Humanization of critical care—psychological effects on healthcare professionals and relatives: a systematic review

Humanisation des soins critiques — effets psychologiques sur les professionnels de la santé et les membres de la famille : une revue systématique

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Abstract

Purpose To systematically review and evaluate the effects of humanized care of the critically ill on empathy among

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healthcare professionals, anxiety among relatives, and burnout and compassion fatigue in both groups.

Source MEDLINE, PsycINFO, EMBASE, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), and ProQuest Dissertations were searched from inception to 29 June 2017 for studies that investigated the effects of interventions with potential to humanize care of the critically ill on the following outcomes: empathy among critical care professionals, anxiety among relatives, and burnout and compassion fatigue in either group. We defined a humanizing intervention as one with substantial potential to increase physical or emotional proximity to the patient. Two reviewers independently selected studies, extracted data, and assessed risk of bias and data quality.

Principal findings Twelve studies addressing four discrete interventions (liberal visitation, diaries, family participation in basic care, and witnessed resuscitation) and one mixed intervention were included. Ten studies measured anxiety among 1,055 relatives. Two studies measured burnout in 288 critical care professionals. None addressed empathy or compassion fatigue. Eleven of the included studies had an overall high risk of bias. No pooled estimates of effect were calculated as a priori criteria for data synthesis were not met.

Conclusions We found insufficient evidence to make any quantitative assessment of the effect of humanizing interventions on any of these psychologic outcomes. We observed a trend towards reduced anxiety among family members who participated in basic patient care, liberal visitation, and diary keeping. We found conflicting effects of liberal visitation on burnout among healthcare professionals.

Résumé

Objectif Étudier et évaluer systématiquement les interventions de soins au potentiel « plus humain » chez les patients en état critique sur l'empathie chez les professionnels de la santé, l'anxiété des proches et l'épuisement et la compassion dans les deux groupes.

Source La recherche a été menée dans les bases de données MEDLINE, PsycINFO, EMBASE, CINAHL, le Registre des essais cliniques Cochrane Central (CENTRAL), et ProQuest Dissertations depuis leur création jusqu'au 29 juin 2017 pour identifier les études portant sur les effets d'interventions susceptibles d'humaniser les soins de patients en état critique sur les critères d'évaluation suivants : empathie chez les professionnels de soins critiques, anxiété chez les membres de la famille, épuisement et usure de la compassion dans l'un ou l'autre groupe. Nous avons établi qu'une intervention d'humanisation était une intervention susceptible d'augmenter la proximité physique et émotionnelle avec le patient. Deux chercheurs ont sélectionné les études de façon indépendante, en ont extrait les données et évalué les risques de biais ainsi que la qualité des données.

Constatations principales Douze études abordant quatre interventions particulières (ouverture libérale des visites, journaux personnels, participation de la famille aux soins de base et ressuscitation devant témoin) et une intervention mixte ont été incluses. Dix études ont mesuré l'anxiété chez 1 055 membres de la famille. Deux études ont mesuré l'épuisement chez 288 professionnels de soins critiques. Aucune étude n'a abordé l'empathie ou l'usure de la compassion. Onze des études retenues comportaient un risque global élevé de biais. Aucune estimation groupée de l'effet n'a été calculée, car les critères préétablis pour la synthèse des données n'ont pas été satisfaits.

Conclusions Nous avons trouvé une insuffisance de données probantes pour quantifier une évaluation des interventions d'humanisation sur l'un ou l'autre des critères d'évaluation psychologiques. Nous avons observé une tendance à la baisse de l'anxiété chez les membres des familles ayant participé aux soins de base aux patients, ayant bénéficié d'horaires de visites libéraux et de la tenue de journaux personnels. Nous avons constaté des effets contradictoires de la libéralisation des visites sur l'épuisement chez les professionnels de la santé.

Dehumanization is the process of depriving someone of positive human qualities. It is usually seen as an overt, active, extreme, conflict-driven phenomenon¹ and not typically thought of as being associated with healthcare.

