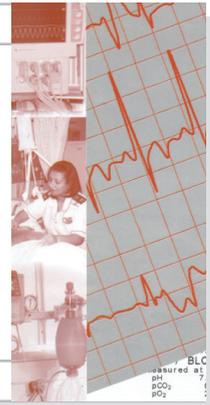


The effectiveness of in-hospital psychosocial intervention programmes for families of critically ill patients – a systematic review



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Background. A review of in-hospital psychosocial intervention studies for families with a relative in a critical care unit was conducted.

Purpose of review. To review the literature on studies addressing the topic, discuss research methods critically, describe clinical outcomes and make recommendations for future research efforts. In doing so, empirically tested interventions producing positive outcomes may be applied to support families who have a relative in a critical care unit.

Data sources. Research citations from 1991 to 2006 from CINAHL, Medline, Pubmed, PsycInfo, SABINET, Cochrane and SCOPUS databases, Internet search engines and unpublished abstracts through NEXUS were searched.

Review methods. Citations were reviewed and evaluated for sample, design, intervention, threats to validity and outcomes. Review studies were limited to those that evaluated in-hospital interventions in family members of patients in a critical care unit.

Results. Six studies were reviewed. Positive outcomes were reported for all of the intervention strategies. All but one of the studies reviewed studied small samples and single critical care units, and were poor in design.

Conclusions. The paucity of interventional studies and the lack of systemic empirical precision to evaluate effectiveness of these interventions necessitate that future studies be methodologically rigorous.

Background

Families experience severe stress following the hospitalisation of a critically injured loved one. Such hospitalisation is often unexpected, and families face the possibility that their loved one may die or be severely disabled. There is the added burden of the economic impact, both in terms of hospital costs and possible loss of future earnings, as well as potential legal implications of, for example, a motor vehicle collision. In addition, the critically injured patient is often admitted to a critical care unit (CCU), which is a very unfamiliar and intimidating environment for families. Families may experience a feeling of powerlessness and a lack of communication and relevant information from the health care team. Health organisations have a responsibility to foster an environment that protects the physical and emotional health of severely stressed family members.¹

The psychosocial consequences of having a loved one in a CCU for families in South Africa have not been adequately explored and need to be investigated in order to ensure that culturally appropriate interventions are developed. The psychosocial implication of trauma in South Africa is a neglected area of research, and this study would contribute to increased knowledge in this field.

Psychosocial consequences

The prevalences of anxiety and depression in family members who have a loved one admitted to a CCU were reported² to be 69.1% and 35.4%, respectively. Anxiety or depression was present in 72.7% of family members and 84% of spouses. Three hundred and fifty-seven patients were included in another study³ and 544 family members completed the Hospital Anxiety and Depression Scale. Symptoms of anxiety

and depression were found in 73.4% and 35.3% of family members, respectively; 75.5% of family members and 82.7% of spouses had symptoms of anxiety or depression ($p = 0.007$). Symptoms of depression were more prevalent in family members of non-survivors of CCU (48.2%) than of survivors (32.7%) ($p = 0.008$). The authors of this study³ concluded that the prevalence of symptoms of anxiety and depression remains high at the end of the CCU stay, whether the patient is well enough to be discharged or is near death. Levels of dissociative symptoms associated with acute stress disorder were found to be elevated in family members just after admission of a loved one to a CCU, but decreased significantly after discharge.⁴ Post-traumatic stress symptoms consistent with a moderate to severe risk of post-traumatic stress disorder were found in 30% of family members of a patient admitted to a CCU.⁵ Severe post-traumatic stress reactions were associated with an increased rate of anxiety and depression and a decreased quality of life.

