order to help self-management of their chronic disease, patients presenting chronic conditions benefit from multidisciplinary care and Therapeutic Patient Education (TPE). The World Health Organization (WHO) has stated that “though acutely ill patients may benefit from TPE, it appears to be an essential part of treatment of long-term diseases and conditions”(4).

On the other hand, patients presenting acute pathologies should also have access to written information about their condition. In fact, giving patient information can be difficult in the context of a consultation in an Emergency Department (ED). Indeed, the number of visits has been increasing since the 1990s reaching 17,5 million consultations in 2010 in France and French Overseas Departments (5). As a result, emergency physicians have limited time for each patient and a Patient Information Leaflet (PIL) can be a useful tool to complement oral information given during a brief and sometimes stressful consultation. In 2015, Musso in a pilot study in an ED, pointed out the fact that patients’ understanding of a consultation can be limited and that Doctor-Patient Communication (DPC) is a skill that can be improved (6). To promote the development of written information, the French National Authority for Health (FNAH) issued in 2008 a methodologic guide on how to elaborate written information for patients (7). Sources for written medical information are multiple, and enhancing the quality of written information is a way of improving healthcare.

Indeed, PILs of variable quality have been developing since the end of the 1970s. PILs as an intervention have been studied since that time and studying multiple PILs instead of only one PIL allows to differentiate the impact of the leaflet from the impact of the pathology on different outcomes (8–11). Thus, there was a need for generic validated scales to measure DPC, satisfaction and adherence in the context of acute pathologies. Fong Ha in 2010 pointed out that “comparisons between studies are difficult as numerous tools (to assess DPC and health outcomes) are available but no single tool is completely satisfactory. Different studies use combinations of different tools for this reason.” (12). To this purpose, in a study in 2014, we created and validated 3 new scales: a Global Adherence scale (GA), a Doctor-Patient Communication scale (DPC) and a satisfaction scale (13,14). We used the 3 scales in a "before-after" study to ensure comparability. In this prospective multicenter before-after study, we explored the role of written information in the management of six acute pathologies (medical and traumatic), in an emergency ward, as a means of improving doctor-patient communication, satisfaction and global adherence.

METHODS

1. Literature search

An exhaustive literature search was conducted with a systematic search performed on different databases: Pubmed, google scholar, Psychinfo, and Cochrane library between 1979 and 2015.

The keywords and their MeSH synonyms used were:

« Acute disease », « Pamphlets », « Physician patient relations », « Ambulatory care », « Primary health care », « Emergency medical services » (ANNEXE 1).

The French institutional websites (FNAH, French Minister of Health and Solidarity) were also consulted.

Finally, a site-search of website referenced articles and theses dealing with the subject was conducted.

Each database was queried for the last time in August 2015.

Included were: all Randomised Controlled Trial (RCT), non-randomised trial, and literature reviews in which the effect and the evaluation of PILs outpatient had been studied, in the context of acute pathologies. We searched for articles in French and English.

There were no further restrictions.

A selection was made first of all on the title, then on the summary, and finally on reading the article.

For each of the references selected (ANNEXES 2 and 2 bis), an assessment of the methodological quality was performed: CONSORT and PRISMA sheets for RCT and review literature respectively (ANNEXES 3 and 3 bis).

2. The before-after study

2.1. Type of study

An interventional study, two-center, prospective was conducted from declarative data within the ED of the Clinic Hospital Group Mutualiste Grenoble and Chambéry Hospital.

Phase 1 (before study) conducted between November 2013 and May 2014 and phase 2 (after study) between September 2014 and June 2015.

The study protocol was set up by a multidisciplinary team of physicians, pharmacists, psychologists, statisticians and methodologists (ANNEXE 5).

2.2. Population

The inclusion criteria were: adult patient or guardian accompanying a minor aged under 15 years and 3 months consulting for one of the 6 AP (ankle sprain, acute pyelonephritis, acute prostatitis, pneumonia, acute diverticulitis or infectious colitis) and who could be reached by telephone 7 to 10 days after the consultation.

Patients who were hospitalised for more than 48 hours were excluded.

2.3. Intervention

There were two arms:

- Oral delivery of information (before study)
- Oral and written (PIL) delivery of information (after study)

The doctor proposed to participate in the study, any patient consulting for one of the six chosen acute pathologies (and fulfilling the inclusion criteria).

If the patient agreed, the doctor, medical student or nurse gave him a PIL corresponding to his pathology.

2.4. The creation and updating of six PILs

The six PILs (ANNEXE 4) were updated and created according to the recommendations of FNAH (7) and to a method defined and validated in previous studies (8)(45).

A literature search and a reading by professionals and patients were conducted and corrections were made according to their remarks.

Finally, a minimum readability Flesh score of 60 was provided, corresponding to a standard level of reading (5th-4th grade level) (ANNEXE 4).

2.5. Data collection

Between 7 and 10 days after the consultation, patients were telephoned by one of the two investigators. They answered the general questionnaire, the DPC specific questionnaire (DPC-13 scale), satisfaction questionnaire and GA questionnaire (13,14).

If they were unreachable the first time, we would call them again, twice. If we were not able to contact them, we called the support person designated by the patient on the inclusion sheet. In case of failure, the patients were considered lost to follow-up. Data from the telephone survey was entered using Excel software. A quality control was carried out by a reading of all the data entered by each interviewer.

2.6. Questionnaires

Satisfaction, DPC and GA scores were created and validated in a previous study (13,14).

2.6.1. Doctor-patient communication

Questionnaire composed of 13 questions. 4 answers were possible on a Likert scale (yes, agree, disagree or no) and the total score went from 13 to 52. A high score represented a high level of communication (ANNEXE 8).

2.6.2. Satisfaction

Questionnaire composed of 5 questions, 4 answers were possible (yes, agree, disagree and no). The total went from 5 to 20 (ANNEXE 8).

2.6.3. Global adherence

Questionnaire composed of 4 parts: adhesion to drug prescription, adhesion to non-drug prescription (further exams, appointment with a specialist, follow-up with general physician), adhesion to advice and instructions and the use of health care facilities for medical advice (ANNEXE 8).

2.7. Sample size

The number of patients lost to follow-up was estimated at 25 %.

A minimum of 75 questionnaires by type of pathology (traumatic or infectious) were desirable.

It was therefore necessary to include 150 patients.

2.8. Study objective

The main objective was to measure the impact of six PILs on the DPC, satisfaction and GA during a consultation for acute pathology in two ED.

2.9. Ethical approval

A favourable ethical opinion was obtained on 31/10/2013 (CECIC Rhône-Alpes-Auvergne, Clermont-Ferrand, IRB 5891).

The study was registered on Clinical Trials (ClinicalTrials.gov Protocol Record N°IRB 5891).

2.10. Data analysis

Statistical analysis was performed with the usual procedures of data management and base gel, via the Stata version 13.0 software (Stata Corp, College Station, Texas) OSX.

Statistical tests were carried out with the risk of error first alpha usual case equal to 0,05.

Numbers and percentages were used to describe variables and median and IQR [25th and 75th percentiles] for continuous variables.

For quantitative variables, the Mann-Whitney test was used to compare two groups.

For qualitative variables, the Chi2 test was used if the application conditions were met, otherwise the Fisher exact test was used.

Multivariate logistic regression was used for the DPC score in 2 classes to test the difference between the two phases. It was adjusted to parameters which were significantly different at baseline. When the dependent variable was the DPC score in 3 classes, a polytomous logistic regression was used.

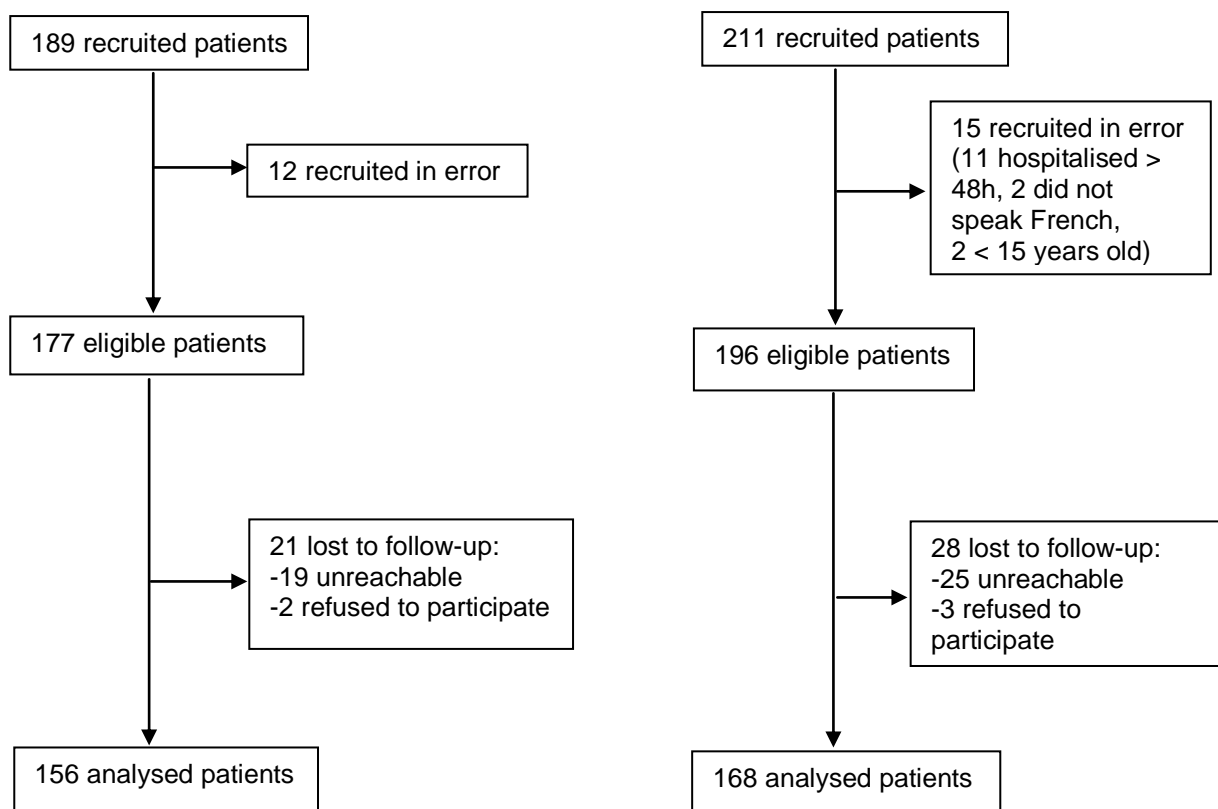
Graphs were plotted by the box plot or histogram.

RESULTS

1. Population

211 patients were included in our study. 14,2 % were lost to follow-up. A total of 168 patients answered the 5 different questionnaires (general questionnaire, satisfaction questionnaire, DPC questionnaire, adherence questionnaire and GA questionnaire) (ANNEXE 8).

Figure 1: Patient flow through trial, in phase 1 and 2



A significant difference was found between patients working in the health sector in phase 1 (14,7 %) and phase 2 (7,7 %) ($p = 0,045$).

Table 1: Comparison of baseline characteristics of patients in phase 1 and 2. Values are numbers (percentages) or median (interquartile range)

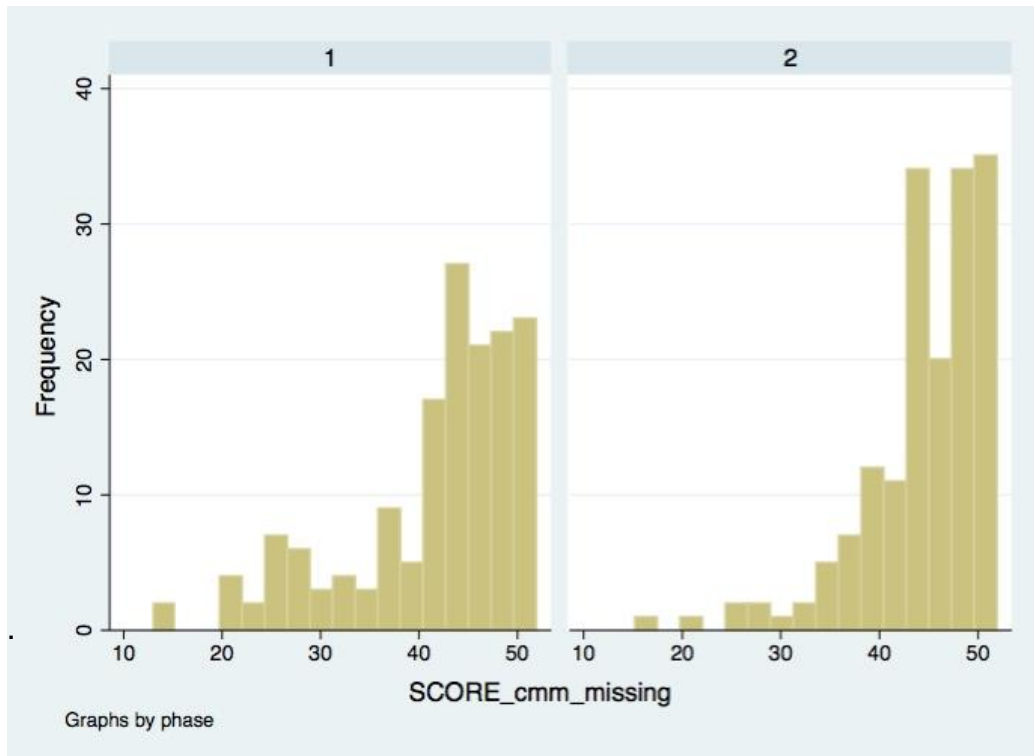
Variables	Phase 1 (n=156)	Phase 2 (n=168)	p-value
Condition			0,252
Ankle sprain	83 (53,2 %)	100 (59,5 %)	
Infectious disease	73 (46,8 %)	68 (40,5 %)	
Male	61 (39,1 %)	80 (47,6 %)	0,122
Age	36 [23-57]	37.5 [24-56]	0,745
Age ≥ 40	71 (45,5 %)	76 (45,2 %)	0,960
Education level			0,551
Middle school	62 (39,7 %)	62 (36,9 %)	
Secondary school	39 (25 %)	37 (22 %)	
University	55 (35,3 %)	69 (41,1 %)	
Work in health sector	23 (14,7 %)	13 (7,7 %)	0,045
Socio-professional category			0,902
1-2	7 (4,5 %)	6 (3,6 %)	
3-4	30 (19,2 %)	32 (19 %)	
5-6	43 (27,6 %)	52 (31 %)	
7-8	76 (48,7 %)	78 (46,4 %)	
Marital status			0,058
Single	79 (50,6 %)	67 (40,1 %)	
In a relationship	77 (49,4 %)	100 (59,9 %)*	

* 1 missing value

2. Main outcome: DPC score

DPC score's median was 44 [38-48] in phase 1 and 46 [42-49] in phase 2 ($p < 0,01$).

Figure 2: Doctor patient communication score in phase 1 and 2



We created 3 classes with DPC score: ≤ 35 , 36-50 and > 50 to compare the 2 phases.

Table 2: Comparison of high, medium and low DPC between phase 1 and 2

(numbers and percentages)

Phase DPC score	Phase 1 (n=156)	Phase 2 (n=168)	p-value
			< 0,01
≤ 35	31/155 (20 %)	14/167 (8,4 %)	
36-50	108/155 (69,7 %)	123/167 (73,6 %)	
> 50	16/155 (10,3 %)	30/167 (18 %)	

We applied polytomous logistic regression analysis to parameters which had a p -value < 0,20 at baseline (working in the health sector, being male and being in a relationship). The analysed parameters were not determinant of good or correct communication however the differences between the 2 phases were still significant after analysis.

3. Secondary outcomes: satisfaction score and global adherence score

3.1. Satisfaction score

Analysis was performed for 324 patients (156 in phase 1 and 168 in phase 2).

Median was 19 in both phases (IQR went from 16 to 20 in phase 1 and 17 to 20 in phase 2, $p = 0,20$).

3.2. Morisky score

Prescription on demand and/or systematic was made for 130 patients in phase 2 and 134 in phase 1. Comparison between phase 1 and 2 found no statistical difference in the Morisky score ($p = 0,87$).

3.3. Global adherence score

After consulting the further results it was decided not to measure the global adherence score.

There were 22,6 % (38) patients who were discharged without a drug prescription in phase 2, versus 14,1 % (22) in phase 1 ($p = 0,049$).

In phase 2:

- 83,9 % (141) patients were given a prescription for further exams, an appointment with a specialist or follow-up versus 62,8 % (98) in phase 1 ($p < 0,01$).
- 73,2 % (123) patients were given advice versus 57,4 % (89) patients in phase 1 ($p < 0,01$).
- 50,9 % (84) patients were told when to consult a doctor again, versus 50,9 % (79) patients in phase 1 ($p = 0,99$).

Table 3: Grouped answers to questions concerning global adherence in phase 1 and 2 (numbers and percentages)

Question Answer	Yes and agree		No and disagree		<i>p</i> -value
	Phase 1	Phase 2	Phase 1	Phase 2	
Did you take all the treatment that was prescribed?	108 (80,6 %)	107 (82,3 %)	26 (19,4 %)	23 (17,6 %)	<i>p</i> = 0,721
Did you take the treatment as prescribed (posology)?	127 (94,7 %)	122 (98,3 %)	7 (5,2 %)	2 (1,6 %)	<i>p</i> = 0,114 Fisher's exact = 0,175
Did you take the medicine on time?	113 (84,3 %)	116 (93,5 %)	21 (15,6 %)	8 (6,4 %)	<i>p</i> = 0,019
Have you been to the appointment or have had the exam that was prescribed?	87 (88,7 %)	119 (84,4 %)	11 (11,2 %)	22 (15,6 %)	<i>p</i> = 0,335
Did you follow the advice you were given?	82 (92,1 %)	104 (84,5 %)	7 (7,8 %)	19 (15,4 %)	<i>p</i> = 0,097
Do you think that consulting another doctor was consistent with the advice the emergency department physician gave you?	75 (96,1 %)	81 (97,5 %)	3 (3,8 %)	2 (2,4 %)	<i>p</i> = 0,599 Fisher's exact = 0,674

4. PILs questionnaire

Table 4: Answers to questions concerning the PIL (numbers and percentages)

Question \ Answer	Yes	No	Does not remember
Did you receive a PIL?	94,6 % (159)	4,8 % (8)	0,6 % (1)
Was the PIL signed?	34,6 % (55)	26,4 % (42)	39 % (62)
Did you find the PIL easy to understand?	97,1 % (133)	2,2 % (3)	0,7 % (1)
Did you receive information when you were given the PIL?	52,8 % (84)	45,9 % (73)	1,3 % (2)
Did you keep the PIL?	93,7 % (149)	5,7 % (9)	0,6 % (1)
Did you find the PIL useful?	80,3 % (110)	19 % (26)	0,7 % (1)
Did other people in the household use the PIL?	35,2 % (56)	63,5 % (101)	0,6 % (1) (+0,6 % (1) non applicable mention)

Of the 168 patients we questioned, 79,9 % (127) received a PIL from a doctor, 17,6 % (28) from a nurse, 0,6% (1) from a caregiver (1,9% (3) do not remember). 79,8 % (127) patients read the PIL in full detail and 6,2 % (10) read just part of the PIL. 70,4 % (112) patients read the PIL immediately, 15,7 % (25) read it a few days later and 13,8 % (22) did not read the PIL. 36,5 % (50) of the patients who had read the PIL, read it again.

DPC score was higher when patients received the PIL with an explanation ($p = 0,02$). 86,3 % (63) patients who did not receive an explanation versus 96,3 % (80) patients who received an explanation had a DPC score over 35.

13,7 % (10) patients who had no explanation versus 3,6 % (3) patients who had an explanation had a DPC score less or equal to 35.

Moreover, satisfaction was higher when patients received the PIL with an explanation ($p = 0,02$).

72,6 % (53) patients who did not receive an explanation versus 86,9 % (73) patients who received an explanation had a satisfaction score over 16.

27,4 % (20) patients who had no explanation versus 13,1 % (11) patients who had an explanation had a satisfaction score less or equal to 16.

The fact that the PIL was given by the doctor did not influence DPC or satisfaction.

The fact that the PIL was signed or not and whether the patient came to the emergency alone or accompanied did not have an impact on satisfaction or DPC.

5. Relation between scores

The analysis of the relation between DPC score and satisfaction score in phase 1 and 2 showed a statistical relation ($p = 0,00$ and Fisher's exact = 0,00).

In phase 2, the analysis of the relation between DPC score and the recommendation of the emergency ward to friends and family showed a statistical relation ($p < 0,01$ and Fisher's exact = 0,00).

62,2 % (28) patients who had a DPC score equal to or under 35 recommended the department compared to 93,4 % (43) who had a DPC score over 50.

DISCUSSION

1. Definitions

1.1. Acute pathologies

“Acute” is defined in the dictionary as “(of a disease or its symptoms) severe but of short duration” (15).

There is no precise definition but the duration of symptoms remains the main indicator to define the character of an acute pathology (AP). However, it is different for each pathology and it is not unanimous for a given disease. For example, Francis in 2009, defined "acute respiratory tract infection" lasting 7 days or less (16), while Little 2005 and Macfarlane 2002), defined it as lasting up to 21 days (16)(17).

1.2. Chronic pathologies

Chronic conditions are defined as health problems that require ongoing management over a period of years or decades (diabetes, heart disease, asthma, cancer, HIV/AIDS, depression...) (19).

There is therefore a time interval not defined between a few days or weeks for AP and years for chronic pathologies. Moreover, some chronic diseases are also characterized by the repetition of acute attacks (low back pain, chronic obstructive pulmonary disease, inflammatory bowel diseases, inflammatory rheumatism...).

1.3. Comparison: acute versus chronic pathologies

« Therapeutic Patient Education » commonly used in the management of chronic diseases represents a comprehensive program of support and multidisciplinary long learning courses. It combines complementary activities and varied techniques, followed by assessment. It takes into account the clinical and biological aspects of health and the entire psychosocial dimension of the patient (20).

Likewise, acute pathologies require comprehensive care including “all promotive, preventive, curative, rehabilitative or palliative actions”. But the “primary purpose is to improve health, and effectiveness largely depends on time-sensitive and, frequently, rapid intervention” (21). The "acute vs chronic" border is again undefined when, for example palliative patients with a chronic disease have acute pathologies.

Moreover, these definitions of acute or chronic pathologies are not precise enough to cover all situations encountered by doctors (scheduled surgical procedure, prevention, what to do in case of missed oral contraceptive pill...).

To ensure comprehensive care, interventions concerning the management of acute pathologies need to be studied. Acute pathologies such as acute respiratory tract infection (16–18), gastroenteritis and tonsillitis (8), acute chest pain (9) and urinary infection (22) have been studied. Traumatic conditions have also been studied: traumatic injury (23)(24) and low back pain (25).

Main outcomes often explored in RCTs and reviews dealing with AP are : satisfaction (9,10,16,18,25–27), knowledge (8,25–27,29), patient's behavior (8,9,30), consultation rates (16–18,31,32), anxiety (9,10,23,26), and medical practices: number of investigations (10,32) and number of prescriptions (10,16,32,33).

