

Proactive care programs in the emergency department: effectiveness and feasibility

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CHAPTER 4

The effect of a telephone follow-up call for older patients, discharged home from the emergency department on health-related outcomes: a systematic review of controlled studies

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ABSTRACT

Background

Older patients discharged from the emergency department (ED) are at increased risk for adverse outcomes. Transitional care programs offer close surveillance after discharge, but are costly. Telephone follow-up (TFU) may be a low-cost and feasible alternative for transitional care programs, but its effects on health-related outcomes are not clear.

Aim

We systematically reviewed the literature to evaluate the effects of TFU by healthcare professionals after ED discharge to an unassisted living environment on health-related outcomes in older patients compared to controls.

Methods

We conducted a multiple electronic database search up until December 1, 2019 for controlled studies examining the effects of TFU by healthcare professionals for patients aged \geq 65 years, discharged to an unassisted living environment from a hospital ED. Two reviewers independently assessed eligibility and risk of bias.

Results

Of the 748 citations, two randomized controlled trials (including a total of 2120 patients) met review selection criteria. In both studies, intervention group patients received a scripted telephone intervention from a trained nurse and control patients received a patient satisfaction survey telephone call or usual care. No demonstrable benefits of TFU were found on ED return visits, hospitalization, acquisition of prescribed medication, and compliance with follow-up appointments. However, many eligible patients were not included, because they were not reached or refused to participate.

Conclusions

No benefits of a scripted TFU call from a nurse were found on health services utilization and discharge plan adherence by older patients after ED discharge. As the number of high-quality studies was limited, more research is needed to determine the effect and feasibility of TFU in different older populations.

PROSPERO registration number CRD42019141403.

INTRODUCTION

Background

Older patients discharged from the emergency department (ED) are at increased risk of functional decline, ED return visits, hospitalization and death.(1–5) Risk factors associated with these outcomes are pre-existing functional and cognitive impairment, but also lack of social support, living alone and feeling depressed.(1,6) Therefore, older patients, discharged home from the ED may need close medical surveillance and adequate care transition from the ED to home.

In the last decades, many transitional care programs were started with the aim of preventing and reducing problems after discharge from the ED, and limiting ED return visits and hospitalization. Most transitional care programs focus on older high-risk patients, detected by geriatric assessment. These programs consist of discharge arrangements for community services and patient-education, which usually start during the patients' ED stay and are continued afterwards, either by home visits, telephone calls, or both.(1,7,8)

Several studies examining the effect of these transitional care programs found some positive effects, e.g., reduction in ED return visits,(9) hospital admissions,(10) and nursing home admissions.(11) However, many of these programs proved to be time-consuming and therefore involved deployment of additional staff, leading to considerable personnel costs.(9,12) This may be beyond the ability of many EDs to implement.

As an alternative intervention, telephone follow-up (TFU) is described as an inexpensive and easy to organise method of post-discharge care in various medical populations and settings.(13–16) Feasibility has been demonstrated in multiple medical settings, including the ED.(17–19) However, previous systematic reviews examining the effect of TFU by hospital-based and primary care professionals after hospital admission in (adult) patients of all ages found inconclusive evidence about the effects of TFU. The authors of the reviews reported a large variety in study methods and outcome measures and low methodological quality of the included studies.(13,20,21) The effect of TFU in older patients discharged home from the ED has not yet been examined in a systematic review, apart from one "short-cut review", solely focusing on compliance with follow-up visits and discharge instructions.(22) The effects of TFU in older adults, discharged from the ED, on other outcomes, like ED return visits and hospitalization, are still unknown.

Aim

The aim of this systematic review of controlled studies was to determine the effects of a telephone follow-up (TFU) call from a healthcare professional for older patients after discharge from the ED to an unassisted living environment on health-related and patient-oriented outcomes. These outcomes include ED return visits and hospitalization, but also compliance with discharge instructions, general functioning, patient satisfaction and emotional well-being.

METHODS

This systematic review was conducted in adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.(23,24)

Protocol and registration

A protocol describing the research question, search strategy, in-and exclusion criteria, and methods of the analysis was made in advance and registered in PROSPERO (registration number: CRD42019141403).

Search strategy and selection criteria

We performed an electronic search of MEDLINE, Ovid EMBASE and the Wiley Cochrane Library in the Cochrane Database of Systematic Reviews and Central Register of Controlled Trials from the beginning of indexing until December 1, 2019. Search terms used were a combination of Medical Subject Heading terms and relevant keywords; no restriction with respect to language was used. Full details of the search strategy are available in Additional file 1. Detailed selection criteria are described in Table 1.

Besides searching in electronic databases, we hand-searched several clinical trial websites (presented in Additional file 2) to identify relevant unpublished and ongoing research and publications in journals that are not peer-reviewed. Reference lists of selected full-text articles were hand-searched for other potentially relevant articles. Original, full-text articles with case-control or (randomized) controlled clinical trial design were eligible for inclusion.

Study selection

Two investigators (MvL and BvW) independently screened the electronic search results on title and abstract to identify potentially relevant articles, according to the predefined selection criteria (see Table 1). Disagreements concerning which citations were suitable for full-text review were resolved by discussion in the presence of a third author (MCvdL) until consensus was achieved. In case of disagreement, the full text of the article was retrieved and reviewed. Full-text articles of relevant citations were reviewed independently by two investigators (MvL and BvW). Agreement about which

articles were suitable for inclusion was again achieved by discussion in the presence of the third author (MCvdL). Records were managed using [®] 2020 Mendeley Ltd.

Risk of bias assessment

Using the Cochrane risk of bias tool, two reviewers (MvL and MCvdL) independently assessed the risk of bias for each individual study on seven domains (Additional file 3).(25)

Category	Inclusion criteria	Exclusion criteria
Population	Patients aged 65 years and older, discharged from the ED to an unassisted living environment	Patients aged under 65 years; Patients discharged from the ED to an assisted living environment
Intervention	Telephone follow-up call by healthcare professional after ED discharge	Any other kind of transitional care; Telephone follow-up not conducted as independent intervention; Telephone follow-up calls by others than healthcare professionals
Control condition	Usual care or patient satisfaction survey telephone call	
Outcome measures	Any health-related, patient-oriented outcome, including: Health services utilization, including ED return visits, hospitalization, follow-up visits Physical health outcomes, including level of activities of daily living, independence Psychosocial health outcomes, including quality of life, mood, satisfaction Other patient-oriented outcomes, including treatment adherence, knowledge of disease and symptom management	Outcomes not health-related or patient-oriented
Setting	Discharged from hospital-based ED	Discharged from hospital ward or primary care setting
Study type	Case-control or (randomized) controlled clinical trials	Uncontrolled studies

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ED, emergency department

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Data extraction and synthesis

We developed a data extraction sheet, based on the Cochrane Consumers and Communication Review Group's data extraction template (see Additional file 3).