There is however a more subtle form of dehumanization called *infrahumanization* that can occur outside conflict situations. First described by Leyens,² *infrahumanization* differs from blatant dehumanization in that the latter involves the denial of primary emotions (fear, sadness, anger, joy, and disgust) while *infrahumanization* involves the denial of uniquely human secondary emotions (compassion, admiration, fondness, contempt, and disillusionment).¹ Individuals tend to attribute more positive secondary emotions (e.g., compassion) to 'in groups' and more negative secondary emotions (e.g., contempt) to 'out groups', suggesting that *infrahumanization* is not simply an expression of dislike but rather a general diminution of the humanity of those perceived to be outside one's group.² *Infrahumanization* can occur whenever groups identify others as being outside their cohort and has been shown to occur in medical settings.^{3,4} Capozza found that physicians and nurses caring for oncology patients perceived their own professional group as possessing more uniquely human traits than the patient group.³ A study of nursing professionals working in different specialties in an urban hospital showed that denial of uniquely human traits (reasoning, rationality, morality, and intellectual ability) to patients was associated with lower levels of stress among nurses who exhibited high levels of organizational and affective commitment, suggesting that *infrahumanization* is a subconscious coping strategy to reduce the emotional burden of caring for patients.⁴

Those suffering from critical illness are particularly vulnerable to this unintentional dehumanization. Several factors contribute:

Critical illness often impairs agency and capability. Loss of agency can be seen as loss of competence and so, although viewed with warmth, those with life-threatening illness may be subconsciously regarded by others as being less human.^{5,6}

Evidence shows that people are more likely to dehumanize those who appear different from themselves.^{6,7} The physical changes of critical illness, reduced mobility, and a standard hospital gown serve to make patients similar to each other and dissimilar to both their usual selves and their carers. This is further exacerbated by dependency on mechanical devices, breathing tubes, intravenous lines, ventilators, and extracorporeal circuits. Unlike most animals, humans rely on shape and facial recognition rather than smell to identify another human.⁶ The addition of equipment distorts the basic human shape, may obscure facial features, and impedes our ability to perceive the face as a whole. Piece-by-piece as opposed to whole facial processing is the mode our brain uses to distinguish objects and is known to be a dehumanizing mode of facial perception.⁸ Functional magnetic resonance imaging has shown that medial prefrontal cortex activation is necessary

for social cognition and is activated when seeing other humans but is not activated when seeing objects.⁶

Critically ill patients are often sedated, reducing their ability to make eye contact. Eye contact is a powerful communication tool that conveys a host of social information. Direct gaze triggers increased activity in the amygdala and activation of approach-related responses, preparing us for social interaction. Averted gaze triggers feelings of disengagement and disinterest.⁹

Critical illnesses themselves are complex, multifactorial, and difficult to treat. Communication between healthcare professionals requires rapid and accurate appreciation of complicated disease processes. Labelling facilitates this. Mr. Jones, a 52-yr-old farmer with septic shock, diabetes, and renal failure, is often more easily understood as a case of septic shock in a diabetic with acute-on-chronic renal dysfunction.

In an effort to refocus care of the critically ill through a more person-centred lens, several initiatives have been advocated, including diaries, liberal visitation policies, involvement of relatives in basic patient care, and opportunities for relatives to be present during resuscitation.^{10–12} To know if these initiatives allow care providers to see patients in a more human light, we need to determine what effect they have on expressions of empathy among healthcare professionals, empathy being essential to the appreciation of another's humanity.^{1,13}

In the light of evidence that dehumanization may be protective against burnout and¹⁴ that subtle dehumanization may be motivated by the need to reduce the emotional cost of caring,^{4,15} and recognizing that care of the care giver is a key component of humanized care,¹² we also need to find out what effect humanizing interventions have on the risk of burnout and compassion fatigue among both healthcare professionals and relatives.

Finally, as anxiety is common among relatives of the critically ill and can impede critical decision-making,¹⁶ and since many of these initiatives focus on increased relative presence and involvement, we also need to determine the effect of humanized care on anxiety among relatives. The objectives of this review were therefore to systematically review the literature to determine the effects of interventions that humanize care of the critically ill on empathy in healthcare professionals, burnout and compassion fatigue among healthcare professionals and relatives, and anxiety among relatives.

Methods

This systematic review was conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses PRISMA guidelines.^{17,18} A study protocol

was designed and was not published separately (available as Electronic Supplementary Material [ESM] appendix 1- Methods section of protocol).