Family needs

A large number of studies have explored the needs of the families of critically ill patients admitted to CCUs. A literature review of existing studies divided family needs into four categories, namely cognitive, emotional, social and practical needs.⁶

The most important cognitive need was for accurate information, specifically regarding the condition, the prognosis and specific daily treatment.⁶ Factors associated with poor outcomes for the family included failure to provide complete information to them.^{4,5} Families want to know about their critically ill loved one's situation and the care that is planned, and this should be the basis for health professionals' support of families in a CCU.⁷ More interpersonal contact with health professionals can help to meet the family's information needs, and families should be encouraged to participate in their loved one's care where possible.⁴

The emotional needs of families include a need for hope and reassurance as well as spiritual support.⁶ Families described the need to be empowered, and that they needed support to enable them to use both internal and external resources to cope with having a family member in a CCU. Ways to achieve this empowerment included being able to trust the health care team, encountering charity and encountering professionalism. It is essential that health professionals understand how important it is for families to have control over their vulnerable situation and that staff also reflect upon how they would like to be treated themselves in a similar situation.⁸

Social needs centre on keeping families as close to their loved one as possible, for example by having flexible visiting hours.⁶ The whole family is affected when one of its members is in a CCU, and it has been shown that

it is important for partners to be near to their critically ill loved one even if the environment is frightening.⁷

Practical needs were rated as the least important by families, and involved help with financial and family problems, or provision of a waiting room, toilet facilities, etc.⁶

Family interventions

When a loved one is admitted to a CCU, interventions that address family stress and develop coping mechanisms are needed.⁹ While there is substantial literature examining interventions for critically injured patients, little has been written (nationally or internationally) on in-hospital interventions for their families and how effective these could be in reducing the psychosocial consequences of this trauma.

Studies have reported that families who received intervention had less anxiety and better information.¹⁰ Appleyard *et al.*¹¹ evaluated the effectiveness of a 'nurse-coached' volunteer programme to meet the needs of patient families in a CCU, but demonstrated that the only category showing significant improvement was comfort. In contrast, interventions such as structured communication (which decreased telephone calls into the CCU) and family advocates¹³ reported greater family satisfaction than before the programme began. However, studies relating to interventions for families in a CCU have been underreported and often lack empirical methodology and/or statistical analysis of effectiveness.

Purpose of the review

The purpose of the review was to evaluate the literature on studies addressing the topic, discuss research methods critically, describe clinical outcomes and make recommendations for future research efforts. In doing so, empirically tested interventions producing positive outcomes may be applied to support families who have a relative in a CCU.

Review questions

1. What is the effectiveness of in-hospital psychosocial intervention programmes for families of critically ill patients?
2. What/which interventions are most effective in improving the psychosocial consequences for families?

Definitions of terms

Critically ill patient

This will refer to a patient, adult or paediatric, who is admitted to a critical care unit (CCU) for specialised critical care services – either involving a medical or a surgical condition.

Family

This will refer to relatives or significant others of the patient.

Psychosocial in-hospital family interventions

This will refer to interventions targeting psychosocial (psychological and social) needs of families of critically ill patients in a CCU/hospital. Interventions can include information needs.

Outcome

This will refer to psychosocial consequences, including though not restricted to depression, anxiety, and post-traumatic stress syndrome.

Research method

A systematic review of the literature was carried out to retrieve international and national evidence and to translate the results of the search into evidence summaries suitable for clinicians to transfer the knowledge into the clinical areas. Articles published in the last 15 years (1991 - 2006) in English and Afrikaans were searched.

Literature search

The search strategy was designed to access both published and unpublished material.

Electronic search. A limited search of the Cumulative Index of Nursing and Allied Health Literature (CINAHL) and Medline was initially undertaken to identify relevant keywords contained in the title, abstract and subject descriptors. Terms were then identified by the researchers, after much discussion, and the synonyms used by respective databases were used in an extensive search of the literature. The search terms used were: Participants: *Family, Spouse*; Setting: *In-hospital, Critical care, Intensive care units, Trauma*; Interventions: *Psychosocial intervention; family support programs/programmes, information, anxiety/depression programs/programmes*. The following databases were searched using the search terms: CINAHL, Medline, Pubmed, PsycInfo, SABINET, Cochrane, SCOPUS and internet search engines (Google and Google Scholar). Unpublished abstracts were searched through NEXUS.

Hand searching. The reference lists of key articles reviewed were searched and appropriate articles identified and accessed.