One reviewer (MvL) independently extracted data on patient and study characteristics and another reviewer (MCvdL) checked the extracted data on the sheets. Disagreements were resolved by discussion until consensus was reached. We contacted the author of the two included studies for further information concerning the methods, blinding of research staff and numerical outcome data. The author did not respond and hence the questions we had could not be clarified.

RESULTS

Study selection

Of the 748 citations until December 1, 2019, only two studies met the selection criteria for our systematic analysis (Figure 1). Searching clinical trial websites did not yield any relevant ongoing unpublished research.

Overview of included studies

Table 2 summarizes the study characteristics and outcome measures of the two included studies. Both studies were single-centred randomized controlled trials (RCTs) from the same author, performed in the same academic ED, but with a different study population in a different study period.(26,27)

The studies involved a total of 2120 patients aged \geq 65 years who were discharged home from the ED. Study sample sizes were 120 and 2000 patients, respectively. The duration of follow-up ranged from 30 to 35 days. In both studies, trained nurses recruited patients by telephone. Older patients or, if they were not available, their caregivers or spouses, had to pass a mental cognition screening examination before participation. Patients in the intervention group received a post-discharge telephone intervention in which they were surveyed about their wellbeing, understanding of their ED diagnoses, discharge instructions, follow-up appointments and management of medications. The nurse provided review and re-emphasis of discharge instructions, reinforcement of follow-up appointments, assistance in making appointments and advice if not feeling well. Control group patients received either a telephone call during which satisfaction with their care during the ED visit was assessed, or no telephone call after discharge. One study (Biese et al. 2014) compared the outcomes of three patient groups: an intervention group, a placebo group in which patients received a patient satisfaction survey telephone call, and a control group in which patients received no telephone call after discharge. The primary objective of this study was to investigate whether TFU improved discharge plan adherence.(26) The second study (Biese et al. 2018) consisted of two patients groups: an intervention group in which patients received an intervention telephone call and a control group in which patients received a patient satisfaction survey telephone call. The primary outcome measures of the study were the rates of ED return visits, hospital admissions or death within 30 days after ED discharge. Only this study was of sufficient sample size to detect a significant difference on these outcome measures between the study groups.(27)



Figure 1. Flow diagram of study selection. n, number; ED, Emergency Department

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Characteristics	Biese et.al. 2014	Biese et.al. 2018
Setting, country	Academic center ED, USA	Academic center ED, USA
Study design	RCT	RCT
Aim(s)	To investigate whether an ED postdischarge telephone intervention by nurse improves discharge plan adherence.	To investigate whether an ED postdischarge telephone intervention by call-center nurse decreases ED return visit rates, hospitalization or death within 30 days after ED visit.
Study period	From September 5 until November 9, 2010	From August 2013 to March 2016
Study patients	Patients ≥65 years, discharged home from ED	Patients ≥65 years, discharged home from ED
Recruitment of study patients	Randomization before first call Recruitment by telephone after mental cognition screening examination was passed and informed consent was obtained.	Recruitment by telephone after mental cognition screening examination was passed and informed consent was obtained. Subsequent randomization.
Description of intervention: intervention group	Telephone call following pre-written script from trained study nurse within 1-3 days after ED discharge to review discharge instructions and offer assistance with discharge plan compliance.	Telephone call following pre-written script from call-center nurse within 1-3 days after ED discharge to identify problems, review discharge instructions and offer assistance with discharge plan compliance, advice if not feeling well.
Description of intervention: control group(s)	<i>Placebo group:</i> scripted patient satisfaction survey telephone call from research assistant 1-3 days after ED discharge. <i>Control group:</i> no telephone intervention	Scripted patient satisfaction survey telephone call from call-center nurse 1-3 days after ED discharge.
Sample size	Intervention group: n=39; placebo group: n=35; control group: n=46	Intervention group: n=999; control group: n=1001

Table 2. Characteristics, outcome measures and feasibility of included studies.

Characteristics	Biese et.al. 2014	Biese et.al. 2018
Outcome measures	Primary outcome measures: Scheduled physician appointment within 5 days. Filled medication prescription. Knowledge of name, dosage, indication of prescribed medication.	Primary outcome measures: Days from ED discharge to ED return visit, 30-day hospitalization or death.
	Secondary outcome measures: 35-day hospitalization 35-day ED return visits	<u>Secondary outcome measures:</u> Scheduled physician appointment within 30 days. Difficulty acquiring prescribed medication.
Results of outcome measures	Primary outcome measures: Physician appointment ≤ 5 days: 54% (I), 20% (P), 37%(C); p=0.04 Filled prescription: 96% (I), 94%(P), 94% (C); NS. Knowledge name/dosage of medication: 92%(I), 94%(P), 89%(C); NS. Knowledge of reason for medication: 96%(I), 100% (P), 100%(C); NS.	Primary outcome measures: ED return visits ≤30 days: 12.2% (I) vs. 12.5% (C); NS. Hospitalization ≤30 days: 9.0% (I) vs. 7.4%(C); NS. Death ≤30 days: 0%(I) vs. 0.51% (C); NS.
	Secondary outcome measures: ED return visits/hospitalization ≤35 days: 22%(I), 33%(P), 27%(C); NS.	Secondary outcome measures: Physician appointment ≤ 30 days: 80.8% (I) vs. 80.8%(C); NS. Difficulty acquiring medication: 15.5% (I) vs. 15.6%(C); NS.
Feasibility	178 eligible patients: 120 (67%) included, 18 (10%) declined and 19 (11%) not reached during follow- up. 12 (7%) Were disqualified from primary outcome analysis, because of return to ED or other hospital setting within 5 days. Three were excluded for other reasons. Six had incomplete surveys. No patients failed mental screening examination. Inclusions only on Sunday, Monday, Tuesday and not more than 9 inclusions per day.	Of the 6463 eligible patients, 2000 (31%) consented to participate. 2712 (42%) Patients were not reached, 1683 (45%) patients who were reached declined participation, 37 were lost on call back and 31 failed mental screening examination. Inclusions 24/7.

Table 2. Continued.

C, control group; *ED*, emergency department; *I*, intervention group; *NS*, not significant (p<0.05); *P*, placebo group; *RCT*, randomized controlled trial; *USA*, United States of America

Risk of bias assessment of included studies

In both studies, the randomization process was well performed and described, ensuring a low risk of selection bias. Patients were not aware of the interventions, but blinding of personnel was not possible. However, the telephone calls were scripted in order to prevent performance bias. It was unclear whether the nurses who performed the data collection calls were (completely) blinded, but these telephone calls were also scripted to prevent detection bias. Loss to follow-up and incomplete data of included patients was limited. Methods were followed and expected outcomes were reported as planned in previously published study protocols. In the first study of Biese et al., it was not clear whether patients were analyzed according to intention to treat.(26) In both studies, patients who did not pass the mental cognition screening examination were not included.(26,27) However, this group involved a small number of patients (n=31) in the second study only (Biese 2018).(26,27) More details concerning the risks of bias are presented in Additional Table 1.

