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Family presence during resuscitation (Review)

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[Intervention Review]

Family presence during resuscitation

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ABSTRACT

Background

Patients and their relatives often expect to be actively involved in decisions of treatment. Even during resuscitation and acute medical care, patients may want to have their relatives nearby, and relatives may want to be present if offered the possibility. The principle of family presence during resuscitation (FPDR) is a triangular relationship where the intervention of family presence affects the healthcare professionals, the relatives present, and the care of the patient involved. All needs and well-being must be balanced in the context of FPDR as the actions involving all three groups can impact the others.

Objectives

The primary aim of this review was to investigate how offering relatives the option to be present during resuscitation of patients affects the occurrence of post-traumatic stress disorder (PTSD)-related symptoms in the relatives.

The secondary aim was to investigate how offering relatives the option to be present during resuscitation of patients affects the occurrence of other psychological outcomes in the relatives and what effect family presence compared to no family presence during resuscitation of patients has on patient morbidity and mortality.

We also wanted to investigate the effect of FPDR on medical treatment and care during resuscitation. Furthermore, we wanted to investigate and report the personal stress seen in healthcare professionals and if possible describe their attitudes toward the FPDR initiative.

Search methods

We searched CENTRAL, MEDLINE, Embase, PsycINFO, and CINAHL from inception to 22 March 2022 without any language limits. We also checked references and citations of eligible studies using Scopus, and searched for relevant systematic reviews using Epistomonikos. Furthermore, we searched ClinicalTrials.gov, WHO ICTRP, and ISRCTN registry for ongoing trials; OpenGrey for grey literature; and Google Scholar for additional trials (all on 22 March 2022).

Selection criteria

We included randomized controlled trials of adults who have witnessed a resuscitation attempt of a patient (who was their relative) at the emergency department or in the pre-hospital emergency medical service.

The participants of this review included relatives, patients, and healthcare professionals during resuscitation.

We included relatives aged 18 years or older who have witnessed a resuscitation attempt of a patient (who is their relative) in the emergency department or pre-hospital. We defined relatives as siblings, parents, spouses, children, or close friends of the patient, or any other descriptions used by the study authors. There were no limitations on adult age or gender.

We defined patient as a patient with cardiac arrest in need of cardiopulmonary resuscitation (CPR), a patient with a critical medical or traumatic life-threatening condition, an unconscious patient, or a patient in any other way at risk of sudden death. We included all types of healthcare professionals as described in the included studies. There were no limitations on age or gender.

Data collection and analysis

We checked titles and abstracts of studies identified by the search, and obtained the full reports of those studies deemed potentially relevant. Two review authors independently extracted data. As it was not possible to conduct meta-analyses, we synthesized data narratively.

Main results

The electronic searches yielded a total of 7292 records after deduplication. We included 2 trials (3 papers) involving a total of 595 participants: a cluster-randomized trial from 2013 involving pre-hospital emergency medical services units in France, comparing systematic offer for a relative to witness CPR with the traditional practice, and its 1-year assessment; and a small pilot study from 1998 of FPDR in an emergency department in the UK.

Participants were 19 to 78 years old, and between 56% and 64% were women. PTSD was measured with the Impact of Event Scale, and the median score ranged from 0 to 21 (range 0 to 75; higher scores correspond to more severe disease). In the trial that accounted for most of the included participants (570/595), the frequency of PTSD-related symptoms was significantly higher in the control group after 3 and 12 months, and in the per-protocol analyses a significant statistical difference was found in favor of FPDR when looking at PTSD, anxiety and depression, and complicated grief after 1 year. One of the included studies also measured duration of patient resuscitation and personal stress in healthcare professionals during FPDR and found no difference between groups. Both studies had high risk of bias, and the evidence for all outcomes except one was assessed as very low certainty.

Authors' conclusions

There was insufficient evidence to draw any firm conclusions on the effects of FPDR on relatives' psychological outcomes.

Sufficiently powered and well-designed randomized controlled trials may change the conclusions of the review in future.

PLAIN LANGUAGE SUMMARY

Family presence during resuscitation

Why is this question important?

Patients and their relatives increasingly expect to be actively involved in the decisions of treatment. However, there are concerns that family presence during resuscitation (FPDR) can lead to post-traumatic stress disorder (PTSD)-related symptoms in relatives, or have a negative impact on the performance of healthcare professionals, thereby hampering the quality of critical care. There are also concerns that patient confidentiality can be violated, as the patient's thoughts and preferences in the situation are unspoken. The needs of all participating individuals must be balanced, as the actions involving patients, relatives, and healthcare professionals is seen as a triangular relationship that may impact one another.

What did we want to find out?

We wanted to examine the existing evidence for the effect of FPDR, including cardiac arrest, trauma, and acute medical care.

The primary aim of this review was to investigate how offering relatives the option to be present during cardiac arrest, trauma, or acute medical care of their loved ones affects the occurrence of PTSD-related symptoms in the relatives.

The secondary aim was to investigate how offering FPDR affects the occurrence of depression, anxiety, and grief in the relatives, and what effect FPDR has on the length of time the medical care is performed, how healthcare professionals are affected, the quality of medical care, and patient's chance of survival.

What did we do?

We searched medical databases on 22 March 2022 without any language limits. We checked references and contacted study authors to identify additional studies. We included randomized controlled trials (a type of study where participants are randomly assigned to one of two or more treatment groups) of adults who were present during resuscitation of their relative.

What we found

We included 2 trials (3 papers) involving a total of 595 participants who were between the ages of 19 and 78. One trial involved 15 pre-hospital emergency medical services units in France, investigating FPDR in patients with cardiac arrest. This trial had a one-year evaluation that we included in the review. The other included trial was a small pilot study of FPDR in patients with cardiac arrest or trauma in an emergency department in the UK.

Key results

There was not enough evidence to draw any firm conclusions on the effects of FPDR on any of the outcomes studied. Overall, it appeared that FPDR decreased PTSD, anxiety and depression, and grief; however, as the studies are very few and were at high risk of bias, this effect is very uncertain. One of the included studies also measured duration of patient resuscitation and personal stress in healthcare professionals during FPDR and found no difference between study groups.

How reliable are the results?

Our confidence (certainty) in the evidence is very low. There is too little evidence to draw any firm conclusions on the effects of FPDR on psychological outcomes of relatives or any other of the outcomes studied.

SUMMARY OF FINDINGS

Summary of findings 1. Family presence during resuscitation

Population: relatives, patients, and healthcare professionals during resucitation

Settings: emergency department or pre-hospital setting

Intervention: to offer relatives the opportunity of FPDR

Comparison: not to offer relatives the opportunity of FPDR systematically in a standardized way

Note: In both included studies outcomes were calculated as median and interquartile range (IQR) or presented as numbers and %.

Outcomes, Time point of assessment	Illustrative comparative risks*		Relative effect (95% CI)	No. of participants (studies)	Certainty of the evidence (GRADE)[a,b]	Comments
	Assumed risk with intervention	Corresponding risk without intervention				
PTSD in the relatives IES (0 to 75; > 30 = presence of PTSD) measured at 3 months and > 3 months	Both studies found median scores in the range of 8 to 15.5 for both IES subscores at 3 months, and in the range of 0 to 17.5 after more than 3 months. See Table 1.	Both studies found median scores in the range of 8 to 16.5 for both IES subscores at 3 months, and in the range of 5 to 21 after more than 3 months. See Table 1.	NA	493 or 426 (2 RCTs)**	⊕⊖⊖⊖ VERY LOW [c]	The difference between the 2 groups was found to be statistically significant in favor of the intervention when measured at 12 months in Jabre 2014.
Anxiety and depression in the relatives HADS (0 to 42; subscale score > 10 (range, 0 to 21) = presence of anxiety or depression) measured at 3 months and > 3 months	Both studies found median scores in the range of 2.5 to 7 for both HADS subscores at 3 months, and in the range of 0 to 7 after more than 3 months. See Table 1.	Both studies found median scores in the range of 5 to 8 for both HADS subscores at 3 months, and in the range of 4 to 8.5 after more than 3 months. See Table 1.	NA	493 or 426 (2 RCTs)**	⊕⊖⊖⊖ VERY LOW [c]	The frequency of people with symptoms of anxiety was significantly higher in the control group at 3 months in Jabre 2013, and the frequency of people with symptoms of depression was significantly higher in the control group at 12 months in Jabre 2014. However, this was not clinically relevant, as the subscale scores are < 10 at both short- and long-term follow-up.

Grief in the relatives ICG (0 to 95; > 25 = presence of complicated grief) measured at 12 months TRIG (21 to 105; lower scores indicate higher levels of grief) measured at 3 and 9 months	ICG score measured at 12 months: 16 (9 to 23) TRIG score measured at 3 months: 46.5 (37.8 to 57.8) TRIG score measured at 9 months: 38.5 (33.5 to 52.5)	ICG score measured at 12 months: 19 (9 to 28) TRIG score measured at 3 months: 46 (36.3 to 57.8) TRIG score measured at 9 months: 57 (38 to 64.0)	NA	426 (2 RCTs)	⊕⊖⊖⊖ VERY LOW [c]	The difference between the 2 groups was found to be statistically significant in favor of the intervention when measured by ICG at 12 months.
	Family member present	**Family member absent**				
Survival of patients	In the Jabre 2013 trial, "survival to hospital admission" was 18% and "survival to day 28" was 3% in their per-protocol analysis. In the Robinson 1998 trial, 3 patients "survived to hospital discharge".	In the Jabre 2013 trial, "survival to hospital admission" was 16% and "survival to day 28" was 4% in their per-protocol analysis. In the Robinson 1998 trial, no patients "survived to hospital discharge".	NA	493 (2 RCTs)	⊕⊖⊖⊖ VERY LOW [c]	No statistical difference in either "survival to hospital admission" or "survival to day 28" was found. Robinson 1998 did not make a statistical calculation.
Duration of resuscitation in minutes	30 (23 to 40)	30 (20 to 40)	NA	475 (1 RCT)	⊕⊕⊖⊖ LOW [d]	No statistical difference in duration of advanced resuscitation was found in the per-protocol analysis.
Stress intensity in the medical team members VAS (0 to 100; 0 = no stress; 100 = maximum stress)	Emergency physician: 8.5 (0 to 20) Nurse: 5 (0 to 15) Ambulance driver: 0 (0 to 15)	Emergency physician: 10 (0 to 20) Nurse: 5 (0 to 15) Ambulance driver: 0 (0 to 10)	NA	1710 (1 RCT)	⊕⊖⊖⊖ VERY LOW [d,e]	No statistical difference in stress intensity was found in the per-protocol analysis. Numbers regarding how many physicians, nurses, and ambulance drivers were asked to fill out the VAS score were obtained after contact with the trial author.

*The basis for the **assumed risk** is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the intervention group and the **relative effect** of the intervention (and its 95% CI).
**Short-term outcomes for the Jabre trial in Jabre 2013 and for the long-term outcomes in Jabre 2014. Both articles are from the same RCT. 493 participants were included for IES and HADS score measurement at 3 months, and 426 after > 9 months.