Study type

We included clinical studies (both with and without comparator groups) that measured our pre-specified psychologic outcomes of interest. We excluded non-human studies, studies that did not measure our outcomes of interest, and studies that expressed outcomes qualitatively rather than quantitatively. We applied no language, geographical, or report age restrictions.

Participants

We included studies that measured our outcomes of interest among healthcare personnel who cared for adult (≥ 18 yr of age) critically ill inpatients or among the relatives of these patients. We defined a relative as 'any person (adult or child), related or otherwise who identified themselves or was identified by the healthcare team as being part of the circle of support for the critically ill person and was described in any eligible study as being a relative or family member'.

Interventions

We defined a humanizing intervention as 'one with substantial potential to increase physical or emotional proximity between the patient and healthcare professionals or between the patient and their relatives'. We chose this definition on the basis of evidence that increased physical and psychologic distances are key contributors to dehumanization.^{19,20} Both greater and higher quality inter-group contacts are well supported in the psychologic literature as the most reliable method of overcoming dehumanization.^{1,21–23}

While interventions that increase physical proximity (e.g., rounds in the patient's room, presence of relatives at the bedside, etc.) are easy to identify, those that increase emotional proximity are more subjective. We therefore used a list of potentially humanizing interventions that were agreed on a priori by all authors (Table 1). The list was recognized from the outset as not exhaustive and therefore any non-listed intervention that any author felt might have humanizing potential was discussed with at least one other author. The agreement of at least two authors was required to include or exclude that intervention.

We excluded studies of interventions broadly directed at enhancing the emotional or physical health of healthcare professionals or relatives without substantial potential to

Table 1 Humanizing interventions**Healthcare professional engagement**

Humanized briefing on rounds, encouragement to use patient's name, involvement in diary keeping

Environmental

Photographs, posters providing background information about who the person is, family photos, drawings, personal items, pet visits, music

Revitalization

Sedation minimized, mobilization optimized, hair dressing, own clothes

Patient and family engagement

Open visitation policy, family presence on rounds or during resuscitation, diaries, family involvement in care

increase physical or emotional proximity to the patient. We therefore excluded interventions designed to enhance general coping skills or reduce stress among healthcare professionals or relatives including educational programs, resilience training, relaxation techniques, mindfulness training, general communication improvement strategies, stress management programs, and rearrangement of work patterns. Although some of these interventions may indirectly increase appreciation of the patient's humanity, we felt that it would be impossible to separate out the effects of any indirect humanization from other effects.

Outcomes

To ensure our research question had sound scientific rationale and to optimize the chance that any association observed was likely to be real, we focused on psychologic outcomes that had either been shown in studies of other populations to be associated with humanization (empathy, burnout, compassion fatigue)^{13-15,24} or were outcomes that had a plausible association and were likely to develop while the patient was still in hospital (anxiety).

Primary

Empathy among healthcare professionals measured by any validated method.

Secondary

Burnout and compassion fatigue among healthcare professionals and relatives, anxiety among relatives, measured by any validated method, and adverse events of any type in healthcare professionals, relatives, or patients. We did not pre-specify adverse events so as to capture all adverse events reported by included studies.

Excluded outcomes

We excluded outcomes that had a plausible but unproven association with humanization and could not be expected to fully manifest while the patient was still in hospital.

Therefore, post-traumatic stress disorder, complicated grief, depression, and family post-intensive care unit syndrome were not addressed by this review.

Although plausibly associated with humanization and likely to occur while the patient was still in hospital, moral distress was excluded because of a well-recognized lack of conceptual clarity and substantial global differences in terminology, making identification of any association prone to significant inaccuracy.^{25,26}

Settings

We included studies conducted in hospital settings in any country. We excluded studies conducted in pre- or post-hospital settings. For hospital settings, we included patients cared for in any critical care setting including medical, surgical, or specialist critical care units. We also included those cared for in postoperative recovery units, recognizing that critically ill patients may sometimes be cared for in this setting (beyond the immediate postoperative period) because of bedspace limitations.

Eligibility

For a study to be included at least two review authors had to agree that it satisfied all of the above criteria for study type, participants, interventions, outcomes, and settings. Studies that did not satisfy all of the above criteria were excluded.