Main results: effect of TFU on health-related and patient-oriented outcomes

Both studies didn't find a statistically significant effect of TFU in reduction of ED return visits, hospitalization or death 30 or 35 days after ED discharge (Table 2).(26,27)

In one study (Biese et al. 2014), patients in the TFU group had significantly more often a physician appointment scheduled within 5 days than patients in the placebo and the control groups. However, the authors reported that for a minority of TFU group patients, the calling nurse helped to schedule appointments, which may have contributed to a shorter follow-up time.(26) In the other study (Biese et al. 2018), the authors found no benefit of the intervention on the number of scheduled physician follow-up appointments within 30 days after discharge from the ED.(27) Both studies did not report whether patients actually showed up on the planned appointments.

No significant differences between the groups were found in obtaining prescribed medication and in knowledge of name, dosage or indication of the prescribed medication.(26,27)

Feasibility in daily ED practice

In the included studies, eligible patients were approached for participation by telephone. In the Biese et al. 2014 study, all 178 eligible patients were reached, but in the Biese et al. 2018 study, 2712 (42%) of the 6463 eligible patients could not be reached and hence could not be approached for participation. During follow-up, the included patients were well accessible by telephone in both studies: ≥89% of the included patients was reached. Of the eligible patients who were reached and approached for participate in the Biese et al. 2014 study, whereas in the Biese et al. 2018 study 45% declined.(26,27) In Biese's 2014

study, patients were only enrolled after visits to the ED on Sunday, Monday and Tuesday and not more than nine patients per day, to facilitate follow-up calls during the week, because they did not have enough staff to make calls during the weekend. (26) In Biese's 2018 study, there were no restrictions for inclusion concerning the day and time of the ED visit and the number of inclusions per day.(27)

DISCUSSION

Only two controlled studies, both RCTs, met the inclusion criteria for this review. Both studies reported no effect of a TFU call from a nurse for older patients, discharged home from the ED on hospital admission or ED return visit rates within 30 or 35 days after the index ED visit. However, only the Biese et al. 2018 study was powered to find a significant difference on this outcome.(27) The Biese et al. 2014 study reported that patients in the TFU group had significantly more often a physician appointment scheduled within 5 days than patients in the placebo and the control group. This effect was not found in the other included study, examining differences in scheduled physician appointments within 30 days. TFU was not shown to be helpful in obtaining prescribed medications or knowledge of name, dosage and indication of prescribed medications.

Although patients who were included in the studies were well accessible by telephone for follow-up calls, many eligible patients were not reached and hence, could not be approached for participation. Moreover, a substantial number of eligible patients refused to participate. This questions the feasibility of the intervention in daily practice.

The findings of the studies included in this systematic review, are in accordance with other systematic reviews that examined the effects of TFU after hospital admission in (adult) patients of all ages. Crocker et al. evaluated the impact of TFU, performed by primary care personnel, after hospital admission on ED visit and hospital readmission rates in adults of all ages and did not found TFU to be beneficial.(20) Authors of a 2006 Cochrane review and a review of Bahr et al. found inconclusive evidence about the effects of TFU after hospital discharge. In the included studies, TFU was performed in a large variety of ways and by different kinds of healthcare professionals in different patient populations. Most studies were of low methodological quality and many different outcomes were measured, ranging from outcomes related to health services utilization to physical and psychosocial health outcomes. Effects were not constant across the included studies and overall, the evidence was inconclusive.(13,21) In 2019 Nasser et al. published a review evaluating the effect of TFU on compliance with follow-up and discharge instructions in older patients, discharged home from the ED. It was concluded that TFU can identify non-compliance with discharge instructions, but evidence to improve compliance was not found.(22)

Some previously published uncontrolled studies reported that TFU after ED discharge was feasible as only few patients declined participation or were not reached.(17.28) The patients in the included studies in our review were also well accessible by phone for follow-up. However, this may reflect participation bias, as in one of the studies many eligible patients were not reached by phone and therefore could not be approached for inclusion. These may well have been patients with physical or other impairments who were unable to answer the telephone, but could have benefited from TFU.(17) Problems concerning telephone accessibility of patients are also mentioned in other studies.(14,21,29) Many studies report the lack of a correct phone number, which could be addressed by verifying the patient's telephone number at discharge. The telephone number of a caregiver or family member can also be asked in case the patient cannot be reached for TFU. It is probable that for many older patients, involvement of family members or other caregivers in TFU increases accessibility and improves discharge plan adherence and other postdischarge outcomes. (29,30) A substantial number of eligible patients refused to participate. This was also reported in a study, investigating the effect of telephone support calls by volunteers on feelings of loneliness and depression by older patients, discharged home from the ED.(31) Patients may have refused participation, because they did not want to be involved in a study, but they may also judge TFU as unnecessary interference. Although less time-consuming than other transitional care programs, TFU still requires sufficient staff to approach all eligible patients.(21) This is illustrated in the Biese et al. 2014 study, enrolling patients only on specific weekdays and up to a maximum of nine per day, because they did not have enough staff to perform more telephone calls.(26) Not including patients on other weekdays may undoubtedly have led to missing eligible patients who presented outside this inclusion window. The substantial number of eligible patients that was not reached or refused participation underlines the efforts that are needed to make FTU feasible in daily practice.(26,27,31)

The studies included in this review investigated the effect of TFU on health services utilization and understanding of and compliance with discharge instructions. The effects of TFU on other, more difficult to measure outcomes, such as psychosocial health outcomes, were not measured. A systematic review investigating older patients' expectations of emergency care, reported that insufficient or poorly-understood explanations about diagnosis or discharge instructions were associated with less satisfaction with care.(32) It may be that with TFU ED staff could meet these expectations by providing additional explanations and care. Besides that, TFU can be regarded as a socially complex intervention, characterized by difficult to define and to standardize interactions and by various contextual factors, which may mask potential effects. To support this idea, the Dutch Patients and Costumers Federation stated that TFU deserved a place in aftercare, despite the negative findings of the 2006 Cochrane review, because patients had indicated that they highly appreciated the call.(13) In accordance with this, some studies suggest that several older patients

are in need of social and emotional support following an ED visit and that (repetitive) TFU could provide for this.(28,31) It would be worth exploring in future research how care transition interventions after an ED visit affect perceived emotional and social support and specific needs and barriers that older ED users experience.(30)

The limited number of controlled studies concerning this subject is remarkable, given the increasing number of proactive care programs for older patients in many EDs.(27) Apart from the two studies that met the inclusion criteria for this review, we found one more suitable study. This cohort study with pre-post design, published in Dutch in a non-peer reviewed journal, also reported no effect of TFU on hospital admission or ED return visit rate within 30 days after discharge from a general hospital ED.(33) The small number of available studies, all showing no benefit of the intervention may underline the absence of effect of TFU on health-related outcomes. More controlled intervention studies are needed to investigate the effect of TFU in older ED patients. Future studies should best focus the intervention on individuals at highest risk of hospital use, such as those with functional or cognitive impairments, mental health conditions, limited social support, or with complex medical regimens, to determine whether there are different effects of TFU in these populations.(1,30,34) Interesting outcome measures, in addition to health service utilization, would be functional decline, perceived social and emotional support and feelings of anxiety or depression. Failure to reach eligible patients could be addressed by appointing sufficient staff members to perform the intervention, by verifying the patient's telephone number at discharge, and by involving the patients' caregivers. It would also be interesting to investigate the effects and feasibility of TFU performed by other personnel than ED staff, e.g., primary care personnel or nurses from a commercial call center.