CI: confidence interval;**HADS**: Hospital Anxiety and Depression Scale; **ICG**: Inventory of Complicated Grief; **IES**: Impact of Event Scale; **NA**: not applicable; **PTSD**: post-traumatic stress disorder; **RCT:** randomized controlled trial; **TRIG**: Texas Revised Inventory of Grief; **VAS:** visual analogue scale.

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

[a]Study limitations rated as very serious for all outcomes, as overall high risk of bias was found in both studies in crucial domains.
[b]Imprecision rated as very serious for all outcomes, as the small number of heterogeneic studies precluded meta-analysis.
[c]Inconsistency rated as very serious due to clinical heterogeneity.
[d]As only a single study investigated this outcome, it is not possible to downgrade for inconsistency and publication bias.
[e]Indirectness of evidence rated as serious due to the self-assessed measurement on the VAS instead of measurement of cortisol level in saliva or heart rate variability.

BACKGROUND

Family members often expect to be actively involved in care decisions involving the treatment of their relatives (Lederman 2014). Even during resuscitation, patients may prefer to have their relatives nearby, and many relatives want to be present when given the choice (Benjamin 2004; Bradley 2017; Chew 2014; De Stefano 2016; Dwyer 2015; Meyers 2000; Robinson 1998). This could be why family presence during resuscitation (FPDR) is a growing healthcare practice, even though the majority of the evidence is of low quality and lacking investigation of the relatives' perceptions and psychological outcomes, and the impact on patient morbidity and mortality (Oczkowski 2015).

Description of the condition

Resuscitation can be described in general as a process of correcting the physiological disorders in a patient suffering from critical illness or reviving someone from unconsciousness or apparent death. The term 'resuscitation' in this review is therefore used as a description of either cardiopulmonary resuscitation (CPR), resuscitation after trauma, or critical care of acutely ill patients. In the USA, more than 200,000 adults undergo CPR annually in hospitals, and in Germany more than 2000 in the emergency room (ER) (Mallikethi-Reddy 2017; Merchant 2011; Zwingmann 2016). Furthermore, in the USA, 2.2 million emergency department visits result in admission to critical care out of a total of 145.6 million visits (1.5%) (National Center for Health Statistics 2016).

Description of the intervention

When relatives (e.g. siblings, parents, spouses, children, or close friends) of the patient are present in the resuscitation room with the patient, it is described as FPDR. The family member should preferably be accompanied by a designated support person (Mentzelopoulos 2021).

There are concerns that FPDR can lead to post-traumatic stress disorder (PTSD) in the relatives (Compton 2011); have a negative impact on the quality of critical care (Fernandez 2009); and that patient confidentiality can be violated as the patient's thoughts and preferences in the situation are unknown (Benjamin 2004; Lederman 2014). When FPDR is practiced, the relatives are in direct contact with both the patient and the healthcare professionals during the resuscitation attempt and not placed outside (e.g. in a special waiting room). This means that they can interact with the patient (e.g. hold the patient's hand if they want to and talk to or with them) whenever needed.

How the intervention might work

Some clinicians believe that family members being present during resuscitation may have more advantages than disadvantages, as it allows the relatives to feel both needed and of use in the care and comfort of the patient (Holzhauser 2008). Especially in the event of death, it may help the relatives to acknowledge that all possible measures were taken to save the patient (De Stefano 2016; Holzhauser 2006). Watching the procedures and the communication—both verbal and non-verbal—among the healthcare professionals can play a role in supporting the understanding of the circumstances of the patient's death and help the relatives to cope with the patient's death in the context of the critical care performed (De Stefano 2016). A quasi-experimental historical study and a large pre-hospital cluster-randomized controlled trial (RCT) indicated that FPDR may have positive effects on relatives' psychological outcomes (Jabre 2013; Soleimanpour 2017). The communication between relatives and the emergency care team is considered very important, and a qualitative analysis of the pre-hospital cluster-RCT by Jabre and colleagues concluded that the emergency care team could facilitate the relatives' acceptance of the reality of death (Jabre 2014). A designated support person focusing on the relatives, as a part of the resuscitation team, therefore became recommended (Downar 2013; Dudley 2009; Mentzelopoulos 2021; Meyers 2000).

It is important to investigate how family presence might influence the patient. A patient who had survived cardiac arrest felt "aware of his wife's presence", and also felt that this had encouraged him to fight on (Belanger 1997). Three other patients who survived resuscitation reported that they felt supported by their relatives' presence and did not feel their confidentiality or dignity had been compromised (Robinson 1998). A qualitative study of nine surviving patients found several themes concerning the positive effects that family presence during invasive procedures, or CPR, had on patients: "it comforted them, provided help, and served, the patients believed, to remind providers of a patient's "personhood"—he wasn't just a patient; he was a person and had a family" (Eichhorn 2001).

A relevant concern is whether FPDR negatively affects the members of the resuscitation team, and whether the relatives get in the way of the work of the healthcare professionals. Jabre and colleagues found no increase in the level of stress of the healthcare providers or difference in patient mortality and stated that "survival, the duration of advanced resuscitation, the type or dose of infused medications, and the number of electric shocks delivered to the heart were not affected by the presence or absence of the family member" (Jabre 2013). A study of physicians' performance during a simulated cardiac arrest with relatives in different states of mind indicated that relatives may have a negative impact on the quality of acute medical care, especially if the relatives are agitated (Fernandez 2009). In contrast, a pediatric study of FPDR found no differences in the success rate of the critical interventions, and the healthcare providers surveyed believed there was a minimal negative effect of FPDR on resuscitation (Dudley 2009). Mangurten and colleagues believe a protocol for FPDR of pediatric patients was effective, and the providers in their study reported that the presence of parents did not negatively affect medical care (Mangurten 2006).

Why it is important to do this review

We believe that much of the evidence concerning FPDR is qualitative. When investigating this literature, different themes emerge concerning relatives' perceptions, and knowledge about the effect of and how to best involve relatives is scarce. Danish researcher Camilla Bernild reports that even though nurses in an orthopedic ward had the best intention to involve the patients' relatives, they often found it difficult to implement involvement, and this resulted in an individual and random effort to achieve the goal. Many patients and relatives thus experienced that the involvement was tokenism, and that their opinions and wishes were not actually taken into account (Bernild 2018).

In 2018, Shadia Alshahrani explored how relatives' involvement was experienced in Saudi Arabia and Australia, finding that "In both fields, relatives and nurses faced ongoing ambiguity about

the role relatives should play in the hospital environment. Nurses were challenged by the unpredictability of relatives' participation in patient care. The nurses' fear of taking responsibility and uncertainty about the relatives' role led them to take varied and individualized approaches to the involvement of relatives in patient care. Relatives were unclear about how to behave in the role; what was the preferences and needs of patients; and whether they were contributing positively to care; all this resulted in frustration" (Alshahrani 2018).

Since the first known case of FPDR in 1983 (Hanson 1992), and the first published study in 1987 (Doyle 1987), to our knowledge only three RCTs have focused on relatives' perspectives concerning FPDR (Holzhauser 2006; Jabre 2013; Robinson 1998). Two studies found psychological benefit for the relatives present in the ER during resuscitation in general, and not only during CPR (Holzhauser 2006; Robinson 1998). A cluster-RCT and its one-year follow-up assessment, and a qualitative analysis of this RCT, showed positive effects of FPDR on relatives' psychological outcomes, including improved clinical indicators related to PTSD, better anxiety and depression scale scores, less complicated grieving as a result of pre-hospital CPR, and no negative effects on mortality (De Stefano 2016; Jabre 2013; Jabre 2014). However, a retrospective study suggests that family members who witness ER resuscitations may be at increased risk of PTSD symptoms after one month (Erogul 2020), as the experience can be too traumatic for some to experience.

Whether family members should be offered the opportunity to be present during resuscitation or not is an important question to answer. This is because their presence during the resuscitation attempt may impact the relatives psychologically, the patient receiving care, and the performance of the healthcare professionals. The European Resuscitation Council (ERC) recommends that relatives be offered the choice of being present during CPR (Mentzelopoulos 2021). The American Heart Association (AHA) does not offer a recommendation, although they do encourage FPDR (Mancini 2015). This lack of a clear recommendation leads to disagreements among clinicians regarding FPDR, because the evidence is sparse (Bossaert 2016; Downar 2013; Lederman 2016; Meyers 2000; Porter 2013; Sak-Dankosky 2014; Youngson 2016). The disagreements are perhaps caused by fear of legal consequences, or as noted in the reasons described by relatives for whether or not to engage in FPDR, "The anticipated fear of negative or positive reactions was often mentioned as a reason for their choice about being present for the resuscitation" (De Stefano 2016). However, the feeling of exclusion when relatives are not offered FPDR is a relevant factor to be aware of (De Stefano 2016).

To our knowledge, no studies in the pre-hospital environment have been conducted covering FPDR in general, other than during CPR (Jabre 2013; Oczkowski 2015). Robinson and colleagues looked at FPDR including CPR, trauma, and critical care in the ER, but they had to terminate their trial prematurely, as the clinical team considered it unethical not to offer FPDR, even though the preliminary results were not convincing (Robinson 1998). Holzhauser and colleagues also looked at FPDR during both CPR and critical care in the ER, but excluded trauma patients (Holzhauser 2006). Dudley and colleagues investigated FPDR of pediatric patients (Dudley 2009).

We hypothesize that FPDR may positively impact relatives' psychological outcomes, including PTSD symptoms. It is also possible that FPDR affects the performance of healthcare professionals and influences patient morbidity and mortality. Considering the public health perspective, it may also be possible that family presence leads to overtreatment. As a relative stated, "When I saw that they were being so aggressive [with the treatment], I felt it as an aggression, an assault on my husband" (De Stefano 2016). If such a tendency is discovered to be associated with FPDR, its identification can lead to the development of policies to decrease this risk.

These factors suggest the necessity of a high-quality systematic review to evaluate the evidence.

OBJECTIVES

The primary aim of this review was to investigate how offering relatives the option to be present during resuscitation of patients affects the occurrence of PTSD-related symptoms in the relatives.

The secondary aim was to investigate how offering relatives the option to be present during resuscitation of patients affects the occurrence of other psychological outcomes in the relatives and what effect family presence compared to no family presence during resuscitation of patients has on patient morbidity and mortality.

We also wanted to investigate the effect of FPDR on medical treatment and care during resuscitation. Furthermore, we wanted to investigate and report the personal stress seen in healthcare professionals and if possible describe their attitudes toward the FPDR initiative.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomized controlled trials (RCTs) and cluster-RCTs.

Types of participants

The participants of this review included relatives, patients, and healthcare professionals during resuscitation.

We included relatives aged 18 years or older who have witnessed a resuscitation attempt of a patient (who is their relative) in the ER or pre-hospital. We defined relatives as siblings, parents, spouses, children, or close friends of the patient, or any other descriptions used by the study authors. There were no limitations on adult age or gender.