Concerning chronic diseases such as hypertension (34,35), inflammatory bowel disease (36), and diabetes (37–39), outcomes studied were: relapse (36), quality of life (39), biological criteria such as blood glucose (37–39) or clinical criteria such as blood pressure (35).

1.4. The choice of acute pathologies in ED

We thought it was interesting and innovative to explore information for AP. They are often neglected in this area in favour of chronic diseases. Literature is poor in evaluating the impact of PILs in the context of AP. Moreover, patients, in an ED, are taken care of by a doctor they encounter for the first time. Therefore they do not have the trusting relationship they would have with their usual physician. The ED is also a place where lack of comfort, the short time given to each patient, and the important influx may be upsetting. Therefore this is a place where information delivered to the patient is important but sometimes complicated if neglected.

2. Results, relevance and comparison with other studies

2.1. Main findings: impact on the patient

2.1.1. Doctor-Patient communication

With PILs, there were almost twice as many patients who found that DPC was very good (DPC score > 50). It was shown that they were those who recommended the ED to friends and family. Improving DPC by the use of PILs can positively impact patients' visits to the institution.

Moreover, with PILs, it was observed that half as many patients thought that DPC was insufficient (DPC score \leq 35). They represent a target to reduce complaints. In fact, Ha and Longnecker in 2010 stated that "most complaints about doctors are related to issues of communication, not clinical competency" and that "effective doctor-patient communication is a central clinical function in building a therapeutic doctor-patient relationship." (12).

Thus, doctor-patient relationship process relies on communication and communication skills are essential. Shared decision making is a two step process between a health professional and a patient: an information exchange then a dialogue achieves mutual agreement about health issues. The patient is helped in exploring all possible options and eliciting preferences. Options concern prevention, diagnosis or treatment and also choosing not to do anything (3).

Similarly, providing information implies that patients understand it. PILs are considered easy to understand if they are written according to strict criteria (26). It was shown in Musso's study that 65,9 % of patients had a poorer understanding of the information provided during an ED visit in at least one field. Information regarding diagnosis and blood tests results are the least understood (6). This information corresponds to two information items in our leaflets. It therefore underlines the work that has to be made for better communication resulting in better understanding.

2.1.2. Satisfaction

Patient satisfaction was not improved by PILs. However, there was a ceiling effect with a high score in both phases. Obtaining a higher score seems difficult. Then, the satisfaction questionnaire of this before-after study explored different components of satisfaction other than medical care, probably explaining the absence of impact on satisfaction score. Patients were asked if they were satisfied with medical and paramedical services and with how well they had been received (time spent waiting, institutional food, reception). They were also asked if they would recommend the service to family and friends (ANNEXE 8).

The study of satisfaction with its determinants analysis showed the importance of the weight of the structure in overall satisfaction (61 %), followed by medical weight (15 %) and paramedical weight (5-7 %) (13). But it is interesting to mention that in an ED, the more severe the pathology, the less importance the patient gives to the structure and the more satisfied he is (40).

This raises the question of the sensitivity of the satisfaction questionnaire. It is surprising to find a score so high in an ED, where patients formulate many complaints (because of waiting time, lack of comfort...). It would be interesting to test the satisfaction scale in other services and institutions.

Satisfaction is an outcome that has often been studied. However, results concerning satisfaction linked to PILs are not unanimous. One explanation is the lack of a generic validated scale and heterogeneity of the questions in each scale used. In a trial published in 2009, Arnold used a 12-question patient satisfaction survey developed from the Group Health Association of America consumer satisfaction survey (9). This survey (41) explored overall satisfaction, accessibility of care, carers relationship (rapport, interest in the patient, reassurance), overall quality of care, waiting times, practical information delivered (costs of care...). Some of these items were also found in our satisfaction scale. Like in the before-after study, Arnold used a Likert scale with response allowing ratings of poor, satisfactory, good, very good, and excellent. He conducted a pilot study to test comprehensibility. He also found that "both groups had high scores for each dimension of patient satisfaction and there was no evidence that the information sheet was associated with any change in satisfaction with care", again asking the question of the sensitivity of our questionnaire and that of Arnold.

On the other hand, Little (10), in 2004, measured satisfaction with the medical interview satisfaction scale and its subscales (42), using a 7-point Likert scale ranging from “very strongly agree” to “very strongly disagree”. This scale reflected aspects of doctor-patient communication (relieving distress, intention to comply with management decisions, communication, degree of information delivered, confidence in the doctor, rapport), which can also be found in the DPC scale. He showed that “the general leaflet increased patient satisfaction and was more effective with shorter consultations”. Indeed, for a 10 minute consultation satisfaction was improved by 7 % and for a 5 minute consultation by 14 %. Thus, in an ED, where consultation time is short, PILs represent a good complement to oral information given by the doctor.

In the end, different satisfaction scales used explore different dimensions and by looking at the content of various scales, we noted that our results were consistent with literature data.

2.1.3. Correlation satisfaction / DPC

There was a correlation relationship between the DPC score and the satisfaction score. Gauchet’s study in 2007 also revealed “significant associations between adherence and patients’ beliefs about treatment, satisfaction with treatment” (concept included in our satisfaction scale with a question about satisfaction concerning doctor care), and “confidence in the physician” (one question of the DPC scale) (43).

Harrington 2002 stated that “the importance of doctor-patient communication in the process of health care has been established, with studies demonstrating clear links between the quality of communication and patient satisfaction, adherence and clinical outcomes” (44).

DPC and satisfaction scales explored different and complementary dimensions of healthcare: satisfaction scale concerned the hospital in general and DPC scale evaluated one aspect of the quality of the medical consultation.

Moreover, this before-after study showed that DPC and satisfaction increased when the leaflets were explained to the patient. This is consistent with other studies. For example, in 2007, Grime described that “most (patients) wanted detailed explanations about medicines and, when given a choice, more rather than less information” (30). One determinant of DPC is the level of information delivered to patients such as dietary and lifestyle guidelines and instructions on when to consult a doctor again. These two pieces of information are sufficient to multiply by 10 the DPC (14). Coudeyre in 2006, found a significant improvement in patient satisfaction in relation to the information supplied on: “relapse prevention”, “when to seek medical advice” and “use of analgesics.” (25).

Concerning distribution of the PIL in literature, they were frequently handed out by the doctor (8,16,17,25,33). More rarely, they were given by the nurse (9), physical therapists or psychologists (24). Sometimes it is not specified in the study (10,18). We found no studies examining the impact of PILs depending on who handed them out.

In the before-after study, DPC was not higher if the PIL was given specifically by the doctor or if it was signed by the doctor. These results suggest that explaining the PIL to the patient could be a task accomplished by other medical staff, once the diagnosis is made, freeing some time for the physician in the current context of a lack of doctors.

2.1.4. Adherence

In this study, the Morisky score (ANNEXE 8) evaluating treatment adherence was high. The medication adherence score in both phases was also high and higher than the Morisky score. The Morisky scale corresponds to the questions in the part "medication adherence" of the GA questionnaire. However, GA scale seems more sensitive as a difference was observed when patients followed drug intake instructions closely or not. Moreover, a Likert scale was used in GA scale whereas a binary response ("yes" or "no") was proposed in the Morisky scale. It would be interesting to confirm these differences in other studies.

We can assume that high adherence to treatment can be explained by the fact that patients are more motivated to take their treatment in relation with their potentially severe medical state. They have waited some time for their consultation (some patients leave the ED before seeing a doctor), they are stressed and anxious and are eager to get better. Moreover, medical treatment for an acute pathology is usually short, contributing to better adherence. It was pointed out in phase 1 that having an infectious disease multiplied by 3 the GA score. In phase 2, the study of the impact of PILs on the 3 scores (DPC, satisfaction and GA) showed no difference for the type of pathology diagnosed.

We found no studies comparing multiple PILs dealing with traumatic and infectious diseases.

However, in this study, PILs had an impact on patient's behavior. More patients took their medication as indicated (at a specific time, on an empty stomach or during a meal). It is an interesting fact to consider when there is self-medication and use of over-the-counter medicines. Indeed, 93,7 % patients kept the PIL and 35,2 % shared it with household members. This transmission of information can have positive outcomes, like fewer visits for the same symptoms by household members of patients

who had been given leaflets (8), a reduction of the consultation rate for acute lower respiratory tract illness when patients used an information leaflet (31), and a reduction of intention to consult for the same symptoms with the use of a PIL (32).

Finally, in phase 1, there was a correlation between DPC and AG scores ($p < 0,01$) but not in phase 2. There was probably a ceiling effect of AG with a high score in the two phases.

2.1.5. Complementary results

As in Turpin's study, the majority of patients (80 %) considered PILs as useful (23). In the EDIMAP study, 61,4 % of patients thought that the PIL was useful or quite useful and 96 % thought that doctors should use PILs more often (45). At home, patients can refer to it whenever they want (46). This was observed in the before-after study (ANNEXE 6). PILs can be considered as a resource for the patient and the doctor. Indeed, they have a role in the continuity of care by enabling hospital outpatient transition. The FNAH, in a note to support the coordination between the hospital and primary care health professionals, spoke of clinical procedures aiming at developing therapeutic education (47).

2.2. Impact on the doctor

Physicians' practices were modified by PILs. Indeed, a decrease in drug prescriptions, an increase in medical investigations and instructions to follow were observed.

Other studies also found an increase in the number of investigations (10) and a decline in drug prescriptions, including antibiotic prescription (16, 32). Altiner in 2007 aimed to reduce unnecessary antibiotic prescriptions in primary care by motivating GPs to change their attitudes to communication and by empowering patients with an educational intervention (GPs were visited by peers, patients were given a leaflet and a poster was put up in the waiting room). Altiner found a relative reduction of 60 % in antibiotic prescription rates at 6 weeks and a 40 % relative reduction persisted at 12 months (33).

3. Limitations and strengths

3.1. Limitations

3.1.1. Selection bias

Physicians included patients who could potentially change their behavior at the time of consultation. This bias present in both phases is related to the inclusion of non-blind patients, underestimating the impact of PILs.

3.1.2. Comparability of groups

Patients' characteristics at baseline were not similar: in phase 2 there were twice as many patients working in the medical sector. This difference can be explained by the fact that the question was not precise enough. It was asked only if the patients worked in the medical sector. But does working in the medical sector include people working in the administrative department of a hospital? This question will in future be specified (ANNEXE 9). However, the two populations were comparable at baseline

for other aspects and subgroup analysis on "the medical sector " showed no difference. This did not have an impact on results.

Leaflets selected under samples according to the changes in medical practice (investigations, drug prescriptions, and instructions). The groups of phase 1 and 2 were therefore not comparable, explaining why we did not proceed to measure GA score. A reading of the questionnaire had been held with all interviewers before the start of phase 2. In spite of this, telephone interviewers in phases 1 and 2 were different, inducing an investigator bias. In this study, DPC score was different between the 2 interviewers ($p = 0,014$). Keeping the same interviewers in different phases of a study is essential to minimize this bias. Conducting a RCT would have avoided it, however it was not possible due to lack of financial resources.

3.1.3. Center effect

The center of Chambéry included very few patients (16 %). This may reflect a center effect related to the absence of the coordinator on site. Thus it was not possible to proceed to analyzes in subgroups.

3.1.4. Follow-up

There was a high percentage of lost to follow-up (14%) compared to other studies with telephone data collection (8,16). We can imagine that they correspond to the less satisfied patients. In addition, this is perhaps related to the time of day at which patients were called. To avoid this, patients were asked when they wished to be called and reported it on the inclusion sheet. Moreover, PILs as a subject of research may be considered by patients as less important than research on medication.

Another explanation is that in this study children were included, and the median age was 37,5 [24-56].

One hypothesis explaining the high number of lost to follow-up is that younger people may be:

- less often ill and recover more quickly from their illnesses,
- not as concerned as older people about their health
- give less importance to medical research.

However, the percentage of lost to follow-up between phase 1 (12 %) and phase 2 (14 %) (13,14) remains similar.

Finally, 15 patients were included by error, mainly at the start of the study. Inclusion criteria were therefore posted in the emergency medical rooms of the two centers to minimize errors.

3.1.5. Memorization bias

Some patients had trouble remembering what had happened inducing difficulties in answering the questionnaire. To minimize this bias, a delay of 7 to 10 days after the consultation was chosen. This left enough time for patients to take their medicine for at least a week and to go for further tests (to evaluate adherence). In addition, the organization of the collection of remote consultation data allowed patients not to be influenced by the presence of a doctor.

3.1.6. Questionnaire

It was often considered too long by patients but it seemed difficult to make a shorter questionnaire (5 questions for satisfaction, 13 questions for the DPC, 6 questions for the Morisky score, 4 questions for medication adherence and 4 questions for non medication adherence). Moreover, this questionnaire comprises several scales, which can be used separately in future studies. Some patients did not understand the issues or the nuances of the questions and of the answers of the Likert scale.

This scale is subjective and the questionnaire should contain examples of rephrasing questions and precise instructions for use.

A revised questionnaire with clarifications for future studies is available (ANNEXE 9).

3.2. Strengths

3.2.1. The number and choice of pathologies

The number of six pathologies was chosen to be exhaustive compared to other studies. In our RCT table, 76 % of studies dealing with PILs in acute context evaluated only one PIL (16–18, 23, 25, 31, 33) (ANNEXES 2 and 2 bis). Some studies evaluated more than one PIL: 4 PILs on patient behavior for patients consulting for gastroenteritis or tonsillitis (8). Arnold in 2009 studied if giving written information (4 PILs) to patients with acute chest pain decreased anxiety; improved health related quality of life; satisfaction with care; or modified subsequent symptoms or actions (9).

It was also a good compromise between the completeness (evaluation of two different acute clinical situations: trauma and infectious medicine) and feasibility. Moreover, these pathologies are frequently encountered in emergency services. The support and advice given in PILs are twofold: medicinal and non-medicinal (lifestyle and dietary rules, proposed follow-up and additional examinations), according to recommendations (7,45), unlike others studies not describing any methodology (18). The majority wrote PILs without respecting all the criteria (9) (ANNEXES 2 and 2 bis). This way both sides of global adherence could be assessed.

3.2.2. Scores

Three generic scales (DPC, satisfaction and GA scores) created by a multidisciplinary team (doctors, psychologists...) and validated in previous studies (13,14) were used. The use of these scales could allow a comparison of different pathologies with a single tool measurement, which has never been done in the literature.

Moreover, this is the first study examining PILs and the relationship between 3 major and complementary health indicators: DPC, satisfaction and GA.

The originality of the study is that this is the only study that evaluated:

- PILs drafted according to recommendations
- For 6 acute pathologies
- Through 3 generic scales validated
- With an adhesion scale evaluating both medication and non-medication adherence

4. Generalization

PILs are therefore a quality tool for improving patient healthcare, benefiting both the patient and the doctor. In addition, the different generic scales could be used in other studies for or any type of intervention and pathology.

THESE SOUTENUE PAR : Marisa TISSOT et Julie TYRANT

TITRE : « Etude EDIFIP : Evaluation De l'Impact des Fiches Information Patient sur la communication médecin malade, la satisfaction et l'adhérence globale du patient pour 6 pathologies aiguës infectieuses et traumatique, dans 2 services d'urgences. Etude interventionnelle multicentrique avant-après »

CONCLUSION

Doctor-patient communication is an essential part of the relation between the doctor and his patient. Patient information leaflets created for the management of acute illnesses aim at improving the quality of information given to the patient. Our before-after study explored the role of written information in the management of 6 acute illnesses (medical and traumatic), in an emergency ward, as a means of improving communication between doctor and patient. We used 3 validated scales (doctor-patient communication, satisfaction and global adherence scales) in a "before-after" study to ensure comparability. In this prospective multicenter study, patients consulting in 2 emergency departments (Grenoble and Chambéry) for an acute condition (medical or traumatic) were included. 7 to 10 days later, they were reached by phone and answered questionnaires.

First, analysis of 168 patients (14,2 % were lost to follow-up) showed that PILs improved DPC (p -value = 0,002). In phase 1, the median was 44 [38-48]. In phase 2, DPC score's median was 46 [42-49]. Our analysis also showed that with leaflets, there were almost twice as many patients who found that DPC was very good (DPC score > 50). They represent those who recommend the department. Furthermore, we observed half as many patients who thought that DPC was insufficient (DPC score

≤ 35). They represent a target to reduce complaints. Moreover, our results showed that DPC and satisfaction increased when our leaflets were explained to patients. Then, PILs modified patient's behavior: more patients (93,5 % in phase 2 versus 84,3 % in phase 1, Pr = 0,019) took their medication as indicated (at a specific time, on an empty stomach or during a meal). Finally, physicians' practices were also modified by our PILs. We observed a decrease in drug prescriptions (77,3 % in phase 2 were prescribed drugs versus 85,9 % in phase 1, Pr = 0.049) and an increase in medical investigations (83,9 % patients were given a prescription for further exams, an appointment with a specialist or a follow-up compared to 62,8 % in phase 1, Pr = 0.000) and instructions to follow (73,2 % were given advice compared to 57,4 % in phase 1, Pr = 0.003).

Written information is a precious tool for patients and doctors. The use of PILs modifies patients' and doctors' behavior, leading to better healthcare.

VU ET PERMIS D'IMPRIMER

Grenoble, le 06/11/15

LE DOYEN


J.P. ROMANET


LE PRESIDENT DE LA THESE

PROFESSEUR J. L. BOSSON


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ANNEXE 1 : Research equations

Les mots clés MeSH (et leurs synonymes) utilisés pour notre recherche bibliographique étaient : « Acute disease », « Pamphlets », « Physician patient relations », « Ambulatory care », « Primary health care », « Emergency medical services ».

Deux premières équations de recherche ont été effectuées :

1. « Acute disease » + « Pamphlets » : 9 résultats

"acute disease"[MeSH Terms] AND "pamphlets"[MeSH Terms] AND ((Clinical Trial[ptyp] OR Review[ptyp]) AND ("1979/01/01"[PDAT] : "2015/12/31"[PDAT]))

2. « Acute disease » + « Physician patient relations » : 33 résultats

"acute disease"[MeSH Terms] AND "physician-patient relations"[MeSH Terms] AND ((Clinical Trial[ptyp] OR Review[ptyp]) AND ("1979/01/01"[PDAT] : "2015/12/31"[PDAT]))

Afin de réaliser une recherche exhaustive, nous avons également effectué 4 autres équations de recherche:

3. « Pamphlets » + « Physician patient relations » : 30 résultats

"pamphlets"[MeSH Terms] AND "physician-patient relations"[MeSH Terms] AND ((Clinical Trial[ptyp] OR Review[ptyp]) AND ("1979/01/01"[PDAT] : "2015/12/31"[PDAT]))

4. « Pamphlets » + « Ambulatory care » : 4 résultats

"pamphlets"[MeSH Terms] AND "ambulatory care"[MeSH Terms] AND ((Clinical Trial[ptyp] OR Review[ptyp]) AND ("1979/01/01"[PDAT] : "2015/12/31"[PDAT]))

5. « Pamphlets » + « Primary health care »: 51 résultats

"pamphlets"[MeSH Terms] AND "primary health care"[MeSH Terms] AND ((Clinical Trial[ptyp] OR Review[ptyp]) AND ("1979/01/01"[PDAT] : "2015/12/31"[PDAT]))

6. « Pamphlets » + « Emergency medical services »: 26 résultats

"pamphlets"[MeSH Terms] AND "emergency medical services"[MeSH Terms] AND ((Clinical Trial[ptyp] OR Review[ptyp]) AND ("1979/01/01"[PDAT] : "2015/12/31"[PDAT]))

Au total, 153 résultats ont été obtenus. Après double lecture, 16 essais randomisés et 24 revues de littérature ont été retenus pour leur pertinence en rapport avec notre travail.

ANNEXE 2 : Tableur résumé des RCT évaluant l'impact des FIP pour des pathologies aiguës

Author, date	Objective	Methodological quality	Design	Setting	Population	Intervention	Primary outcomes	Conclusions
Arnold, 2009	To determine whether providing an information sheet to patients with acute chest pain reduces anxiety, improves health related quality of life, improves satisfaction with care, or alters subsequent symptoms or actions.	Very good: very few criteria are missing	Randomised, controlled	Hospital (emergency department)	700 consecutive patients with acute chest pain	A. oral information (n=351) B. Oral information + PIL (n=349)	1. Anxiety 2. Depression 3. Satisfaction 4. Behavior	1-2. Non significant reduction of anxiety and depression 3-4. No impact on satisfaction and behavior
Sustersic, 2013	To describe the impact of 4 PILs on the subsequent behavior of patients evaluating the specific effect of PIL, regardless of the pathological context.	Good: few criteria are missing	Randomised, controlled, multicenter, cluster trial	Ambulatory	388 patients with gastroenteritis or tonsillitis	A. Oral information + PIL (n=181) B. Oral information (n=207)	1. Behavior 2. Knowledge	1. Fewer visits for the same symptoms by household members of patients 2. Increase of knowledge
Little, 2004,	To assess the impact of leaflets encouraging patients to raise concerns and to discuss symptoms or other health related issues in the consultation.	Good: few criteria are missing	Randomised, controlled, multicenter	Ambulatory, GP (5)	636 consecutive patients	A. General leaflet B. Depression leaflet C. General + depression leaflets D. No leaflet	1. Satisfaction 2. Consultation time 3. Doctor's behavior (number of prescriptions, investigations)	1. Increase of satisfaction with general leaflet, more effective with shorter consultations 2. Non-significant increase in consultation time 3. Increase of the numbers of investigations with general leaflet.

