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The Role of Pharmacists in the Discharged Patients with Cardiovascular Diseases: A Literature Review

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SUMMARY

Background and Objective: The incidence of heart failure is increasing in developed countries. In the aged population, heart failure is a common cause of hospitalization and hospital readmis- sion, which in conjunction with post-discharge care, impose a significant cost burden. Inappro- priate medication management and drug-related problems have been identified as major contrib- utors to hospital readmissions. In order to enhance the care and clinical outcomes, and reduce treatment costs, heart failure disease management programmes (DMPs) have been developed. It is recommended that these pro- grammes adopt a multi-disciplinary approach,and pharmacists, with their understanding and knowledge of medication management, can playa vital role in the post-discharge care of heart failure patients.

The aim of this literature review was to assessthe role of pharmacists in the provision of post- charge services for heart failure patients.

Method: An extensive literature search was undertaken to identify published studies andreview articles evaluating the benefits of anenhanced medication management service for patients with heart failure post-discharge.

Results: Seven studies were identified evaluating 'outpatient' or 'post-discharge' pharmacy services for patients with heart failure. In three studies, services were delivered prior to discharge with either subsequent telephone or home visit follow-up. Three studies involved the role of a pharmacist in a specialist heart failure

outpatientclinic. One study focused on a home-based intervention. In six of these studies, positive outcomes, such as decreases in unplanned hospital read- missions, death rates and greater compliance and medication knowledge were demonstrated. Onestudy did not show any difference in the numberof hospitalizations between intervention and control groups. The quality of evidence of the randomized controlled trials was assessed using the Jadad scoring method. None of the studies achieved a score of more than 2, out of a maximumof 5, indicating the potential for bias.

Discussion: The DMPs carried out by pharmacists have contributed to positive patient outcomes, which has highlighted the value of extending the traditional roles of pharmacists from the provi- sion of professional guidance to the delivery ofcontinuity of care through a more holistic and direct approach.

Conclusion: This review has demonstrated the effectiveness of pharmacists' interventions to reduce the morbidity and mortality associated with heart failure. However, there is an on-going need for the development and evaluation of pharmacy services for these patients.

Keywords: continuity of care, heart failure, phar- macist, post-discharge management

INTRODUCTION

Heart failure, a chronic debilitating disease, is an escalating public health issue affecting all devel- oped countries. In Australia, the prevalence of heart failure in patients aged 60 years and above was found to be 13Æ2% (1). In UK, the prevalence of heart failure is about 3% in people aged 45 years or more (2).

Heart failure is a common cause of hospitaliza- tion and hospital readmission in the aged popula- tion in developed countries (3, 4, 5). In Australia, there were 41 052 hospitalizations in which heart failure was the principal diagnosis between the years 2002 and 2003 (6). In America, heart failure is the most common reason for hospitalization among older individuals [American Heart Association cited in Radford et al. (7)]. Heart failure is also reported to be the fourth most common cause of cardiovascular deaths in Australia, accounting for 2432 deaths in 2003 (6).

The cost burden of the disease is significant because patients with heart failure often represent for admission at hospital within the first year after discharge (2, 8). Although hospital admissions are a major contributor to the high costs associated with heart failure, post-discharge care also poses a significant expense (9). Furthermore, lower quality of life and premature death inevitably increases the overall costs (6). In Australia, Mathers & Penn (1999) reported that hospitalization associated with the management of heart failure patients accounts for about 38% of health care expenditure (2).

The frequency of unplanned readmission for patients with heart failure can be as high as 30–40% (10). Inappropriate medication management and drug-related problems have been identified as major contributors to hospital readmissions (4, 11, 12). Hospital admissions and readmissions are often related to failure to adhere to

prescribed medication regimens or fluid and dietary restrictions, as well as failure to seek early treatment for escalating symptoms (3, 11). Page & Henry (2000) identified that some medications which exacerbate heart failure, such as non-steroidal anti-inflammatory agents are a common cause of drug-related admissions. Poor continuity of post-discharge care and a lack of communication between the hospital and community sectors have also been identified as contributing factors to the high hospital read- mission rates of patients with heart failure (12). Other factors contributing to hospital readmissions include multiple comorbidities, polypharmacy, poor cognitive function, poor social support and depression (13, 14, 15, 16). Despite the potential for improved outcomes in heart failure via effective pharmacological options including angiotensin converting enzyme inhibi- tors (ACEIs), b-blockers and spironolactone, clinical management of these patients remains suboptimal (4, 17). Hence, the healthcare system is currently focusing on reducing hospital readmis- sions in patients with heart failure (3) by optimi- zing community or clinic-based care which includes pharmacists' interventions.