We defined patient as a patient with cardiac arrest in need of CPR, a patient with a critical medical or traumatic life-threatening condition, an unconscious patient, or a patient in any other way at risk of sudden death. We included all types of healthcare professionals as described in the included studies. There were no limitations on age or gender.

Types of interventions

The intervention was to offer the relatives the opportunity of FPDR in the ER or in the pre-hospital setting.

The control was not to offer the relatives the opportunity of FPDR systematically in a standardized way, but instead to offer any other intervention including following standard practice (e.g. waiting in a special room with no opportunity of witnessing the resuscitation) or no intervention at all.

Regarding the patients and the healthcare professionals, the intervention was if there had been FPDR or not.

Types of outcome measures

We reported on any outcome specified in the included studies.

Primary outcomes

- PTSD evaluation of the relatives measured short term (at 0 to 3 months) and long term (more than 3 months).

Secondary outcomes

- Depression, anxiety, or complicated grief in the relatives according to ICD-11 measured short term (at 0 to 3 months) and long term (more than 3 months).
- Patient morbidity: readmission to hospital within 30 days, number of intensive care unit (ICU) admissions within 30 days.
- Patient mortality as measured in the included studies. If a study included several time points, we used the one closest to 30 days.
- Adverse events in the patient population: number of adverse cardiac and pulmonary events or other adverse events described in the included studies and total number of adverse events.
- Personal stress in healthcare professionals during resuscitation as measured by the included studies.
- Duration of patient resuscitation as reported in the included studies.
- Healthcare professionals' attitudes towards FPDR as measured in the included studies.

Search methods for identification of studies

Electronic searches

We searched for studies as described in Chapter 4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2019). There were no language, publication year, or publication status restrictions.

We searched the following databases for relevant trials:

- Cochrane Central Register of Controlled Trials (CENTRAL; 2022, Issue 3 of 12) in the Cochrane Library (searched 22 March 2022);
- MEDLINE (Ovid, 1946 to 22 March 2022);
- Embase (Ovid, 1974 to 22 March 2022);
- CINAHL (Cumulative Index to Nursing and Allied Health Literature) (EBSCO, 1980 to 22 March 2022);
- PsycINFO (EBSCO, 1806 to 22 March 2022).

We developed a search strategy for MEDLINE and modified it as appropriate for the other databases. The search strategies can be found in Appendix 1.

Searching other resources

We scanned the reference lists and citations of included trials using Scopus online database, and checked relevant systematic reviews identified in Epistomonikos online database for references to additional trials. We also scanned the abstracts of conference proceedings of the AHA and the European Resuscitation Council.

When necessary, we contacted trial authors for additional information. This was relevant regarding in both included studies.

We also searched ClinicalTrials.gov (clinicaltrials.gov), the WHO International Clinical Trials Registry Platform (trialsearch.who.int/), and the ISRCTN registry (www.isrctn.com) for unpublished and ongoing studies; OpenGrey (opengrey.eu) for grey literature; and Google Scholar for additional trials.

We searched for errata and retractions of included studies in PubMed and Retraction Watch Database (retractiondatabase.org/).

The search strategy was developed by the Cochrane Emergency and Critical Care Information Specialist. The search date was 22 March 2022.

Data collection and analysis

Selection of studies

Two review authors (MAR and TS) independently and in duplicate screened the search results for eligible studies by scanning titles and abstracts. We used Covidence for transparency (Covidence). We obtained the full-text records of all presumably eligible studies, and evaluated them before final inclusion. Any disagreements were resolved by discussion, or by consulting a third review author (AMM) when needed. We recorded the selection process in sufficient detail to complete a PRISMA flow diagram (Figure 1) (Moher 2009).

Figure 1. Study flow diagram.

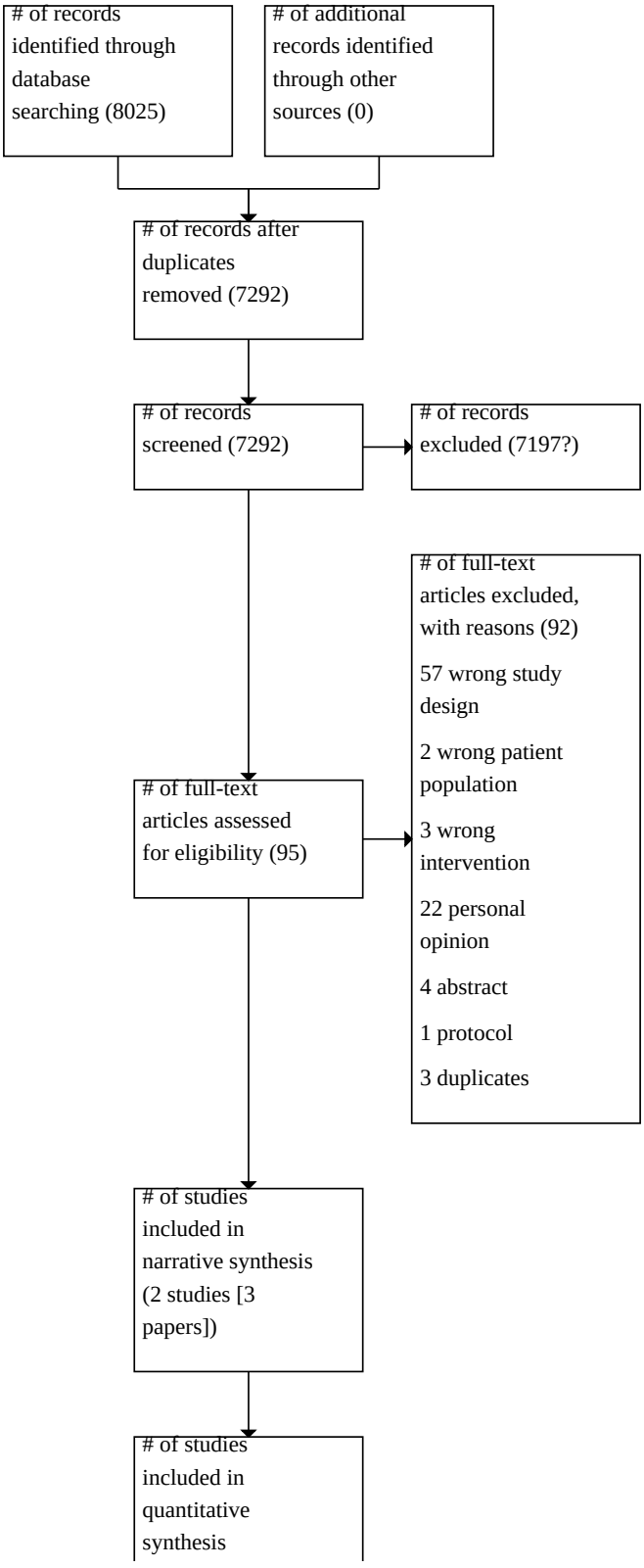
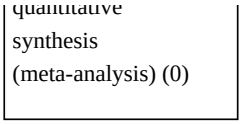


Figure 1. (Continued)



Data extraction and management

One of the review authors (PJ) is the first author of an included primary study in this review (Jabre 2013). She did not extract data from any included studies.

Two review authors (MAR and TS) independently and in duplicate extracted relevant data using pre-designed data extraction forms (Appendix 2). Given that we only included two studies, we did not perform a pilot run to evaluate the data extraction form as mentioned in our protocol (Afzali 2020), but refined it during the data extraction. After data extraction, we compared data, resolving any disagreements by discussion, aided by a third review author (AMM) when necessary. We contacted study authors for clarification during data extraction as needed. This was relevant once (Jabre 2013).

Assessment of risk of bias in included studies

One of the review authors (PJ) is the first author of an included primary study in this review (Jabre 2013). She did not assess the risk of bias of any included study.

For each study, two review authors (MAR and TS) independently used Cochrane's risk of bias tool RoB 2 to evaluate risk of bias (Sterne 2019). We used the RoB 2 tool including the cribsheet tools (10 November 2020 version) to assess bias for intention-to-treat (ITT) effects for the included primary and secondary outcomes. We judged each item as having low, high, or some concerns regarding risk of bias in the following domains.

- Bias arising from the randomization process
- Bias due to deviations from intended interventions
- Bias due to missing outcome data
- Bias in measurement of the outcome
- Bias in selection of the reported result

We also assessed the following domain for the included cluster-randomized trial.

- Bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial

Any disagreements were resolved by discussion, aided by a third review author (AMM) when needed. A visual representation of the risk of bias assessment was made using robvis (McGuinness 2020).

As part of the risk of bias assessment, we looked for protocols within the online study databases to assess selective reporting, and contacted the trial authors of both included studies.

Measures of treatment effect

Dichotomous outcomes

Concerning the presence of PTSD and other psychological outcomes, mortality, morbidity, and adverse events, we originally planned to convert the effect of treatment to risk ratios (RR) if presented, and use meta-analysis to summarize treatment effects as such. However, a meta-analysis was not possible.

Continuous outcomes

We planned to present and analyze the severity of PTSD, anxiety and depression, and duration of resuscitation as mean difference (MD) with 95% confidence intervals (CIs). We originally planned that if continuous outcomes were measured on different scales but considered to be measuring the same outcome, we would use standardized mean difference (SMD) for analysis and presentation. However, this was not relevant as the two included studies were too heterogeneous to be compared.

Unit of analysis issues

Analysis issues could be present given that we included a cluster-RCT (Jabre 2013); however, as the included trial takes the clustering into account (Higgins 2019), we were able to use the results as they are. As the authors state for psychological-assessment analyses, Generalised Estimating Equations (GEE) were used for categorical outcomes and mixed models of ANOVA were used for quantitative outcomes, using center as a random effect and adjusting for the relative's relationship to the patient. When necessary, normalizing transformation was performed (De Stefano 2016).

Dealing with missing data

To ensure completeness of data, we planned to contact trial authors in order to obtain and incorporate any relevant missing data. Both included trials performed ITT analysis. We planned that if trials had more that 20% dropout, we would explore the impact of missing data on the overall effect. However, this was not relevant.

Where individual studies did not account appropriately for missing data, or did not report how these data were handled, we considered whether data were likely to be missing at random, or not affecting the risk of bias assessment. We planned that where outcome data were missing, and could be recovered, we would adopt the approach suggested in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019), and use available-case analysis. We included data only for those participants whose results were known, and addressed the potential impact of missing data using the risk of bias tool. Ultimately, we considered the potential impact of including such studies in the overall assessment of intervention effect.

Assessment of heterogeneity

We considered clinical, methodological, and statistical diversity (Higgins 2019).

The included studies were neither clinically nor statistically comparable. We have therefore presented and summarized the results narratively.

However, we assessed methodological diversity using the Cochrane risk of bias tool RoB 2 (Sterne 2019).