STRENGTHS AND LIMITATIONS

Strengths

In this systematic review, only quantitative, controlled studies were included. Both included studies were RCTs and serious efforts had been made to limit the risks of bias. The risk of missing relevant publications was minimized by searching multiple databases and trial websites and by assessing citations and full-text articles for eligibility by two reviewers.

Limitations

The two RCTs included in this review were conducted in the same tertiary ED in the United States. This may limit generalizability of the study results to other countries. However, a Dutch study did not show a beneficial effect of TFU either.(33) Only one of the studies was of sufficient sample size to detect a significant effect of TFU on hospitalization and ED return visits. This study compared TFU with a telephone

satisfaction survey call, but not with no telephone call. In future research it would be worth comparing the outcomes of patients receiving TFU with those of patients who do not receive any telephone intervention. Patients or their caregivers or spouses who did not pass the mental cognition screening examination were excluded from both studies. Although cognitively impaired, these individuals might have benefited from a telephone intervention. However, the number of patients excluded for this reason was limited. Due to the small number of included studies, the heterogeneity of the study methods and the negative results, a quantitative analysis of the studies, including assessment of heterogeneity and publication bias by creating a funnel plot, was considered not to be of added value. Therefore, we used a qualitative approach to synthesize the literature.

CONCLUSIONS

Telephone follow-up is considered to be a low-cost intervention, that probably allows the opportunity to detect problems and complications, clarify discharge instructions and initiate other forms of aftercare for older adults discharged home from the ED. However, our systematic review of two published randomized controlled studies found no demonstrable effect of TFU for older adults, discharged from the ED on health services utilization and understanding of and compliance with discharge instructions. Furthermore, feasibility of the intervention appeared to be low. Considering the limited number of high-quality studies on this topic, more research is needed to explore whether TFU is an effective and feasible intervention to reduce hospitalization and ED return visit rates or to improve older patients' discharge plan adherence after an ED visit. In future studies, it is important to also investigate whether TFU promotes psychosocial wellbeing in older patients after ED discharge.

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- Lowthian J, Straney LD, Brand CA, Barker AL, De Villiers Smit P, Newnham H, et al. Unplanned early return to the emergency department by older patients: The Safe Elderly Emergency Department Discharge (SEED) project. Age Ageing. 2016;45(2):255– 61.

SUPPLEMENTARY INFORMATION

Additional file 1. Search strategy

Date	Database	Strategy	Number of references
09-12- 2019	PubMed (www.		252
	pubmed. gov)	Most recent	
		("Aged"[Mesh] OR aged*[tiab] OR aging*[tiab] OR ageing*[tiab] OR elder*[tiab] OR geriatr*[tiab] OR geront*[tiab] OR frail*[tiab] OR octogenarian*[tiab] OI octo-genarian*[tiab] OR nonagenarian*[tiab] OR nona-genarian*[tiab] OI non-agenarian*[tiab] OR centenarian*[tiab]) AND ("Emergency Medica Services"[Mesh] OR "Emergency Services, Psychiatric"[Mesh] OR "Emergency Treatment"[Mesh] OR "Emergency Nursing"[Mesh] OR "Emergency Medicine"[Mesh] OR emergenc*[tiab] OR emer-genc*[tiab] OR "ed"[tiab OR "eds"[tiab] OR ed's*[tiab] OR "er"[tiab] OR "ers"[tiab] OR er's*[tiab] OR accident department*[tiab] OR "accident dept"[tiab] OR (trauma*[tiab] OR heat to the test of te] R R I V J]]

AND (center*[ti] OR centre*[ti])) OR trauma center*[tiab] OR trauma centre*[tiab] OR (trauma*[ti] AND hospital*[ti]) OR trauma hospital*[tiab] OR (acute*[ti] AND (service*[ti] OR care*[ti] OR centre*[ti] OR center*[ti])) OR acute service*[tiab] OR acute care*[tiab] OR acute center*[tiab] OR acute centre*[tiab] OR (urgen*[ti] AND (service*[ti] OR care*[ti] OR centre*[ti] OR center*[ti])) OR urgency service*[tiab] OR urgent service*[tiab] OR urgent care*[tiab] OR urgent center*[tiab] OR acute centre*[tiab] OR urgent-centre*[tiab]) AND (("Aftercare"[Mesh] AND "Telephone"[Mesh]) OR post-discharge follow-up*[tiab] OR postdischarge follow-up*[tiab] OR post-discharge-followup*[tiab] OR postdischarge followup*[tiab] OR (interven*[ti] AND (phone*[ti] OR telephon*[ti])) OR ((phone*[ti] OR telephon*[ti]) AND (postdischarge*[ti] OR discharge*[ti] OR follow-up*[ti] OR followup*[ti])) OR postdischarge phon*[tiab] OR post-discharge-phon*[tiab] OR postdischarge telephon*[tiab] OR post-discharge telephon*[tiab] OR discharge-phon*[tiab] OR discharge telephon*[tiab] OR phone followup*[tiab] OR phone-followup*[tiab] OR telephone follow-up*[tiab] OR telephone followup*[tiab] OR follow-up phon*[tiab] OR followup-phon*[tiab] OR follow-up telephon*[tiab] OR followup telephon*[tiab]) AND ("Clinical Trial" [Publication Type] OR "Comparative Study" [Publication Type] OR "Evaluation Studies" [Publication Type] OR "Cross-Over Studies" [Mesh] OR "Multicenter Study" [Publication Type] OR "Random Allocation" [Mesh] OR "Double-Blind Method" [Mesh] OR "Single-Blind Method" [Mesh] OR "Placebos" [Mesh] OR "Research Design" [Mesh: NoExp] OR "trial" [tiab] OR trial'*[tiab] OR random*[tiab] OR placebo*[tiab] OR sham*[tiab] OR comparison*[tiab] OR controlled-clinical-trial*[tiab] OR controlled-clinicalstud*[tiab] OR crossover*[tiab] OR cross-over*[tiab] OR double-blind*[tiab] OR doubleblind*[tiab] OR "group"[tiab] OR group'*[tiab] OR groups*[tiab] OR "control" [tiab] OR control'* [tiab] OR "controls" [tiab] OR controls'* [tiab] OR controll*[tiab] OR controlgroup*[tiab] OR volunteer*[tiab] OR ((singl*[tiab] OR doubl*[tiab] OR trebl*[tiab] OR tripl*[tiab]) AND (mask*[tiab] OR blind*[tiab])) OR latin-square*[tiab] OR multicenter*[tiab] OR multi-center*[tiab] OR multicentre*[tiab] OR multi-centre*[tiab] OR 4-arm*[tiab] OR four-arm*[tiab])