Disease management programmes (DMPs) have evolved to enhance the care and clinical outcomes of patients with heart failure with the ultimate aim of reducing hospital readmissions and associated costs for these patients (9, 13, 18, 19, 20, 21, 22). A multi-disciplinary team approach is recommended (18, 23). As pharmacists are the health professionals who have the required awareness, understanding and knowledge of medication management, they play a key role in the care of patients with heart failure post-discharge, in particular to ensure their safe, effective and appropriate use of medicines (9). The care provided by a heart failure pharmacist may encompass care delivered prior to discharge, home-based follow-up or at a specialist heart failure clinic (4, 15).

AIM

The aim of this literature review was to assess the role of pharmacists in the provision of outpatient or post-discharge services for patients with heart failure.

METHOD

An extensive literature search was undertaken to reveal published studies and review articles eval- uating the benefits of an enhanced medication management service for patients with heart failure post-discharge. A variety of databases were sear- ched using various word combinations. Databases used were MEDLINE (via Ovid), International Pharmaceutical Abstracts (via Ovid), Academic Search Elite, Blackwell Synergy and Science Direct. The search strategy included key terms such as 'heart failure' or 'cardiac failure' which were combined with 'management'; 'management and pharmacist'; 'readmissions'; 'heart failure man- agement'; 'home-based interventions'; 'home medicines review', 'home-based interventions and pharmacists'; 'pharmacist'; 'pharmacy services' and 'hospital admission and discharge'. Full-text articles published in the English language between 1990 and April 2006 were included. Reference lists and bibliographies of retrieved articles were also checked for further relevant articles.

Inclusion criteria: studies focusing on the role of the pharmacist in the post-discharge management of heart failure patients, studies which included a home-based

intervention or a medication review service by pharmacists. Studies assessing home-based interventions carried out by a team of health professionals in which the role of the pharmacist could not be isolated were excluded.

RESULTS

Seven studies evaluating 'outpatient' or 'post-dis- charge' pharmacy services for patients with heart failure were identified addressing the role of a pharmacist in the hospital outpatient clinic and the community setting. Of these seven studies, three studies delivered services prior to discharge with either subsequent telephone or home visit follow- up (24, 25, 26). Three studies involved the role of a pharmacist in a specialist heart failure outpatient clinic (4, 15, 21). One study focused on a home-based intervention (27). Five of these studies (4, 15, 27) were randomized controlled trials (RCTs). Studies were conducted in UK (15, 21, 27), USA (24,

25) , Australia (5) and Northern Ireland (4). These papers are summarized in Table 1.

Randomized controlled trials

Stewart et al. (5, 26), Rainville (25), Varma et al. (4) and Gattis et al. (15) each gained a Jadad score of 2, and Goodyer et al. (27), a score of 1. Given the qualitative nature of the research, it is not surpri- sing that none of the studies received a Jadad score higher than 2 (see Appendix A).

Stewart et al. evaluated the impact of a home- based intervention among 97 'high risk' patients with heart failure, who were discharged from an acute hospital care (5). The intervention was delivered by a nurse and a pharmacist and involved a single home visit within 1 week post- discharge to optimize medication management, identify early clinical deterioration and to identify if medical follow-up was necessary. The effects of these home-based interventions were compared with standard post-discharge care. The predis- charge counselling was done by the nurse, whereas the home visit involved both the nurse and the pharmacist. The pharmacist's role during the home visit included, performing an assessment of the patient's knowledge of prescribed medications and compliance. Patients who had poor medication knowledge and/or mal-compliance, received the following supports: verbal medication counselling, a daily reminder to take medications, a dosage administration aid to enable predistribution of medications, provision of a medication information and reminder card, increased monitoring by care- givers and referral to a community pharmacist (CP) for regular review. The main outcome measures were the frequency of unplanned readmissions and out-of-hospital deaths, which were measured 6 months later. Patients in the intervention group had fewer unplanned readmissions (36 vs. 63) and less out-of-hospital deaths. Patients in the control group who received usual care had more days of hospitalization. A concern in this study is that the interventions were not standardized for the patients in the intervention group, whereby only patients who demonstrated poor medication knowledge or non-compliance received the combination of interventions.