Assessment of reporting biases

We did not create a funnel plot, as the number of included trials was fewer than 10.

Data synthesis

We did not perform meta-analysis. The designs of the included studies were too diverse, therefore statistical combination would have been inappropriate. We have therefore presented the findings in a narrative fashion using the Synthesis Without Meta-analysis (SWiM) guideline (Campbell 2020).

A selection of extracted data describing the included studies is presented in a study characteristics table (Table 2), as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions*, with four distinct categories: methods; participants; interventions; and outcomes (Higgins 2019).

Subgroup analysis and investigation of heterogeneity

We originally planned to perform an adult/pediatric subgroup analysis to examine if the effects are modified by the age of patients; subgroup analyses concerning cardiac arrest/other critical situations and trauma/medical; and a subgroup analysis to explore if location of resuscitation (i.e. in or out of hospital) has significance. However, these analyses were precluded by too few studies.

Sensitivity analysis

In the case of unavailable data, we planned to assess whether the data were missing at random, or if the missing data might be a source of bias. We planned to omit randomly missing data from analysis, while non-randomly missing data would be imputed as sensitivity analyses, as deemed appropriate by the review authors, according to the cause of their omission. In addition, we planned to challenge analyses that included imputed data by sensitivity analyses to ensure the robustness of the findings when assumptions were changed.

For dichotomous outcomes, we planned to impute missing values as experiencing or not experiencing the event. For continuous outcomes, we planned to impute missing values using different fixed values for all missing values.

We planned to perform sensitivity analyses by excluding trials we judged to be at high risk of bias.

However, all of these analyses were precluded by too few studies.

Summary of findings and assessment of the certainty of the evidence

We used the principles of the GRADE system to assess the certainty of the body of evidence associated with specific outcomes in our review, and constructed a summary of findings table including all mentioned outcomes in the included studies. In the protocol, we stated that we would use GRADEpro GDT software (GRADEpro GDT; Guyatt 2008); however, given our narrative presentation of outcomes, we decided to do the evaluation by hand instead.

We evaluated the certainty of evidence according to the GRADE domains as described in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019). Two review authors (MAR and AMM) independently undertook the GRADE assessments. We have reported agreement reached by consensus in Summary of findings 1 and all reasons for downgrading.

The overall RoB 2 judgement was used to feed into the GRADE assessment.

RESULTS

Description of studies

See Included studies and Excluded studies.

Results of the search

Our electronic search yielded a total of 7292 records after deduplication (see Figure 1). Handsearching of reference lists revealed no additional potentially relevant studies. Two review authors (MAR and TS) independently performed title and abstract screening. After excluding obviously irrelevant records, we retrieved 95 potentially relevant records for full-text assessment. Following full-text reading, we excluded a total of 92 records and included 2 trials (3 papers) with 595 participants.

When screening for systematic reviews in Epistemonikos, we found a recently published umbrella review including systematic reviews between 1 January 2009 and 31 December 2018 (Tíscar-González 2021). However, this umbrella review did not include the review we found in Scopus (Barreto 2019). We found no further relevant studies when handsearching the reference lists of either review.

Included studies

We included 2 studies (3 papers) in the review: a prospective, cluster-RCT involving 15 pre-hospital emergency medical services units in France, comparing systematic offer for a relative to witness CPR with the traditional practice (Jabre 2013), its 1-year assessment (Jabre 2014), and a small pilot study of FPDR in a single ER in the UK (Robinson 1998).

The two studies were conducted in 1998 and 2013. The more recent study included 570 family members of patients receiving CPR (Jabre 2013). The older study was a pilot study that was ended prematurely due to the risk of altered randomization (Robinson 1998); this study included 25 relatives. The age of participants across studies ranged from mean 19 to 78 years, and between 56% and 64% of participants were women. For study-specific outcomes and overall risk of bias, see Table 2. Only Jabre 2013 mentioned funding: "Funded by Programme Hospitalier de Recherche Clinique 2008 of the French Ministry of Health"; this was also the only study to declare possible conflict of interest.

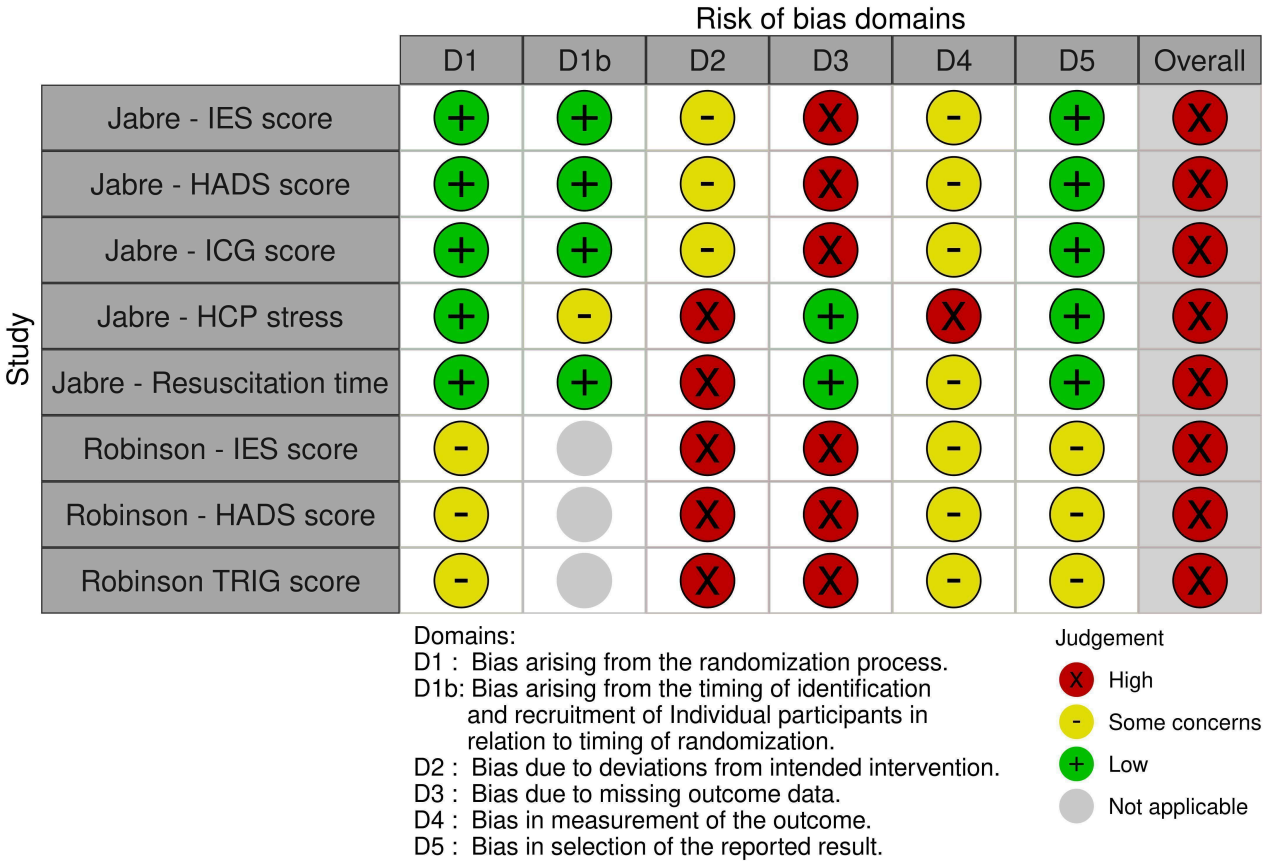
Excluded studies

We excluded 92 studies. Reasons for their exclusion are provided in Characteristics of excluded studies tables. However, a few studies are worth mentioning in particular. We excluded one study due to lack of randomization, as it was a historical trial (Soleimanpour 2017), and one study because they evaluated the wrong intervention, that is whether training of relatives before their presence in the resuscitation room could lower their anxiety (Alireza 2019). We excluded two studies due to wrong study design, as they had only asked the participants in a qualitative way about their experience without measuring it on any scale (Holzhauser 2006; Holzhauser 2008). Finally, we excluded one study due to lack of randomization, as it was a quasi-randomized study including participants related to odd and even days (Dudley 2009).

Risk of bias in included studies

We used RoB 2 to assess risk of bias and followed the RoB 2 cribsheets (10 November 2020 version), which can be accessed in the supplementary material (Rubin 2021). We found both studies to have an overall high risk of bias for all domains. Summaries of risk of bias assessments within and across studies are provided in Figure 2.

Figure 2. Risk of bias.



1. Bias arising from the randomization process

We initially assessed both studies as being at low risk of bias arising from the randomization process for all outcomes as we believed the allocation sequence to be random and concealed. Baseline characteristics of the participants did not appear to differ. However, due to the low number of participants it was not possible to evaluate baseline characteristics in Robinson 1998. Furthermore, we decided to overturn our judgement of low risk of bias to some concerns in Robinson 1998 because the study was stopped prematurely. To quote from the trial, "They decided to stop the study early because the randomisation process was at risk of being altered by staff who had become convinced of the benefits of allowing relatives to witness resuscitation".

1b. Bias arising from the timing of identification or recruitment of participants in a cluster-randomized trial

This domain was relevant to the assessment of the Jabre 2013; Jabre 2014 trial, which was a cluster-randomized trial. All participants were identified or recruited after randomization: the pre-hospital care units were randomized in clusters at the beginning of the study, and when they arrived at the scene, they offered relatives to be present during resuscitation or the traditional practice (relatives were asked to wait in a special room or perhaps allowed to witness CPR—but the process was not standardized), respectively to the cluster to which they had been randomized. As the included outcomes were related to relatives, patients, and healthcare professionals, some signaling questions in this domain were assessed differently according to

outcome. We assessed this domain as low risk of bias for all outcomes but healthcare professional stress, which we judged to be some concerns due to the fact that there were no baseline data and no information on whether the selection of individual participants could have been affected by knowledge of the intervention assigned to the cluster. There was no information in the article on how the healthcare professional participants were chosen, but after contact with the authors we learned that healthcare professional participants were the medical team that arrived on the scene. The choice was random; no specific team was allocated to this study. There was only one physician, one ambulance driver, and one nurse at the resuscitation scene each time.

2. Bias due to deviations from intended interventions

We assessed this domain as some concerns in the Jabre 2013; Jabre 2014 trial related to the psychological outcomes, and high risk of bias related to healthcare professional stress and resuscitation time. Overall, the trial followed a very thorough protocol, which was published beforehand, but it was not possible to assess if there were deviations from the intended intervention arising from the trial context, and it was not possible to blind the healthcare professionals delivering the intervention. Participants were not aware that they were participants in a trial before randomization.

We assessed this domain as high risk of bias for all the psychological outcomes in Robinson 1998 as they did not publish a protocol prior to the study and stopped the study prematurely due to risk of altered randomization. This resulted in selection bias and a deviation from the intended intervention.