Number of

references 297

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Date
       Database Strategy
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Advanced Search

(exp aged/ OR aged*.ti,ab,kw. OR aging*.ti,ab,kw. OR ageing*.ti,ab,kw. OR elder*.ti,ab,kw. OR geriatr*.ti,ab,kw. OR geront*.ti,ab,kw. OR frail*. december ti,ab,kw. OR octogenarian*.ti,ab,kw. OR octo-genarian*.ti,ab,kw. OR nonagenarian*.ti,ab,kw. OR nona-genarian*.ti,ab,kw. OR non-agenarian*. Embase ti,ab,kw. OR centenarian*.ti,ab,kw.) AND (exp emergency health service/ OR exp emergency medical dispatch/ OR exp hospital emergency service/ OR exp psychiatric emergency service/ OR exp emergency treatment/ OR exp emergency nursing/ OR exp emergency medicine/ OR emergenc*.ti,ab,kw. OR emer-genc*.ti,ab,kw. OR "ed".ti,ab,kw. OR "eds".ti,ab,kw. OR ed's*. ti,ab,kw. OR "er".ti,ab,kw. OR "ers".ti,ab,kw. OR er's*.ti,ab,kw. OR accident department*.ti,ab,kw. OR "accident dept".ti,ab,kw. OR (trauma*.ti. AND (center*.ti. OR centre*.ti.)) OR trauma center*.ti,ab,kw. OR trauma centre*. ti.ab.kw. OR (trauma*.ti, AND hospital*.ti.) OR trauma hospital*.ti.ab.kw. OR (acute*.ti. AND (service*.ti. OR care*.ti. OR centre*.ti. OR center*.ti.)) OR acute service*.ti,ab,kw. OR acute care*.ti,ab,kw. OR acute center*.ti,ab,kw. OR acute centre*.ti,ab,kw. OR (urgen*.ti. AND (service*.ti. OR care*.ti. OR centre*.ti. OR center*.ti.)) OR urgency service*.ti,ab,kw. OR urgent service*. ti,ab,kw. OR urgent care*.ti,ab,kw. OR urgent center*.ti,ab,kw. OR acute centre*.ti,ab,kw. OR urgent-centre*.ti,ab,kw.) AND (((exp rehabilitation/ OR aftercare/) AND exp telephone/) OR post-discharge follow-up*.ti,ab,kw. OR postdischarge follow-up*.ti,ab,kw. OR post-discharge-followup*.ti,ab,kw. OR postdischarge followup*.ti,ab,kw. OR (interven*.ti. AND (phone*.ti. OR telephon*.ti.)) OR ((phone*.ti, OR telephon*.ti,) AND (postdischarge*.ti, OR discharge*.ti. OR follow-up*.ti. OR followup*.ti.)) OR postdischarge phon*. ti,ab,kw. OR post-discharge-phon*.ti,ab,kw. OR postdischarge telephon*. ti,ab,kw. OR post-discharge telephon*.ti,ab,kw. OR discharge-phon*. ti,ab,kw. OR discharge telephon*.ti,ab,kw. OR phone follow-up*.ti,ab,kw. OR phone-followup*.ti,ab,kw. OR telephone follow-up*.ti,ab,kw. OR telephone followup*.ti,ab,kw. OR follow-up phon*.ti,ab,kw. OR followup-phon*.ti,ab,kw. OR follow-up telephon*.ti,ab,kw. OR followup telephon*.ti,ab,kw.) AND (exp clinical trial/ OR exp comparative study/ OR exp evaluation study/ OR exp crossover procedure/ OR exp multicenter study/ OR exp randomization/ OR exp double blind procedure/ OR exp single blind procedure/ OR exp placebo/ OR "trial".ti,ab,kw. OR trial'*.ti,ab,kw. OR random*.ti,ab,kw. OR placebo*.ti,ab,kw. OR sham*.ti,ab,kw. OR comparison*.ti,ab,kw. OR controlled-clinical-trial*.ti,ab,kw. OR controlled-clinical-stud*.ti,ab,kw. OR crossover*.ti,ab,kw. OR cross-over*.ti,ab,kw. OR double-blind*.ti,ab,kw. OR doubleblind*.ti,ab,kw. OR "group".ti,ab,kw. OR group'*.ti,ab,kw. OR groups*. ti,ab,kw. OR "control".ti,ab,kw. OR control'*.ti,ab,kw. OR "controls".ti,ab,kw. OR controls'*.ti,ab,kw. OR controll*.ti,ab,kw. OR controlgroup*.ti,ab,kw. OR volunteer*.ti,ab,kw. OR ((singl*.ti,ab,kw. OR doubl*.ti,ab,kw. OR trebl*. ti,ab,kw. OR tripl*.ti,ab,kw.) AND (mask*.ti,ab,kw. OR blind*.ti,ab,kw.)) OR latin-square*.ti,ab,kw. OR multicenter*.ti,ab,kw. OR multi-center*.ti,ab,kw. OR multicentre*.ti,ab,kw. OR multi-centre*.ti,ab,kw. OR 4-arm*.ti,ab,kw. OR four-arm*.ti,ab,kw.)