Search strategy

The following databases were searched: MEDLINE, PsycINFO, Embase, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL), and ProQuest Dissertations and Theses. The initial search covered their dates of inception to 29 June 2016, with an updated search by the same librarian (SM^cK) using the same search criteria covering 29 June 2016 to 29 June 2017. Reference lists, conference abstracts, and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) were searched for additional unpublished studies and ongoing studies (available as ESM; Appendix 2-MEDLINE search strategy).

The full electronic search strategies for all databases can be accessed via QSpace, Queen's University's research repository service [<http://hdl.handle.net/1974/23768>].

Study selection

Search results were uploaded to Covidence systematic review software,²⁷ from where four authors (I.M.G., J.L., R.G., and K.P.) independently screened citations. This was done in two stages. In the first stage, authors independently examined all citations and voted ‘Yes’, ‘No’, or ‘Maybe’ using the Covidence blinded voting system. Citations that received a ‘No’ vote by a minimum of two authors were excluded at this stage. All other citations went on to full-text screening.

In the second stage, two authors (I.M.G. and J.L.) independently examined the full-text version of the studies selected in the first stage to determine eligibility. Full-text articles that received two ‘Yes’ votes were included in the review, those that received two ‘No’ votes were excluded, and those that received any other combination (‘Yes/No’, ‘Yes/ Maybe’, ‘No/Maybe’, or ‘Maybe/Maybe’) were examined by a third author (K.P. or R.G.) to determine eligibility. Any conflicts were resolved by discussion among all four authors. To reduce the risk of missing relevant outcomes that might have been measured but not reported by otherwise eligible studies, one author (J.L.) contacted authors of studies of humanizing interventions that did not report our outcomes of interest.

Data extraction

Two authors (I.M.G. and J.L.) independently extracted data from the included studies using a comprehensive data extraction form. Any conflicts were resolved by discussion among the authors.

Risk of bias assessment

Two authors (I.M.G. and J.L.) independently assessed risk of bias for all included studies using Cochrane’s tool for assessing risk of bias as described in the Cochrane Handbook of Systematic Reviews for Interventions.²⁸ Any discrepancies were resolved by discussion. For each included study, bias was assessed in the following seven domains, random sequence generation, allocation concealment, blinding of participants, blinding of outcome assessors, losses to follow-up, reporting bias, and other bias, and deemed to be ‘low’, ‘unclear’, or ‘high risk’, using a priori criteria based on the effect that bias in each domain may have on the validity of the primary outcome (i.e., empathy).

An overall high risk of bias was defined as either a high-risk rating in four or more of the seven domains of bias or a

high-risk rating in at least three domains and an unclear risk rating in one or more domains.

Study quality of individual cohort studies

Additionally, for included cohort studies we assessed quality using the Newcastle Ottawa Scale (NOS), a nine-point scale that assigns scores in three domains: selection, comparability, and outcome.²⁹ A score of 7 or above was considered high quality; 5–7, moderate quality; 4 or less, low quality.

Data synthesis

We planned to calculate pooled estimates of effect for the above outcomes where all of the following conditions are met:

- Outcomes were reported by at least two studies (both judged to have an overall low or moderate risk of bias) using comparable scales and time points.
- Absence of substantial clinical or methodologic heterogeneity between included studies.

Clinical heterogeneity was assessed by comparing participants, settings, interventions, outcomes, timing of outcome measures, and ancillary treatments. Methodologic heterogeneity was assessed by comparing risk of bias. Where quantitative analysis was feasible, we planned to assess statistical heterogeneity by visual inspection of forest plots, the Chi² test, and calculation of the I² statistic, with a *P* value < 0.1 in the Chi² test and an I² statistic > 50% being indicative of significant statistical heterogeneity. Where significant statistical heterogeneity was present, we planned to present the pooled estimate of effect with subsequent discussion as to the likely impact of heterogeneity on the accuracy and quality of the effect estimate.