3. Bias due to missing outcome data

We assessed this domain as high risk of bias for our primary outcome, PTSD, and the secondary psychological outcomes in the Jabre 2013; Jabre 2014 trial. The proportion of missing outcome data was large; however, the missing numbers were similar in both control and intervention groups. Figure 1 in Jabre 2014 shows that out of the 570 participants, there were missing data for 6% in the intervention group and 11% in the control group after 3 months, but after 12 months missing data amounted to 28% in total for all psychological outcomes. Withdrawal from the study could have been related to participants' health status, as we assume that someone affected deeply by grief might not want to attend for a repeated psychological assessment. It is therefore possible that missingness in the outcome was influenced by its true value. As mentioned in the footnote of Table 2, the inclusion of participants from each of the 15 clusters varied between 8 and 104. This information was obtained by contacting the study author, and we were informed that the deviation was because some clusters consisted of five pre-hospital units and others only one, resulting in some clusters including fewer participants than others. The authors did not state that any clusters dropped out.

As the outcome resuscitation time was related to the patient and hence the clusters of units, no outcome data were missing, resulting in a judgement of low risk of bias for this domain for this outcome. We also assessed this domain as low risk of bias for the outcome healthcare professional stress, as the authors did not state that any clusters had dropped out, and most outcome data were available (Table 2: the total missing outcome data are 44/1710 = 2.57%).

We assessed the Robinson 1998 trial as at high risk of bias due to missing outcome data for all included outcomes, as 38% of participants were missing in the intervention group and 17% in the control group, and we were not provided with the missing outcome data.

In the protocol we stated that "if trials have more that 20% dropout we will explore the impact of missing data on the overall effect"; however, given that we did not perform a meta-analysis, this was not relevant.

4. Bias in measurement of the outcome

We assessed this domain as some concerns for our primary outcome, PTSD, the secondary psychological outcomes, and resuscitation time in the Jabre 2013; Jabre 2014 trial. Outcome assessors were aware of the intervention received by study participants, as blinding of personnel performing CPR was not possible, and the relatives knew whether they had been present or not when reporting their outcomes in an interview. We assessed this domain for healthcare professional stress as high risk of bias because it was measured with a self-assessment questionnaire the healthcare professionals completed themselves. Additional or alternative tools completed by others may conflict with or validate this questionnaire. Furthermore, outcome assessors were aware that a trial was taking place, and, therefore, assessment of the outcome could have been influenced by knowledge of intervention received.

We also assessed bias in measurement of the outcome as some concerns for all of the included outcomes in the Robinson 1998 trial. This was mostly because the relatives could not be blinded to the intervention. It is also unclear how the relatives were interviewed, making it possible that the relatives, who were the outcome assessors, could be influenced psychologically by the interviewer.

5. Bias in selection of the reported result

We assessed this domain to be low risk of bias for all outcomes in the Jabre 2013; Jabre 2014 trial, as the measurement of stress in the healthcare professional was detached from the randomization, and this was in accordance to a prespecified protocol and analysis plan. Furthermore, the Impact of Event Scale (IES) and Hospital Anxiety and Depression Scale (HADS) subscale scores where obtained after contact with the author and hence not published in the article. It is also important to note that as these results are a part of the overall score, this did not add to the bias devaluation. Regarding the outcome of stress, we were also interested in the types of healthcare professionals participating in this trial, and their frequencies; these numbers are mentioned in the footnotes of Table 2.

We assessed the Robinson 1998 trial as some concerns related to bias in selection of the reported result for all outcomes because the study lacked a published study protocol.

Effects of interventions

See: **Summary of findings 1** Family presence during resuscitation

Table 1 summarizes the effect estimates using the descriptive statistics of median and interquartile range (IQR) from the included trials.

Overall, there is an indication that FPDR decreases PTSD, anxiety and depression, and complicated grief, but as the studies were few and at high risk of bias, this effect is very uncertain.

Only a few of our outcomes were measured in the included studies, and are all mentioned in Summary of findings 1. For our primary outcome, PTSD, evaluation of the relatives was measured at 0 to 3 months and after more than 3 months in both studies. PTSD was evaluated by the IES scale, which is composed of two subscales, "the IESI is the intrusion subscale and consists of seven statements on intrusive thoughts and images of the event, dreams, and repetitive behaviour. The avoidance subscale, IESA, consists of eight statements about ideational constriction, denial of the meaning and consequence of the event, blunted sensation, behavioural inhibition, counterphobic activity, and emotional numbness" (quote from Robinson 1998) (Horowitz 1979). Overall, the results were in favor of FPDR.

Regarding our secondary outcomes, both studies measured depression and anxiety at 0 to 3 months and after more than 3 months using the HADS (Zigmond 1983), as well as mortality, but only Jabre 2014 measured complicated grief at 12 months, which was in favor of FPDR. Furthermore, Jabre 2013 measured duration of patient resuscitation and personal stress in healthcare professionals during resuscitation. None of the studies assessed our other secondary outcomes (i.e. patient morbidity, adverse events, and healthcare professionals' attitude toward FPDR).

The median stress level measured on the visual analogue scale (VAS) was 5 out of 100 (IQR, 0 to 15), evaluated by 1710 healthcare professionals. After contacting the author of Jabre 2013, we received data on how many healthcare professionals completed the VAS stress evaluation: physicians: n = 567 (3 missing), nurses: n = 556 (14 missing), ambulance drivers: n = 543 (27 missing).

Certainty of the evidence

Overall, there is not much evidence regarding FPDR. One of the included trials was large, but it was cluster-randomized. The other included trial was a very small pilot study that was ended prematurely due to the risk of tampered randomization. Both studies had high risk of bias, and based on the GRADE approach, we assessed the certainty of the evidence for all outcomes except one as very low. It was not possible to downgrade for publication bias due to the overall lack of trials.

DISCUSSION

The aim of this review was to investigate the evidence for the effect of offering relatives the option to be present during resuscitation, measured by the occurrence of PTSD-related symptoms in the relatives. We conducted a broad search that retrieved a substantial number of studies, suggesting that there is considerable interest in FPDR and family-centered care in acute settings. We included two studies (three papers) and found insufficient evidence to draw any firm conclusions on the effects of family presence during resuscitation on any outcome. Overall, there is an indication that FPDR decreases PTSD, anxiety and depression, and complicated grief, but as the studies were few and at high risk of bias, this effect is very uncertain.

The two studies (three papers) included in the review had comparable participants. However, both the size and design of the studies were different: one study was a prospective, cluster-randomized, controlled trial from 2013 involving 15 pre-hospital emergency medical services units in France including 570 participants, comparing the systematic offer for a relative to witness CPR with the traditional practice (Jabre 2013), and its 1-year assessment (Jabre 2014); the other study was a small pilot study from 1998 of FPDR in the ER including 25 participants (Robinson 1998). The Robinson study was ended prematurely due to the risk of altered randomization by staff who had become convinced of the benefits of FPDR.

When we look at emergency medicine and intensive care therapy, the available evidence is very scarce. Hypothetically, patients and their relatives would benefit from a greater involvement of close relatives in critical situations like cardiac arrest and other life-threatening situations, as well as during treatment in intensive care wards. Jabre found some evidence that relatives experienced less anxiety and PTSD if they had witnessed the resuscitation—whether successful or not—of their loved ones (Jabre 2014).

The principle of FPDR is a *triangular relationship*, where the intervention of family presence affects both the healthcare professional, the relatives present, and the care of the patient involved. The needs and well-being of all of these individuals must be balanced in the context of FPDR, as the actions of all three groups may impact one another.

There is a lack of high-quality research on the effect on any part of this *triangular relationship*, and it is controversial that the procedure is being so strongly recommended by some. The European Resuscitation Council recommends, based on very few trials but strong expert opinion, that relatives should be offered the choice of being present during CPR (Bossaert 2015), and the Emergency Nurse Association has made an official guideline with a moderate recommendation policy for FPDR (ENA 2009). This recommending of interventions before they are fully investigated can lead to misunderstandings regarding the true effect. Once the interventions are implemented, the opportunity to test the effects is hampered, either because it is believed the effects are already known—in this particular situation that the effect of FPDR is positive—or because there is too much resistance from the control group (Freedman 1987). Another possibility is that this context is very complex and the effects, both positive and negative, are difficult to measure. We have seen FPDR become the modern working model in pediatrics and obstetrics (Vincent 2017). The practice has been widely debated in much the same way as FPDR is now (Bauchner 1996), but the evidence from high-quality RCTs is still sparse (Dainty 2021). It is possible that in this area we have to look at other study designs to evaluate the complex impact of FPDR. In 2022, the International Liaison Committee on Resuscitation (ILCOR) conducted a systematic review of family presence during adult resuscitation from cardiac arrest that included the 2 RCTs included in our review, 16 other quantitative studies, 12 qualitative studies, and 1 mixed-methods study (Considine 2022). This review also showed that there was variability in the effect of family presence during resuscitation on patient outcomes, family and provider outcomes with very low- or low-certainty evidence.

Reviews have shown that physicians often perceive more barriers associated with FPDR than nurses (De Robertis 2017; Sak-Dankosky 2014; Tíscar-González 2021), which may be enhanced by the higher risk for legal actions against physicians.

Summary of main results

Our electronic search yielded a total of 7292 records. We included two trials involving a total of 595 randomized patients and their relatives undergoing critical care including CPR: a cluster-randomized trial from 2013 involving pre-hospital emergency medical services units in France, comparing the systematic offer for a relative to witness CPR with the traditional practice (Jabre 2013), and its one-year assessment (Jabre 2014); and a small pilot study from 1998 of FPDR in an emergency department in the UK (Robinson 1998). The two included studies (three papers) had comparable participants. However, the Jabre study was much larger than the Robinson study, which furthermore was ended prematurely due to the risk of altered randomization by staff who had become convinced of the benefits of FPDR.

The included participants were 19 to 78 years old, and between 56% and 64% were women. PTSD was measured with the IES; the median score ranged from 0 to 21 (range 0 to 75; higher scores correspond to more severe disease). The presence of PTSD is estimated as IES > 30, which was not found as a median score in either groups in any of the ITT analyses. However, in the French trial (Jabre 2013; Jabre 2014), which accounts for most of the included participants (570/595), the frequency of PTSD-related symptoms was significantly higher in the control group after both 3 and 12 months, and in the per-protocol analyses a significant statistical difference was found in favor of FPDR for PTSD, depression, and complicated grief after 1 year. However, the included studies were at overall high risk of bias, and most of the evidence was of very low certainty.

In both included studies there was a large amount of missing outcome data.

Overall completeness and applicability of evidence

Unfortunately, the results of this systematic review show that we still have too little knowledge about the effect of FPDR on any part of the triangular relationship consisting of healthcare professionals, patients, and relatives. The included studies appeared to be in favor of FPDR with respect to our review aims; however, we could not perform a meta-analysis, and both the risk of bias assessment and the GRADE evaluation were remarkably low.