Francis, 2009	To establish whether an interactive booklet on respiratory tract infections in children reduces reconsultation for the same illness episode, reduces antibiotic use, and affects future consulting intentions, while maintaining parental satisfaction with care.	Good: few criteria are missing	Randomised, controlled, multicenter, cluster trial	Ambulatory	558 children with an acute respiratory tract infection (7 days or less).	A. Interactive booklet (n= 274) B. Usual consultation (n= 284)	1. Rate of reconsultation 2. Future consulting intentions 3. Satisfaction 4. Antibiotic prescriptions	1.No impact on number of reconsultation 2. Fewer future intentions to consult for the same symptoms 3. No impact on satisfaction 4. Reduction of antibiotic prescriptions
Turpin, 2005	To assess the efficacy of providing information booklets to patients serially attending an Accident and Emergency (A&E) department following physical injury	Good: few criteria are missing	Randomised, controlled	Emergency room	291 patients randomised who attended A&E	A. Booklet mailed (n=146) B. A letter (n=145)	1. PTSD (Post-Traumatic Stress Disorder) scale 2. Anxiety 3. Depression	1. Non significant reduction of PTSD 2. Non significant reduction of anxiety 3. Reduction of depression
Heaney et al, 2001	To investigate the effect of patient information booklets on overall use of health services, on particular types of use, and on possible interactions between use, deprivation category of the area in which respondents live, and age.	Intermediate: some criteria are missing	Randomised, controlled, multicenter	Ambulatory, GP (20)	4953 patients	A. Leaflet What Should I Do? (n= 1702) B. Health Care Manual (n= 1688) C.No leaflet (n= 1563)	1. Use of health services	1.No impact on health service use for either booklet

Little, 2005	To estimate the effectiveness on symptoms, beliefs, and behavior of 3 prescribing strategies and an information leaflet for acute lower respiratory tract infection.	Very good: very few criteria are missing	Randomised, controlled, factorial design	Ambulatory, GP (37)	Patients with uncomplicated acute illness (21 days).	I. PIL A. Immediate antibiotics (n= 129) B. Delayed antibiotics prescription (n= 136) C. No offer of antibiotics (control) (n= 140) II. No PIL A. Immediate antibiotics (n=133) B. Delayed antibiotic prescription (n=136) C. No offer of antibiotics (control) (n= 133)	1. Symptom duration and severity 2. Satisfaction 3. Reporting antibiotics use 4. Reconsultation rate	1. No impact on symptom duration and severity 2. Decrease of satisfaction in the "delayed" and control group 3. Reduction antibiotics use in the delayed and control groups 4. Increase of reconsultation rate with leaflet
Macfarlane et al, 2002	To assess whether sharing the uncertainty of the value of antibiotics for acute bronchitis in the form of written and verbal advice affects the likelihood of patients taking antibiotics.	Good: few criteria are missing	Randomised, controlled, single blinded	Ambulatory , GP (3)	259 consecutive patients with acute bronchitis	I. No antibiotics (n=212) A. Leaflet (n= 106) B. No leaflet (n= 106) II. Antibiotics (n=47)	1. Antibiotic use 2. Reconsultation for the same symptoms	1. Reduction of antibiotic use for patients receiving leaflet in group 1 2. No impact of PILS on reconsultation rate
Coudeyre, 2006	To compare the efficacy of an information booklet or oral information about back pain in reducing disability and fear-avoidance beliefs among patients with subacute and chronic low back pain referred to a rehabilitation department.	Intermediate: some criteria are missing	Randomised, controlled, alternate-month design	Hospital	142 patients with subacute or chronic low back pain	A. Written information: (the "back book")+ usual therapy (n= 72) B. Oral information + usual therapy (n=70)	1. Disability 2. Knowledge 3. Satisfaction 4. Fear-avoidance beliefs	1. Reduction of disability 2. Increase of knowledge 3. Increase of satisfaction 4. Non significant effect on fear-avoidance beliefs.

Mac Farlane, 1997	To investigate the impact of providing a simple leaflet regarding the natural history of Lower Respiratory Tract (LRT) symptoms on reconsultation rates for previously well adults presenting to their GP with an LRT infection.	Intermediate: some criteria are missing	Randomised, controlled, single blinded	Ambulatory, GP (76)	1014 adults with lower respiratory tract infection	A. Leaflet (n= 505) B. No leaflet (n= 501)	1.Reconsultation for the same symptoms	1. Reduction of reconsultation rate with leaflet
Robinson, 2013	To examine the role of fear following Whiplash-Associated Disorder (WAD) and assessed the effectiveness of three treatments targeting fear.	Intermediate: some criteria are missing	Randomised, controlled	Ambulatory?	191 patients with WAD symptoms	A. Informational booklet (IB) (n= 57) B. IB + didactic discussions (DD) (n=64) C. IB + imaginal and direct exposure desensitization (ET) to feared activities (n=70)	1. Pain severity 2. Fear of specific neck movements.	1. Reduction of pain severity with ET 2. Reduction of fear levels with ET
Altiner, 2007	To assess the efficacy of an educational intervention that aimed to reduce unnecessary antibiotic prescriptions in primary care by motivating GPs to change their attitudes to communication and by empowering patients.	Good: few criteria are missing	Cluster-randomised, controlled	Ambulatory, 104 GPs (104)	1651 consecutive patients with acute cough	A. GPs (n=52) visiting by GP peers + patient leaflet + poster for the waiting room (n= 753 patients) B. Control group: no intervention (n=52 GPs) (n= 898 patients)	1. Rate of antibiotic prescriptions	1. Reduction of antibiotic prescriptions

Morrell, 1979	To measure the effect of this booklet on the pattern of medical demand of patients registered with a group practice with an attached health visitor providing medical care.	Poor: many criteria are missing	Randomised, controlled	Ambulatory, GP	999 individuals in the practice with at least one child under the age of 5 years and identified from the attached health visitor's record	A. Booklet (n=521) B. No booklet (n=478)	1. Rate of patient-initiated consultations	1. No impact on mean number of patient-initiated consultation. For some symptoms (sore throat, diarrhoea and vomiting, fever and abdominal pain), reduction of patient-initiated consultation
Anderson, 1980	To measure the mother's knowledge of the management of the symptoms described.	Poor: many criteria are missing	Randomised, controlled (pilot study of Morell's study)	Cf previous study	Cf previous study	Cf previous study	1. Knowledge 2. Use of booklet 3. Behavior	1. No impact on knowledge 2. 76% of patients refer to the booklet at some time 3. No impact on behavior
Gauld, 1981	To discover, firstly, whether reinforcing spoken instructions with written advice improves patients' recall of advice and, secondly, whether it improves compliance with both medication and advice.	Poor: many criteria are missing	Prospective, randomised, controlled	Ambulatory, GP (18)	62 female patients with urinary tract symptom and for whom the doctor prescribed an antibiotic.	A. Oral information + leaflet (n=30) B. Oral information (n=32)	1. Recall 2. Compliance 3. Satisfaction	1. Increase of recall 2. No impact on compliance in either medicine taking or the behavioural aspects of the advice. Lower compliance for patients under 25 than in patients in two older age ranges. 3. Increase of satisfaction

Everitt, 2006	To assess different management strategies for acute infective conjunctivitis.	Good: few criteria are missing	Open, factorial, randomised, controlled	Ambulatory, GP (30)	307 patients with acute infective conjunctivitis	<p>I. Immediate antibiotics (n= 104) A. Leaflet (n=49) B. No leaflet (n=55)</p> <p>II. Delayed antibiotics (n=109) A. Leaflet (n=53) B. No leaflet (n=56)</p> <p>III. No antibiotics (n=94) A. Leaflet (n=48) B. No leaflet (n=46)</p>	<p>1. Severity of symptoms 2. Duration of symptoms 3. Antibiotic use 4. Belief in the effectiveness of antibiotics for eye infections.</p>	<p>1. No impact on severity of symptoms 2. Lower duration of moderate symptoms with antibiotics. 3. Increase of antibiotic use in the immediate antibiotic group 4. Increase of belief in the effectiveness of antibiotics in the immediate antibiotic group</p>
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ANNEXE 2 bis : Tableur résumé des revues évaluant l'impact des FIP pour des pathologies aiguës

Author, year	Type of review	Protocol		Number of studies	Number of patients	Population	Outcomes	Impact
		Intervention : description	Methodologic quality/PRISMA checklist					
Forster et al, 2012	Systematic review	Patient information leaflet (PIL) versus usual care/ PIL and another intervention versus the same intervention	Very good	21 randomised trials	2289	Stroke and transient ischaemic attack	Knowledge about stroke and stroke services, impact on mood	Patient knowledge, carer knowledge, one aspect of patient satisfaction, patient depression scores + Number of cases of anxiety or depression in patients, carer mood or satisfaction, death -
Henrotin et al, 2006	Systematic review	Information-based intervention (booklet, video program, multimedia campaign, Internet-based information)	Good	11 RCT	8558	Low back pain (acute or chronic)	Pain, disability, return to work, use of health resources or patient's knowledge, beliefs, attitudes about back pain	Knowledge + Absenteeism - Healthcare use +/-
Raynor et al, 2007	Systematic review	Written information (WI) vs nothing/ WI + verbal information vs verbal information/ WI vs WI (2 or more information interventions)/ WI vs various interventions/ WI risk descriptor vs WI risk descriptor	Very good	64 papers reporting 70 studies: 36 papers reporting 43 RCTs in the effectiveness strand and 28 in the role and value strand	/	/	Treatment-related knowledge, treatment-related attitudes (satisfaction with information, perceived health or side-effect risk, intention to comply with or favour treatment, rating of side-effect severity), treatment-related behaviour (relating to taking the medicine or reporting of side-effects)	Knowledge +/- Adherence to treatment instructions in long-term therapy or change the reporting of side-effects -
Kitching, 1990	Literature review	/	Poor	30 studies	/	/	Knowledge, compliance, therapeutic outcome	Knowledge + Compliance and therapeutic outcomes +/-
Nicolson et al, 2009	Systematic review	Interventions using WI about an individual medicine, such as information contained in a medicine pack insert or a supplementary leaflet intended for the medicine user	Very good	25 RCT	4788	Written medicines information for chronic conditions, for acute conditions and for both chronic and acute conditions	Knowledge, changes in patients' attitudes towards taking the medicine, changes in patients' medicine-taking behaviour, changes in patients' health outcomes	Knowledge + Attitudinal and behavioural outcomes +/-

Author, year	Type of review	Protocol		Number of studies	Number of patients	Population	Outcomes	Impact
		Intervention : description	Methodologic quality/PRISMA checklist					
Grime et al, 2007	Systematic review	WI on specific medicines, from the perspective of patients and professionals	Good	27 studies (17 quantitative, 9 qualitative, 1 qualitative and quantitative)	/	/	Compliance, decision-making, ways in which patients and professionals use written information and a set of factors which patients and professionals use to evaluate the material	The policy initiative and compliance studies reported that most patients were generally positive about written information received
Kenny et al, 1998	Literature review	/	Poor	/	/	/	The patient's and doctor's perspective, "what makes a good leaflet", clinical content of leaflet, the best use of leaflet, "A case for clinical trials?", storage, retrieval and distribution of leaflets, patient leaflets with medicines, computer-generated leaflets, the drawbacks of computer-generated leaflets	/
Trevena et al, 2006	Systematic review	Decision aids/ PIL/ Videos/ Websites/ Tailored computer programs/ Verbal advice/ Structured counselling compared to no tool or other tools	Good	10 systematic reviews of RCTs and 30 additional RCTs	/	Case scenario: PSA screening for prostate cancer	Understanding, knowledge, comprehension, satisfaction with decision, adherence to decision, anxiety, decisional conflict, involvement in decision-making	Understanding and knowledge in health care decision making +
Johnson and Sandford, 2005	Systematic review	Effectiveness of written discharge information + verbal information with verbal information provision only	Good	2 RCT	320	Acute thermal injury, otitis media	Knowledge, satisfaction	Knowledge and satisfaction +

Author, year	Type of review	Protocol		Number of studies	Number of patients	Population	Outcomes	Impact
		Intervention : description	Methodologic quality/PRISMA checklist					
Morris and Halperin, 1979	Literature review	WI vs usual pharmacy dispensing procedures/ 1 group: intramuscular injections, the 2nd group: prescription + "routine verbal instructions" given to parents, 3rd group of parents: prescription, counseling + WI / WI with counseling vs usual pharmacy services/ WI with medication vs no WI/ WI vs counseling of a pharmacist or a nurse/ Intensive program including brochures, slide-tape presentations, pill taking reminders.../ WI and a sticker for the medication container that reiterated dosage instructions vs no WI/ Verbal and WI vs verbal instructions/1) only verbal instructions 2) verbal instructions + a medication calendar or 3) verbal instructions + a medication identification card	Poor	/	/	Oral contraception, streptococcal pharyngitis, hypertension, asthma, tuberculosis, a vaginal cream and the Progestasert intrauterine device	Compliance, knowledge, visits to the emergency rooms, pill counts, reporting and experience of adverse reactions	Knowledge of information, such as precautions, side effects, or special directions + Reporting of adverse reactions +/- Compliance -
McDonald et al, 2002	Systematic review	Instructions (oral + WI + programmed learning)/ Increased communication + counseling/ Ways to increase the convenience of care (provision at the work-site, simplified dosing)/ Involving patients more in their care through self-monitoring of their blood pressure, seizures, or respiratory function/ Reminders/ Dose-dispensing units of medication + medication charts/ Reinforcement or rewards for both improved adherence and treatment response	Good	33 RCT	/	30 studies were concerned with chronic diseases and 3 studies with acute infections	Clinical outcome (ex: throat culture, adverse effects, urea breath test, blood pressure...), adherence outcome (ex: presence of drug in urine, telephone interview and pill count, patient self-report, nurse assessment...)	Medication adherence and treatment outcomes +/-
De Bont et al, 2015	Systematic review	Information leaflet or interactive booklet vs no intervention	Very good	8 studies (7 RCT, 1 non randomised study)	3407	Respiratory tract infections, conjunctivitis, urinary tract infections, gastroenteritis and tonsillitis	Antibiotic prescription rates and antibiotic use, reconsultation during the same illness episode and intention to reconsult	Reducing antibiotic prescription by GPs, and antibiotic use by patients and their intention to reconsult for future similar episodes of illness + Reconsultation rates +/-

Tableur des autres revues évaluant l'impact des fiches

Author, year	Type of review	Protocol		Number of studies	Number of patients	Population	Outcomes	Impact
		Intervention : description	Methodologic quality according to PRISMA checklist					
Köpke et al, 2014,	Systematic review	1. Patient information leaflet (PIL) 2. Educational programmes or lectures 3. Audiovisual aids 4. Web 2.0 systems 5. decision support tools 6. personal information	Very good	10 RCT	1314	Multiple sclerosis	Disease-related knowledge measured by any type of instrument used in the included studies, measures of shared-decision making	No adverse event, knowledge + Effects on decision making quality of life -
McPherson et al, 2001	Systematic review	PIL, audiotapes, audiovisual aids or interactive media	Good	10 RCT	/	Cancer	Knowledge acquisition, recall, understanding, use of educational resources, preferences for information, attitudes toward the intervention, uncertainty and satisfaction, affective states (depression, anxiety, expectations, mood state, fears about the appointment), symptom management, expectations, health service utilization, coping	Knowledge and recall, symptom management, satisfaction, preferences, health care utilization and affective states + Psychological indices -
Montgomery, 2006 (updated version, 1st version in 2001)	Systematic review	Media-based therapy (audiotape, book, computer manual, videotape, or some combination). The comparison group could be a no-treatment group, a waiting-list group or a standard treatment group (a series of face-to-face therapy sessions delivered by a clinical psychologist, psychiatrist or social worker)	Very good	10 RCT, 1 quasi RCT	943	Behavioural problems in childhood	Incidence or severity of externalising or internalising behaviour problems including sleep problems, rates of study attrition, need for medication or other therapies, economic outcomes	Media-based therapies when compared with both no-treatment controls and as and adjunct to medication, addition of up to 2 hours of therapist time +
Desplenter et al, 2006	Systematic review	PIL / PIL + counselling/ Patient +/- family guidelines: PIL + read aloud, PIL + read aloud + questions and experiences/ Individual educational session + group discussion + questions + PIL/ Oral + PIL oral + audiotape, oral + PIL + audiotape/ PIL read aloud + review group + PIL/ Easy, moderate, difficult readable PIL/ 1 or 3 educational sessions/ Written presentation of consent form, oral presentation of consent/ Oral information on side-effects, oral + written information (WI) on side-effects/ Oral + WI on beneficial effects/ Drug counselling Control : no intervention/ Usual advice / Printed information read aloud/ No oral + no WI on beneficial or side-effects/ Standard oral education	Good	17 RCT	/	Mental illness	Adherence, knowledge of the medication such as name, dosage, side-effects and benefits, clinical (measurements of side-effects, symptoms, admissions and relapses), humanistic (measurement of satisfaction and quality of life of participants)	Adherence, knowledge + Satisfaction, frequency of side-effects, relapse or admission rates, symptoms and quality of life -

Van der Meulen et al, 2008	Systematic review	Individual education from a nurse vs additional general take-home instructional video /Audiotaped recording of their consultation and written recommendations vs written recommendations only /General audiotape about cancer vs patients receiving an audiotape of their consultation vs standard consultation /Audiotapes of bad news consultations with a physician vs standard consultation /Audiotaped recording of the consultation but no provided copy vs a copy of the consultation to take home /Audiotape on recall of information vs a standard consultation /Audiotape of the consultation with a physician vs group control group /Letter and then, the tape vs the tape followed by a letter /Summary letter after the consultation vs no letter /Standard care vs question prompt sheet (QPS) which was actively endorsed by the doctor vs QPS which was not actively endorsed	Very good	8 RCT, 1 CT, 1 RT	/	Cancer	Recall of information	Recall with audiotape, QPS endorsed by doctor + Recall with general audiotape or letter -
Gaston and Mitchell, 2005	Systematic review	Interventions to improve information giving (audio recording of consultation + written summary/ Patient held record with patient input, postal survey of health professionals/ Sending individual summary letter to patient,survey of doctors/ Consultation tape vs general info tape vs no tape/ Tape vs no tape vs choice of having tape/ Video based on (written information) WI vs WI alone/ Offering tape of consultation/ Consultation tape vs summary letter/ Professionally made video + standard WI), interventions to improve participation in treatment decisions (question prompt sheet with/without endorsement by doctor, coaching, control, question prompt sheet vs PIL, prompt sheet vs PIL, computer programme to identify info/ Participation preferences and coach in use, effect of giving audiotape on 2nd consultation)	Good	12 RCT, 3 RT, 32 uncontrolled, observational, qualitative studies	/	Advanced cancer	Patient preference for involvement in the decision-making process, knowledge of diagnosis, prognosis and aims of treatment,knowledge or understanding, psychological outcome, satisfaction with the encounter, anxiety	Anxiety, satisfaction, knowledge and understanding + Psychological outcome -
Friedman et al, 2011	Systematic review	Teaching intervention (traditional lectures, discussions, simulated games, computer technology , written material, audiotapes, videotapes, verbal, demonstration) vs standard care (control) and teaching intervention vs another teaching intervention	Very good	23 systematic reviews and meta-analyses	/	Chemotherapy, type 2 diabete, asthma, analgesia	Knowledge, anxiety, satisfaction	Knowledge, anxiety, satisfaction +

Zapata et al, 2013	Systematic review	Exposure to some written material (e.g., patient package insert, brochure)	Good	9 studies: 3 RCTs, 1 intervention study and 5 descriptive studies	/	Contraception	Knowledge of MPI after exposure to written material, impact of different types of MPI, women's intended actions after missing pill in response to online guidance, MPI on women's comprehension, knowledge and understanding of MPI	Knowledge + Women's intended actions after missing pill -
Laccourreye et al, 2008	Literature review	PIL delivered during a consultation before programmed surgery	Poor	/	/	Surgery	Recall, patient's perception of information on the risks	Recall, anxiety +/-
Galaal et al, 2011 (updated version, 1st version in 2007)	Meta-analysis	Written information /Educational and counselling (pre-colposcopy sessions, telephone) /Cognitive behavioural therapy /Drugs /Hypnotherapy /Acupuncture /Relaxation therapy /Music /Video colposcopy (1) PIL vs no information leaflets (2) PIL and video + counselling vs information leaflets and video + no counselling (3) Listening to music during colposcopy vs usual care (no music) (4) PIL + information video vs PIL only (active comparison)	Very good	6 RCT	886	Colposcopic examination	Anxiety, quality of life measures, patient satisfaction, psychosexual scores (all using a validated scale), pain during and after colposcopy, knowledge	Knowledge, patient quality of life, psychosexual dysfunction + Anxiety -
Fox, 2006	Literature review	PIL vs an illustrated decision aid /Mailed leaflet vs usual care /Mailed leaflet or video vs usual care /PIL vs conventional information /PIL vs a video vs an evidence-based booklet /Evidence-based midwifery care PIL vs usual care /PIL vs PIL and video vs expanded PIL vs expanded PIL + video /Genetic testing PIL vs breast cancer information /basic vs extended information	Very good	9 RCT	/	Screening programs (prostate cancer, antenatal, genetic, pancreatic cancer)	Knowledge, attitudes to screening, intention to be screened, uptake, anxiety, satisfaction with decision-making, discussions about screening with care providers and agreement that enough information had been provided to allow informed choice	Knowledge + Informed choice -
Pelletier et al, 2014	Systematic review	Administration of self-help materials, such as PIL/ Faxed referrals to other programs, such as tobacco cessation phone programs/ Delivery of brief advice to quit/ Counseling/ Nicotine replacement therapy (NRT)/ Motivational interviewing-based interventions. Most studies compared 2 or more of these interventions; however, a standard control group was not present across the studies reviewed	Very good	13 RCT	/	Smoking cessation	Smoking cessation rate, patient satisfaction	Satisfaction + Cessation intervention groups - (except for 2 studies reporting significant differences in cessation using motivational interviewing-based interventions)

Abréviations et légende des tableaux

WI: written information
MPI : missed pill instructions

+ Impact positif

- Absence d'impact

+/- Résultats discordants

ANNEXE 3 : CONSORT sheets

1. Arnold, 2009

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	<u>1</u>
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<u>1</u>
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	<u>1</u>
	2b	Specific objectives or hypotheses	<u>1</u>
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	<u>1-2</u>
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	<u>/</u>
Participants	4a	Eligibility criteria for participants	<u>2</u>
	4b	Settings and locations where the data were collected	<u>2</u>
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	<u>2</u>
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	<u>2-3</u>
	6b	Any changes to trial outcomes after the trial commenced, with reasons	<u>/</u>
Sample size	7a	How sample size was determined	<u>3</u>
	7b	When applicable, explanation of any interim analyses and stopping guidelines	<u>/</u>
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	<u>2</u>
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	<u>2</u>
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	<u>2</u>
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	<u>2</u>
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	<u>/</u>
	11b	If relevant, description of the similarity of interventions	<u>2</u>
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	<u>3</u>

	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	/
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	2
	13b	For each group, losses and exclusions after randomisation, together with reasons	2-3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	4-5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	4
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	4-5
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	6

2. Sustersic, 2013

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Rationale for using a cluster design	3-4
	2b	Whether objectives pertain to the the cluster level, the individual participant level or both	4
Methods			
Trial design	3a	Definition of cluster and description of how the design features apply to the clusters	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for clusters	4
	4b	Settings and locations where the data were collected	4
Interventions	5	Whether interventions pertain to the cluster level, the individual participant level or both	4
Outcomes	6a	Whether outcome measures pertain to the cluster level, the individual participant level or both	4-5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Details of stratification or matching if used	6
Allocation concealment mechanism	9	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	4
	10a	Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	
Implementation		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	
		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomization	

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	/
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	How clustering was taken into account	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	6
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	6
	13b	For each group, losses and exclusions for both clusters and individual cluster members	6
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	/
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each group	7
Numbers analysed	16	For each group, number of clusters included in each analysis	6
Outcomes and estimation	17a	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	6-7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	7
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8
Generalisability	21	Generalisability to clusters and/or individual participants (as relevant)	/
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	9

3. Little, 2004

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	<u>1</u>
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<u>1</u>
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	<u>1</u>
	2b	Specific objectives or hypotheses	<u>1</u>
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	<u>/</u>
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	<u>/</u>
Participants	4a	Eligibility criteria for participants	<u>1</u>
	4b	Settings and locations where the data were collected	<u>1-2</u>
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	<u>2</u>
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	<u>2</u>
	6b	Any changes to trial outcomes after the trial commenced, with reasons	<u>/</u>
Sample size	7a	How sample size was determined	<u>1</u>
	7b	When applicable, explanation of any interim analyses and stopping guidelines	<u>/</u>
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	<u>2</u>
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	<u>2</u>
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	<u>2</u>
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	<u>/</u>
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	<u>/</u>
	11b	If relevant, description of the similarity of interventions	<u>/</u>
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	<u>2</u>
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	<u>2</u>