In 1999, Stewart et al. (28) carried out an extended 12 month follow-up study of all surviving patients from the Stewart et al. 1998 study, previously mentioned. This follow-up study demonstrated fewer unplanned readmissions, out- of-hospital deaths and days of hospitalization for the home-based intervention patients. There was also a significant lowering in hospital-based costs. In the UK, Goodyer et al. (27) conducted a study to determine whether pharmacists providing intensive counselling to elderly patients with chronic heart failure can influence subjective and objective measures of heart failure. The random- ized patients received either a 3-month counselling programme or no counselling at all. Patients in the intervention group were counselled on their med- ications using a 'standard written protocol', the details of which were not provided. Compliance was measured by a tablet count whereas medica- tion knowledge was assessed using a question- naire. Mean compliance scores by tablet count were

Table 1. Studies evaluating post-discharge management of heart failure (HF) patients by the pharmacist

References	Study characteristics	Study design	Main components of intervention	Outcome
Stewart et al. (5, 26)	Australian study Interventions prior to discharge with follow-up	Randomized controlled study	Single home visit within 1 week post-discharge By a nurse and pharmacist Optimize medication management,	Fewer unplanned re-admissions plus out-of-hospital deaths in intervention group patients

Rainville (25) • US study

- Interventions prior to discharge with follow-up

Patel et al. (24) • US study

- Interventions prior to discharge with follow-up

Varma et al. (4) • Northern Ireland study

- Out patient clinic services

Gattis et al. (15) • UK study

- Out patient clinic services

Whellan et al. (21) • UK study

- Out patient clinic services

Goodyer et al. (27) • UK study

- Home based intervention

Randomized controlled study

Controlled study (not stated if randomized or not)

Randomized controlled study

Randomized controlled study

Non-randomized (pre-enrolment

vs. post-enrolment)

Randomized controlled study identify clinical deterioration, intensify

necessary medical follow-up

- By a pharmacist and nurse specialist
- Patient information provided, identification of hospital re-admission risk factors, recommendation of medication changes

to physicians 'if necessary', pharmacist reviewed pharmacotherapy and weight monitoring issues

- By a pharmacist
- Drug therapy evaluation, counselling over the telephone, recommended drug therapy changes to the physician
- By a pharmacist
- Education on HF, prescribed drugs and symptom management, contacted community pharmacists and physicians
- By a clinical pharmacist
- Extensive education and counselling on medications, discussed and optimized patient's drug regimen with physician, necessary recommendations regarding HF therapy, discussed changes made in drug

therapy with the patients

- Telephone follow-up
- By a pharmacist
- Reviewed medications with patients, provided a medication appraisal

for physicians

- By a pharmacist
- Intensive counselling using a 'standard written protocol'

Less patients from intervention group were readmitted,

less HF readmissions

No difference in number of hospitalizations between intervention and control groups

Improved exercise capacity, better compliance with drug therapy, fewer hospital readmissions

Reduction in clinical events, hospitalization and death rates

Increased b-blocker use, decreased hospitalization rates

Intervention group patients showed significantly higher compliance and improved medication knowledge

calculated, the mean indicating the percentage of the maximum number of tablets that should have been consumed. At the beginning of the study, mean compliance was 49% in the control group as compared to 61% for the intervention group, which was not statistically significant (P = 0Æ98). After the counselling programme, compliance was signifi- cantly higher in the intervention group (93% vs. 51%). Medication knowledge also improved significantly (P < 0Æ001). However, precise details of this improvement were not provided. A 6-min exercise test that was carried out at the beginning and at the end of the study demonstrated worse results for the control group at the end of study period. In the intervention group, these test results improved, suggesting that counselling improved the patient's medication compliance, which in turn led to improved exercise capacity. Patients who received medication counselling also demonstrated improved signs of oedema, which was also attrib- uted to improve medication compliance.