The effects of stress due to the presence of family on physician's performance in clinical situations with FPDR is poorly understood, but it is known that elevated stress levels can impede performance on tasks that require divided attention, working memory, retrieval of information from memory, and decision-making (Leblanc 2009). Before investigating the effect of FPDR on relatives' psychological outcomes further, we believe that the effect on healthcare professionals and patient care should be investigated with high-quality trials. This could be done at first in a controlled simulated environment following the Simulation-Based Research Extensions for the CONSORT Statement (Cheng 2016), where healthcare professionals could be randomized according to FPDR or not, and healthcare professional stress could be measured by heart rate variability during the simulation, looking at the effect of FPDR. Patient care could be monitored as time to critical event throughout the scenario. Afterwards, a similar design randomizing the offering of FPDR to the relatives, measuring healthcare professionals heart rate variability, could be implemented in an ER including follow up of patient outcomes, and finally the measurement of psychological outcomes in relatives (similar to Jabre 2013). It could also be of interest to ask healthcare professionals, in a questionnaire, about the effect of FPDR on their self-considered performance right after a resuscitation event.

Quality of the evidence

In both included studies, the same scales to measure PTSD, anxiety, and depression were used. To measure PTSD, the Impact of Event Scale (IES) and its subscales were used (Horowitz 1979), and the Hospital Anxiety and Depression Scale (HADS) was used for measuring the level of anxiety in relatives (Zigmond 1983). Neither of these scales is validated for these specific kinds of participants, but to our knowledge no scales are. The IES was previously found to be relevant for use in this context (Sundin 2003). Jabre 2014 used the Inventory of Complicated Grief (ICG) score to measure complicated grief, which seems more relevant when exploring the literature compared to the Texas Revised Inventory of Grief (TRIG) score used in Robinson 1998, as the grief-related symptoms investigated with the TRIG score "seem more likely to reflect greater difficulty accepting the death and to predispose the bereaved to enduring complications in the adjustment to bereavement" and "may also be under-inclusive with respect to symptoms of complicated grief" (Prigerson 1995). Furthermore, we have not been able to locate a cut-off value for the TRIG score.

We assessed the overall risk of bias as high in both included studies, and the GRADE assessment indicated very little confidence in the effect estimates. We believe the true effect is likely to be substantially different from the estimate of effect. Only the outcome resuscitation time was graded as low certainty.

To account for the high risk of bias, we recommend that future studies include enough participants, ideally in an emergency department, including both relatives to patients undergoing CPR but also trauma and critical care, and the trials must be truly randomized to eliminate confounders. It is also important to be aware of the possible selection bias when proposing FPDR, and why it is important to have prespecified eligible participants, for instance as Jabre did (i.e. spouse, parent, offspring, sibling). However, this is a highly sensitive area to conduct research in. We suggest that there should be an exclusion criterion where healthcare professionals are given the opportunity to exclude relatives from the study due to ethical reasons, as it may be presumed harmful for some relatives to participate and for others to stay outside the patient room.

It is imperative that trials concerning FPDR be conducted in settings that are true to the RCT design and on the premise that true equipoise exists. If we do not know what is best, we should test it (Freedman 1987). Bias could, perhaps, be explored by investigating healthcare professionals attitudes qualitatively toward the initiative in advance and including the information in the statistics. Personal communication with authors of the Jabre 2013 trial revealed that before inclusion phase started in each center, medical teams that preferred not to participate in the study were allowed not to participate, which may have led to selection bias.

Potential biases in the review process

A very important potential bias in this review process is that one of the review authors (PJ) is the first author of an included primary

study in this review (Jabre 2013). However, PJ did not extract data from any included studies and was not included in the risk of bias assessment or the GRADE evaluation. Another potential bias is that two review authors (MAR and AMM) are included in other research project regarding FPDR, including a PhD project; however, none of these projects are pre- or in-hospital clinical trials.

A potential bias could be that indexing of studies in the area is poor, but as we searched many other resources, we believe this bias in our review to be minimal.

Agreements and disagreements with other studies or reviews

We found an umbrella review of the evidence including all systematic reviews completed (Tíscar-González 2021). The only systematic review we found of RCTs, Oczkowski 2015, included both our included studies, but also included two studies we excluded (Dudley 2009; Holzhauser 2006), and on this basis completed meta-analyses which seemed to be in favor of FPDR. Most meta-analyses, however, were based on just one study (Jabre 2013), which is not recommended practice. In addition, in one of its meta-analyses, the Oczkowski 2015 systematic review reported unpublished data about mortality outcomes from the Holzhauser 2006 study, which were obtained after personal contact with the study authors. The mortality data provided by Holzhauser 2006 to Oczkowski 2015 were the number of survived and deceased from resuscitation, as in-hospital mortality at 28 or 30 days was outside the scope of the Holzhauser 2006 paper.

AUTHORS' CONCLUSIONS

Implications for practice

There was insufficient evidence to draw any firm conclusions on the effects of family presence during resuscitation on relatives' psychological outcomes.

Sufficiently powered and well-designed randomized controlled trials may change the conclusions of the review in future.

Implications for research

This review highlights the lack of evidence for the effect of family presence during resuscitation (FPDR).

Several reasons can account for the lack of comparative research in this field, as follows.

- Evaluation of FPDR often takes place in difficult conditions and a hostile environment.
- Many confounding factors (e.g. the degree of trauma, the success/failure of the resuscitation, the length of time the patient had chronic disease, the skill or sympathy of the staff, the way the staff are affected) must be considered.
- The important clinical, cultural, and personal heterogeneity between relatives requires large-scale studies allowing specific subgroup analyses.
- From a practical point of view, cluster-controlled trials seem to be the most reasonable study design for assessing the psychological effects of FPDR. However, with this type of design, other outcomes such as patient mortality and healthcare professional performance and stress could be biased.
- The main trial included in this review was at risk of attrition bias; future studies should ensure that they take the necessary actions to reduce dropout and loss to follow-up.

The area of FPDR should also be investigated more by qualitative research, which could elaborate on the phenomenon in relation to the whole triangular relationship of patient, relative, and healthcare professional.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Jabre 2013

Study characteristics	
Methods	Prospective, cluster-randomized controlled trial **Setting:** Pre-hospital emergency medical service units* **Country:** France **Groups:** Family presence offered versus no family presence offered **Period:** November 2009 to October 2011
Participants	**Sample size:** 15 clusters randomized (8/7) resulting in 266/304 relatives in each group **Included:** Adult family members of adult patients in cardiac arrest occurring at home. Only 1 first-degree relative per patient. The relative was chosen in accordance with the legislation on hospitalization at the request of a third party in the following order of preference: spouse, parent, offspring, sibling. **Excluded:** Communication barriers with the relative and cardiac arrest cases in which resuscitation was not attempted **Missing:** None; all are accounted for in the flowchart
Interventions	Clusters were assigned in a 1:1 manner. A blinded statistician used a simple randomization method employing SAS software. **Intervention:** Relatives offered to witness resuscitation of patients in cardiac arrest occurring at home **Control:** traditional practice (Relatives asked to wait in a special room or allowed to witness CPR)
Outcomes	**Primary:** PTSD evaluation of the relatives measured at 3 months **Secondary:** • Depression and anxiety in the relatives measured at 3 months • Duration of resuscitation

Jabre 2013 *(Continued)*

	Measured by: IES and HADS
Notes	*The units are ambulance base stations equipped with 1 or more mobile intensive care units, consisting of an ambulance driver, a nurse, and a senior emergency physician as the minimum team. **Published protocol:** ClinicalTrials.gov number NCT01009606. NEJM final protocol. **Funding:** Programme Hospitalier de Recherche Clinique 2008 of the French Ministry of Health **Conflict of interest:** The following authors have conflict of interests (not related to this publication): Azoulay E. has received payment from Pfizer and Gilead. Borron S. has received funding from Vidacare for a study of EZ-IO in resuscitation. Tazarourte K. has received payment from LFB, France for a VKA study. Vivien B. has received accommodations costs from Hutchinson Technology Inc. related to a meeting on StO2. **Contact with authors:** Author emailed (patricia.jabre@aphp.fr) in January 2020 for more information regarding the randomization process and receiving the HADS and IES subscales.

Jabre 2014

Study characteristics	
Methods	
Participants	
Interventions	
Outcomes	**Primary:** PTSD evaluation of the relatives measured at 12 months **Secondary:** • Depression and anxiety in the relatives measured at 12 months • Complicated grief **Measured by:** IES, HADS, Inventory of Complicated Grief (ICG), and the structured diagnosis of a major depressive episode (MINI)
Notes	This is the long-term follow-up of the Jabre 2013. The relative was deemed unreachable after 15 calls went unanswered.

Robinson 1998

Study characteristics	
Methods	Prospective, randomized controlled trial **Setting:** Emergency department, single center **Country:** UK **Groups:** Family presence offered versus no family presence offered **Period:** November 1995 to February 1997
Participants	**Sample size:** 25 randomized (13/12)

Robinson 1998 *(Continued)*

	Included: Eligible resuscitations were those in which the patient was accompanied by a relative and 1 of 3 specific senior staff members were present. The person most closely related to each patient was chosen. Random selection was used if assigned relatives were equally close to the patient. **Excluded:** • Successful resuscitation of patient • Relative refusal or lost to follow-up **Missing:** None; all are accounted for in the flowchart.
Interventions	The unit of randomization was the patient and not the relative. Patients were assigned in a 1:1 manner by sealed envelope. **Intervention:** Relatives offered to witness resuscitation of patients who required resuscitation for cardiac arrest or multiple trauma **Control:** Relatives not offered to witness resuscitation
Outcomes	**Primary:** PTSD evaluation of the relatives measured at 3 and 9 months **Secondary:** Depression and anxiety in the relatives measured at 3 and 9 months **Measured by:** IES and HADS
Notes	No published protocol, preliminary pilot study. **Conclusion**: They recommend that relatives should be offered the choice to remain with the patient during resuscitation, but no pressure should be applied to those who are reluctant. If the family choose to remain in the resuscitation room, they must be continuously accompanied and supported by an experienced member of staff. **Funding:** Not stated **Conflict of interest:** Not declared, however the study was stopped early because the randomization process was at risk of being altered by staff who had become convinced of the benefits of allowing relatives to witness resuscitation.