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	2
	13b	For each group, losses and exclusions after randomisation, together with reasons	2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	1
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	2-3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	/
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	3
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4

4. Francis, 2009

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Rationale for using a cluster design	1-2
	2b	Whether objectives pertain to the the cluster level, the individual participant level or both	2
Methods			
Trial design	3a	Definition of cluster and description of how the design features apply to the clusters	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for clusters	2
	4b	Settings and locations where the data were collected	2
Interventions	5	Whether interventions pertain to the cluster level, the individual participant level or both	2
Outcomes	6a	Whether outcome measures pertain to the cluster level, the individual participant level or both	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	2
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Details of stratification or matching if used	2 (block sizes, stratification)
Allocation concealment mechanism	9	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	2
Implementation	10	Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	2
		Mechanism by which individual participants were included in clusters for the purposes of the trial	/

		(such as complete enumeration, random sampling)	/
		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomization	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	/
	11b	If relevant, description of the similarity of interventions	3 (telephone interviewers)
Statistical methods	12a	How clustering was taken into account	3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	3
	13b	For each group, losses and exclusions for both clusters and individual cluster members	3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	/
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each group	4
Numbers analysed	16	For each group, number of clusters included in each analysis	5
Outcomes and estimation	17a	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	5 to 7
Generalisability	21	Generalisability to clusters and/or individual participants (as relevant)	5
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	4 to 7
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	7

5. Turpin, 2005

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	<u>1-2</u>
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<u>2</u>
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	<u>2</u>
	2b	Specific objectives or hypotheses	<u>2</u>
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	<u>2</u>
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	<u>/</u>
Participants	4a	Eligibility criteria for participants	<u>2</u>
	4b	Settings and locations where the data were collected	<u>2</u>
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	<u>2</u>
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	<u>2-3</u>
	6b	Any changes to trial outcomes after the trial commenced, with reasons	<u>/</u>
Sample size	7a	How sample size was determined	<u>3</u>
	7b	When applicable, explanation of any interim analyses and stopping guidelines	<u>/</u>
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	<u>2</u>
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	<u>/</u>
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	<u>/</u>
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	<u>2</u>
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	<u>/</u>
	11b	If relevant, description of the similarity of interventions	<u>/</u>
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	<u>3</u>
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	<u>3</u>

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3
	13b	For each group, losses and exclusions after randomisation, together with reasons	3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	2
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	5
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5 (non comparable groups)
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	6
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	5
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	7

6. Heaney, 2001

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	<u>1</u>
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<u>1</u>
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	<u>1</u>
	2b	Specific objectives or hypotheses	<u>1-2</u>
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	<u>2</u>
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	<u>/</u>
Participants	4a	Eligibility criteria for participants	<u>2</u>
	4b	Settings and locations where the data were collected	<u>2</u>
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	<u>2</u>
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	<u>2</u>
	6b	Any changes to trial outcomes after the trial commenced, with reasons	<u>/</u>
Sample size	7a	How sample size was determined	<u>2</u>
	7b	When applicable, explanation of any interim analyses and stopping guidelines	<u>/</u>
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	<u>2</u>
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	<u>2</u>
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	<u>/</u>
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	<u>/</u>
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	<u>2 (nurses)</u>
	11b	If relevant, description of the similarity of interventions	<u>/</u>
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	<u>2</u>
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	<u>2</u>

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3
	13b	For each group, losses and exclusions after randomisation, together with reasons	/
Recruitment	14a	Dates defining the periods of recruitment and follow-up	/
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	/
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	/
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3-4
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	/
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	3-4
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4

7. Little, 2005

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	3029
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3029
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3029-3030
	2b	Specific objectives or hypotheses	3030
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3030 (factorial)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	3030
	4b	Settings and locations where the data were collected	3031
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3030-3031
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3031
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	3030
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	3030
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3030(block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3030
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3030
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	/
	11b	If relevant, description of the similarity of interventions	+/- 3031(notes review)

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	3031
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3031
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3032
	13b	For each group, losses and exclusions after randomisation, together with reasons	3032
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3031
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	3032
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3032
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	3032-3033
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	3031 (placebo)
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3034-3035
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	3034-3035
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	3034-3035
Other information			
Registration	23	Registration number and name of trial registry	/
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	3035

8. Mac Farlane, 2002

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	1
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	1
	4b	Settings and locations where the data were collected	1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	3
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	1-2 (permuted block sizes)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	2 (sealed envelope)
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	2 (GP, research assistant)
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	4
	13b	For each group, losses and exclusions after randomisation, together with reasons	3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	1
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	/
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	/
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	3-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	4-5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	4-5
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	4-5
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	4 (creation of leaflet)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	5

9. Coudeyre, 2006

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	600
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	600
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	601
	2b	Specific objectives or hypotheses	602
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	602
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	602
	4b	Settings and locations where the data were collected	602
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	602
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	602-603
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	602
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	/
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	602 (alternate-month design)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	/
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	602(patients)
	11b	If relevant, description of the similarity of interventions	/

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	603
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	/
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	604
	13b	For each group, losses and exclusions after randomisation, together with reasons	603
Recruitment	14a	Dates defining the periods of recruitment and follow-up	/
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	603
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	/
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	603 to 605
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	606-607
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	605 to 607
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	605-606
Other information			
Registration	23	Registration number and name of trial registry	600
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	/

10. Mac Farlane, 1997

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	719
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	719
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	719
	2b	Specific objectives or hypotheses	719
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	719
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	719
	4b	Settings and locations where the data were collected	719
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	719
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	719
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	/
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	/
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	719 (block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	719
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	719 (GP)
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	/
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	/

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	720
	13b	For each group, losses and exclusions after randomisation, together with reasons	720
Recruitment	14a	Dates defining the periods of recruitment and follow-up	/
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	/
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	720
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	720
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	720-721
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	721
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	720-721
Other information			
Registration	23	Registration number and name of trial registry	719
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	/

11. Robinson, 2013

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	/
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1-2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	+/-2 (referrals)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3-4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	/
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3 (block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	/
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	/
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5-6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	5-6

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13
	13b	For each group, losses and exclusions after randomisation, together with reasons	3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	/
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16-17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	/
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	6-7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	9
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	7 to 9
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	/

12. Altiner, 2007

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a cluster randomised trial in the title	<u>638</u>
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<u>638</u>
Introduction			
Background and objectives	2a	Rationale for using a cluster design	<u>638-639</u>
	2b	Whether objectives pertain to the the cluster level, the individual participant level or both	<u>639</u>
Methods			
Trial design	3a	Definition of cluster and description of how the design features apply to the clusters	<u>639</u>
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	<u>/</u>
Participants	4a	Eligibility criteria for clusters	<u>639</u>
	4b	Settings and locations where the data were collected	<u>639</u>
Interventions	5	Whether interventions pertain to the cluster level, the individual participant level or both	<u>639-640</u>
Outcomes	6a	Whether outcome measures pertain to the cluster level, the individual participant level or both	<u>+/- 640</u>
	6b	Any changes to trial outcomes after the trial commenced, with reasons	<u>/</u>
Sample size	7a	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty	<u>639</u>
	7b	When applicable, explanation of any interim analyses and stopping guidelines	<u>/</u>
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	<u>639</u>
	8b	Details of stratification or matching if used	<u>639 (pairs)</u>
Allocation concealment mechanism	9	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	<u>639</u>
Implementation	10	Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	<u>/</u>
		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	<u>/</u>
		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	<u>/</u>

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	/
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	How clustering was taken into account	641
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	641
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	642
	13b	For each group, losses and exclusions for both clusters and individual cluster members	642
Recruitment	14a	Dates defining the periods of recruitment and follow-up	641
	14b	Why the trial ended or was stopped	/
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each group	643
Numbers analysed	16	For each group, number of clusters included in each analysis	641-642
Outcomes and estimation	17a	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	/
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	641
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	642-643
Generalisability	21	Generalisability to clusters and/or individual participants (as relevant)	643-644
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	642 to 644
Other information			
Registration	23	Registration number and name of trial registry	638-639
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	644

13. Morell, 1979

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	/
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	/
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	769
	2b	Specific objectives or hypotheses	769
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	769
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	769
	4b	Settings and locations where the data were collected	769
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	769
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	/
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	/
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	/
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	/
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	/
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	769 (doctors)
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	770
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	770

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	770
	13b	For each group, losses and exclusions after randomisation, together with reasons	/
Recruitment	14a	Dates defining the periods of recruitment and follow-up	769
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	/
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	/
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	770
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	770
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	/
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	771
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	770-771
Other information			
Registration	23	Registration number and name of trial registry	/
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	771

14. Anderson, 1980

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	/
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	924
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	924
	2b	Specific objectives or hypotheses	924
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	/
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	924
	4b	Settings and locations where the data were collected	924
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	924 (study group)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	+/- 924
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	/
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	/
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	/
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	/
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	924 (interviewers)
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	/

	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	/
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	924
	13b	For each group, losses and exclusions after randomisation, together with reasons	924
Recruitment	14a	Dates defining the periods of recruitment and follow-up	/
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	/
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	/
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	924-925(no confidence interval and p value)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	/
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	925
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	925-926
Other information			
Registration	23	Registration number and name of trial registry	/
Protocol	24	Where the full trial protocol can be accessed, if available	924(previous study)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	926

15. Gauld, 1981

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	553
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	553
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	553
	2b	Specific objectives or hypotheses	553
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	553
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	553
	4b	Settings and locations where the data were collected	554-555
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	554
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	554-555
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	/
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	/
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	/
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	/
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	/
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	554 (interviewers)
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	555

	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	/
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	555
	13b	For each group, losses and exclusions after randomisation, together with reasons	555
Recruitment	14a	Dates defining the periods of recruitment and follow-up	/
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	/
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	/
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	555
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	556
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	556
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	555-556
Other information			
Registration	23	Registration number and name of trial registry	553
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	/

16. Everitt, 2006

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	1
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	/
Participants	4a	Eligibility criteria for participants	1
	4b	Settings and locations where the data were collected	1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	2
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	2
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	2 (block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	2 (sealed opaque envelopes)
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	2 (GPs, nurses)
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	2
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	2

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	2
	13b	For each group, losses and exclusions after randomisation, together with reasons	/
Recruitment	14a	Dates defining the periods of recruitment and follow-up	1
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	3
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3 to 5 (in tables)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	2 to 4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	/
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	5
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	5
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	/
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	5-6

ANNEXE 3 bis : PRISMA sheets

1. Forster, 2012

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4 (no registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5 (OS not fully described)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8-9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	78-79-80-81-82-95-96-106-107-110-113-114
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	76-77
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	7
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	11-12-14-15
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	17
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	18
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	18
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	19

2. Henrotin, 2006

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no discussion on limitations, no registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1-2 (no mention of study design)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	/
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3-4
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	7-8
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	8
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	8
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	1 (no fund)

3. Raynor, 2007

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	5
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	15-16-17
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	17
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	21-22
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	21-22
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	115 →121
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	23-24
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	24-25-27 125 →131
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	25 125→131
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	25
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	27-23
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	/
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	31-36-40-46-47-49-50-52-54-56-57-59-61-63-64-66-133→147
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	48-53-60-62
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	133 →147
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	47
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	81
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	81-82
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	103
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	4

4 Kitching, 1990

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	/
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	/
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	/
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	/
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	/
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	/
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	/
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	/
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	3
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	/
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

5 Nicolson, 2009

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4 (no review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6 (not all PICOS described)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6 (no access described)
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	62
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7-8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	25→44
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9-10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	50→61
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	9-10
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	15
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	64

6. Grime, 2007

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (not all PICOS mentioned)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2-3 (not all characteristics mentioned)
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2 (not all databases mentioned)
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2-3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	3
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	/
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	3 (authors requested additional data)
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2-3
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	4-5
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	11

7. Kenny, 1998

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1 (review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (only results, no systematic review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	/
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	/
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	1
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta analysis).	/
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	/
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	/
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	/
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	6-7
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	7
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

8. Trevena, 2006

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no discussion of limitations, no registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (no mention of outcomes or study design)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2-3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	3
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2-4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	3-4
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	4
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	4
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	4-5
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6-7
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	8
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	8
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

9. Johnson, 2005

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (not all criteria mentioned)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (not all PICOS described)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2-3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	3
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	4
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	5-6
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	6
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	6
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

10. Morris, 1979

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (literature review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (not fully detailed)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1-2 (not all PICOS mentioned)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	/
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	/
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	/
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	/
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	/
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	2-3-4-5 (not fully detailed)
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	5
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	5
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

11. Mc Donald, 2002

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no systematic review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2-3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2-3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	4-5-6-7
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9-10
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	10
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	11
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	11

12 . De Bont, 2015

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (not all PICOS described)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2 (items not listed)
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	2
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	2 (5 authors were contacted of which 2 provided additional details, publication bias not assessed)
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2-4
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	2-4
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	6
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	6-7
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	7
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	8

13. Fox, 2006

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (Literature review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (PICOS not fully detailed)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3-4-5
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	6
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	3-4-5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	3-4-5
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	6
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	7
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	7
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	8
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

14. Galaal, 2011

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5 (study design not mentioned)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	5-6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	31-32
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7-8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	9

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7-8-9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	9
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	19→24
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	11-12
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	12-13-27→30
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	12-13
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	33

15. Zapata, 2013

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 comparisons, outcomes, study design not mentioned)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	2
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3→7
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	3→7
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	3→7
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9-10
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	10
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	10-11 (no mention of future research)
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

16. Laccourreyre, 2008

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (extremely brief summary)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1 (very briefly)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	/
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	/
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	/
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	/
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	/
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	1-2-3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	/
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	4
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	4
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

17. Friedman, 2011

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no data sources, no limitations, no registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	1-2 (not all PICOS described)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	8
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	/
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	2
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2 (only number of studies included is mentioned)
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	4-5-6 (results presented in the text, not in a table)
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	4-5
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	7
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	7
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	8
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	8

18. Van der Meulen, 2008

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (not all PICOS mentioned)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	2
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	2-3

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	3
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	4-5
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	3
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	4-5
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	7-8 (Best Evidence Synthesis)
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	8
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	8
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	9
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	9
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

19. Gaston, 2005

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (not all criteria mentioned)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (not all PICOS described)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	/
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	/
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	3→7
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	/
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	/
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9-10
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	9
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	10
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

20. Desplenter, 2006

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no systematic review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	2
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2 (study design not mentioned)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	/
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	3
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3 (no list)
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	/
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	4
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6-7-8
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	11
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	9-10
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	5-8
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	8-9
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	12
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	/

21. Montgomery, 2001

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	4-5 (no review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6 (not all PICOS mentioned)
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	/
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	43
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7-8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8-9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-21→28
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9-10-21→28
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	31→42
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	10
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	13-14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	/
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	45

22. Pelletier, 2014

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (no review registration number)
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Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	2
METHODS			
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Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	2
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	2
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	9
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	2-3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	2
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	2-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	2-3
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	/
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	/

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	2-3
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	/
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	3-7
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	4-5-7
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	7
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6 (no effect estimates or confidence intervals)
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	/
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	3
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	/
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	8
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	8
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	8
FUNDING			
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23. Mc Pherson, 2001

Section/topic	#	Checklist item	Reported on page #
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Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1 (not all criteria mentioned)
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24. Köpke, 2014

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	/ (review)
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4 (no review registration number)
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	6-7
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Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	57
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RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10-11
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	29→48
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	15-16-17
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	5 (no effect estimates or confidence intervals)
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DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20-21
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	21
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	22
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Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	58

ANNEXE 4: Lisibility score and PILs

Score de lisibilité (score de Flesh) appliqué aux FIP:

Pathologie	ASL	ASW	Score total
Entorse	430/90	1,82	68,2
Pyélonéphrite aigue	379/89	1,92	61,37
Prostatite aigue	352/77	1,91	61,80
Pneumopathie	353/77	1,85	66,19
Diverticulite	310/85	1,94	60,52
Entérocolite infectieuse	263/78	1,95	60,06

ASL = nombre de mots/nombre de phrases

ASW = nombre moyen de syllabes/ nombre de mots

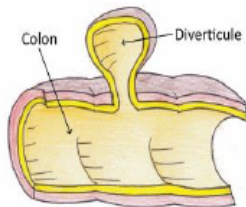
Score de Flesh total = $207 - (1,015 \times \text{ASL}) - (73,6 \times \text{ASW})$

La diverticulite aigue



Les points clés

Les diverticules sont des zones de faiblesse ou petites poches dans la paroi de l'intestin. Ils concernent près de 50% de la population après 70 ans, ils sont liés à l'âge. Ils ne sont pas une maladie.

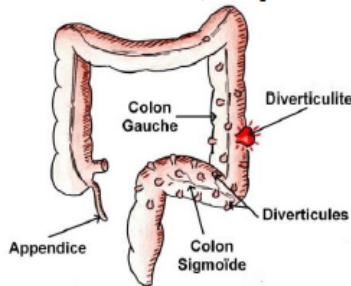


Les diverticules ne donnent pas de signes en dehors d'une complication : une infection (diverticulite) ou une hémorragie.



Les signes

- > Douleurs du bas ventre
- > Fièvre
- > +/- Troubles du transit (constipation ou diarrhée).



L'évolution à court terme

Au début, l'infection reste au niveau de la paroi intestinale. Les signes s'améliorent en général en 48h avec le traitement.

Consultez un médecin. Parfois, une hospitalisation sera nécessaire.

Sans traitement, l'infection peut se compliquer :

- D'un abcès
- D'une perforation : la péritonite
- D'une fistule : un conduit anormal avec un autre organe à proximité (ex : vessie, utérus)
- D'un arrêt du transit : l'occlusion intestinale.



L'évolution à long terme

Le risque de récurrence est fréquent. En cas de récurrences fréquentes ou de forme compliquée une chirurgie est parfois proposée.



Le diagnostic

L'examen clinique est complété par :

- une prise de sang à la recherche de signes infectieux
- un scanner ou une échographie dans un délai court à la recherche de complications.



Le suivi

Consultez un gastro-entérologue pour discuter d'une coloscopie. Elle sera réalisée après l'épisode aigu (à 2 mois).



La prise en charge



Le traitement

- **PARACETAMOL** (si fièvre, douleurs) ;
- **ANTIBIOTIQUES** : Respecter la durée prescrite ;
- **GLACE** sur le ventre : cela peut soulager ;
- **ANTI-SPASMODIQUES** ;
- **EVITER LES ANTI-INFLAMMATOIRES ET CORTICOIDES** (aspirine, ibuprofène...).



Les conseils hygiéno-diététiques

- **BIEN BOIRE** de l'eau toute la journée
- **REGIME SANS RESIDUS** (voir tableau) tant que les signes persistent. Reprenez peu à peu une alimentation normale. Commencez par les légumes et fruits cuits puis crus.

Aliments déconseillés

- Légumes et fruits crus ou cuits
- Viande et poisson en sauce, charcuterie
- Les céréales, pain complet
- Lait, fromage fermenté
- Œufs frits, omelette
- Graisses (huile, mayonnaise...), épices, alcool
- Pâtisseries

Aliments autorisés

- Riz, pain blanc, biscotte
- Poisson et viande cuits sans matière grasse
- Œufs durs
- Fromage blanc, yaourt nature, fromages à pâte cuite (gruyère etc)
- Biscuits secs, sucre
- Compote pomme-coing, pomme-banane



Quand revoir votre médecin ?

- > Dans les 48 heures pour contrôle de l'évolution
- > Si votre état ne s'améliore pas ou s'aggrave.

Nom et signature du médecin :

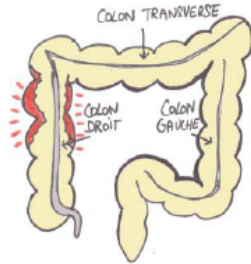
Rédigé par Dr M.SUSTERSIC, M.TISSOT
nov.2014//Relecteurs : Dr ROUSSEAU, Dr BERTHELET et
Dr FRICAMPS-PIRONI. Sources : HAS 2006, EM-consulte,
snfge, pubmed 2014 ; ssmg.be avril 2012//Contact :
melaniesustersic@yahoo.fr, marisa_tissot@hotmail.fr
//Illustration : P-Y Rabattu.

Entérocolite infectieuse



Les points clés

L'entérocolite infectieuse est une inflammation aiguë (<14 jours) du colon. Elle est liée à la présence anormale de germes dans l'intestin (virus, bactérie ou parasite).



Les signes

- Douleurs au niveau du ventre
- Diarrhée (parfois avec du pus, des glaires ou du sang)
- +/- Nausées, vomissements
- +/- Fièvre; fatigue ou soif intense.



L'évolution

Le plus souvent, vous vous sentirez mieux en quelques jours.



Les risques

Ils sont rares :

- Déshydratation (en cas de diarrhée abondante)
- Infection sévère
- Hémorragie (en cas de diarrhée sanglante).



Le diagnostic

Parfois, des examens sont utiles :

- La coproculture (analyse des selles fraîches) à la recherche de germes;
- Une prise de sang (à la recherche de signes infectieux) ;
- Rarement, un scanner et/ou une coloscopie pour préciser le diagnostic ou la gravité de l'infection.

Nom et signature du médecin :



La prise en charge



Le traitement

- ANTIBIOTIQUES (si diarrhée bactérienne). Respecter la durée prescrite ;
- GLACE sur le ventre, pour soulager la douleur ;
- PARACETAMOL: si fièvre ou douleur ;
- ANTI-SPASMODIQUES
- ANTI-VOMITIFS



Les conseils hygiéno-dietétiques

- SE LAVER LES MAINS (pour éviter la contamination)
- DESINFECTER LA CUVETTE DES WC à chaque passage
- BIEN BOIRE de l'eau toute la journée
- REGIME SANS RESIDUS (voir tableau) : tant que les signes persistent. Reprenez peu à peu une alimentation normale. Commencez par les légumes et fruits cuits puis crus.

Aliments déconseillés

- Légumes et fruits crus ou cuits
- Viande et poisson en sauce, charcuterie
- Les céréales, pain complet
- Lait, fromage fermenté
- Œufs frits, omelette
- Graisses (huile, mayonnaise...), épices, alcool
- Pâtisseries

Aliments autorisés

- Riz, pain blanc, biscotte
- Poisson et viande cuits sans matière grasse
- Œufs durs
- Fromage blanc, yaourt nature, fromages à pâte cuite (gruyère etc)
- Biscuits secs, sucre
- Compote pomme-coing, pomme-banane



Quand revoir votre médecin ?

- A 48h-72h pour contrôler l'évolution
- Si votre état ne s'améliore pas ou s'aggrave.

Rédigé par: Dr M. SUSTERSIC // Actualisation: TISSOT M. ; TYRANT J décembre 2014 // Révisé par: Dr Raouf, Dr Barthelet, Dr Fricamps-Prou // Sources: HAS 2006, Société Nationale Française de Gastro-Entérologie, Elsevier Masson, FMC gastro-entérologie, Vidal recommandations // Contact : ssmg.be 2012//melaniesustersic@yahoo.fr // Illustration : Meles

Pyélonéphrite de l'adulte



Les points clés

Il s'agit d'une infection du rein. Elle est souvent due à une infection urinaire (cystite) passée inaperçue ou négligée. Elle concerne surtout la femme.