Varma et al. (4) evaluated a structured pharma- ceutical care programme for patients with heart failure aged more than 65 years in Northern Ireland. The intervention group of patients (group A) received education from a pharmacist on heart failure, prescribed drugs and about the management of heart failure symptoms and writ- ten information in the form of a 'take home' printed booklet. Patients were also encouraged to monitor their symptoms and comply with their medi- cations. Patients were required to self-monitor using diary cards to be shown to their physician and CPs and later mailed to the researchers. Group A also recorded their weight on a daily basis and adjusted their diuretic doses accordingly based on a specific increase in weight or if they had worsening decline in symptoms, such as increased shortness of breath or ankle swelling. The pharmacist-researcher contacted the CPs and physicians via telephone to discuss the project and the self-monitoring programme. Patients in the control group (group B) received standard man- agement. All patients were assessed at baseline and at 3, 6, 9 and 12 months for the following: 2-min walk test, blood pressure, body weight, pulse, forced vital capacity, quality of life, knowledge of symptoms and drugs, compliance with therapy and use of health care facilities. From these assessments, patients in group A demonstrated better compliance with drug therapy which led to improved exercise capacity compared with patients in group B. Over the 12 months of this study, group A patients also exhibited considerable enhanced knowledge of their drug therapy and had fewer hospital admissions compared with group B patients. Quality of life, as an outcome, was not shown to have statistically significant changes following pharmacy interventions when compared with usual care. The authors acknow- ledged that the results of the study may have been limited by the small sample size. Patients also reported the skipping of doses, taking an extra dose, or running out of their heart failure drugs during the 12 months. These lapses in compliance combined with the possibility that

the patients may have given socially desirable answers that bring the accuracy of the self-reported data into question.

Gattis et al. conducted the Pharmacist in Heart

Failure Assessment Recommendation and Monit- oring Study in the UK, to examine the benefits of the addition of a clinical pharmacist to the heart failure management team on outcomes in outpa- tients with heart failure (15). In the intervention group, patients attended an outpatient clinic and received extensive medication education and counselling. The pharmacist discussed and opti- mized the patient's drug regimen by negotiating with the patient's physician, implemented changes to the patient's heart failure drug therapy and then discussed the changes with the patients. Follow-up was conducted via telephone at 2, 12 and 24 weeks after the initial clinic visit to identify any issues with drug therapy. The control group patients received usual care. The clearly defined primary end point was the combination of all-cause mortality and non-fatal heart failure events (i.e. emergency department visits or hospitalizations for heart failure). There were four events in the intervention group as compared with 16 events in the control group. The effect on all-cause mortality was not found to be statistically significant but the effect on non-fatal heart failure events was signifi- cant. This difference may be due to the closer fol- low-up by the clinical pharmacist of the patients in the intervention group. This close follow-up may have led to the early recognition of signs and symptoms of fluid overload, which in turn allowed quicker reviews by the physician and dose adjust- ments of diuretics which inevitably prevented the deterioration of heart failure. In addition, patients in the intervention group were more likely to receive target ACE inhibitor doses. The follow-up by the pharmacist also allowed the re-evaluation of the patient's medication regimen, recognition of potential drug interactions, the significance of medication compliance and the reinforcement of dietary sodium intake. Although neither the patients nor the physicians were told directly of the treatment assignment, the study could not be completely blinded, which the authors acknow- ledged as a weakness of this study (15). Also, as this study was located at a referral clinic, there was inconsistency in the medication adjustments made by the primary care physician and reasons for these adjustments (15). A further limitation of this study is that patient report was the only method to identify clinical events for those patients admitted to hospitals other than The Duke University Med- ical Centre, where the study was carried out. Patients may not have given an accurate answer when questioned on the telephone as to whether they had been to the emergency department or admitted to hospital.

In a study based in an acute care facility in the US, Rainville (25) evaluated the impact of phar- macist interventions on the functional health status of heart failure patients and their rate of readmis- sions. The patients, nurses and physicians were blinded to the allocation to minimize the potential of bias. Control group patients received routine care, which involved written prescriptions, physi- cian-discharged instructions, a nurse review of diet, treatment plan, medication and drug infor- mation sheets. The intervention group received routine care plus education from a pharmacist and nurse specialist, and patient issues that could con- tribute to readmission were also

identified and corrected if necessary. The pharmacist also reviewed the pharmacotherapy and pathology of heart failure with the patient or their caregiver, monitored the patient's weight and reviewed risk modifications, provided a patient information brochure, medication organizer, weight log book- let, a video tape and recommended medication changes to the physician when necessary. Both patient groups received a follow-up telephone call after 30, 90 and 12 months of post-discharge. Patients in the intervention group also received a telephone follow-up 3 and 7 days post-discharge.There was a significant improvement in hospital readmissions for heart failure in the intervention group as compared with the control group (24% vs. 59%) over the 12-month period. In addition, there was a significantly longer time to readmission for the patients in the intervention group (25). However, it was not reported by whom the statis- tical analysis had been carried out. A potential source of bias could have arisen if this analysis had been done by the research pharmacist. The author concluded that the pharmacist intervention in this study 'led to significantly fewer readmissions for heart failure' (p. 1314), noting that the validity of this study would need to be evaluated in a larger study (25).