Eligibility criteria. The type of studies considered for inclusion in this review included randomised controlled trials, quasi-experimental studies (before-and-after studies) cohort, interrupted time series and case control studies. This review considered studies that included families of critically ill patients in

hospital. The inclusion criteria included all psychosocial interventions on families of critically ill patients (adult or paediatric) in hospital. The exclusion criteria included all psychosocial interventions on families of critically ill patients out of hospital. All articles in any language other than English and Afrikaans were excluded, as were articles published before 1991. All qualitative studies were also excluded.

Abstract review. The two reviewers screened the titles and abstracts of articles identified independently for full article review. If the title or abstract did not provide sufficient information the full article was retrieved for review. Where the two reviewers disagreed, this was discussed and where no agreement was reached, the full article was retrieved for review.

Article review. The retrieved articles were assessed by two reviewers and their suitability for inclusion was evaluated. A format was developed to confirm eligibility for full article review, assess study characteristics and extract data relevant to the review. All information was entered into a database. Studies were independently assessed with four levels of recommendations: Unequivocal, Credible, Unsupported and Inappropriate, with articles rating Unequivocal and Credible being eligible for inclusion. A kappa statistic was calculated to assess the level of agreement for eligibility for inclusion.

Data abstraction

A review form was developed to systematically evaluate the methodological rigour of the eligible articles based on guidelines for intervention studies.¹⁴ For each eligible study the reviewers extracted author, journal, publication year, the type of setting (CCU (adult/paediatric)), the type and number of participants (family members), the interventions (information, education, support, structural), the outcomes (increased comprehension, satisfaction, decreased anxiety and depression), and the comparison groups, study design and sample size. Information on study design was also extracted, namely type of design, number of participants, comparison groups, sampling, randomisation, comparability of groups, allocation concealment, loss to follow-up, consistent treatment, standard outcomes, before and after measurement, appropriate statistics and adequate follow-up.

Assessment of methodological rigour of studies

The type of study was evaluated according to the study design based on the modified Oxford Evidence Based Levels¹⁵ and classified from I to V (see Table I for a full description). Based on the recommendations of the NHMRC (1999)¹⁶ that strength of evidence entails aspects of studies other than study design, factors such as bias, statistical significance of results and relevance of evidence were taken into consideration.

I	Evidence obtained from a systematic review of all relevant randomised controlled trials
II	Evidence obtained from at least one properly designed randomised controlled trial
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group
IV	Evidence obtained from case series, either post-test or pretest/post-test
V	Evidence obtained from surveys only or not enough information provided to make a judgement

The quality of the study design was therefore rated as high, moderate or poor based on the following: Did the study (i) provide information on the setting; (ii) provide information on the participants; (iii) describe the intervention in enough detail; (iv) use a concurrent and control group; (v) have blinded allocation of participants and staff; (vi) report inclusions and exclusions; and (vii) report the effect size of the intervention? Following the data extraction process, all studies rated less than III were further excluded.

Results

Literature search and review process

Of the 74 articles retrieved, 57 were excluded after the abstract and article review process, leaving 17 articles that yielded data on an intervention study for family members of patients in a CCU and were eligible for data extraction. A kappa statistic of 0.9 was found across the two reviewers and illustrated excellent agreement. The most common reasons for exclusion of the articles were no evaluation of an intervention described, no targeting of a CCU or families, and not an in-hospital intervention.

After data abstraction, a further 11 studies were excluded owing to low evidence design and poor methodological rigour, for example, cross-sectional study, small sample size, no comparison group or interventions, and outcomes not clearly described.

Characteristics of the 17 selected studies

Study characteristics are summarised in Table II.^{1,11,13,17-30} Most of the studies were published after 2000 with participants being family members of adult patients in a CCU. Most were observational analytical studies with no control group, a historical control, two or more single-arm studies, or interrupted time series without a parallel control group.