Les symptômes

- Fièvre et/ou des frissons
- Douleurs dans le rein ou le dos, parfois dans le bas du ventre
- Parfois, brûlures urinaires, envie fréquente d'uriner, urines troubles ou teintées de sang, troubles digestifs (nausées, diarrhées).

Les causes

Le plus souvent, liée à des bactéries de l'intestin ou du vagin. Lorsqu'elles prennent un chemin anormal (les voies urinaires), elles infectent d'abord la vessie (causant une infection urinaire), puis parfois les reins (la pyélonéphrite).

Les facteurs favorisants

- Le contexte : boissons insuffisantes; rapports sexuels; constipation; diarrhée; grossesse, etc...
- Une pathologie urologique (calculs dans les reins, reflux vésico-urétéral ...)

L'évolution et les risques

En général, l'évolution est favorable avec les antibiotiques. Parfois, l'infection peut être grave et mettre en jeu la vie.



La prise en charge

L'examen clinique

Son but : chercher des signes de gravité imposant une hospitalisation (malaise, tension basse, infection rénale récente). Une analyse d'urines est d'abord réalisée par bandelette urinaire (résultats instantanés). Il sera complété par :

- une analyse d'urines
- une prise de sang
- parfois, une échographie des voies urinaires (ou un scanner selon les cas)

Nom et signature du médecin :

L'analyse d'urines au laboratoire

Faire d'abord une toilette intime avec des compresses, de l'eau stérile et du savon ;

- Chez les femmes : aller d'avant en arrière pour la toilette, et écarter les grandes lèvres ;
 - Chez les hommes : décalotter
- Puis recueillir les urines du milieu du jet dans le flacon stérile.

Le traitement

- **ANTIBIOTIQUES** à la maison ou à l'hôpital (par la bouche ou en piqûre) : essentiels à la guérison. A débiter le jour même, après l'analyse d'urines, sans attendre les résultats. Respecter la durée prescrite (7 à 21 jours selon les cas). Ne pas les stopper (même en cas d'amélioration avant la fin du traitement).

- **PARACETAMOL** : à prendre toutes les 6 heures si fièvre ou douleurs.

- **BOIRE** +/- 1,5 litre d'eau par jour. Le but : éliminer les bactéries.

Le suivi

Revoir votre médecin dans les 2 à 3 jours qui suivent l'épisode. Il s'assurera :

- de l'efficacité du traitement (grâce aux résultats d'analyse d'urines obtenus en 48 heures) ;
- de l'absence de complications sur l'imagerie.

Il prévoira parfois une analyse d'urines de contrôle à distance.



Eviter les récurrences

Quelques conseils (non prouvés par la science) :

- Ne pas se retenir d'uriner ;
- Uriner après chaque rapport sexuel ;
- S'essuyer d'avant en arrière ;
- Toilette intime régulière, sans excès (une fois par jour, pas de douches vaginales) avec du savon doux ;
- Lutter contre la constipation (manger des fibres, des fruits et légumes,...) ;
- Bien boire (> 2 L d'eau par jour)



Quand reconsulter?

- Si la fièvre persiste après 72 h d'antibiotiques ;
- Si les signes réapparaissent ;
- Pour tout renseignement.

Rédigé par: Dr A Meneau/ Avril 2011. Actualisation J.Tyran/janvier 2015.
Relecteurs: Dr J Vanderstraeten, Dr Forestier. Sources: SPILF juin 2014; ANAES 2000 ; AFSSAPS 2002, 2005 et 2008; E.Pily 2012 item 93 ;Recommandations du CIAFU, Progrès en Urologie 2008. Contact: aurelia.meneau@free.fr
Illustration: O.Roux.

La prostatite aiguë



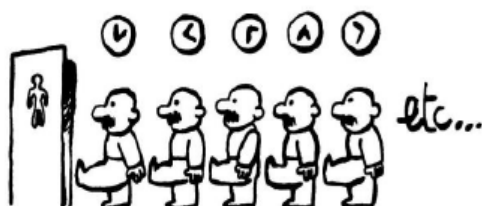
Les points clés

La prostate est une glande qui entoure l'urètre, canal qui conduit l'urine de la vessie à la verge. Elle produit le liquide de transport des spermatozoïdes. Quand elle s'infecte, on parle de prostatite aiguë.



Les signes

- Fièvre et/ou frissons
- Malaise, courbatures
- Signes urinaires: brûlures urinaires ; envies fréquentes d'uriner ; difficultés pour uriner ; urines teintées de sang.
- Parfois : douleurs dans le bas-ventre; en regard du pénis ou de l'anus.



Les causes

- Certaines bactéries de l'intestin peuvent emprunter de manière inappropriée les voies urinaires et s'y multiplier.
- Certaines bactéries contractées lors de rapports sexuels non protégés peuvent infecter la prostate.

Les facteurs favorisants:

- une baisse du volume des urines (peu de boissons, urines retenues).
- des troubles du transit (constipation, diarrhée).
- tout obstacle à l'écoulement des urines (adénome de prostate, calcul dans les reins, cancer de prostate...).



Evolution et risques

- Elle est en général favorable avec les antibiotiques.
- Parfois, l'inflammation est telle que les urines ne passent plus. On parle de **rétenion aigue d'urine**. Il faut faire un sondage en urgence pour évacuer les urines.
- Négligée, la prostatite peut évoluer vers une septicémie (infection générale), un abcès de prostate, une pyélonéphrite (infection d'un rein) ou encore vers une prostatite chronique.

NB. Les signes peuvent durer 2 à 3 jours après le début du traitement.

Nom et signature du médecin :



La prise en charge



Le diagnostic

L'examen médical et l'analyse d'urine par bandelette urinaire vont confirmer le diagnostic et éliminer les signes de gravité.

Des examens sont nécessaires :

- une analyse d'urines
- une prise de sang
- une échographie de la prostate et des reins.



Le traitement

Il est réalisé en ville ou à l'hôpital. Il comprend :

- **DES ANTIBIOTIQUES** (essentiels à la guérison). A prendre le jour même après avoir fait l'analyse d'urines et sans attendre les résultats. Respecter la durée prescrite. Le traitement est long (10 à 21 jours) pour être efficace.
- **PARACETAMOL** (en cas de douleurs ou de fièvre).



Les mesures associées

Buvez au moins 1.5 litres d'eau par jour afin d'éliminer les bactéries et de compenser les pertes d'eau liées à la fièvre. Privilégiez des sous-vêtements serrés (type slip ou boxer).



Le suivi

- Consultez au 2^{ème} et 7^{ème} jour après le début du traitement pour contrôler l'évolution et vérifier l'efficacité du traitement.
- Dans certains cas, une analyse d'urines de contrôle ou un bilan urologique seront nécessaires.



Eviter les récives

- Boire au moins 1,5 l d'eau par jour ;
- Ne pas se retenir d'uriner;
- Régulariser le transit (lutter contre la constipation ou la diarrhée).



Quand reconculter ?

- Si la fièvre réapparaît.
- Si des douleurs dans le dos surviennent.
- Si les signes persistent au-delà de 3 jours ou réapparaissent dans le mois.

Rédigé par Dr Sustersic, Mars 2012//Actualisation : TYRANT J. Janvier 2015//sustersic.melanie@gmail.com // Relecteurs: Pr. Stahl, Dr Forestier // Sources: 1. Recommandations SPILF juin 2014 2. Afsaps :2010; 3. Urofrance 2011/ Progres en urologie 2008// Illustration: O.Roux.

Pneumopathie



Les points clés

La pneumonie ou pneumopathie est une infection des alvéoles du poumon (l'endroit qui permet de faire passer l'oxygène dans le sang). Elle peut être grave et entraîner le décès.



Les signes

Vous pouvez avoir :

- une fièvre de plus de 38 °C;
- une toux, des crachats;
- du mal à respirer;
- une douleur sur le côté du thorax;
- un pouls rapide.

Vous n'avez probablement ni rhume, ni angine. Chez les personnes âgées et les enfants, les signes sont souvent moins francs.

Les causes de l'infection

Des bactéries sont en cause 1 fois sur 3. Le reste du temps, l'infection est due à un virus (grippe, rougeole, etc). La contamination se fait par les sécrétions respiratoires d'un individu malade (transmission lors de la toux).

Quels sont les risques?


Les pneumonies sont de gravité très variable. Les ¼ guérissent avec le traitement à la maison. Les autres nécessitent un traitement à l'hôpital. Certaines peuvent avoir des complications graves (surtout chez les personnes âgées, les personnes qui ont une maladie chronique):

- insuffisance respiratoire;
- diffusion de l'infection à une grande partie du poumon, à la plèvre (l'enveloppe du poumon), voire au reste du corps;
- aggravation d'une autre maladie.

Nom et signature du médecin :



La prise en charge

 **Le diagnostic est parfois difficile**
L'examen clinique permet de suspecter la pneumonie et de chercher des signes de gravité qui imposeraient votre hospitalisation. Votre médecin vous demandera de faire une radiographie des poumons et parfois un scanner pour confirmer le diagnostic. Il pourra vous prescrire une prise de sang ou une analyse d'urine.

Le traitement

Les antibiotiques sont indispensables. Ils mettent 48 à 72 heures avant d'être efficaces (baisse de la fièvre). Vous devez les prendre pendant toute la durée prescrite (de 7 à 14 jours en général), même si vous vous sentez mieux avant.

Surveillance

Consultez votre médecin 48-72h après le début du traitement antibiotique pour le suivi.

Les autres mesures

Évitez de fumer tant que vous êtes malade. Buvez bien, surtout si la fièvre est importante. Votre médecin pourra vous demander de faire une radiographie de contrôle après la guérison.



Prévention

Pour éviter la transmission, quelques règles d'hygiène essentielles:

- se laver les mains après s'être mouché;
- mettre la main devant la bouche lors de la toux;
- jeter à la poubelle les mouchoirs usagés;
- mettre un masque jetable.

Que pouvez-vous faire pour limiter le risque de pneumopathie?

- arrêter de fumer;
- vous faire vacciner contre le pneumocoque selon les conseils de votre médecin (personnes fragiles...).



Quand reconsulter ?

- si la fièvre persiste plus de 3 jours malgré le traitement ou si elle réapparaît;
- si votre essoufflement augmente;
- si de nouveaux signes apparaissent.

Rédigé par: A. Meneau / juillet 2011. Actualisation: TISSOT Marisa / janvier 2015. Relecteur : Dr Forestier. Sources: Cochrane 2009, AFSSAPS 2010 et 2005, SPILF 2006, Recommandation et pratique 2005, Pilly 2014 Contact: memauiat@hotmail.com, marisa_tissot@hotmail.fr
Illustration: O.Roux.

Entorse de la cheville



Les points clés

Les ligaments de la cheville stabilisent l'articulation lors de la marche. Ils s'insèrent de chaque côté de la cheville et du pied. Lorsque l'on se tord la cheville, les ligaments sont sollicités de manière excessive. Certaines fibres sont étirées ou déchirées et on parle d'entorse de cheville.



Les signes

Lors de la torsion, la cheville peut "craquer". La douleur apparaît d'emblée ou plus tard. Un œdème de la malléole apparaît tout de suite ou au bout de quelques heures (le plus souvent la malléole externe). Parfois un bleu apparaît. Lorsque les ligaments sont déchirés, la cheville peut être instable. La douleur peut être telle que l'appui est impossible.

Les facteurs favorisants

Votre cheville est plus fragile:

- si vous avez déjà eu une entorse de cheville;
- si vos chaussures ne sont pas adaptées à l'activité;
- si vos lacets sont mal serrés.

Le diagnostic

L'examen de votre médecin est souvent suffisant. Dans certains cas, la réalisation de radiographies et/ou échographie sera nécessaire.

L'évolution et les risques

Les ligaments cicatrisent en 30 à 45 jours. Lorsque la rééducation n'est pas faite ou que la reprise du sport est trop précoce, le risque de récurrence est majeur. Les entorses à répétition sont source d'une instabilité car les ligaments ne cicatrisent plus.

Que faire immédiatement ?

Il est conseillé d'appliquer le protocole "RICE" tout de suite après le traumatisme :

R: Repos. Arrêter immédiatement l'activité.

I: Ice. (Glace). Appliquer de la glace entourée d'un linge mouillé sur la cheville pendant 20 à 30 minutes. Répéter l'opération plusieurs fois par jour tant que la douleur et le gonflement persistent

C: Compression. Elle doit être légère, mais suffisante pour limiter les gonflements.

E: Élévation. En position assise ou allongée, surélever la cheville pour diminuer le gonflement.

Nom et signature du médecin :



Le traitement

⇒ Les médicaments

Leur but est de diminuer la douleur et l'inflammation (antalgiques, anti-inflammatoires)

⇒ L'immobilisation

Elle dépend de la gravité de l'entorse (évaluée par le médecin) et de votre degré de gêne à la marche.

- Parfois, des béquilles seront nécessaires, avec reprise de la marche le plus tôt possible.
- Le strapping est réalisé avec des bandages plus ou moins rigides. Il est à refaire tous les 3- 4 jours, lorsqu'il est distendu. Il ne supporte pas l'humidité.
- Les attelles stabilisatrices sont à mettre au-dessus d'une paire de chaussettes en coton pour la durée indiquée par votre médecin, même si la douleur disparaît avant. Vous pouvez l'enlever avec prudence pour la douche.
- Le plâtre est proposé dans certains cas particuliers.

⇒ La chirurgie

Elle est réservée aux entorses graves et à distance du traumatisme. Elle est rarement proposée lors d'une première entorse.

⇒ La kinésithérapie

Elle est essentielle car elle permet de :

- diminuer la douleur et l'œdème ;
- retrouver une mobilité et une stabilité normales ;
- éviter les récurrences,

Commencez-la dès que possible.

⇒ Les mesures associées

La marche est possible dès que la douleur le permet, si vous gardez le strapping ou l'attelle. Le sport pourra être repris selon l'évolution de la rééducation et après l'aval d'un médecin.



Chaussez-vous bien!



Quand revoir votre médecin ?

- ⇒ Votre médecin pour qu'il réexamine votre cheville entre le 3^{ème} et 5^{ème} jour après le début du traitement
- ⇒ Si vous avez mal au mollet ou supportez mal le strapping ou l'attelle.
- ⇒ Si la douleur augmente ou ne cède pas au bout de 5 jours.

Rédigé par: A. Meneau, M.Sustersic / Juin 2010. Actualisation : J.Tyrant, M.Tissot / janvier 2015. Relecteurs: Dr GRIMALDI, Dr ORTEGA. Sources: HAS 2012, ANAES 2000 et 2004, Vème conf. de consensus en médecine d'urgence, Cochrane, Elsevier Masson.
Contact: sustersic.melanie@hotmail.fr; Illustration: O.Roux.

ANNEXE 5 : Study protocol

PROTOCOLE

INFORMATIONS GENERALES

Titre : Etude avant-après évaluant l'impact de 6 Fiches Information Patient (entorse de cheville, pyélonéphrite aiguë, prostatite, pneumopathie, colite infectieuse, diverticulite) sur la communication médecin malade (CMM) lors d'une consultation pour pathologie aiguë dans deux services d'Urgences Médicales. Mesure de l'impact sur l'adhérence globale et la satisfaction des patients consultant dans deux services d'urgences.

Méthodologie : Étude observationnelle multicentrique prospective à partir de données déclaratives

Investigateurs coordonnateurs autorisés à signer le protocole: Dr Mélanie SUSTERSIC, Pr Jean-Luc BOSSON

Investigateurs coordonnateurs : Amélie DUVERT, Laure GONNET, Julie TYRANT, Marisa TISSOT, internes en Médecine Générale

Investigateurs : Médecins Urgentistes et Internes (Service d'Urgences de la Clinique Mutualiste à Grenoble et Service d'Urgences du Centre Hospitalier de Chambéry)

Intervenants : Pr Jean-Luc BOSSON (CIC, TIMC IMAG), Dr Aurélie Gauchet (Laboratoire Inter universitaire de Psychologie, UPMF), Pr Benoît ALLENET (TIMC IMAG).

Centre coordonnateur de l'étude : CIC
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PROTOCOLE – RESUME

Investigateurs coordonnateurs autorisés à signer le protocole : Dr Mélanie SUSTERSIC, Pr Jean-Luc BOSSON

Investigateurs coordonnateurs : Amélie DUVERT, Laure GONNET, Julie TYRANT, Marisa TISSOT

Investigateurs : Médecins Urgentistes et Internes (Service d'Urgences de la Clinique Mutualiste à Grenoble et Service d'Urgences du Centre Hospitalier de Chambéry)

Intervenants : Pr. Jean-Luc BOSSON, Pr Benoît ALLENET, Dr Aurélie GAUCHET

Méthodologie : Étude observationnelle multicentrique prospective

Objectif principal : Mesurer l'impact de 6 Fiches Information Patient (FIP) : entorse de cheville, pyélonéphrite aigue, prostatite, pneumopathie, colite infectieuse et diverticulite sur la communication médecin malade (CMM) lors d'une consultation pour pathologie aigue dans deux services d'Urgences Médicales.

Critère de jugement principal : Mesure du score de CMM entre J7 et J10 au décours d'une consultation dans deux services d'urgences.

Objectifs secondaires :

1. Mesure de l'impact de la FIP sur l'adhérence globale des patients consultant dans deux services d'urgences.
2. Mesure de l'impact de la FIP sur la satisfaction des patients consultant dans deux services d'urgences.

Critères de jugement secondaires :

1. Evaluer la corrélation entre CCM et AG
2. Evaluer la corrélation entre CMM et satisfaction
3. Evaluer la corrélation entre AG et satisfaction

Critères d'inclusion principaux : majeur, ou responsable légal accompagnant un mineur âgé de 15 ans et 3 mois ou plus, lettré, francophone, ayant consulté dans un des services d'urgence pour une des pathologies choisies (entorse de cheville, pyélonéphrite aigue, prostatite, pneumopathie, colite infectieuse, diverticulite) et pouvant être joint par téléphone dans les sept à dix jours qui suivent.

Nombre total de sujets à inclure : 200 pour obtenir une précision suffisante dans l'étude descriptive des objectifs principaux (IC95% de l'ordre de $\pm 5\%$)

Durée totale de l'étude : 18 mois

Durée de l'étude par sujet : 7 à 10 jours

I. JUSTIFICATION DE L'ÉTUDE, INTÉRÊT ET CONTEXTE GENERAL

La loi [HPST](#) (Loi n°2009-879 du 21 juillet 2009 portant sur la réforme de l'hôpital et relative aux patients, à la santé et aux territoires) (1) instaure l'obligation de développement professionnel continu (DPC) des professionnels de santé. Selon l'[article 59](#) de cette loi, le DPC a pour objectifs « l'évaluation des pratiques professionnelles, le perfectionnement des connaissances, l'amélioration de la qualité et de la sécurité des soins ainsi que la prise en compte des priorités de santé publique et de la maîtrise médicalisée des dépenses de santé ».

Plus particulièrement, l'arrêté du 26 février 2013 fixe deux orientations nationales particulières pour l'année 2013 :

- « contribuer à l'amélioration de la prise en charge des patients » (via notamment « la connaissance de l'état de santé de la patientèle » et « les programmes d'études cliniques et épidémiologiques visant à évaluer des pratiques »)
- « contribuer à l'amélioration de la relation entre professionnels de santé et patients » (via notamment « le développement de l'information et de l'autonomie du patient ; » et avec des DPC ayant pour objectif « de favoriser le bon usage et l'observance des traitements » ; ainsi que « la formation à la relation professionnel de santé-patient ou au partenariat soignant-soigné. »)

Il n'est pas étonnant que ces deux concepts d'observance thérapeutique (OT) et de communication médecin-malade (CMM) soient à l'ordre du jour des objectifs nationaux de Santé Publique.

En effet, concernant l'OT, selon Haynes « [elle] se définit par l'importance avec laquelle les comportements (en termes de prise de médicaments, de suivi de régime ou de changements de mode de vie) d'un individu coïncident avec les conseils médicaux ou de santé » (3). L'évaluation de l'observance a fait le sujet de nombreuses publications récentes. Améliorer l'observance est une des actions permettant d'atteindre l'un des objectifs principaux des soignants : l'amélioration de l'état de santé et de la qualité de vie des patients (4). Pour l'OMS « Optimiser l'observance médicamenteuse aurait plus d'impact en terme de santé mondiale que le développement de nouveaux médicaments »(5).

L'importance de l'OT a été soulignée, par l'OMS notamment, pour les maladies chroniques principalement (6). Qu'il s'agisse de pathologie aiguë ou chronique, il est pourtant essentiel que tous les patients puissent comprendre et connaître la pathologie et le traitement qui les amènent à consulter (7,8,9).

De plus, la « non observance » a de nombreuses conséquences au niveau médical et économique (4,10).

L'observance est donc une dimension importante qui reflète le comportement du patient en termes de suivi des prescriptions médicamenteuses et des conseils hygiéno-diététiques et ainsi qui est un des reflets de la qualité d'une consultation.

Cependant l'observance est un « phénomène instable, dynamique et modifiable » (11). De nombreux facteurs l'influençant ont été identifiés. L'OMS en répertorie 5 classes, dont ceux liés au système de soins qui comprennent la qualité de la relation thérapeutique (5). De même pour de nombreux psychologues en santé (12), c'est la communication médecin-malade au cours de la consultation qui est cruciale dans la formation de l'observance ou de l'inobservance (11). En effet différents paramètres entrent en compte : la délivrance de l'information et la compréhension de celle-ci par le patient ainsi que la dimension affective de la relation. « Le sentiment d'être compris et informé améliore la compliance » (13).

Les relations thérapeutiques « pauvres » seraient un facteur de non adhésion (4, 14,15,16).

Pouvoir évaluer ces deux paramètres (OT et CMM) facilement, nous paraît donc crucial dans une démarche de DPC, en visant à terme leur amélioration.

Cependant, il n'existe pas dans la littérature de score générique évaluant la communication médecin-malade ni l'observance thérapeutique, pouvant être comparables d'une pathologie à l'autre. Deux scores génériques, un de CMM et un d'observance globale (OG) ont donc été créés à cette fin, par la même équipe de chercheur, lors d'une phase préparatoire (détails dans le protocole).