HADS: Hospital Anxiety and Depression Scale
IES: Impact of Event Scale
PTSD: post-traumatic stress disorder

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Albarran 2009	Wrong study design
Albarran 2009a	Personal opinion
Aldridge 2005	Wrong study design
Alireza 2019	Wrong intervention
Anon 2000a	Personal opinion
Anon 2000b	Wrong study design

Study	Reason for exclusion
Anon 2001	Personal opinion
Anon 2007	Personal opinion
Anon 2008a	Personal opinion
Anon 2008b	Personal opinion
Barrat 1998	Personal opinion
Blättler 2014	Wrong study design
Boie 2007	Personal opinion
Boschini 2007	Wrong patient population
Boucher 2010	Wrong study design
Bredahl 2011	Wrong study design
Broome 2000	Personal opinion
Broyles 2016	Wrong study design
Carter 2008	Wrong study design
Cavlovich 2011	Wrong study design
Clark 2005	Wrong study design
Compton 2009	Wrong study design
Compton 2010	Abstract to a screened study
Compton 2011	Wrong study design
Davidson 2011	Wrong study design
Day 2011	Wrong study design
De Stefano 2016	Wrong study design
Decker 2012	Personal opinion
DelVecchio Gilbert 2013	Personal opinion
Dill 2006	Wrong study design
Dolan 1997	Personal opinion
Dudley 2009	Wrong study design
Dwyer 2016	Wrong study design
Edwards 2012	Wrong study design

Study	Reason for exclusion
Egging 2011	Wrong study design
Ellison 1997	Wrong study design
Fromm 2016	Wrong study design
Fulbrook 2008	Personal opinion
Gaucher 2012	Wrong intervention
Goldberger 2015	Wrong study design
Gomez 2016	Wrong study design
Hagan 2008	Wrong study design
Hardin Fanning 2014	Wrong study design
Herrera 2016	Wrong study design
Hodge 2009	Wrong study design
Holzhauser 2006	Wrong study design
Holzhauser 2007	Wrong study design
Holzhauser 2008	Wrong study design
Islekdemir 2016	Wrong intervention
Itzhaki 2012	Wrong study design
Jabre 2012	Duplicate
Jabre 2013a	Duplicate
Jabre 2014a	Personal opinion
Jaques 2014	Personal opinion
JeongLim 2013	Wrong study design
Jermark 2017	Wrong study design
Kenny 2017	Wrong study design
KurtogluCelik 2013	Wrong study design
Leske 2010	Wrong study design
Leske 2012	Wrong study design
Leske 2017	Wrong study design
Lomas 2007	Personal opinion

Study	Reason for exclusion
Loyacono 2001	Personal opinion
Lynch 2008	Wrong study design
Mangurten 2005	Wrong study design
Mangurten 2006	Wrong study design
Mangurten 2006a	Abstract to a screened study
Maxton 2008	Wrong study design
McClement 2008	Wrong study design
McClement 2010	Abstract to a screened study
Mian 2007	Personal opinion
Mitchell 2008	Wrong study design
Moon 2008	Personal opinion
Morris 1998	Personal opinion
NCT01009606	Protocol of a screened study
Ong 2004	Wrong study design
Parra 2018	Wrong study design
Pasquale 2010	Wrong study design
Petterson 1999	Personal opinion
Piiparinen 2020	Abstract. Unfortunately, the whole study has not been published as a full article. Contact with the author said it was not an RCT.
Powers 2017	Wrong study design
Pye 2010	Wrong study design
Sacchetti 2005	Wrong study design
Selos 2010	Personal opinion
Shirazi 2009	Wrong study design
Soleimanpour 2017	Wrong study design
Stauffer 2012	Wrong study design
Tosh 2015	Wrong study design

Study	Reason for exclusion
Weslien 2006	Wrong study design
Wolfram 1996	Wrong patient population
Wolfram 1997	Duplicate
Yanfang 2012	Wrong study design

RCT: randomized controlled trial

ADDITIONAL TABLES

Table 1. Summarized effect estimates

Median and interquartile range (IQR) for the Impact of Event Scale (IES) and Hospital Anxiety and Depression Scale (HADS) including their subscales in the 2 included studies when comparing the effect estimates of the relatives that were offered to witness resuscitation compared to those who were offered the traditional practice (relatives asked to wait in a special room or allowed to witness CPR)

		IES*	IESI	IESA	HADA	HADD	HADS**		IES	IESI	IESA	HADA	HADD	HADS
Study ID	**Intervention:** offering relatives the opportunity of FPDR													
Jabre 2013 Jabre 2014	3 months	22 (12 to 33)	14 (8 to 21)	8 (3 to 13)	5 (3 to 8)	4 (2 to 8)	10 (6 to 16)	12 months	19 (7 to 28)	2 (0 to 13)	0 (0 to 8)	4 (2 to 8)	3 (1 to 5)	8 (4 to 13)
Robinson 1998	3 months	-	15.5 (11.5 to 24.8)	8 (3.3 to 18)	7 (5 to 8.8)	2.5 (1 to 5)	-	9 months	-	17.5 (3 to 27.8)	7 (0.8 to 18.3)	6.5 (2.3 to 10.3)	6.5 (0.8 to 9.3)	-
	Comparison:not offering relatives the opportunity of FPDR													
Jabre 2013 Jabre 2014	3 months	24 (13 to 35)	15 (8 to 21.75)	8 (4 to 15.75)	6 (3 to 10)	5 (2 to 9)	11 (6 to 19)	12 months	20 (11 to 35)	9 (0.25 to 17.75)	5 (0 to 12)	5 (2 to 9)	4 (1 to 8)	10 (5 to 16)
Robinson 1998	3 months	-	16.5 (11.5 to 21.8)	10 (5.8 to 13.3)	8 (5 to 12)	5 (3 to 6.5)	-	9 months	-	21 (10 to 25)	18 (9 to 20)	8.5 (3.3 to 11.3)	4.5 (1.6 to 6.8)	-

Abbreviations: CPR: cardiopulmonary resuscitation; FPDR: family presence during resuscitation; HADA: HADS anxiety subscale; HADD: HADS depression subscale; HADS: Hospital Anxiety and Depression Scale; IES: Impact of Event Scale; IESA: IES avoidance subscale; IESI: IES intrusion subscale; PTSD: post-traumatic stress disorder
*Scores on IES range from 0 (no PTSD-related symptoms) to 75 (severe PTSD-related symptoms). The IESI subscale ranges from 0 to 35, and the IESA from 0 to 40. The presence of PTSD is defined by an IES score > 30.
**Scores on HADS range from 0 to 42, with higher scores indicating greater anxiety and depression. The presence of anxiety or depression is defined by a HADS subscale score higher than 10 (range, 0 to 21).

Table 2. Characteristics of included studies

Study[a]	Country	Setting	Methods	Outcomes	Sample size	Age range	% women	Partici-pants	Risk of bias
Jabre 2013	France	Pre-hospital emergency medical service units	cluster-RCT	Primary: PTSD evaluation Secondary: anxiety and depression, resuscitation time,	570[b]	41 to 73 52 to 84[c]	63, 68 33, 33[c]	475 1666[d]	High

Table 2. Characteristics of included studies *(Continued)*

				healthcare professional stress evaluation					
Jabre 2014	-	-	-	Primary: PTSD evaluation Secondary: anxiety, depression and complicated grief	-	-	-	408	-
Robinson 1998	UK	Emergency department	RCT	Primary: PTSD evaluation Secondary: anxiety and depression	25	19 to 78	55, 56	18	High

Abbreviations: PTSD: post-traumatic stress disorder; RCT: randomized controlled trial; VAS: visual analogue scale

[a]The two first studies are part of the same trial with short- and long-term effect measured.

[b]15 clusters included: n = 104, 16, 17, 29, 56, 64, 15, 32, 35, 88, 45, 14, 8, 26, 21.

[c]Patient demographic.

[d]Through communication with the trial author, we obtained the following numbers of healthcare professional participants by profession, from those who completed the VAS stress evaluation: physicians: n = 567 (3 missing); nurses: n = 556 (14 missing); ambulance drivers: n = 543 (27 missing).

APPENDICES

Appendix 1. Search strategy

MEDLINE (MedAll, Ovid)

1. *Family/px [Psychology]
2. *Parents/px [Psychology]
3. *Professional-Family Relations/
4. ((famil* or next of kin* or kinship or relativ* or significant other* or spouse* or husband* or wife* or partner* or parent* or sibling* or friend* or companion* or brother* or sister* or father* or mother* or bereave*) adj5 (presen* or attend* or observ* or witness* or perception* or participat*)).mp.
5. (family cent?red adj2 care).mp.
6. 1 or 2 or 3 or 4 or 5
7. exp emergency medical services/
8. emergency medicine/
9. exp resuscitation/
10. exp Emergency Treatment/
11. exp heart arrest/
12. ((Emergen* or acute) adj3 (servic* or medicine or treat* or room*)).mp.
13. (resuscitat* or CPR).mp.
14. (prehospital* or pre-hospital* or out of hospital or trauma*).mp.
15. ((cardiac or heart or cardiopulmonary) adj2 arrest*).mp.
16. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17. 6 and 16
18. (FPDR or FWR).mp.
19. 17 or 18
20. ((randomized controlled trial or controlled clinical trial).pt. or randomi?ed.ab. or placebo.ab. or drug therapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (exp animals/ not humans.sh.)
21. 19 and 20

Embase (Ovid)

1. exp family/ and (outcome assessment/ or exp psychologic assessment/ or psychological aspect/)
2. ((famil* or next of kin* or kinship or relativ* or significant other* or spouse* or husband* or wife* or partner* or parent* or sibling* or friend* or companion* or brother* or sister* or father* or mother* or bereave*) adj5 (presen* or attend* or observ* or witness* or perception* or participat*)).mp.
3. (family cent?red adj2 care).mp.
4. 1 or 2 or 3
5. exp emergency health service/
6. exp emergency medicine/
7. exp resuscitation/
8. exp heart arrest/
9. exp emergency treatment/
10. emergency ward/
11. ((emergen* or acute) adj3 (servic* or medicine or treat* or room*)).mp.
12. (resuscitat* or CPR).mp.
13. (prehospital* or pre-hospital* or out of hospital or trauma*).mp.
14. ((cardiac or heart or cardiopulmonary) adj2 arrest*).mp.
15. 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16. 4 and 15
17. (FPDR or FWR).mp.
18. 16 or 17
19. (randomized controlled trial/ or controlled clinical study/ or random$.ti,ab. or trial.ab. or randomization/ or intermethod comparison/ or placebo.ti,ab. or (compare or compared or comparison).ti. or ((evaluated or evaluate or evaluating or assessed or assess) and

(compare or compared or comparing or comparison)).ab. or (open adj label).ti,ab. or ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab. or double blind procedure/ or parallel group$1.ti,ab. or (crossover or cross over).ti,ab. or ((assign$ or match or matched or allocation) adj5 (alternate or group$1 or intervention$1 or patient$1 or subject$1 or participant$1)).ti,ab. or (assigned or allocated).ti,ab. or (controlled adj7 (study or design or trial)).ti,ab. or (volunteer or volunteers).ti,ab. or human experiment/ or trial.ti.) not (((random$ adj sampl$ adj7 (cross section$ or questionnaire$1 or survey$ or database$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)) or (cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group$1.ti,ab.)) or (((case adj control $) and random$) not randomi?ed controlled).ti,ab. or (Systematic review not (trial or study)).ti. or (nonrandom$ not random$).ti,ab. or Random field$.ti,ab. or (random cluster adj3 sampl$).ti,ab. or ((review.ab. and review.pt.) not trial.ti.) or (we searched.ab. and (review.ti. or review.pt.)) or update review.ab. or (databases adj4 searched).ab. or ((rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset$1).ti. and animal experiment/) or (Animal experiment/ not (human experiment/ or human/)))