Date	Database	Strategy	Number of references
09-12- 2019	Cochrane Library	Advanced search	199
		Search manager	
		Four <i>separated</i> searches, combined <i>afterwards</i> : (aged* OR aging* OR ageing* OR elder* OR geriatr* OR geront* OR frail* OR octogenarian* OR (octo NEXT genarian*) OR nonagenarian* OR (nona NEXT genarian*) OR (non NEXT agenarian*) OR centenarian*):ti,ab,kw AND	
		(emergenc* OR (emer NEXT genc*) OR "ed" OR "eds" OR "er" OR "ers" OR (accident NEXT department*) OR (accident NEXT dept) OR (trauma NEXT center*) OR (trauma NEXT center*) OR (trauma NEXT center*) OR (acute NEXT service*) OR (acute NEXT center*) OR (acute NEXT center*) OR (acute NEXT center*) OR (acute NEXT center*) OR (urgent NEXT center*)) OR (urgent NEXT center*) OR (urgent NEXT center*) OR (urgent NEXT center*)) OR (urgent NEX	
		center*)) OR (urgen* AND (service* OR care* OR centre* OR center*))):ti AND ((post NEXT discharge NEXT follow NEXT up*) OR (postdischarge NEXT follow NEXT up*) OR (post NEXT discharge NEXT followup*) OR (postdischarge NEXT followup*) OR (postdischarge NEXT phon*) OR (post NEXT discharge NEXT phon*) OR (postdischarge NEXT telephon*) OR (post NEXT discharge NEXT telephon*) OR (discharge NEXT phon*) OR (discharge NEXT telephon*) OR (phone NEXT follow NEXT up*) OR (phone NEXT followup*) OR (telephone NEXT follow NEXT up*) OR (telephone NEXT followup*) OR (follow NEXT up NEXT follow NEXT up*) OR (telephone NEXT followup*) OR (follow NEXT up NEXT follow NEXT up*) OR (follow NEXT up NEXT telephon*)	
		OR (follow NEXT telephon*)):ti,ab,kw OR ((interven* AND (phone* OR telephon*)) OR ((phone* OR telephon*)) AND (postdischarge* OR discharge* OR (follow NEXT up*) OR followup*))):ti AND	
		("trial" OR trial'* OR random* OR placebo* OR sham* OR comparison* OR (controlled NEXT clinical NEXT trial*) OR (controlled NEXT clinical NEXT stud*) OR crossover* OR (cross NEXT over*) OR (double NEXT blind*) OR doubleblind* OR "group" OR group'* OR groups* OR "control" OR control* OR "controls" OR controls'* OR controll* OR controlgroup* OR volunteer* OR ((singl* OR doubl* OR trebl* OR tripl*) AND (mask* OR blind*)) OR (latin NEXT square*) OR multicenter* OR (multi NEXT center*) OR multicentre* OR (multi NEXT centre*) OR (4 NEXT arm*) OR (four NEXT arm*)):ti,ab,kw	

Additional file 2. Overview of websites that were searched on December 9, 2019 to identify eligible articles and studies:

Netherlands Trial Register: www.trialregister.nl ClinicalTrials.gov: <u>https://ClinicalTrials.gov/</u> Australian Clinical Trials: <u>https://www.australianclinicaltrials.gov.au/</u> Australian New Zealand Clinical Trials Registry: <u>http://www.anzctr.org.au/</u> World Health Organization's International Clinical Trials Registry Platform: <u>http://</u> <u>apps.who.int/trialsearch/</u> EU Clinical Trials Register: <u>https://www.clinicaltrialsregister.eu/</u> OpenGrey: <u>http://www.opengrey.eu/</u> Google Scholar

Additional file 3. Data extraction template

Form version/date (eg. Version 1.4, 5 August 2019)

Review Title

Study ID (Surname and Year)

Name of review author completing this form

Date form completed

Name of review author checking the data extracted to this form Other information and notes

Author contact details for study	
Further information required	
Correspondence with authors successful or not; what information was received and when	
Will any additional unpublished data supplied by the authors be included in the review? If so, note that the study will include unpublished data	
Notes (Unpublished – for own use) eg. references to be followed up, source of information especially if multiple reports of same trial, or unpublished data/personal communication included.	

Section 2: Methods of the study

<u>Details of Study (to be reported in the Characteristics of Included Studies tables)</u> Aim of study (As stated in the trial report/s. What was the trial designed to assess?) Study design

Number of arms or groups (including control groups); briefly describe each Consumer involvement (eg. In design of study and/or intervention; in delivery of intervention; in evaluation of intervention; in interpretation of study findings)

Funding source (also include any details about possible or explicit conflicts of interest)

Informed consent obtained? (Yes/No/Unclear) Ethical approval (Yes/No/Unclear)

Section 3: Risk of Bias assessment

Domain	Review authors' judgement	Instructions
Random sequence generation ¹	High risk Unclear Low risk	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
Allocation concealment	High risk Unclear Low risk	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.
Blinding of participants and personnel Assessments should be made <u>for each main</u> <u>outcome</u> (or class of outcomes)	High risk Unclear Low risk	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. <u>Note</u> that the impact of performance bias <u>must</u> be considered and reported even if blinding of participants and/or personnel is <u>not</u> possible for the type of intervention being evaluated ^{2,3}

This has been adapted directly from Cochrane Handbook: The Cochrane Collaboration's tool for assessing risk of bias

Blinding of outcome	High risk Unclear	
assessment		
Assessments should	Low risk	
be made <u>for each main</u>		
<u>outcome</u> (or class of		
outcomes)		

1. Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received.

2. Provide any information relating to whether the intended blinding was <u>effective</u>. Blinding of outcome assessment can be feasible even if blinding of participants and personnel is not.

Notes on rating

Quasi-RCTs and Controlled Before and After (CBA) studies must be rated as 'High risk' for random sequence generation as the methods were not, by definition, truly random.

If you are including only RCTs in your review, papers marked 'High risk' should be excluded as they are not truly randomised.

<u>Note</u> that to exclude a study on this basis there must be agreement on this decision by at least two authors.

Quasi-RCTs are likely to be rated 'High risk' but there may be exceptions. CBA Studies should be rated 'High risk.

Consider:

- 1. Did the study attempt to blind the participants and/or personnel so that they did not know who received the intervention? Note that it may be possible to blind one but not the other (*eg participants but not personnel, or vice versa*)
- 2. Were the measures that the study took to blind participants and/or personnel to study groups <u>effective</u> (or not)?

These points will help to make the decision about whether the study is likely to be affected by performance bias (high, unclear, or low risk).

Even in studies of informational or educational interventions it may be possible (though difficult) to effectively blind participants and/or personnel to intervention status (*eg measures such as a 'placebo' video, control information brochure, blank instructional booklet*).

Please note that when making sense of the risk of bias ratings, you will need to consider the effects of blinding and incomplete outcome data <u>by outcome</u>, not just by study.

The implications of whether outcome assessment was blinded, and how effectively, may differ across outcomes. Blinding of outcome assessment should therefore be considered separately <u>for</u> <u>each outcome</u>.³

Outcomes may be assessed using subjective or objective measures, and by self-reported or other means. They may be assessed by research personnel or by participants.

To deal with this complexity, the following points are suggested as a guide:

For personnel-measured outcomes:

eg case notes, observed medicine taking, rate of participation

- Participants blinded
 - Personnel blinded: LOW risk
 - Personnel not blinded: HIGH risk
- Participants not blinded
 - Personnel blinded: UNCLEAR risk
 - Personnel not blinded: HIGH risk

For self-reported outcomes:

eg knowledge, self-reported compliance, anxiety

- Participants blinded
 - Personnel blinded: LOW risk
 - Personnel not blinded or unclear whether blinded: UNCLEAR risk
- Participants not blinded
 - Personnel blinded or unclear whether blinded: UNCLEAR risk
 - Personnel not blinded: HIGH risk

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Domain	Review authors' judgement	Instructions
Incomplete outcome data Assessments should be made for <u>each main</u> <u>outcome</u> (or class of outcomes)	High risk Unclear Low risk	Describe the completeness of outcome data for each main outcome, including attrition (loss to follow up, withdrawn) and exclusions from the analysis. Note that the participant numbers and reasons reported in the 'Participants' section of this form (below) should be used as a basis for making these decisions. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/ exclusions where reported, and any re-inclusions in analyses performed by the review authors.