Notre étude se déroulera en 2 phases :

- Une première phase ayant pour objectif d'une part de faire un état des lieux des niveaux de communication médecin malade (CMM), d'observance globale (OG) et de satisfaction des patients dans un service d'urgences en vue d'améliorer les pratiques ; et d'autre part, l'évaluation des qualités intrinsèques de ces 2 scores (Coefficient de Cronbach). Ces deux scores ont pour but d'être utilisés comme indicateur de la qualité des pratiques professionnelles pour toute situation clinique.
Nous évaluerons dans le même temps les liens de corrélation entre l'OG, la CMM et la satisfaction des patients à l'état basal, dans un service d'urgences. En effet, si ce lien existe, tout programme visant à l'amélioration de la CMM, permettrait donc de ce fait d'améliorer l'OG.
- Puis un deuxième projet (lancement prévu pour l'hiver 2014), aura pour objectif d'évaluer l'amélioration des pratiques professionnelles par l'usage de six Fiches d'Information pour les Patients (entorse de la cheville, pyélonéphrite aigue, prostatite, pneumopathie, colite infectieuse et diverticulite) dans un service d'urgences. Il s'agira d'une étude de type avant/après qui aura pour but de mesurer l'impact sur la CMM, l'OG et la satisfaction des patients de ces six FIP délivrées en complément de l'information orale, au cours de la consultation. Notre projet actuel permettra de décrire les différents scores, de les améliorer en cas de redondance d'information et de justifier précisément les hypothèses du deuxième projet interventionnel de type avant-après.

En effet, l'utilisation de Fiches Information Patient (FIP) est d'usage courant et est l'une des pistes actuelles dans l'amélioration globale des soins ainsi qu'en éducation thérapeutique (17). Notre postulat est que la distribution d'une information écrite (les FIP), délivrée en complément de l'information orale, dans des situations très courantes (les consultations aux Urgences pour des pathologies aiguës et nécessitant une prise en charge médicamenteuse et non-médicamenteuse), permettrait d'améliorer la CMM et l'OG. Si un lien de corrélation était établi entre les deux, il suffirait alors de mesurer isolément la CMM pour obtenir un reflet de la qualité de la prise en charge.

Les FIP que nous utiliserons sont issues d'un premier travail, débuté à l'université de médecine de Grenoble en 2007 (18, 19) qui avait permis d'élaborer une méthodologie d'aide à la réalisation de fiches d'information patient (FIP) puis 125 FIP concernant des pathologies ou des situations courantes en soins primaires.

Enfin, ce sont les spécificités d'un service d'Urgences qui nous ont conduits à choisir un tel service pour la réalisation de cet axe de recherche. En effet, la rapidité des consultations, la nécessité de prendre en charge « l'urgence » et non les « petits-bobos », le peu de temps de communication et d'échange possible entre le médecin et le patient, le temps d'attente, le manque de confidentialité dans la plupart des cas et surtout le problème de l'engorgement des services d'Urgences en France (20,21,22), sont autant de paramètres qui nous ont semblé rendre d'autant plus justifiés cette étude puis l'usage des FIP.

II. OBJECTIF DE L'ETUDE

II.1. Objectif principal :

Mesurer l'impact de 6 Fiches Information Patient (entorse de cheville, pyélonéphrite aigue, prostatite, pneumopathie, colite infectieuse et diverticulite) sur la communication médecin malade (CMM) lors d'une consultation pour pathologie aigue dans deux services d'Urgences Médicales.

Critère de jugement principal :

Mesure du score de CMM entre J7 et J10 au décours d'une consultation dans deux services d'urgences.

Ce score sera mesuré lors d'une enquête téléphonique après la consultation.

II.2. Objectifs secondaires :

1. Mesure de l'impact de la FIP sur l'adhérence globale des patients consultant dans deux services d'urgences
2. Mesure de l'impact de la FIP sur la satisfaction des patients consultant dans deux services d'urgences

Critères de jugement secondaires :

1. Evaluer la corrélation entre CCM et AG
2. Evaluer la corrélation entre CMM et satisfaction
3. Evaluer la corrélation entre AG et satisfaction

III. CONCEPTION DE LA RECHERCHE

III.1. Type d'étude

- Étude observationnelle
- Étude multicentrique
- Étude prospective à partir de données déclaratives

III.2. Organisation générale de l'étude

III.2.1. Schéma expérimental

Enquête par questionnaire téléphonique avec mesure unique à J7-10 pour les 6 situations cliniques. Le patient consulte aux urgences pour une entorse ou une infection. Il est informé de l'étude et donne son accord ou non pour y participer. S'il est d'accord, il remplit la fiche d'inclusion et est appelé dans les 7 à 10 jours pour répondre aux questionnaires.

III.2.2. Déroulement pratique de l'étude

III.2.2.1. Phase préparatoire d'élaboration des questionnaires

Afin de pouvoir évaluer l'observance thérapeutique ainsi que la CMM, avec des scores pouvant être comparables d'une pathologie à l'autre, nous avons créé, lors d'une première phase, des scores d'observance globale et de CMM génériques, communs à toutes les pathologies (et non un score spécifique à chaque pathologie, comme existant dans la littérature).

III.2.2.1.1. Le score d'observance (annexe 1)

Il comprend 2 grandes parties :

- La première partie A/ du questionnaire correspond au score d'observance thérapeutique de Morisky-Green (23)

Il s'agit d'un score validé, adapté à la langue Française et utilisé pour l'hypertension artérielle, très utilisé (il est la référence en matière de pathologies chroniques et est en ligne sur le site de la Sécurité Sociale pour permettre aux médecins d'évaluer l'observance de leurs patients).

Ce score n'a pas été utilisé en situation aiguë sous sa version initiale. Il a donc d'abord été modifié, en adaptant les questions dans le contexte de la situation aiguë par un comité d'experts restreint (Pr JL Bosson, Dr M Sustersic, Dr A Gauchet). Le score reste inchangé sur le fond avec les 6 mêmes questions et la même définition d'un patient non-observant (score ≥ 3).

- La deuxième partie B/ correspond au score d'OG nouvellement créé.

Étant donné qu'il n'existe pas dans la littérature de score générique d'observance concernant les pathologies aiguës, ni de score évaluant à la fois les aspects médicamenteux et non médicamenteux

de l'observance pour les pathologies aiguës, nous avons donc élaboré, un nouveau score composite. Nous nous sommes appuyés sur divers questionnaires dont un score validé utilisé dans l'évaluation de l'observance au traitement du VIH par anti-rétroviraux (13), le SATMED-Q (24) et des questionnaires de l'AHRQ (25).

Nous appellerons le score d'observance nouvellement créé, score d'observance global (OG) par opposition au score d'observance médicamenteuse de Morisky Green ou au concept d'OT défini précédemment. Ce score d'OG comprend 4 sous-dimensions :

- l'observance des prescriptions médicamenteuses (même cible que le score de Morisky Green) ;
- l'observance des prescriptions autres que médicamenteuses (examens complémentaires) ;
- l'observance des règles hygiéno-diététiques ;
- le comportement en termes de consommation de soins (reconsultations...).

Nous mesurons le score de Morisky-Green en première partie, afin de nous appuyer sur un score validé. En effet, si cette deuxième partie, c'est-à-dire notre score d'OG nouvellement créé, s'avère corrélée à la première partie, nous pourrions donc par la suite utiliser le score d'OG de façon autonome, sans avoir à utiliser le score de Morisky-Green.

III.2.2.1.2. Le score de communication médecin-malade (annexe 2) :

Son élaboration a fait l'objet d'une étude préliminaire, menée par la même équipe de chercheurs (médecins, statisticiens, psychologues de la santé, pharmaciens, internes en médecine, et étudiants en psychologie). Une revue de la littérature concernant les différents scores et échelles existants a été effectuée. À partir de ces échelles ont été extraits les items pertinents pour évaluer la CMM (annexe 4 : Méthodologie d'élaboration du score de CMM), ce qui a donné lieu à un nouveau questionnaire de CMM (annexe 2).

III.2.2.1.3. Le questionnaire général : données sociodémographiques et score de satisfaction (annexe 5)

Il a été élaboré pour permettre d'éliminer certains biais dus aux données sociodémographiques et de réaliser des analyses en sous-groupes.

De plus l'analyse de la satisfaction des patients (de façon globale et sur certains détails de la prise en charge) lors de leur passage aux urgences est indispensable pour permettre la validation des modifications de pratiques professionnelles.

Il sera ainsi recherché des liens de corrélation entre satisfaction et CMM ou OG.

III.2.2.2. Recrutement des investigateurs

Prise de contact avec le cadre administratif et le médecin chef du service des Urgences de la Clinique Mutualiste de Grenoble pour leur présenter le projet, ainsi qu'avec le cadre administratif et le médecin chef du service des Urgences du Centre Hospitalier de Chambéry.

Puis courte formation et remise d'une lettre explicative sur l'étude aux médecins urgentistes et internes susceptibles de participer à l'inclusion des patients (annexe 6).

III.2.2.3. Inclusion des patients

Pendant la période d'inclusion, lorsqu'un patient consultera pour une des 6 situations suivantes : entorse de cheville, pyélonéphrite aiguë, prostatite, pneumopathie, colite infectieuse ou diverticulite, le médecin investigateur lui proposera de participer à l'étude et lui remettra le formulaire d'information et de non-opposition (annexe 7), expliquant le déroulement et l'intérêt de celle-ci. Le patient recevra de même une FIP correspondant à la pathologie pour laquelle il a consulté. S'il est d'accord, les médecins rempliront, pour chaque patient, une fiche d'inclusion (annexe 8) qui sera récupérée par les coordonnateurs de l'étude sur place, dans un délai maximum de 3 jours. Cette fiche contiendra tous les éléments d'identification nécessaires à un suivi de qualité. Ces données nominatives ne seront pas

informatisées ; elles serviront uniquement au suivi téléphonique et seuls les résultats seront intégrés à la base de données de façon anonyme.

En cas de refus de participer à l'étude, la case refus de participation sera cochée sur la fiche d'inclusion qui sera remplie le jour de la consultation et récupérée également par les coordonnateurs dans un délai maximum de 3 jours suivant la consultation.

III.2.2.4. Enquête téléphonique

Entre 7 et 10 jours après la consultation du patient aux urgences, nous l'interrogerons par téléphone à l'aide du questionnaire général (annexe 5) et des questionnaires des scores d'OG (annexe 1) et de CMM (annexe 2).

S'il n'est pas joignable la première fois, nous tenterons de le joindre à nouveau 2 fois (nous lui aurons demandé au préalable, lors de l'inclusion, sur quelle plage horaire il désire être contacté). En dernier recours nous appellerons un de ses proches (uniquement si celui ou celle-ci est une personne de confiance, au sens du Code de la Santé Publique, préalablement identifiée par le patient avant l'inclusion.) En cas d'échec le patient sera considéré comme perdu de vue.

III.2.3. Procédures d'investigation menées et différences par rapport à la prise en charge habituelle

La prise en charge se fera de façon habituelle, le patient recevra en plus la FIP correspondant à sa pathologie. Seul un contact téléphonique avec le patient est prévu. Une lettre d'information lui demandant son autorisation lui sera remise (annexe 7).

La procédure d'appel téléphonique du patient entre J7 et J10 est la suivante :

- L'appelant se présentera par son nom et demandera à parler au participant, sans préciser le motif de l'appel à un tiers.
- Puis il se présentera au participant par son nom, son affectation, et fera référence à l'étude, après s'être assuré qu'il s'agit bien du patient lui-même.

III.2.4. Tableau synoptique

Phase préparatoire de 6 mois	Élaboration des questionnaires Prise de contact et formation brève des médecins investigateurs
Phase 1 : J0	Consultation aux urgences et inclusion ou non du patient
Phase 1 : J0 à J7	Retour du patient à domicile
Phase 1 : J7 à J10	Appel du patient et enquête téléphonique avec questionnaire élaboré, recueil de données
Phase 1 : M2-M4	Analyses statistiques des résultats et interprétation
Phase 2 : préparation (1mois)	Elaboration et mise à jour des FIP, modification des questionnaires selon les résultats de la phase 1
Phase 2 : M2 à M11	Inclusion des patients
Phase 2 : M12	Analyses statistiques des résultats et interprétation

IV. POPULATION ÉTUDIÉE

IV.1. Modalités de recrutement des sujets

Patient majeur, ou responsable légal d'un mineur âgé de 15 ans et 3 mois ou plus, qui consulte au service des Urgences de la Clinique Mutualiste de Grenoble pour l'une des 6 pathologies suivantes : l'entorse de cheville, la pyélonéphrite aiguë, la prostatite, la pneumopathie, la colite infectieuse ou la diverticulite.

IV.2. Critères d'inclusion

Seront proposés pour l'étude les sujets répondant à chacun des critères suivants :

- Patient majeur
- Ou responsable légal d'un mineur (âgé de 15 ans et 3 mois ou plus), consultant pour la pathologie de l'enfant
- Patient pouvant être joint par téléphone dans les 7 à 10 jours qui suivent.

IV.3. Critères d'exclusion

Ne pourront pas être inclus les sujets répondant à au moins un des critères suivants :

- Patient analphabète
- Patient refusant le suivi téléphonique
- Patient porteur d'une déficience visuelle ou auditive
- Patient non francophone
- Personne privée de liberté par décision judiciaire ou administrative, personne faisant l'objet d'une mesure de protection légale.
- Patients hospitalisés pour une durée supérieure à 48h.

V. CHOIX DES PATHOLOGIES

Le nombre de 6 pathologies paraît être un bon compromis entre l'exhaustivité (évaluation de 2 situations cliniques aiguës différentes : l'une concernant de la traumatologie et l'autre la médecine infectieuse) et la faisabilité de l'étude.

Nous avons choisi 6 pathologies fréquemment rencontrées dans des services d'urgences et pour lesquelles la prise en charge et les conseils donnés sont doubles : médicamenteux et non médicamenteux (règles hygiéno-diététiques et proposition d'un suivi et d'examens complémentaires), afin que les deux versants de l'observance thérapeutique puissent être évalués.

VI. VARIABLES MESUREES ET METHODES DE MESURE

Réponses aux questionnaires lors de l'enquête téléphonique entre J7 et J10 suivant l'inclusion et calcul des scores.

- Score d'observance (annexe 1) : Le score d'observance médicamenteuse selon Morisky est coté de 0 à 5. Le score d'observance globale proposé par notre équipe comprend 4 sous-dimensions cotées chacune de 1 à 4 selon une échelle de Likert. Le score étant est la médiane des sous-dimensions.
- Score de communication médecin-malade coté sur 52 points (annexe 2),
- Score de satisfaction (annexe 5) : calculé à partir des questions 6 à 10 du questionnaire général, afin d'obtenir un score total coté sur 20 points (échelle de Likert de 1 à 4).
- Test de corrélation entre le score de communication médecin-malade, le score d'observance global et le score de satisfaction.

VII. RECUEIL ET GESTION DES DONNÉES

VII.1. Les données nominatives

Les informations concernant les patients inclus seront recueillies par l'investigateur et notées sur la fiche d'inclusion (annexe 8) : nom, prénom et coordonnées téléphoniques.

Pour chaque patient, un code d'identification est construit : il correspond aux 2 premières lettres de son nom suivies de la première lettre de son prénom.

Les coordonnateurs récupéreront l'ensemble des fiches à la Clinique Mutualiste, dans un délai maximum de 3 jours suivant la consultation.

Ceux-ci serviront à contacter les patients et seront archivés dans un dossier spécifique au protocole, qui constituera les données sources.

Les données nominatives ne donneront lieu à aucun traitement informatisé.

Seuls les codes d'identification des patients seront utilisés pour le traitement informatique des données de l'enquête téléphonique.

VII.2. Les questionnaires

Les données sont collectées au moyen d'une enquête téléphonique, menée par les coordonnateurs : Amélie DUVERT, Laure GONNET, Marisa TISSOT et Julie TYRANT internes de médecine générale en fin de cycle. Le support utilisé correspond à des questionnaires (annexes 1, 2, et 5), ils seront remplis au cours de l'appel téléphonique.

VIII. ANALYSE STATISTIQUE DES PARAMÈTRES MESURÉS

VIII.1. Calcul du nombre de sujets

L'objectif est l'obtention d'un minimum de 75 questionnaires remplis par type de pathologie. Étant donné que nous testons 2 fiches, il faudra 150 questionnaires.

Pour obtenir 150 questionnaires, avec un nombre de perdus de vue estimé à 25%, il faudra inclure 200 patients soit 100 par pathologie.

VIII.2. Responsables des analyses

- Rédacteur du plan d'analyse statistique : Professeur J-L Bosson
- Personnes chargées de réaliser l'analyse : les coordonnateurs, Amélie DUVERT et Laure GONNET

VIII.3. Lieu d'analyse des données et logiciels utilisés

Centre d'Investigation Clinique du CHU de Grenoble.

Les données seront saisies via une interface de saisie ad hoc. Un contrôle qualité sur 100 % des données et 10% des individus sera effectué.

L'analyse statistique et l'archivage de la base de données (après procédure de gel de base) se fera sous la responsabilité du Professeur Jean Luc Bosson. L'analyse statistique se fera avec le logiciel STATA Version 10 OSX (StataCorp LP 4905 Lakeway Drive College Station, Texas 77845 USA).

VIII.4. Méthode d'analyse des données

L'analyse descriptive porte sur l'ensemble des variables recueillies. Elle utilisera les descripteurs visuels (nombre et fréquence pour les variables quantitatives, médiane et inter quartile pour les variables continues). Les tests statistiques de corrélation entre scores seront faits avec le risque d'erreur de première espèce usuel $\alpha = 0.05$. Les critères principaux seront mesurés avec calcul de l'intervalle de confiance à 95%.

Pour chaque score une ACP et le calcul du coefficient de Cronbach permettront de caractériser ces scores.

IX. CALENDRIER PRÉVISIONNEL DE L'ÉTUDE

- Durée de la phase préparatoire : élaboration des questionnaires : printemps – été 2013
- Durée de l'étude par patient : 7 à 10 jours
- Durée totale de l'étude : 4 mois
- Date prévue pour le début des inclusions : novembre 2013
- Date prévue pour la fin des inclusions : janvier 2014
- Date prévue pour la fin de l'étude : février 2014
- Date prévue pour la phase secondaire de l'étude (Évaluation de l'impact des FIP sur la CMM et l'OG) : année 2014

X. ARRÊT PRÉMATURÉ DE L'ÉTUDE

X.1. Critères d'arrêt de l'étude pour un sujet qui y participe

- Sujet non joignable après 3 essais de contact téléphonique
- Sujet refusant de répondre au questionnaire
- Sujet décédé

X.2. Arrêt de l'étude par le coordonnateur

Lorsque le coordonnateur aura reçu un maximum de 100 fiches d'inclusion pour une pathologie donnée, les investigateurs seront avertis de l'arrêt de l'inclusion pour cette pathologie, afin d'assurer la représentativité des deux situations.

X.3. Arrêt de l'étude par l'investigateur

En cas d'impossibilité d'effectuer le protocole, l'investigateur peut arrêter l'étude en accord avec le coordonnateur.

XI. ASPECTS MATÉRIELS ET LÉGAUX

XI.1. Information du patient

Conformément aux Bonnes Pratiques Cliniques et aux dispositions légales en vigueur, tout sujet présélectionné sera préalablement informé par l'investigateur des objectifs de l'étude, de sa méthodologie, de sa durée, de ses contraintes. Il sera notamment précisé au patient qu'il est entièrement libre de refuser de participer à l'étude à tout moment sans encourir aucune responsabilité ni aucun préjudice de ce fait. Un document résumant les renseignements donnés par l'investigateur lui sera remis (annexe 7).

XI.2. Secret professionnel, confidentialité

L'investigateur sera tenu au respect du secret professionnel. Les données recueillies, y compris les résultats des analyses, seront rendues anonymes par tout moyen approprié. Les coordonnateurs seront soumis aux mêmes obligations de secret professionnel que les investigateurs. Le présent document et ses annexes seront remis aux investigateurs à titre confidentiel et ne devront être remis ou communiqués qu'aux personnes nommément impliquées dans l'essai avec l'accord ou à la demande du coordonnateur.

XI.3. Financement de l'étude

Aucun financement.

Soutien méthodologique et statistique du CIC du CHU de Grenoble.

XI.4. Comité d'éthique

Cette étude est observationnelle, évaluation de pratiques sans procédure particulière de surveillance (le suivi téléphonique n'étant pas considéré comme interventionnel pour le patient). La soumission à une CPP et à l'autorité compétente n'est donc pas requise.

Un avis éthique consultatif favorable a été obtenu le 31/10/2013 (CECIC Rhône-Alpes-Auvergne , Clermond-Ferrand, IRB 5891). Le CECIC examine et donne un avis consultatif concernant l'aspect éthique de la conduite d'un protocole à la condition que celui-ci ne relève pas de la loi française sur la recherche biomédicale.

XI.5. Amendements au protocole

Toute modification substantielle du protocole fera l'objet d'un amendement soumis pour avis au CECIC.

XI.6. Anonymat des sujets participant à l'étude

Les questionnaires remplis ne porteront que les initiales du patient (deux premières lettres du nom et la première lettre du prénom) et un numéro d'anonymat. Seul ce

numéro sera informatisé. Le fichier informatisé utilisé pour la saisie et le traitement des données fera l'objet d'une demande d'autorisation à la Commission Nationale Informatique et Libertés.

XI.7. Publications

Toutes les données recueillies au cours de cette étude sont la propriété du promoteur de l'étude et ne peuvent être communiquées en aucun cas à une tierce personne sans l'accord écrit de l'investigateur. Toute publication ou communication (orale ou écrite) sera décidée d'un commun accord entre les investigateurs et respectera les recommandations internationales: "Uniforms Requirements for Manuscripts Submitted to Biomedical Journals"

XI.8. Archivage

L'ensemble des dossiers de l'étude sera archivé pour une durée de 15 ans, sous la responsabilité des coordonnateurs.

Le protocole signé et les fiches d'inclusion devront être conservés par les investigateurs pendant la durée minimale de 15 ans à compter de la fin de l'étude.

Les coordonnateurs organiseront, le stockage dans des locaux appropriés les documents suivants :

- Protocole avec annexes, amendements.
- Fiches d'inclusion et questionnaires (originaux) avec documents annexes.
- Toutes les pièces administratives et correspondances liées à l'étude.
- Rapport d'étude.

XII. DATE ET SIGNATURES

Ce protocole a été lu et approuvé à la date notée en en-tête

Investigateurs coordonnateurs signataires

Dr Mélanie SUSTERSIC
Pr Jean-Luc BOSSON

Investigateurs coordonnateurs

Amélie DUVERT
Laure GONNET
Julie TYRANT
Marisa TISSOT

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ANNEXE 4 DU PROTOCOLE

Méthodologie d'élaboration du questionnaire de communication médecin-malade

Objectif : Élaboration d'une échelle et de son score évaluant la qualité de la communication médecin malade à partir d'une revue de la littérature

Travail universitaire effectué avec l'appui méthodologique du CIC (Pr JLBosson), du CNRS (équipe ThEMAS) et de la faculté de psychologie (Dr Aurélie Gauchet, psychologie de la Santé).

Méthodologie :

La première étape a consisté en une recherche bibliographique sur les bases de données « pubmed » et « psychinfo » ainsi que les sites institutionnels français (HAS), anglais (NHS) et américain (AHRQ). Les mots clés étaient « physician-patient relations », « psychometrics », « questionnaires », « scale », « communication ».

Pour élaborer une échelle multidimensionnelle évaluant la qualité de la communication médecin malade, nous nous sommes appuyés sur le modèle de communication suivant: dans un contexte donné commun, émission d'une information par le médecin avec des mots et un discours intelligible -> réception par le patient qui confirme au médecin que le message a bien été reçu. Ce qui peut être résumé de la manière suivante : émission -> information -> réception-> feedback.