The interventions studied varied widely from single interventions to structured intervention programmes

and included written (information leaflets), oral communication, education programmes and structural change in the CCU such as structured visiting arrangements. Most studies measured family outcomes and used standard tools to measure these. Outcomes measured included depression and anxiety (State Anxiety Scale, SAI), family satisfaction of needs

Date of publication		
1992 - 1999	4	24%
2000 - 2006	13	76%
Journal type		
Nursing	6	35%
Medicine	10	59%
Health system	1	6%
Targeted setting		
Paediatric	1	6%
Adult	16	94%
Study design		
RCT	2	12%
Quasi-experimental	4	24%
Other	11	65%
Intervention type*		
Written information	9	53%
Verbal information	8	47%
Education	3	18%
ICU set-up	3	18%
Outcomes measured*		
Anxiety & depression	10	59%
Satisfaction of needs	11	65%
Comprehension	5	29%
Level of evidence		
I	0	0%
II	1	6%
III	5	29%
IV & V	11	65%

*Can be more than one option.
RCT = randomised controlled trial.

(Critical Care Family Needs Inventory, CCFNI) and level of knowledge or comprehension.

Characteristics of the 6 eligible studies (level I, II or III studies)

Only 6 studies met the criteria for inclusion in this review (either a randomised controlled trial or a quasi-experimental study with two groups, and before and after tests), indicating the small number of high-quality intervention trials that have been done on this topic.

Samples. The 6 studies included data from 594 family members of patients (both adults and children) in CCUs (Table III). Three of the studies had small samples (from 30 to 60 participants), and because of the general lack of reported information on power, most of the studies were underpowered. Random sample selection was noted in only two studies,^{18,25} and only one study¹⁸ reported randomisation of allocation groups, making convenient sampling the most common sampling method and method of allocation to groups. Three studies^{18,25,22} reported attrition data, with the study by Medland and Ferrans¹⁷ reporting a 58.2% loss to follow-up at year 1, though it is the only study which followed participants up after a year.

Designs. The studies included in this review were quasi-experimental study designs with three of them being clinical trials. Of the clinical trials, only the study by Azoulay *et al.*¹⁸ was of good quality including random selection of participants, randomisation of participants to treatment groups, concealed allocation of treatment, before and after measurement and adequate follow-up. All the studies except Daly *et al.*²³ included a control group.

Interventions. The studies included a variety of interventions, the most common being information booklets (4 studies), family support groups, phone calls, structured conversations with a nurse (2 studies) and a structured education programme (2 studies).

Outcomes reported of the 6 eligible studies

All of the studies cited positive outcomes using varied statistical methods. Outcomes were measured using standard validated instruments, though outcomes reported in the studies were not always comparable. Differences between groups using changes between pre- and post-tests were measured using relevant parametric and non-parametric tests and some studies converted the outcomes to Cohen's effect size. All studies reported statistical significance, mostly using *p*-values and one study²² providing confidence intervals. The three main outcomes reported were: Need for information and comprehension of situation, Satisfaction of needs using the Critical Care Family

Needs Inventory (CCFNI), and reducing emotional distress such as anxiety using the State Anxiety Inventory (SAI).

Comprehension and information needs. The most common intervention reviewed was the information booklet or brochure. In previous prospective surveys (conducted in a single CCU with small numbers of families) Azoulay *et al.*¹⁸ showed that handing an information booklet to the family during the first interview improved comprehension,²⁰ although the effect on satisfaction was inconsistent.²⁷

Azoulay *et al.*,¹⁸ using the scale validated in the previous study, reported reducing the proportion of family members with poor comprehension from 40.9% to 11.5% ($p < 0.0001$). Medland and Ferrans¹⁷ reported that family members perceived that their information needs were met significantly better following the use of a structured communication programme, which included an information pamphlet.

Needs satisfaction. Satisfaction of needs on the CCFNI was measured in 3 of the 6 studies. Azoulay *et al.*¹⁸ reported that among family members with good comprehension, those who received the intervention (information booklet) had significantly better satisfaction scores than those who did not ($p = 0.01$).¹⁸ Chien *et al.*,²² using the Chinese CCFNI, reported significant differences on the level of satisfaction with needs (effect size 0.21, $p = 0.006$) and most of the subscales ($p < 0.01$) except for the need for proximity ($p = 0.04$). Small sample size and poor study design may have contributed to the non-significant differences between the two family groups' satisfaction on CCFNI ($p = 0.45$) reported by Daly *et al.*²³ Medland and Ferrans¹⁷ reported an increase in satisfaction with care in the experimental group.