Notes on rating

The following ratings are suggested as a guide for rating this item:

High risk

- Reasons for missing data are related to the outcome, and there is imbalance in numbers or reasons for missing data across study groups (*eg more people dropped out of the intervention than control group because of adverse events of a study medication*).
- The proportion of data missing or plausible effect size is large enough to have a clinically relevant effect.
- Analysis was not performed on an 'intention to treat' basis (where people are analysed in the groups to which they were randomly assigned, irrespective of what happened during the study).
- Imputation (entering substitute data to take the place of missing data) was done inappropriately.

Unclear risk

• The data is poorly reported - it is not clear how many participants/ data were lost from the study groups, and/or what the reasons for missing data were.

Low risk

- No data is missing.
- Reasons for missing data are not related to the outcome.
- Missing data is balanced across the study groups, and reasons for missing data are similar across groups.
- The proportion of data missing or plausible effect size is not large enough to have a clinically relevant effect.

The impact of missing data must be assessed for each outcome (or group of outcomes), as it may vary, and must also be considered at different time points if data was collected at different times. Assessing the completeness of outcome data must take into account:

- 1. How much data is missing from each group?
- 2. Why is it missing?
- 3. How was the data analysed?

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Domain	Review authors'	Instructions
	judgement	

Selective reporting

High risk Unclear Low risk State how the possibility of selective outcome reporting was examined by the review authors, and what was found.

Notes on rating

- 1. No simple rule applies across the board; although the overall proportion of missing data is one thing to consider (*eg 50% of data missing would be more of a concern than 5%*). However, a judgement about attrition bias also relies on an assessment of whether enough data is missing that it could meaningfully affect the results. Assessing this means considering:
- For dichotomous data: is the outcome rare or more common? If rare, only a few missing data could change the conclusions, whereas if the outcome is more common much more data could be missing before the conclusions would be altered.
- For continuous data: could the values for the missing participants be extremely different to the
 calcuated mean for the sample available? If the missing values could not be very different to
 the mean value, it would take a lot of missing data to alter the mean. On the other hand, if the
 missing values could be very different to the estimated mean value, fewer missing data could
 produce a different mean.
- 2. Reasons for missing data must also be considered. If the reason is not related to the outcome (eg people moved house and could no longer participate), this is described as data missing at random and is unlikely to systematically influence (bias) the results. If the reason for missing data is related to the outcome however, and this is different across study groups (eg more people dropped out of the intervention than control group because of adverse events of a study medication), this can introduce bias.
- 3. Different re-analysis techniques may disrupt the randomisation set up for an RCT and so should be looked at carefully when assessing this risk of bias item. Refer to online training materials and Handbook.

Please note that when making sense of the risk of bias ratings, you will need to consider the effects of blinding and incomplete outcome data <u>by outcome</u>, not just by study.

The following ratings are suggested as a guide:

High risk:

- If a protocol for the study is available, and outcomes identified in the protocol are not reported by the study; and/or
- Outcomes reported in the methods section are not reported as planned (ie as results for the study); and/or
- Expected outcomes are reported but done in such a way that they cannot be included in the review's analyses (eg the study reports a result as 'statistically significant'; but does not provide the specific numerical or other data that could be included in the analysis of that outcome).

Unclear risk:

 If no protocol for the study is available (and all expected outcomes reported in the methods are reported as planned)

Low risk:

 A protocol for the study is available and all expected outcomes are identified and reported as planned by the study.

80 Chapter 4

Domain	Review authors' judgement	Instructions
Other sources of bias	Note: all answers should follow the format: High risk Unclear Low risk	State any important concerns about bias not addressed in the other domains in the tool.

3 For example, objective outcome measures (eg chart review, electronically recorded medicine taking, mortality) might be less affected by a lack of blinding than the potential effect of unblinded outcome assessment on subjective outcomes (eg pain, self-reported adherence, quality of life). Similarly, for blinding of participants and personnel the risk of bias may be high for some outcomes if unblinded (eg behavioural, socially desirable or some self-reported outcomes) but less likely to affect others such as mortality.

¹ Please note that contact with authors of an included study may mean that some decisions need to be revised. For example, if information from study authors confirms that the allocation method was not truly randomised, even if the study report describes the study as an RCT, (and only RCTs were eligible for inclusion in the review), the study would then need to be excluded from the review.

² For example: if participants and personnel cannot be blinded effectively to the intervention, this item would be rated as at high risk of bias for performance bias, with a reason for this decision reported as (for example) 'Participants and personnel were not able to be blinded to intervention' in the risk of bias tables.

Notes on rating

If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.

Note that any other sources of bias identified here must have the potential to introduce systematic errors in the results of the study (not involve other aspects of the study that should be reported elsewhere in the review).

Assessing other sources of bias is not essential but should be guided by the study designs included in the review.

Do not assess in this domain aspects of conduct of the study, such as those:

- associated with the 'quality' of a study *eg ethical criteria such as whether the study obtained ethics approval;*
- related to precision of the study eg use of a power calculation
- linked to reporting standards or
- related to validity and/or reliability of outcome measures
- These aspects of the study can be collected and reported in the 'Characteristics of included studies' table.

Section 4: Study characteristics - Participants

Description (eg. Patients/consumers; carers; parents of patients/consumers; health professionals; well people in the community) Geographic location (eg. City/State/Country) Setting (eg. Community, home, primary health centre, acute care hospital, extended care facility) Methods of recruitment of participants (How were potential participants approached and invited to participate?) Inclusion/exclusion criteria for participation in study Numbers involved:

Study numbers	Number
Eligible for inclusion	
Excluded	
Refused to take part	
Randomised to intervention group(s)	
Randomised to control group	
Excluded post randomisation (for each group; with reasons if relevant)	
Withdrawn (for each group; with reasons if relevant)	
Lost to follow up (for each group; with reasons)	Intervention group (with reasons)
	Control group (with reasons)
Included in the analysis (for each group, for each outcome)	Outcome 1 Intervention Control
	Outcome 2 Intervention Control

Section 5: Study characteristics - Interventions

Data should be extracted for each relevant (included) intervention arm, as well as the control arm. Information on any co-interventions (if applicable) should also be recorded.