Les échelles ont été sélectionnées selon les critères d'inclusion suivants : échelles validées ; en langue Française ou Anglaise ; évaluant la communication médecin malade (échelles de communication médecin malade, de relation médecin malade, d'écoute, de confiance, d'empathie). Dans notre choix de modèle théorique, les conséquences de la communication sur le comportement (échelles d'observance), le psychisme (échelles de satisfaction, anxiété, dépression, auto efficacité personnelle etc.) ou les symptômes du patient (échelles de douleur...etc.) ont été considérées comme étant extrinsèques à la communication médecin malade. Les échelles mesurant ces dimensions ont donc été exclues. Les autres critères d'exclusion étaient : les échelles spécifiques des pathologies chroniques ; celles mesurant des dimensions hors champ de la consultation (organisation du système de soins, temps d'attente dans la salle d'attente...etc.). Au total, vingt échelles ont été retenues.

La seconde étape a consisté à extraire à partir des échelles retenues tous les items pertinents sur le sujet sans préjuger des dimensions auxquelles ils appartenaient. Ensuite, lorsque deux ou plusieurs items étaient redondants, un seul a été retenu, ce qui nous a permis d'aboutir à un questionnaire à la fois exhaustif et synthétique. Cette démarche (inverse par rapport à la démarche communément utilisée qui aurait été de choisir un modèle théorique en psychologie, de définir ensuite les dimensions caractérisant le modèle et enfin de rédiger les items caractérisant chacune des dimensions) a permis d'éviter plusieurs écueils.

Tout d'abord celui de créer une énième échelle parmi tant d'autres sans prendre en compte les travaux antérieurs réalisés sur le sujet. Ensuite celui d'avoir des items chevauchant potentiellement plusieurs dimensions.

En effet, les dimensions ayant des définitions variables selon les équipes de chercheurs, le choix d'un modèle théorique implique une part d'arbitraire. Aucun modèle théorique n'étant parfait, il est forcément réducteur de choisir un modèle plutôt qu'un autre.

Notre classification par dimensions a eu pour seul objectif de faciliter le tri des items et aucunement d'attribuer à chaque item une dimension. Notre échelle et/ou questionnaire fonctionne donc indépendamment des dimensions qui le composent.

La troisième étape a consisté à reformuler les items afin que les réponses aux questions puissent être mesurées sur une échelle de Likert allant de 1 à 4.

Une étude qualitative réalisée sur une vingtaine de patients est actuellement en cours.

Elle consiste à demander au patient pour chacun des items :

- une reformulation de l'item pour s'assurer qu'il l'a bien compris;
- savoir si l'item lui paraît pertinent par une question ouverte;
- savoir si l'item englobe bien tous les aspects qu'il était censé englober lorsqu'il a été sélectionné, afin de ne pas omettre de notion.

Elle a pour but de vérifier la bonne compréhension du questionnaire par les patients avant d'aborder la seconde étape, quantitative, qui se fera sur environ 200 patients, afin de valider l'échelle et ses propriétés psychométriques.

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ANNEXE 6 : Complementary results

1. Main outcome: DPC score

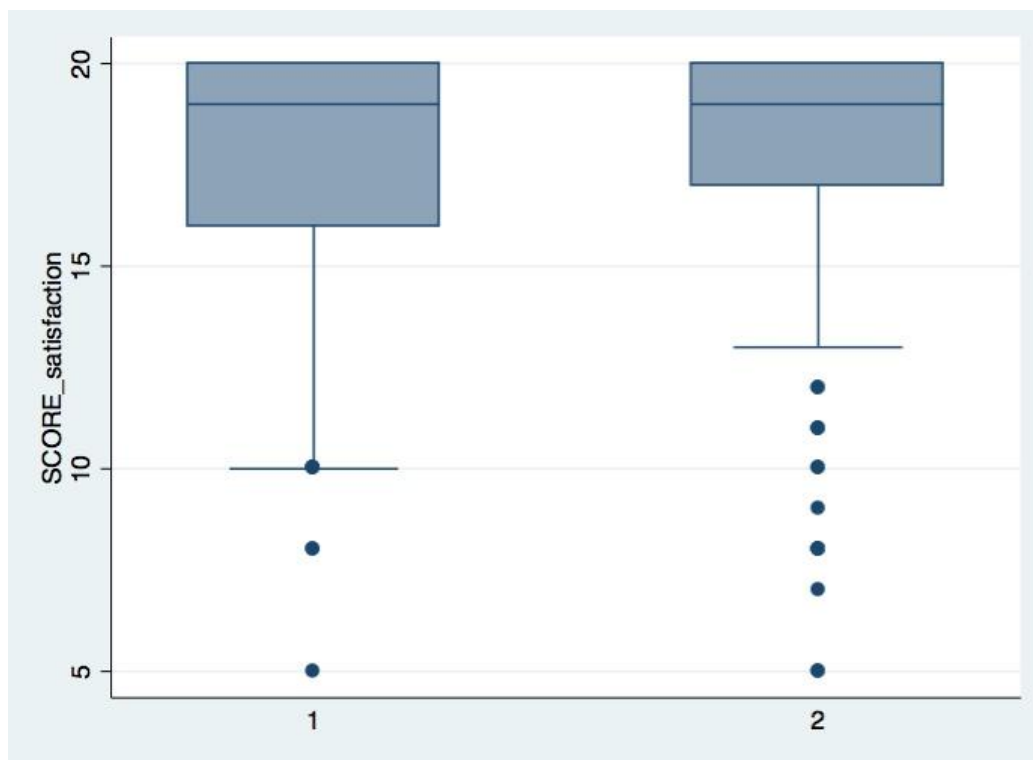
Polytomous multivariate logistic regression analysis was applied to parameters which had a p-value <0.20 at baseline (working in the health sector, being male and being in a relationship). The dependent variable is the DPC score in 3 classes (DPC score ≤ 35 is the reference).

Table 1 : Polytomous logistic regression for a DPC score between 36 and 50 and over 50

DPC score	Explanatory variable	OR	P> z	[95% Conf. Interval]	
36-50	Phase 2	2,70	0,006	1,32	5,49
	Work in the health sector	2,71	0,122	0,76	9,65
	Male	2,07	0,05	1,00	4,31
	In a relationship	1,40	0,315	0,72	2,74
	_cons	2,08	0,010	1,19	3,63
>50	Phase 2	4,09	0,002	1,64	10,22
	Work in the health sector	2,21	0,340	0,43	11,35
	Male	4,70	0,001	1,86	11,89
	In a relationship	2,82	0,024	1,14	6,94
	_cons	0,13	0,000	0,05	0,35

2. Secondary outcome: satisfaction score

Figure 1 : Bow plot representing satisfaction score in phase 1 and 2



3. Secondary outcome : Morisky score

Table 2: Answers to the question : 'did the doctor prescribe a treatment ?' in phase 1 and 2 (numbers)

Prescription	Phase 1	Phase 2
Yes	149	162
No	7	6

Table 3 : Answers to the question : 'was the treatment on demand, systematic or both ?' in phase 1 and 2 (numbers)

Prescription	Phase 1	Phase 2
On demand	15	32
Systematic	49	28
On demand and systematic	54	102
.	31*	0

*Patients who did not answer this question were considered to not be included in the group 'on demand'

Table 4: Morisky score compared in phase 1 and 2 (numbers and percentages)

	Phase 1 (n=156)	Phase 2 (n=168)	p-value
Morisky score			0.879
3	5/134 (3,7 %)	3/123 (2,4 %)	
4	19/134 (14,2 %)	15/123 (12,2 %)	
5	30/134 (22,4 %)	31/123 (25,2 %)	
6	80/134 (59,7 %)	74/123 (60,2 %)	

Table 5: Answers to Morisky questionnaire in phase 1 and 2 (numbers and percentages)

Morisky questionnaire	Answer : No		Pr
	Phase 1	Phase 2	
1: Have you forgotten to take your pills since your visit?	114 (85 %)	106 (86,1 %)	Pr = 0.801
2: Since your visit, have you been short of pills (you did not go to the chemist or there were not enough pill in the box?)	128 (95,5 %)	121 (98,3 %)	Pr = 0.189
3: Have you taken your pills with delay?	104 (77,6 %)	95 (77,2 %)	Pr = 0.943
4: Did you forget to take your pills?	130 (97 %)	118 (95,9 %)	Pr = 0.638
5: Did you sometimes not take your pills because you thought it did you more harm than good?	120 (89,5 %)	116 (94,3 %)	Pr = 0.164
6: Do you think you had too much pills to take?	125 (93,2 %)	112 (91 %)	Pr = 0.506

4. Secondary outcome : Global adherence score

a) Table 6: Medical prescription (except only on demand) in phase 1 and 2 (numbers and percentages):

Medical prescription	Phase 1	Phase 2
No	22 (14,1 %)	38 (22,6 %)
Yes	134 (85,9 %)	130 (77,3 %)

Pr = 0.049

b) Table 7: Prescription of further exams in phase 1 and 2 (numbers and percentages):

Prescription of further exams	Phase 1	Phase 2
No	58 (37,1 %)	27 (16 %)
Yes	98 (62,8 %)	141 (83,9 %)

Pr = 0.000

c) Table 8: Advice to follow in phase 1 and 2 (numbers and percentages):

Advice to follow	Phase 1	Phase 2
No	66 (42,5 %)	45 (26,7 %)
Yes	89 (57,4 %)	123 (73,2 %)

Pr = 0.003

d) Table 9: Information on when to consult a doctor again in phase 1 and 2 (numbers and percentages):

Information on when to consult a doctor again	Phase 1	Phase 2
No	76 (49 %)	81 (49 %)
Yes	79 (50,9 %)	84 (50,9 %)

Pr = 0.992

5. PILs

Table 10: Comparison of DPC score in 2 classes and whether the PIL was given to the patient or by another member of staff (numbers and percentages)

DPC score	PIL given by the doctor	PIL given by another member of staff
≤ 35	10 (7,9 %)	3 (10,3 %)
> 35	116 (92 %)	26 (89,6 %)

Pr = 0.673 Fisher's exact = 0.711

Table 11: Comparison of satisfaction score in 2 classes and whether the PIL was given to the patient or by another member of staff (numbers and percentages)

Satisfaction score	PIL given by the doctor	PIL given by another member of staff
≤ 16	24 (18,9 %)	7 (24,1 %)
> 16	103 (81,1 %)	22 (75,8 %)

Pr = 0.523

Table 12: Comparison of DPC score in 2 classes and whether the PIL was signed by the doctor or not (numbers and percentages)

DPC score	PIL signed by the doctor	PIL given without a signature
≤ 35	5 (9,2 %)	5 (11,9 %)
> 35	49 (90,7 %)	37 (88,1 %)

Pr = 0.674 Fisher's exact = 0.744

Table 13: Comparison of satisfaction score in 2 classes and whether the PIL was signed by the doctor or not (numbers and percentages)

Satisfaction score	PIL signed by the doctor	PIL given without signature
≤ 16	10 (18,1 %)	11 (26,1 %)
> 16	45 (81,8 %)	31 (73,8 %)

Pr = 0.343

Table 14: Comparison of DPC score in 2 classes and whether the patient came to the emergency department or accompanied or on his own (numbers and percentages)

DPC score	Accompanied patient	Unaccompanied patient
≤ 35	9 (10,1 %)	5 (6,41 %)
> 35	80 (89,8 %)	73 (93,5 %)

Pr = 0.389

Table 15: Comparison of DPC score in 2 classes and whether the patient came to the emergency department or accompanied or on his own (numbers and percentages)

Satisfaction score	Accompanied patient	Unaccompanied patient
≤ 16	17 (19,1 %)	17 (21,5 %)
> 16	72 (80,9 %)	62 (78,4 %)

Pr = 0.697

6. Relation between scores

Table 16: Satisfaction score in 3 classes according to DPC score in phase 1 (numbers and percentages)

Satisfaction score	DPC score			Total
	≤ 35	36-50	> 50	
≤ 16	20 (64,5)	20 (18,5)	3 (18,7)	43 (27,7)
> 16	11 (35,4)	88 (81,4)	13 (81,2)	112 (72,2)

Pr = 0,000 Fisher's exact = 0,000

Table 17: Satisfaction score in 3 classes according to DPC score in phase 2 (numbers and percentages)

Satisfaction score	DPC score			Total
	≤ 35	36-50	> 50	
≤ 16	11 (78,5)	21 (17,0)	2 (6,6)	34 (20,3)
> 16	3 (21,4)	102 (82,9)	28 (93,3)	133 (79,6)

Pr = 0,000 Fisher's exact = 0,000

Table 18: Crossing between DPC score in 3 classes and recommending the emergency department (numbers and percentages)

Do you recommend this emergency department to you family and friends?	DPC score			Total
	≤ 35	36-50	> 50	
No	10 (22,2)	8 (3,4)	3 (6,5)	21 (6,5)
Disagree	7 (15,5)	4 (1,7)	0 (0)	11 (3,4)
Agree	10 (22,2)	25 (10,8)	3 (6,5)	38 (11,8)
Yes	18 (40)	194 (83,9)	40 (86,9)	252 (78,2)

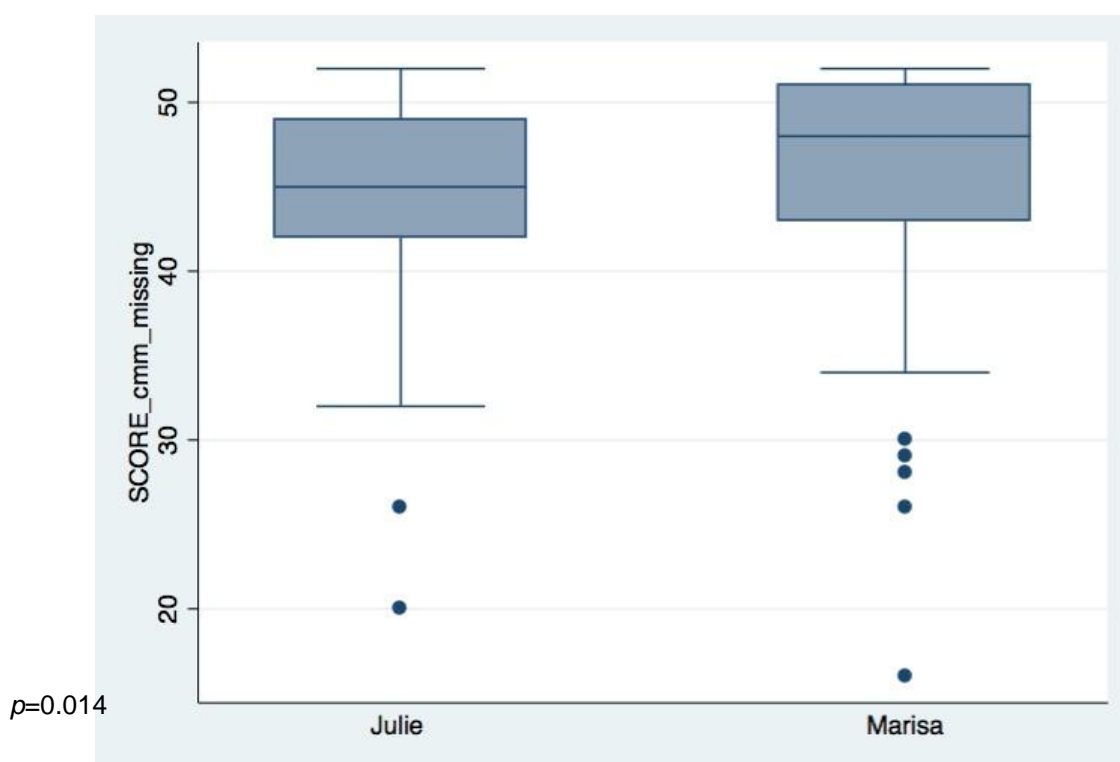
Pr = 0,000 Fisher's exact = 0,000

Table 19: DPC score of the two interviewers

Interviewer	Median	p25	p75	N
TJ	45	42	49	101
TM	48	43	51	66

$p=0,014$

Figure 2: DPC score according to the 2 interviewers (Tyrant J. and Tissot M.)



ANNEXE 7: FICHE D'INCLUSION

FICHE d'INCLUSION (à remettre dans la corbeille prévue à cet effet)

Date de la consultation d'inclusion :

Refus de contact téléphonique :

(si case cochée, ne pas remplir les données nominatives)

Données nominatives du patient (non informatisées) ou du responsable légal si mineur

Nom :

Prénom :

Sexe :

Téléphone fixe patient: /_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/

Téléphone portable patient : /_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/

Téléphone d'un proche (désigné comme personne de confiance) : /_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/_/

/_/_/ (précisez : voisin, parent...)

Jour de la semaine et créneaux horaires préférés par le patient pour être contacté :

Code d'identification du patient :

2 premières lettres du nom du patient : /_/_/_/_/

Première lettre du prénom du patient : /_/_/

Pathologie concernée (entourer la mention utile)

- Entorse de cheville
- Pyélonéphrite aiguë
- Prostatite
- Colite infectieuse
- Diverticulite
- Pneumopathie

FORMULAIRE D'INFORMATION ET DE NON-OPPOSITION

Document constitué en application du Code de Santé Publique.

Madame, Monsieur,

Vous consultez les urgences ce jour pour : (entourer la mention applicable).

- Entorse de cheville
- Pyélonéphrite aiguë / Prostatite aiguë
- Pneumopathie
- Sigmoidite / colite

Nous vous proposons de participer à une recherche médicale dont le but est d'évaluer l'amélioration de la qualité des consultations aux urgences, notamment en termes de communication médecin-malade, et de satisfaction des patients grâce des fiches d'information remises au patient.

Déroulement de l'étude :

Le médecin que vous avez rencontré lors de votre consultation ce jour, vous a prescrit un traitement et/ou des conseils à suivre ainsi qu'une fiche d'information sur la pathologie qui vous concerne ; Vous serez ensuite contacté(e) par téléphone dans une dizaine de jours par un des médecins coordonnateurs de l'étude. Cela durera une dizaine de minutes. Cet appel téléphonique garantit le secret médical. En cas de répondant intermédiaire, aucune information médicale ne sera donnée. Votre participation ne modifie en rien les pratiques médicales vous concernant (examens, traitements). Afin de pouvoir vous joindre, nous avons besoin de vos coordonnées. Nous vous demandons également les coordonnées d'une **personne de confiance, si vous en avez désigné une**, pour permettre aux coordonnateurs d'effectuer l'enquête si vous-même n'êtes pas en mesure de répondre.

Confidentialité des données vous concernant :

Dans le cadre de cette étude les règles usuelles de confidentialité seront respectées. Les données médicales, vous concernant, seront centralisées dans un fichier informatique à des fins de traitement statistique. Elles resteront strictement confidentielles. Ces données seront transmises au Centre d'Investigation Clinique du CHU de Grenoble ou aux personnes agissant pour son compte. Suite à l'enquête téléphonique, vos coordonnées personnelles seront détruites. Vos réponses resteront anonymes. Elles se verront attribuer un code comportant un numéro et les initiales de votre nom et prénom, qui lui seul sera informatisé.

Conformément aux dispositions de la loi relative à l'informatique aux fichiers et aux libertés, vous disposez d'un droit d'accès et de rectification. Vous disposez également d'un droit d'opposition à la transmission de vos données couvertes par le secret professionnel susceptibles d'être utilisées et traitées dans le cadre de cette recherche, en contactant les médecins coordonnateurs de l'étude nommés ci-dessous.

Vous avez bien sûr le droit de refuser de participer à cette recherche, il vous suffit de remplir le bas de ce document et de le remettre au médecin qui vous prend en charge, ce refus ne changera en rien vos relations avec les médecins. Vous avez en outre la possibilité de vous y opposer à tout moment pour la raison de votre choix, sans encourir aucune responsabilité, sans atteinte à la qualité des soins que vous recevrez ultérieurement.

En coopérant à cette enquête, vous participerez à la recherche médicale. Vous aidez les médecins français à utiliser de nouveaux moyens d'information et nous vous en remercions.

Je soussigné(e) Mme, Mr.....

Ne souhaite pas participer à l'étude « Etat des lieux dans un service d'Urgence dans un but d'Amélioration des Pratiques Professionnelles ».

Aucune donnée concernant mon dossier médical ne sera prise en compte pour l'étude. J'ai bien compris que le fait de ne pas participer à l'étude ne changera en rien la façon dont je serai prise en charge.

Fait le, à,

Signature :

Nous vous remercions pour votre participation à cette étude



TISSOT Marisa et TYRANT Julie
Internes en Médecine Générale
Coordonnateurs de l'étude

FORMULAIRE D'INFORMATION ET DE NON-OPPOSITION

Pour responsable légal d'un mineur

Document constitué en application du Code de Santé Publique.

Madame, Monsieur,

Votre enfant, (ou le mineur dont vous êtes le responsable légal) a consulté les urgences ce jour pour (entourer la mention applicable) :

- Entorse de cheville
- Pyélonéphrite aiguë / Prostatite aiguë
- Sigmoidite/ colite
- Pneumopathie

Nous vous proposons de participer à une recherche médicale dont le but est d'évaluer l'amélioration de la qualité des consultations aux urgences, notamment en termes de communication médecin-malade, et de satisfaction des patients grâce des fiches d'information remises au patient.

Déroulement de l'étude :

Le médecin que vous avez rencontré lors de votre consultation ce jour, a prescrit un traitement et/ou des conseils à suivre pour **votre enfant** , ainsi qu'une fiche d'information sur la pathologie qui le concerne.

Vous serez ensuite contacté(e) par téléphone dans une dizaine de jours par un des médecins coordonnateurs de l'étude. Cela durera une dizaine de minutes. Cet appel téléphonique garantit le secret médical. En cas de répondant intermédiaire, aucune information médicale ne sera donnée. Votre participation ne modifie en rien les pratiques médicales concernant **votre enfant** (examens, traitements).

Afin de pouvoir vous joindre, nous avons besoin de vos coordonnées. Nous vous demandons également les coordonnées d'une **personne de confiance, si vous en avez désigné une** , pour permettre aux coordonnateurs d'effectuer l'enquête si vous-même n'êtes pas en mesure de répondre.

Confidentialité des données concernant votre enfant :

Dans le cadre de cette étude les règles usuelles de confidentialité seront respectées.

Les données médicales **concernant votre enfant** , seront centralisées dans un fichier informatique à des fins de traitement statistique. Elles resteront strictement confidentielles. Ces données seront transmises au Centre d'Investigation Clinique du CHU de Grenoble ou aux personnes agissant pour son compte. Suite à l'enquête téléphonique, vos coordonnées personnelles seront détruites. Vos réponses resteront anonymes. Elles se verront attribuer un code comportant un numéro et les initiales de votre nom et prénom, qui lui seul sera informatisé.

Conformément aux dispositions de la loi relative à l'informatique aux fichiers et aux libertés, vous disposez d'un droit d'accès et de rectification. Vous disposez également d'un droit d'opposition à la transmission de vos données couvertes par le secret professionnel susceptibles d'être utilisées et traitées dans le cadre de cette recherche, en contactant les médecins coordonnateurs de l'étude nommés ci-dessous.