Non-randomized controlled trials

In the UK, Whellan et al. (21) undertook a study to evaluate the potential benefit of implementing a heart failure DMPs, the Duke Heart Failure Programme (DHFP). This study assessed the benefits of b-blocker use and the cost to the health care system. The outcomes were assessed based on the rates of pre-enrolment vs. post-enrolment. Although this study involved a myriad of health professionals, the role of the pharmacist was clearly stated as reviewing medications with the patient and providing a medication appraisal for the physician. The pharmacist, with the help of the nurse, emphasized weight monitoring and when to contact a DHFP nurse in the event of experiencing worsening symptoms. The results showed that both b-blocker usage and doses increased signifi- cantly during the study whereas hospitalization rates significantly decreased and the number of clinic visits significantly increased. The doses of ACE inhibitors used increased, although not sig- nificantly. This increase could reflect the increased prescribing rates of ACE inhibitors and b blockers that occurred over the course of the study. How- ever, the use of b blockers was found to be lower at the time of enrolment, probably due to the recent evidence of benefits from b-blocker therapy in heart failure patients as compared with a longer standing known benefit from ACE inhibitors. The authors acknowledged that as the study was con- ducted in a single centre, the results could be biased and specific to the Duke University Health System (21). In the US, a pharmacist was part of a pilot heart failure programme to help prevent exacerbations and hospitalizations among heart failure patients (24). The intervention group received pharmacist interventions such as drug therapy evaluation, telephone counselling and recommended drug therapy changes to the physician by telephone or fax. Patients received pharmacist interventions every 4–6 weeks for 6 months, and outcomes were evaluated after 3 and 6 months. There was no dif- ference in the number of hospitalizations between the intervention and control groups. This study had a number of limitations, including the relat- ively short duration and the small sample size (n = 18). Also, there were no data regarding the patient selection criteria and no statistical data for the results, and the methodology of the evaluation of outcomes was not clearly defined (24).

DISCUSSION

The results of this review demonstrate the value of outpatient or post-discharge pharmacy services for patients with heart failure. The DMPs carried out by pharmacists contributed to positive patient outcomes, highlighting the value of extending the traditional roles of pharmacists from the provision of professional guidance to the delivery of conti- nuity of care via a more holistic and direct approach. Indeed, the value of pharmacists' involvement may have been underestimated, as they may also have a positive influence within a multidisciplinary service, the extent of which was difficult to determine. For instance, the study by Stewart et al. (5) involved both a nurse and phar- macist. Although the pharmacist's role could be isolated, the outcomes of the interventions could not be attributed to either the pharmacist's or nurse's role.

The results also suggest that the pharmacist home visits could be valuable to patients. A Home Medicines Review is an established process whereby an accredited pharmacist visits a patient at home to identify medication related problems and optimize medication management (29, 30). Visiting patients in their own home enables phar- macists to recognize home environmental factors that hinder effective medication management. In addition, patients are often more comfortable and prepared to learn at home (16, 31). The benefits of pharmacists counselling patients in their homes in comparison with counselling patients in hospital include adequate time and more peaceful surroundings (32). Studies discussed in this review (33, 34, 35) highlight the importance of post- discharge follow-up and complement Guiding Principle 9 of the 2005 APAC guidelines (36) which states that 'Patients deemed at risk of medication misadventure should be identified and followed up in the immediate post-discharge period' (p. 44).

The limitations of the individual studies have been noted previously. There are also other limi- tations which need to be considered relating to changing medication use and comparability of studies. Although there is support for the benefits of a heart failure DMP, Peterson (37) argued that the observed benefit from these programmes 'may have been confounded by preferential use of ACE inhibitors and b-blockers by (intervention group) patients' (p. 1366). A number of difficulties were encountered when comparing studies, which included establishing the effect of the pharmacy service on hospital admissions as an outcome measure, due to the dissimilarity in classifying the aetiology of admission. It was also difficult to make comparisons between the studies as there was variation in patient groups between studies, including age, comorbidities and severity of heart failure. The severity of heart failure would be a particularly important factor to consider due to the different level of interventions or care that is required for the different level of severity (38).