ltem	Explanation, notes	Intervention	Control and usual care
1 Intervention name	Include a brief name or phrase that describes the intervention (including definition of any acronyms or abbreviations)		
2 Aims and rationale ('why?')	Aim(s) of intervention (as stated in the trial report/s. What was the problem that this intervention was designed to address?)		
3 What was done?	Materials:Describe the content, format(s) or media, source of materials (if possible, where they can be accessed), and any other information relevant to the physical or information materials provided to participants or in training providers of the intervention.Procedures:Describe each of the processes used in delivering the intervention (eg education, telephone follow-up, case management)Note that some complex interventions require additional support activities to be implemented, and if so details of these should also be reported.Note also that some complex interventions require sequencing of activities, whereas for others the order of delivery is less critical.Mode of delivery:Describe the mode of delivery of the intervention, such as whether it was delivered face-to-face (eg in patient consultation, educational session, training) or at a distance (eg via phone, internet, mail); and whether the delivery was to individuals or groups of participants.Co-interventions:Describe the delivery of any co-interventions (Co-interventions may be separate to the intervention of interest, or they may be other similar elements in a suite of		

ltem	Explanation, notes	Intervention	control and usual care
4 Who delivered the intervention?	Describe who was involved in delivery of each component of the intervention and/or each different intervention provider. 'Intervention provider' could for example be taken to mean a health professional or it could mean a consumer peer advocate. Include description of any specific training given to providers to deliver the intervention, numbers of providers, professional background, specific pre-existing skills or experience required, quality of any specific training received to deliver the intervention, and any measures of competence or consistency in delivering the intervention recorded before or during the study.		
6 Where was the intervention provided?	Describe the features of the setting (location) that might be relevant to intervention delivery (eg country, type of clinic, primary or hospital care). If the location varied this should be described, with relevant features that might affect the intervention delivery; as should any requisite features of the location that might impact on intervention delivery or feasibility (eg location close to participants' usual doctor, availability of equipment)		
7 When and how often or how much of the intervention was provided?	Describe how the intervention was delivered, such as stages, timing, frequency, number of sessions, intensity and duration of intervention delivery.		
8 Was the intervention tailored?	If the intervention was meant to be tailored or personalised in the course of the study, describe the rationale for this and the major features of what was done - such as: how? why? when? and what? was done to tailor the intervention. If particular decision rules were used to determine when or how to tailor the intervention details should be provided.		
9 Was the intervention modified or adapted?	If the intervention was changed during the study, this should be described (eg unforseen modifications required, changes in study circumstances requiring modifications to the intervention). If such modifications happen, why, what, how and when the intervention was changed should be described.		

ltem	Explanation, notes	Intervention	control and usual care
10 How well was the intervention delivered?	Assessment of fidelity: if intervention fidelity was assessed, describe the extent to which the intervention was delivered as intended. (<i>ie the amount or type of intervention planned for delivery</i> <i>might differ from what was actually delivered</i>) If strategies to maintain intervention fidelity were <u>planned</u> before intervention delivery, or were used during the study, describe these, along with any materials or tools used.		

**Table is adapted from Hoffman et al (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ; 348:g1687.

Section 6: Study characteristics - Outcomes and comparison groups

Please also note that it may be useful to include a note about the direction of the effect alongside your extracted data. This may be helpful especially in cases where a number of different scales are used to report findings (across studies) and/or when sometimes an effect of an intervention is framed as a positive effect (eg increased symptom-free days) and as a negative effect (eg decrease in symptoms). This will help to ensure that there are no errors introduced once the extracted data is brought together across different studies (for a given outcome).

Primary outcomes						
Outcome	Method of assessing outcome measures eg phone survey, questionnaire	Method of follow-up for non- respondents	Timing of outcome assessment (including frequency, length of follow up)			

Secondary outcomes						
Outcome	Method of assessing outcome measures eg, phone survey, questionnaire	Method of follow-up for non-respondents	Timing of outcome assessment (including frequency, length of follow up)			

Notes field

For example:

- Contact with author (Yes (information obtained)/No) (SEE NOTE ON PAGE 1)
- Record if the study was translated from a language other than English.
- Record if the study was a duplicate publication.

Section 7: Data and results

All data are numbers (of patients/units), not percentages.

Dichotomous outcomes

_							
Outcome Tim	Timing of	Intervention group*		Control group		Notes	
		outcome assessment (days/ months)	Observed (n)	Total (N)	Observed (n)	Total (N)	
ſ							

*Note: add additional columns if there is more than one intervention group, eg. Intervention Group A, Intervention Group B...

Continuous outcomes

Outcome	tcome Timing of		Intervention group		Control group			Notes
	outcome assessment (days/ months)	*Mean / Mean change	Standard deviation	N	*Mean / Mean change	Standard deviation	N	

*delete as appropriate

Other results or data:

For example:

- additional data collected only for some participants that may be important for understanding the effects of the interventions (particularly if they relate to primary outcomes and/or adverse events)
- qualitative data that sits alongside the evaluation of effectiveness
- statements about the effects of interventions, reported without the numerical
 or supporting data (eg reported as 'knowledge was significantly higher in the
 intervention group'). <u>Note</u> that if this kind of data is reported in the review it must
 be clearly identified as such.

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Author, date, country, setting	Biese et al, 2014, USA, academic center ED	Biese et al, 2018, USA, academic center ED
Random sequence generation	Blinded, block randomization	Randomization with randomly generated block sizes of 4, 6 and 8
Allocation concealment	Blinded, using marbles in a bag	Blinded, using random sequence generator, imbedded in the computer program
Blinding of participants/ personnel	Patients were blinded. Nurse who did intervention was not blinded. Telephone calls were scripted.	Patients were blinded. Nurses who did intervention were not blinded. Calls were scripted, recorded and reviewed to ensure adherence to the scripts.
Blinding of outcome assessment	Research assistants who did data collection phone calls were blinded for randomization, but might have known who was in the control group, as they had to perform a mental screening test only in control group patients, whereas other patients were tested earlier.	Investigators were blinded for randomization. Unclear whether nurses who did data collection phone calls after 30 days were blinded for randomization. Statistician was not blinded.
Incomplete outcome data	Incomplete data of 6 (4.5%) patients. 37 (23.6%) Eligible patients were not included, due to refusal or not being reached. Unclear whether patients were analyzed according to intention to treat.	Loss to follow-up was limited (<1%), equally divided over groups and reasons for missing data were described. Many eligible patients were not included, due to decline or not being reached.
Selective reporting	Research protocol published in advance. Methods are followed and expected outcomes reported as planned.	Research protocol published in advance. Methods are followed and expected outcomes reported as planned.
Other bias	Single center Most outcome data were self-reported by patients. Unknown how often the nurse helped patients making follow-up appointments. Exclusion of potentially important individuals: patients not instructed to seek outpatient follow-up, patients visiting the ED in the weekend and patients and caregivers who did not pass the mental cognition screening examination.	Single center Many outcomes were self-reported by patients. Participation bias not excluded as number of hospital admissions in both groups lower than expected. After all underpowered study due to lower number of hospital admissions than predicted. Patients and caregivers who did not pass the mental cognition screening examination were excluded.

• Additional table 1. Risk of bias of the included studies on seven domains

ED, Emergency department; USA, United States of America