Reducing emotional distress. Emotional distress (anxiety, depression and stress) was an outcome measure in all of the studies except that of Medland and Ferrans.¹⁷ Anxiety was measured in 5 of the studies using the State Anxiety Inventory (SAI). Chien *et al.*,²² with a sample size of 30 and using a Chinese version of the State Anxiety Inventory, reported a significant reduction in anxiety in the treatment group compared with the control group (effect size 0.18, $p = 0.006$). Daly *et al.*²³ and Azoulay *et al.*¹⁸ reported that anxiety and depression was not significantly less prevalent in the intervention groups, though Azoulay provided no specific data. Melnyk *et al.*²⁵ also reported no differences between the groups with respect to anxiety during hospitalisation. However, although no significant between group differences were found, after discharge both treatment and control groups showed significant reduction in anxiety at 3 of the 4 post-discharge points (effect size 0.25 - 0.4). Mitchell and Courtney,³⁰ measuring the change in anxiety after

Table III. Characteristics of 6 studies reviewed

First author (year)	Setting and participants	Study design	Intervention	Outcomes	Level
Azoulay <i>et al.</i> (2002) ¹⁸	114 hospitals Medical surgical adult ICUs (<i>N</i> = 102)	RCT (PP)	Two treatment groups Family information leaflet Standard information control	Anxiety & depression (HADS) ↑Satisfaction of needs (CCFNI) ↑Comprehension*	II Good quality
Melnyk <i>et al.</i> (2004) ²⁵	2 children's hospitals Paediatric ICU (<i>N</i> = 174)	RCT (PP)	Two treatment groups COPE: 3-phase education-behaviour intervention programme 1 - 16 after admission; 2 - 26 h transfer; 2 - 3 d after discharge Structurally equivalent control programme	↓Anxiety (SAI) ↓Depression subscale* ↑Participation* ↓Stress	III Moderate quality
Medland and Ferrans (1998) ¹⁷	1 hospital Medical adult ICU (<i>N</i> = 30)	RCT (PP)	Two treatment groups Structured communication programme: Discussion with nurse, information pamphlet; phone call Standard Care control	↑Satisfaction of needs* (CCFNI) ↑Perception of information needs met* ↓Disruption in ICU (phone calls)*	III Poor quality
Chien <i>et al.</i> (2006) ²²	1 hospital Adult ICU (<i>N</i> = 66)	OE (PP)	Two treatment groups Needs-based education programme by nurse in first 3 d, 1 h session Routine information control	↓Anxiety* (SAI) ↑Satisfaction of needs* (CCFNI)	III Poor quality
Mitchell and Courtney (2004) ³⁰	1 tertiary hospital Adult ICU (<i>N</i> = 162)	OE (PP)	One group structured: Written brochure on transfer to ward Historical control (<i>ad hoc</i>)	↓Anxiety* (SAI) ↑Uncertainty*	III Poor quality
Daly <i>et al.</i> (1994) ²³	1 hospital Adult ICU (<i>N</i> = 60)	OE (PP)	Two groups Family information pamphlet Family group session No control	Anxiety (SAI) Satisfaction of needs (CCFNI) No significant difference	III Poor quality

* Statistically significant.
RCT = randomised controlled trial; PP = pre- and post-test; OE = quasi-experimental.

transfer out of the CCU, showed that both groups had significantly reduced scores (treatment group $p < 0.005$ and control group $p < 0.05$).