Also, the majority of studies did not clearly specify whether the same pharmacist or a number of pharmacists carried out the intervention throughout the entire study period. Thus, it was not possible to assess the extent of pharmacist bias or the impact of the different pharmacists' per- formance or personality on study outcomes. Also,

it is important to note that the patient selection tended to favour those at high risk of readmission, who would be most likely to benefit from the interventions.

Another limitation of this review is that studies from various countries were included, exhibiting a geographical variation. Studies have reported that the geographic variations led to variable 'patient demographics, heart failure aetiology and severity, specialist availability, length of stay, physician's practice patterns…and access to health care' among the countries (39, 40, 41). These differences may well influence the success or failure of the inter- ventions in the different regions. Publication bias may also have an impact on the findings of this review, as studies demonstrating positive out- comes may be more likely to be published than those with negative findings.

Another difficulty in carrying out this review has been that the methods sections did not often pro- vide adequate information to validate or evaluate the quality and exact nature of the interventions. For instance, it is often stated that 'patient educa- tion' was provided, without a precise explanation of 'how' the education was provided. Also, little information was provided about the 'usual care' provided to patients in the control groups. This is an important omission as these patients often showed less favourable outcomes as compared with the intervention group patients.

Hargraves et al. (9) in their review of studies

evaluating outpatient pharmacy services for heart failure, stated that the 'clear definition and robust evaluation of these services is lacking' (p. 7). In addition, the small number of RCTs make the determination of the significance of these services difficult. The varying definitions and methods used to assess compliance may lead to contra- dictory information and make it difficult to make comparisons between the studies. For example, in the study by Stewart et al. (5), compliance was assessed by using pill counts. Varma et al. (4) assessed compliance by 'comparing the [likely] finish dates for a prescription and the date [when] the next prescription was filled, using drug use profiles of patient medication records' (p. 867). He also defined compliance as 'patient self-reported [missing] of doses, taking an [additional] dose, or running out of heart failure medications…' (p. 867).

CONCLUSION

The disease trajectory of heart failure is often complex and care is delivered by a wide variety of health care providers, throughout numerous phases of the continuum of care. This review has demonstrated the effectiveness of pharmacists' interventions to reduce the morbidity and mortal- ity associated with heart failure. However, there is an ongoing need for the development, definition and evaluation of pharmacy services for patients with heart failure post-discharge.

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Table 1. Continued

Deduct 1 point if: For question 1, the method to generate the sequence of randomization was described and it was inappropriate (patients were allocated alternately, or according to date of birth, hospital number, etc).

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APPENDIX A: JADAD SCORING METHOD

The following instrument was designed by Jadad et al. (42) and was used to measure the study quality (i.e. the likelihood of bias) in the random- ized controlled trials.

Read the article and try to answer the following questions:

1. Was the study described as randomized (this includes the use of words such as randomly, random and randomization)?
2. Was the study described as double blind?
3. Was there a description of withdrawals and dropouts?

Table 1. Scoring the items: Either give a score of 1 point for each ‘yes’ or 0 points for each ‘no’. There are no in-between marks and/or: For question 2, the study was described as double blind but the method of blinding was inappropriate (e.g. comparison of tablet vs. injection with no double dummy).

GUIDELINES FOR ASSESSMENT

Randomization

A method to generate the sequence of randomiza- tion will be regarded as appropriate, if it allowed each study participant to have the same chance or receiving each intervention and the investigators could not predict which treatment was next. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should be not regarded as appropriate

Double blinding

A study must be regarded as double blind if the word ‘double blind’ is used. The method will be regarded as appropriate if it is stated that neither the person doing the assessment nor the study participant could identify the intervention being assessed, or if in the absence of such statement the use of active placebos, identical placebos, or dum- mies is mentioned.

Withdrawals and dropouts

Give 1 additional point if:

For question 1, the method to generate the sequence of randomization was described and it was appropriate (table of

random numbers, computer generated, etc).Participants who were included in the study but did not complete the observation period or who were not included in the analysis must be des- cribed. The number and the reasons for withdrawal in each group must be stated. If there were no withdrawals it should be stated in the article. If

and/or:

If for question 2 the method

of double blinding was described and it was appropriate (identical placebo, active placebo, dummy, etc).there is no statement on withdrawals, this item must be given no points.