20.18 and 19

PsycInfo (Ebsco)

S1 (DE "Family" OR DE "Family Members") AND (DE "Perception" or DE "Witnesses" or DE "Health Personnel Attitudes" or DE "Attitudes")

S2 TX ((famil* or next of kin* or kinship or relativ* or significant other* or spouse* or husband* or wife* or partner* or parent* or sibling* or friend* or companion* or brother* or sister* or bereave*) N5 (presen* or attend* or observ* or witness* or perception* or participat*))

S3 TX (family cent*red N2 care)

S4 S1 OR S2 OR S3

S5 DE "CPR" OR DE "Emergency Services" OR DE "Crisis Intervention Services" OR DE "Heart Disorders"

S6 TX ((emergen* or acute) N3 (servic* or medicine or treat* or room*))

S7 TX (resuscitat* or CPR)

S8 TX (prehospital* or pre-hospital* or pre hospital or out of hospital or trauma*)

S9 TX ((cardiac or heart or cardiopulmonary) N2 arrest*)

S10 S5 OR S6 OR S7 OR S8 OR S9

S11 S4 AND S10

S12 TX (FPDR or FWR)

S13 S11 OR S12

S14 (DE "Randomized Controlled Trials" OR DE "Randomized Clinical Trials") OR (TX (random* OR trial) OR AB (groups OR placebo) OR AB (control W5 group) OR AB (cluster W3 RCT))

S15 S13 AND S14

Cinahl (Ebsco)

S1 (MH "Family+/PF")

S2 (MH "Parents+/PF")

S3 (MH "Professional-Family Relations")

S4 TX ((famil* or next of kin* or kinship or relativ* or significant other* or spouse* or husband* or wife* or partner* or parent* or sibling* or friend* or companion* or brother* or sister* or mother* or father* or bereave*) N5 (presen* or attend* or observ* or witness* or perception* or participat*)) or TX (family cent*red N2 care)

S5 S1 OR S2 OR S3 OR S4

S6 (MH "Emergency Medical Services+")

S7 (MH "Emergency Medicine")

S8 (MH "Emergency Treatment+")

S9 (MH "Resuscitation+")

S10 (MH "Heart Arrest+")

S11 TX ((emergen* or acute) N3 (servic* or medicine or treat* or room*))

S12 TX (resuscitat* or CPR)

S13 TX (prehospital* or pre-hospital* or pre hospital or out of hospital or trauma*)

S14 TX ((cardiac or heart or cardiopulmonary) N2 arrest*)

S15 S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14

S16 S5 AND S15

S17 TX (FPDR or FWR)

S18 S16 OR S17

S19 (MH (randomized controlled trials) OR MH (double-blind studies) OR MH (single-blind studies) OR MH (random assignment) OR MH (pretest-posttest design) OR MH (cluster sample) OR TI (randomised OR randomized) OR AB (random*) OR TI (trial) OR (MH (sample size) AND AB (assigned OR allocated OR control)) OR MH (placebos) OR PT (randomized controlled trial) OR AB (control W5 group) OR MH (crossover design) OR MH (comparative studies) OR AB (cluster W3 RCT)) NOT ((MH (animals+) OR MH (animal studies) OR TI (animal model*)) NOT MH (human))

S20 S18 AND S19

Central (Cochrane Library)

#1 MeSH descriptor: [Family] explode all trees and with qualifier(s): [psychology - PX]

#2 MeSH descriptor: [Parents] explode all trees and with qualifier(s): [psychology - PX]

#3 MeSH descriptor: [Professional-Family Relations] explode all trees

#4 ((famil* or "next of kin" or kinship or relativ* or (significant next other*) or spouse* or husband* or wife* or partner* or parent* or sibling* or friend* or companion* or brother* or sister* or mother or father* or bereave*) near (presen* or attend* or observ* or witness* or perception* or participat*)):ti,ab,kw

#5 (family NEAR (centred or centered) NEAR care):ti,ab,kw

#6 #1 or #2 or #3 or #4 or #5

#7 MeSH descriptor: [Emergency Medical Services] explode all trees

#8 MeSH descriptor: [Emergency Medicine] explode all trees

#9 MeSH descriptor: [Emergency Treatment] explode all trees

#10 MeSH descriptor: [Resuscitation] explode all trees

#11 MeSH descriptor: [Heart Arrest] explode all trees

#12 ((emergen* or acute) near/3 (servic* or medicine or treat*)):ti,ab,kw

#13 (resuscitat* or CPR):ti,ab,kw

#14 (prehospital* or (pre next hospital*) or (out next of next hospital) or trauma*):ti,ab,kw

#15 ((cardiac or heart or cardiopulmonary) near/2 arrest*):ti,ab,kw

#16 #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15

#17 #6 and #16

#18 (FPDR or FWR):ti,ab,kw

#19 #17 or #18

#20 #19 in Trials

ClinicalTrials.gov
Advanced search
(family OR relative) AND (presence OR witness OR witnessed) AND (resuscitation OR emergency OR arrest)

ISRCTN
Advanced search
(family OR relative) AND (presence OR witness OR witnessed) AND (resuscitation OR emergency OR arrest)

WHO ICTRP
Basic search
family AND presence AND resuscitation
family AND presence AND emergency
family AND presence AND arrest
relative AND presence AND resuscitation
relative AND presence AND emergency
relative AND presence AND arrest
family AND witness AND resuscitation
family AND witness AND emergency
family AND witness AND arrest
relative AND witness AND resuscitation
relative AND witness AND emergency
relative AND witness AND arrest

Appendix 2. Data extraction form

We extracted the following information where possible.

- Bibliographic data, including date of completion/publication.
- Study settings:
- Study design
- Methods of randomization
- Study length
- Setting
  - Single- or multicenter study
  - Number of centers if multi-center
  - Emergency department or other
- Length of follow-up
- Country of origin
- Source of funding
- Participants:
  - Method for selection of participants
  - Total number
- Number randomized to each group
- Number of exclusions and reasons for exclusions
- Missing
- Age
- Gender distribution
- Inclusion criteria
- Exclusion criteria
- Interventions

Participants being offered to observe

- Resuscitation in the emergency department

  - Both cardiac arrest and
  - Treatment of critical conditions including trauma
- Resuscitation pre-hospital
  - Both cardiac arrest and
  - Treatment of critical conditions including trauma
- Comparators:
  - Participants not offered the opportunity of observation but instead following standard practice of placement in, for instance, a special room, any other intervention, or no intervention at all
- Outcomes:

Primary:

PTSD evaluation of the relatives measured at 0 to 3 months and more than 3 months

Secondary:

- Depression, anxiety, or complicated grief in the relatives according to ICD-11 measured at 0 to 3 months and more than 3 months
- Patient morbidity: readmissions within 30 days, number of ICU admissions within 30 days
- Patient mortality as measured in the included studies. If a study has several time points included, the one closest to 30 days will be used.
- Adverse events in the patient population: number of adverse cardiac and pulmonary events or other adverse events described in the included studies and total number of adverse events
- Personal stress in healthcare professionals during resuscitation as measured by included studies
- Healthcare professionals' attitudes towards FPDR as measured in the included studies
- Duration of patient resuscitation as measured in the included studies
- Number of withdrawals (by group) and number of withdrawals (by group) due to adverse events

HISTORY

Protocol first published: Issue 5, 2020

CONTRIBUTIONS OF AUTHORS

Monika Afzali Rubin (MAR), Tintin Svensson (TS), Suzanne Forsyth Herling (SFH), Patricia Jabre (PJ), Ann Merete Møller (AMM).

AMM is the guarantor. AMM and MAR contributed to the conception of the review. MAR developed the search strategy together with Janne Vendt, Information Specialist of the Cochrane Anaesthesia and Cochrane Critical and Emergency Care Group. AMM, PJ, and SFH provide expertise on family presence during resuscitation (FPDR). All authors, except PJ, contributed to the selection criteria, strategy for assessment of the quality of the evidence, and data extraction forms. MAR drafted, and all other authors have contributed to and approved, the final review.

Co-ordinating the review: MAR

Undertaking manual searches: MAR

Screening search results: MAR, TS

Organizing retrieval of papers: MAR

Screening retrieved papers against inclusion criteria: MAR, TS

Assessing risk of bias: MAR, TS, AMM

Appraising quality of papers: MAR, TS, AMM

Abstracting data from papers: MAR, TS

Writing to authors of papers for additional information: MAR

Providing additional data about papers: MAR

Data management for the review: MAR

Entering data into Review Manager Web software: MAR

Interpretation of data: MAR, TS, PJ, SFH, AMM

Writing the review: MAR

Performing previous work that was the foundation of the present study: PJ

Guarantor for the review (one author): AMM

Person responsible for reading and checking review before submission: MAR

DECLARATIONS OF INTEREST

Monika Afzali Rubin: is a member of the Danish parliament with a special interest in healthcare politics.

Tintin Svensson: nothing to declare.

Suzanne Forsyth Herling: nothing to declare.

Patricia Jabre is the first author of a primary study (which she has conducted) included in this review (Jabre 2013; Jabre 2014). She did not extract data from her own study. Instead, review authors MAR, TS, and AMM extracted these data, and checked the interpretation against the study report and any available study registration details or protocol.

Ann Merete Møller: nothing to declare.

SOURCES OF SUPPORT

Internal sources

- No sources of funding, Other

External sources

- No sources of funding, Other

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the protocol we stated that we would include quasi-randomized trials. However, as this is not recommended by Cochrane, we decided not to include quasi-randomized trials in the final review.

In the protocol we stated that we would use RoB 1, but decided instead to use RoB 2 in the final review, which is a more up-to-date method for assessing risk of bias.

In the protocol we stated that we would include the outcomes for the comparison in three summary of findings tables: one including the post-traumatic stress disorder (PTSD) evaluation of relatives and their depression, anxiety, or complicated grief evaluation; one including patient mortality, length of hospital stay, and adverse events; and one including the personal stress of healthcare professionals as measured by the included studies and duration of patient resuscitation. However, during the review process we decided to include all outcomes in one summary of findings table, as the number of outcomes measured in the included studies was less than expected.

We have refined and finalized the data extraction form, including deleting the phrase to extract "methods of blinding", as this is not possible, and "duration of resuscitation", as this has no clinical relevance. It is not possible to detect whether a long or short resuscitation time is positive or negative.

Since the publication of the protocol, Monika Rubin as become a member of the Danish parliament. The conflicts of interest section has been updated.

INDEX TERMS

Medical Subject Headings (MeSH)

*Anxiety; Anxiety Disorders; Critical Care; Pilot Projects; Randomized Controlled Trials as Topic; *Resuscitation

MeSH check words

Adult; Aged; Child; Female; Humans; Male; Middle Aged; Young Adult