Vous avez bien sûr le droit de refuser de participer à cette recherche, il vous suffit de remplir le bas de ce document et de le remettre au médecin qui prend en charge votre enfant , ce refus ne changera en rien vos relations avec les médecins. Vous avez en outre la possibilité de vous y opposer à tout moment pour la raison de votre choix, sans encourir aucune responsabilité, sans atteinte à la qualité des soins que votre enfant recevra ultérieurement.

En coopérant à cette enquête, vous participerez à la recherche médicale. Vous aidez les médecins français à utiliser de nouveaux moyens d'information et nous vous en remercions.

Je soussigné(e) Mme, Mr....., **responsable légal de l'enfant**

.....
ne souhaite pas participer à l'étude « Etat des lieux de la communication et de la satisfaction dans un service d'Urgence dans un but d'Amélioration des Pratiques Professionnelles ».

Aucune donnée concernant le dossier médical de mon enfant ne sera prise en compte pour l'étude. J'ai bien compris que le fait de ne pas participer à l'étude ne changera en rien la façon dont mon enfant sera pris en charge.

Fait le, à

Signature :

Nous vous remercions pour votre participation à cette étude

TISSOT Marisa et TYRANT Julie
Internes en Médecine Générale
Coordonnateurs de l'étude



ANNEXE 8 : QUESTIONNAIRE

I. Questionnaire général

Date de consultation aux urgences:

Date(s) d'appel téléphonique :

Investigateur :

Patho: 1: Entorse de cheville 2: Pyélonéphrite aigue 3: Pneumopathie 4: Autres patho infectieuses.

Perdu de vue : 1: inclus à tort 2: injoignable 3: refus du patient 4: ne se souvient plus 5: décédé

Nous souhaitons recueillir votre opinion sur votre dernière consultation aux urgences.

Cet entretien va durer environ 15 minutes.

Nous vous remercions du temps que vous allez prendre pour répondre à cette enquête.

Vos réponses sont anonymes.

A/ Données sociodémographiques

Tout d'abord, quelques questions pour mieux vous connaître :

1-Sexe :

2- Quel âge avez-vous ?

3-Quel est votre niveau d'études?

Collège Bac Bac +2 Études supérieures après Bac +2 autres

4-Travaillez-vous dans le milieu médical?

Oui Non

5-A quelle catégorie socio-professionnelle appartenez-vous?

1: agriculteurs exploitants

2:commerçants, artisans, chefs d'entreprise

3:cadres et prof intellect supérieures

4:professions intermédiaires

5: employés

6: ouvriers

7: retraités

8: autres sans activité prof

6-Quelle est votre situation familiale : célibataire / en couple

et nombre d'enfants:

7-Etiez-vous accompagné lors de la consultation aux urgences

Oui Non

B/ Score de Satisfaction:

Suite à votre consultation dans le service d'urgences:

-8a/Quels sont les éléments dont vous êtes satisfaits concernant votre consultation aux urgences? Quelques mots

.....
.....
.....

-8b/Quels sont les éléments qui vous ont déplu concernant votre consultation aux urgences? Quelques mots

.....
.....

9-Diriez-vous que vous êtes satisfait des conditions d'accueil, hors paramètres médicaux (accueil, nourriture, délais d'attente) dont vous avez bénéficié?

Non Plutôt non Plutôt oui Oui

10-Diriez-vous que vous êtes satisfait des soins reçus et de la prise en charge par l'équipe paramédicale (infirmier(e)s, aides-soignants, ASH)?

Non Plutôt non Plutôt oui Oui

11-Diriez-vous que vous êtes satisfait de la prise en charge par le médecin que vous avez rencontré?

Non Plutôt non Plutôt oui Oui

12-De façon globale, diriez-vous que vous êtes satisfait de votre consultation aux urgences?

Non Plutôt non Plutôt oui Oui

13-Recommanderiez-vous ce service à votre famille et vos amis?

Non Plutôt non Plutôt oui Oui

Chacun des items est coté selon la réponse: 1(non), 2, 3 ou 4 (oui).

Score coté sur 20 avec un minimum de 5/20 et un maximum de 20/20.

QUESTIONNAIRE DE COMMUNICATION MEDECIN- MALADE

1-Le médecin vous a-t-il écouté attentivement pendant la consultation ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

2-Le médecin vous a-t-il interrompu pendant que vous parliez ?

Non 4 Plutôt non 3 Plutôt oui 2 Oui 1

3- Le médecin vous a-t-il encouragé à vous exprimer ?

Non1 Plutôt non 2 Plutôt oui 3 Oui 4

4- Le médecin vous a-t-il bien examiné ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

5- Vous-êtes-vous senti compris par le médecin ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

6- Est-ce que le médecin s'est exprimé de façon compréhensible ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

7- Avez-vous eu l'impression d'avoir eu toutes les informations nécessaires ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

8- Le médecin vous a-t-il expliqué les avantages et inconvénients du traitement ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

9- Le médecin vous a-t-il impliqué dans la prise de décision ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

10- D'après vous le médecin a-t-il eu une attitude et un discours rassurants ?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

11- Avez-vous confiance en ce médecin ?

Non 1 Plutôt non2 Plutôt oui 3 Oui4

12- Le médecin s'est-il assuré que vous aviez bien compris ses explications?

Non 1 Plutôt non2 Plutôt oui 3 Oui 4

13- Le médecin a-t-il répondu à toutes vos attentes et/ou préoccupations?

Non 1 Plutôt non 2 Plutôt oui 3 Oui 4

Score total : /52

QUESTIONNAIRE D'ADHERENCE

Merci de répondre aux affirmations suivantes:

Votre médecin vous a-t-il prescrit des médicaments?

OUI NON

Si non, passer directement aux questions II.

Adhérence globale

1/ Si oui : précisez quels médicaments vous ont été prescrits :

.....

2/ Deviez-vous les prendre à la demande (en cas de douleurs)/ en systématique/ ou prescriptions des 2 types de médicaments

3/ Si médicaments à la demande : les avez-vous utilisés ?

OUI NON

A/ Questionnaire d'observance médicamenteuse de Morisky adapté aux pathologies aiguës

1/Depuis la consultation, avez-vous oublié de prendre vos médicaments?

OUI NON

2/Depuis la dernière consultation, avez-vous été en panne de médicament (vous n'êtes pas allés les chercher à la pharmacie ou n'en aviez pas assez)?

OUI NON

3/Vous est-il arrivé de prendre votre traitement avec du retard par rapport à l'heure souhaitée ?

OUI NON

4/Vous est-il arrivé de ne pas prendre votre traitement parce que certains jours votre mémoire vous fait défaut?

OUI NON

5/Vous est-il arrivé de ne pas prendre votre traitement parce que vous aviez l'impression que votre traitement vous fait plus de mal que de bien?

OUI NON

6/Pensez-vous que vous avez eu trop de traitements à prendre?

OUI NON

.....

B- Questionnaire d'observance globale:

I- Observance des prescriptions médicamenteuses

Les questions qui suivent concernent les jours qui ont suivi la consultation :

1/Avez-vous pris l'ensemble du traitement proposé?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

- Si non ou plutôt non:

Il vous est arrivé de ne pas prendre l'un ou plusieurs de vos médicaments :

1a- Parce que vous avez oublié: oui non

1b- Parce que le traitement est trop complexe: oui non

1c- A cause d'effets secondaires: oui non

1d- Parce vos médicaments vous font plus de mal que de bien: oui non

1e- Parce vous pensiez qu'il n'était pas utile ou adapté: oui non

1f- Parce que vous sentiez déjà une amélioration : oui non

1g- Parce que vous n'êtes pas allé chercher les médicaments à la pharmacie: oui non

1h-Si oui : pourquoi:

1i-Parce que vous n'aviez pas mal : oui non

2. Avez-vous respecté les doses prescrites?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

3. Avez-vous respecté les modalités de prises (l'heure, à jeun, avant les repas)?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

4. Avez-vous pris des médicaments autres que ceux prescrits par votre médecin?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

- Si oui plutôt oui

4bis- Quels autres médicaments avez-vous pris ?

4ter-Est-ce que ces médicaments ont été prescrits par un autre médecin ? Oui non

II- Observance des prescriptions non médicamenteuses (examens complémentaires)

Votre médecin vous a-t-il prescrit des examens complémentaires et/ou proposé un suivi et/ou orienté chez un spécialiste ?

OUI NON

Si non, question non comptabilisée.

Si oui: les avez-vous réalisés?

1 (Pas du tout) 2 (plutôt non) 3 (plutôt oui) 4 (Complètement)

III- Observance des consignes/ conseils hygiéno-diététiques et de conduite à tenir selon l'évolution

1. Votre médecin vous a-t-il donné des conseils à respecter ?

OUI NON

(cf. liste ci-dessous pour vous aider)

Par exemple, conseils concernant:

- L'alimentation et/ ou la gestion du poids
- Vos activités habituelles
- Le tabagisme et l'arrêt du tabac
- Quand reconsulter
- La consommation d'alcool
- La consommation d'eau
- L'exercice physique
- Les moyens d'éviter l'aggravation des symptômes, la récurrence, la transmission

Si non: question non comptabilisée.

Si oui:

2. Avez-vous appliqué les conseils donnés et/ou modifié certaines habitudes suite à la consultation?

(Pas du tout) 1 (un peu) 2 (beaucoup) 3
(Complètement) 4

3. Certaines informations données par votre médecin pouvaient-elles intéresser vos proches?

OUI NON

Si non, question non comptabilisée.

Si oui, leur avez-vous transmis ces informations?

(Pas du tout) 1 (un peu) 2 (beaucoup) 3
(Complètement) 4

IV- Comportement de consommation de soins

1/Après la consultation, avez-vous eu besoin d'un nouvel avis médical pour le même problème?

1 (non)

2 (plutôt non)

3 (plutôt oui)

4 (oui, tout à fait)

Si oui :

1a- Avez-vous consulté à nouveau votre médecin ?

OUI NON

1b- Avez-vous consulté un autre médecin ?

OUI NON

1c- Avez-vous consulté un service d'urgences?

OUI NON

1d- Avez-vous appelé le centre 15 concernant le même problème?

OUI NON

2/ Votre médecin vous a-t-il donné des informations sur quand reconsulter?

OUI NON

Si oui :

Selon vous, le fait d'avoir pris un nouvel avis médical ou non, vous paraît-il en accord avec les recommandations de votre médecin?

Pas du tout : 1

Plutôt non: 2

Plutôt oui : 3

complètement : 4

SYSTEME de COTATION:

Le score d'observance médicamenteuse selon Morisky est coté de 0 à 6

Le score d'observance globale proposé par notre équipe comprend 4 sous-dimensions cotées chacune de 1 à 4 selon une échelle de Likert.

Le score total étant est la moyenne des 4 sous-dimensions. Total de 4 à 16/ 16

-L'observance médicamenteuse

-L'observance des prescriptions non médicamenteuses

-L'observance des conseils hygiéno-diététiques

-L'observance de recours au système de soins

Les questions binaires «oui-non» ne sont pas comptabilisées dans le calcul du score.

QUESTIONNAIRE FIP

1/Avez-vous reçu une FIP :

Oui non Ne se souvient plus (NSP)

2/Qui vous l'a donnée ?

1-Médecin 2-IDE 3-AS 4-NSP

3/La FIP est-elle signée ?

Oui non NSP

4/a Avez-vous lu la FIP ?

Oui non NSP

4/b Quand l'avez-vous lue ?

Immédiatement Quelques jours après Pas du tout

4/c L'avez-vous gardée ?

Oui non NSP

5/L'avez-vous relue?

Oui non NSP

6/Avez-vous trouvé la FIP facile à comprendre ?

Oui non NSP

7/La FIP vous a-t-elle été expliquée brièvement ?

Oui non NSP

8/La FIP vous a-t-elle aidé ?

Oui non NSP

9/Vos proches se sont-ils servis de la FIP ?

Oui non NSP

ANNEXE 9 : Questionnaire amélioré

Questionnaire général

Date de consultation aux urgences:

Date(s) d'appel téléphonique :

Investigateur :

Patho: 1: Entorse de cheville 2: Pyélonéphrite aigue 3: Pneumopathie 4: Autres patho infectieuses

Perdu de vue : 1: inclus à tort 2: injoignable 3: refus du patient 4: ne se souvient plus 5: décédé

Nous souhaitons recueillir votre opinion sur votre dernière consultation aux urgences.

Cet entretien va durer environ 15 minutes.

Nous vous remercions du temps que vous allez prendre pour répondre à cette enquête.

Vos réponses sont anonymes.

A/ Données sociodémographiques

Tout d'abord, quelques questions pour mieux vous connaître :

1-Sexe :

2- Quel âge avez-vous ?

3-Quel est votre niveau d'études?

Collège Bac Bac +2 Études supérieures après Bac +2 autres

4-Travaillez-vous dans le milieu médical? Oui Non

(infirmière - aide soignante - médecin - kinésithérapeute - brancardier -secrétaire médicale - ASH -auxiliaire de puériculture - pharmacien - ergothérapeute - orthophoniste - sage femme - manipulateur radiologique)

5-Concernant votre activité professionnelle, êtes-vous ?

En activité Oui Non

Sans activité Oui Non

Au chômage Oui Non

Retraité Oui Non

6-Quelle est votre situation familiale : célibataire / en couple

et nombre d'enfants:

7- Etiez-vous accompagné(e) lors de la consultation avec le médecin aux urgences :

Oui Non

8- Ce service des urgences vous-a-t-il été recommandé ?

Oui Non

B/ Score de Satisfaction:

Suite à votre consultation dans le service d'urgences:

-8a/Quels sont les éléments dont vous êtes satisfaits concernant votre consultation aux urgences? Quelques mots

.....
.....
.....

-8b/Quels sont les éléments qui vous ont déplu concernant votre consultation aux urgences? Quelques mots

.....
.....
.....

9-Diriez-vous que vous êtes satisfait des conditions d'accueil, hors paramètres médicaux dont vous avez bénéficié?

Accueil Non Oui

Délais d'attente Non Oui

Combien de temps avez-vous attendu aux urgences ?

10-Diriez-vous que vous êtes satisfait des soins reçus et de la prise en charge par l'équipe paramédicale (infirmier(e)s, aides-soignants) ?

Non Oui

11-Diriez –vous que vous êtes satisfait de la prise en charge par le médecin que vous avez rencontré?

Non Oui

12-De façon globale, diriez-vous que vous êtes satisfait de votre consultation aux urgences?

Non Oui

13-Recommanderiez-vous ce service à votre famille et vos amis?

Non Plutôt non Plutôt oui Oui

Chacun des items est coté selon la réponse: 1(non), 2, 3 ou 4 (oui).

Score coté sur 20 avec un minimum de 5/20 et un maximum de 20/20.

QUESTIONNAIRE DE COMMUNICATION MEDECIN- MALADE

Score total : /52

Répondez à ces affirmations par « D'accord », « Plutôt d'accord », « Plutôt pas d'accord » ou « Pas d'accord ».

1-Le médecin vous a écouté attentivement pendant la consultation :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

2-Le médecin vous a interrompu pendant que vous parliez :

- Pas d'accord 4 Plutôt pas d'accord 3 Plutôt d'accord 2 D'accord 1

3- Le médecin vous a encouragé à vous exprimer. Il vous a posé des questions :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

4- Selon vous, le médecin vous a bien examiné :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

5- Vous vous êtes senti compris par le médecin :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

6- Le médecin s'est exprimé de façon compréhensible pour vous :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

7- Vous avez l'impression d'avoir eu toutes les informations nécessaires (de la part du médecin) :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

8- Le médecin vous a expliqué les avantages et inconvénients du traitement :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

9- Le médecin vous a impliqué dans la prise de décision (pour le traitement, le retour à domicile ou l'hospitalisation, les examens complémentaires) :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

10- D'après vous, le médecin a eu une attitude et un discours rassurants :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

11- Vous avez eu confiance en ce médecin :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

12- Le médecin s'est assuré que vous aviez bien compris ses explications :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

13- Le médecin a répondu à toutes vos attentes et/ou préoccupations :

- Pas d'accord 1 Plutôt pas d'accord 2 Plutôt d'accord 3 D'accord 4

QUESTIONNAIRE D'ADHERENCE

Merci de répondre aux affirmations suivantes:

Votre médecin vous a-t-il prescrit des médicaments?

OUI NON

Si non, passer directement aux questions II.

Adhérence globale

1/ Si oui : précisez quels médicaments vous ont été prescrits :

.....

2/ Deviez-vous les prendre à la demande (en cas de douleurs)/ en systématique/ ou prescriptions des 2 types de médicaments

3/ Si médicaments à la demande : les avez-vous utilisés ?

OUI NON

Si prescription de médicaments uniquement à la demande et que le patient ne les a pas utilisés, passez directement à la question I.4

A/ Questionnaire d'observance médicamenteuse de Morisky adapté aux pathologies aiguës

Les 5 prochaines questions posées sont en rapport avec le traitement de la pathologie aiguë ayant amené à consulter aux urgences (elles ne concernent pas le traitement des pathologies chroniques du patient).

1/Depuis la consultation, avez-vous oublié de prendre vos médicaments?

OUI NON

2/Avez-vous été en panne de médicament (vous n'êtes pas allé les chercher à la pharmacie ou n'en aviez pas assez)?

OUI NON

3/Vous est-il arrivé de prendre votre traitement avec du retard par rapport à l'heure souhaitée/ indiquée par le médecin ou sur l'ordonnance?

OUI NON

4/Vous est-il arrivé de ne pas prendre votre traitement parce que certains jours votre mémoire vous fait

défaut?

OUI NON

5/Vous est-il arrivé de ne pas prendre votre traitement parce que vous aviez l'impression qu'il vous fait plus de mal que de bien?

OUI NON

6/Pensez-vous que vous avez eu trop de traitement à prendre?

OUI NON

B- Questionnaire d'observance globale:

I- Observance des prescriptions médicamenteuses

Les questions qui suivent concernent les jours qui ont suivi la consultation :

1/Avez-vous pris l'ensemble du traitement proposé (traitement systématique et/ou à la demande)?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

- Si non ou plutôt non:

Il vous est arrivé de ne pas prendre l'un ou plusieurs de vos médicaments :

1a- Parce que vous avez oublié: oui non

1b- Parce que le traitement est trop complexe: oui non

1c- A cause d'effets secondaires: oui non

1d- Parce vos médicaments vous font plus de mal que de bien: oui non

1e- Parce vous pensiez qu'il n'était pas utile ou adapté: oui non

1f- Parce que vous sentiez déjà une amélioration : oui non

1g- Parce que vous n'êtes pas allé chercher les médicaments à la pharmacie: oui non

1h- Si oui : pourquoi:

1i- Parce que vous n'aviez pas mal : oui non

2. Avez-vous respecté les doses prescrites?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

3. Avez-vous respecté les modalités de prises (l'heure, à jeun, avant les repas)?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

4. Avez-vous pris des médicaments (pour la pathologie aigue vous ayant amené aux urgences) autres que ceux prescrits par le médecin des urgences?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

- Si oui plutôt oui

4bis- Quels autres médicaments avez-vous pris ?.....

4ter-Est-ce que ces médicaments ont été prescrits par un autre médecin ? Oui non

II- Observance des prescriptions non médicamenteuses (examens complémentaires)

Le médecin des urgences vous a-t-il prescrit des examens complémentaires et/ou proposé un suivi et/ou orienté chez un spécialiste ? (examens biologiques, radiologiques, séances de kiné, consultation avec un spécialiste, revoir votre médecin traitant)

OUI NON

Si non, question non comptabilisée.

Si oui: les avez-vous réalisés?

1 (Pas du tout) 2 (plutôt non) 3 (plutôt oui) 4 (Complètement)

III- Observance des consignes/ conseils hygiéno-diététiques et de conduite à tenir selon l'évolution

1. Le médecin des urgences vous a-t-il donné des conseils à respecter ?

OUI NON

(cf. liste ci-dessous pour vous aider)

Par exemple, conseils concernant:

- L'alimentation et/ ou la gestion du poids
- Vos activités habituelles
- Le tabagisme et l'arrêt du tabac
- Quand reconsulter
- La consommation d'alcool
- La consommation d'eau
- L'exercice physique
- Les moyens d'éviter l'aggravation des symptômes, la récurrence, la transmission

Si non: question non comptabilisée.

Si oui:

2. Avez-vous appliqué les conseils donnés et/ou modifié certaines habitudes suite à la consultation?

(Pas du tout) 1 (Un peu) 2 (beaucoup) 3 (Complètement) 4

3. Certaines informations données par le médecin des urgences pouvaient-elles intéresser vos proches?

OUI NON

Si non, question non comptabilisée.

Si oui, leur avez-vous transmis ces informations?

(Pas du tout) 1 (un peu) 2 (beaucoup) 3 (Complètement) 4

IV- Comportement de consommation de soins

1/ Après la consultation aux urgences, avez-vous eu besoin d'un nouvel avis médical pour le même problème?

1 (non) 2 (plutôt non) 3 (plutôt oui) 4 (oui, tout à fait)

Si oui :

1a- Avez-vous consulté à nouveau le médecin des urgences?

OUI NON

1b- Avez-vous consulté un autre médecin ?

OUI NON

1c- Avez-vous consulté un autre service d'urgences?

OUI NON

1d- Avez-vous appelé le centre 15 concernant le même problème?

OUI NON

2/ Votre médecin vous a-t-il donné des informations sur quand reconsulter?

OUI NON

Si oui :

Selon vous, le fait d'avoir pris un nouvel avis médical, vous paraît-il en accord avec les recommandations du médecin des urgences?

Pas du tout : 1

Plutôt non: 2

Plutôt oui : 3

Complètement : 4

SYSTEME de COTATION:

Le score d'observance médicamenteuse selon Morisky est coté de 0 à 6

Le score d'observance globale proposé par notre équipe comprend 4 sous-dimensions cotées chacune de 1 à 4 selon une échelle de Likert.

Le score total étant est la moyenne des 4 sous-dimensions. Total de 4 à 16/ 16

-L'observance médicamenteuse

-L'observance des prescriptions non médicamenteuses

-L'observance des conseils hygiéno-diététiques

-L'observance de recours au système de soins

Les questions binaires «oui-non» ne sont pas comptabilisées dans le calcul du score.

QUESTIONNAIRE FIP

1/Avez-vous reçu une FIP :

Oui non Ne se souvient plus (NSP)

2/Qui vous l'a donnée ?

1-Médecin 2-IDE 3-AS 4-NSP

3/La FIP est-elle signée ?

Oui non NSP

4/a Avez-vous lu la FIP ?

Oui non En partie NSP

4/b Quand l'avez-vous lue ?

Immédiatement Quelques jours après Pas du tout

4/c L'avez-vous gardée ?

Oui non NSP

5/L'avez-vous relue?

Oui non NSP

6/Avez-vous trouvé la FIP facile à comprendre ?

Oui non NSP

7/La FIP vous a-t-elle été expliquée brièvement ?

Oui non NSP

8/La FIP vous a-t-elle aidé ?

Oui non NSP

9/Vos proches se sont-ils servis de la FIP ?

Oui non NSP