Threats to validity of the systematic review

This systematic review was conducted following a standard systematic procedure,³¹ but no statistical synthesis of the quantitative data could be done. The data from these studies were not extracted and combined owing to the heterogeneity of study interventions and outcomes and generally poor methodological rigour. Most of the evidence available was from non-randomised designs, observational studies and case series. These designs can introduce 'serious' and 'unpredictable' biases that can lead to 'both over- and under-estimates' of intervention effectiveness.¹⁵

The randomised controlled trial measuring the effect of the information leaflet was clearly the most reliable study in terms of the evidence-based criteria.¹⁴ Only 2 other studies used a randomised controlled trial study design. Of these 2, only 1 had blind allocation concealment,²⁵ but focused mainly on mothers of children in a paediatric CCU and reported over 50% loss to follow-up.²⁵ The reliability of the intervention effects was reduced by the lack of a control group in 1 of the other 3 studies with quasi-experimental design²³ and by the use of a historical control in another.³⁰ Internal validity was compromised in all studies in varying degrees, with convenient sampling being the main method of selecting participants in all the studies except for Azoulay *et al.*¹⁸ External validity was compromised in varying degrees in the three studies, primarily owing to low statistical power of small sample sizes, lack of power calculation, and four samples confined to one setting.

Heterogeneity of study interventions and outcomes also compromised the validity of the review. Though most of the studies used the CCFNI and the SAI, instrument reliability was a threat to the studies measuring comprehension. Inconsistent time frames in post-testing contributed to confounding with measurement after discharge and on transfer to the ward, which may significantly contribute to inaccuracy of these measurements.

Discussion

Although there has been extensive descriptive research on interventions for families of patients in critical care settings, and many reviews on the topic have been published, few systematic empirical studies have examined the effectiveness of intervention strategies. Generalisations about the 6 studies reviewed can be made despite the heterogeneity and low level of evidence. These include the following: (i) interventions were focused on programmes providing oral and

written communication with families of patients in a CCU to aid in their comprehension of diagnosis, treatment and prognosis, to increase their satisfaction with their needs for support, comfort, information, proximity and assurance, and to decrease their stress and anxiety; (ii) study designs were generally of a low level of evidence (mostly level III); (iii) methodology was problematic in many of the examined studies; (iv) interventions differed and were delivered at different times; (v) reports of positive outcomes were noted; and (vi) no studies provided data on cost.

The reviewers can, however, conclude that the study by Azoulay *et al.*¹⁸ was a well-executed randomised controlled trial of a relatively simple intervention that proved effective in improving family comprehension of both diagnosis and treatment. The study did not demonstrate an understanding of prognosis, which as the authors noted is a more difficult concept. Although the booklet may have been seen as an invitation to increase physician-family intervention, there was no difference between the control and the experimental group.³²

Recommendations

Using the Level of Recommendations in Table IV, the following recommendations can therefore be made.

Table IV.	Oxford evidence-based level of recommendations ¹⁵
A:	Consistent level 1 studies
B:	Consistent level 2 or 3 studies or extrapolations from level 1 studies
C:	Level 4 studies or extrapolations from level 2 or 3 studies
D:	Level 5 evidence or troublingly inconsistent or inconclusive studies of any level

Interventions addressing cognitive needs

Recommendation: C. Despite the methodological limitations, the reviewed studies, specifically Azoulay *et al.*,¹⁸ lend support to the benefits of written information, such as a booklet, as part of a communication programme with families, in increasing comprehension of diagnosis and treatment.

Interventions addressing family satisfaction needs

Recommendation: C. Despite the methodological limitations, the reviewed studies lend support to the benefits of written information, such as a booklet, as part of a communication programme with families, in increasing family satisfaction in terms of support, comfort and assurance.



Interventions addressing anxiety and depression

Recommendation: D. Owing to the methodological limitations, inconsistencies in when outcomes were collected and non-significant findings, the reviewed studies do not lend support to the benefits of a communication programme in decreasing anxiety and stress in families while their relative is in a CCU.

One concern that remains, specifically in a country like South Africa, is the culture-specific interpretation of the process and the content of a family information booklet.

Conclusion

Attempts to assist families with a member in a CCU are worth while, and researchers should continue evaluating interventions using methodologically rigorous studies that minimise bias and include cost data. The paucity of reported in-hospital interventions should not lead clinicians to use interventions that are presumed to be effective and efficacious rather than scientifically tested. Rather, attempts to intervene supportively with families should be encouraged but systematically evaluated so that evidence-based practice is ensured.

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