Where studies reported outcomes on a continuous scale, we planned to calculate mean differences and standardized mean differences, where studies used the same and different scales of measurement, respectively. Where studies reported the outcomes as dichotomous variables we planned to calculate risk ratios. We planned to present all pooled estimates of effect with their respective *P* values and 95% confidence intervals. Results were considered statistically significant if a *P* value < 0.05 was achieved. We planned to perform all meta-analyses using a random effects model in Cochrane statistical software Revman 5.3.³⁰ No subgroup or sensitivity analyses were planned.

Fig. 1 Study flow diagram

Results

Study selection

Search results and study selection are depicted in the study flow diagram (Fig. 1).

The initial search returned 11,243 articles and the updated search returned 992 articles, yielding 12,235 articles. Of these, 3,084 were duplicates, leaving 9,151 articles. Nine thousand forty-one were excluded on examination of their abstracts. Articles excluded at this stage included non-human studies, commentaries, letters, and studies in which patient participants were < 18 yr of age.

The remaining 110 articles were assessed for eligibility by examination of their full-text format. Of these, 98 were excluded. Reasons for exclusion were as follows: 41, no

intervention tested; 15, outcomes of interest not addressed; three, systematic reviews (these were examined for additional eligible studies and none were identified); one, duplicate study; one, pre-hospital study; 37, intervention did not have substantial potential to increase physical or emotional proximity to the patient. Details of excluded interventional studies are provided (Table 2).¹⁻⁸¹ The remaining 12 studies were included in the review.⁸²⁻⁹³

Summary of included studies

The characteristics of included studies are described (Table 3) with further details provided (available as ESM; Appendix 3). Only two were randomized-controlled studies,^{82,83} five were pre- and post-intervention cohort studies,⁸⁴⁻⁸⁸ four were prospective cohort studies with non-randomized controls,⁸⁹⁻⁹² and one was a retrospective study.⁹³ Four discrete humanizing interventions were assessed: diaries,^{83,84} liberalization of visitation,⁸⁷⁻⁸⁹ witnessed resuscitation,^{82,92,93} and family participation in basic care.^{85,90,91} One study of a mixed intervention with both humanizing and non-humanizing initiatives was included on the basis that some of the interventions tested had potential to increase physical and emotional proximity to the patient (liberal visitation and family involvement in basic care).⁸⁶ Ten studies measured anxiety among a total of 1,055 family members.^{82-85,88-93} Two studies measured burnout among a total of 288 critical care professionals^{86,87} No studies addressed empathy or compassion fatigue. Two studies of witnessed resuscitation sought unspecified adverse psychologic effects among relatives and reported none.^{82,93}

Risk of bias in individual studies

Eleven of the 12 included studies had an overall high risk of bias.⁸³⁻⁹³ Details of risk of bias assessment for each study are provided (Table 3) (Fig. 2). Commonly occurring themes were lack of randomization, lack of valid control groups, unclear outcome priorities, and failure to provide sample size justification.

Study quality in individual cohort studies

For the ten included cohort studies, none achieved a high-quality rating; five studies received a score of 5,^{84,85,87,90,93} putting them at the lower end of a moderate rating, and five had a low quality rating^{86,88,89,91,92} (Table 4).

Outcomes

No eligible studies were found that measured empathy or compassion fatigue in healthcare professionals or relatives.

Table 2 Excluded interventional studies

Study ID	Intervention
No substantial potential to increase emotional or physical proximity to the patient	
Alford ³¹	Preoperative teaching package
Ali ³²	Different physician staffing schedules
Fernandez ³³	Simulation-based teaching for residents
Barbret ³⁴	Family-directed information package
Barnett ³⁵	Family-directed information package
Barsolaso ³⁶	Nurse-led family support program
Bajoka ³³	Simulation-based teaching for residents
Beumer ³⁷	Staff-focused moral distress workshop
Bokinskie ³⁸	Family-focused conferences to reduce their anxiety about patient transfer from critical care to ward
Chaboyer ³⁹	Family-focused liaison services to reduce their anxiety about patient transfer from critical care to ward
Chavez ⁴⁰	Family-focused education and orientation program
Chien ⁴¹	Family-focused education program
Curtis ⁴²	Family-focused communication facilitator
Daly ⁴³	Family-focused information pamphlet
Dodd	Family-focused communication protocol
McCue ⁴⁴	
Dracup ⁴⁵	Family-focused communication services
Deore ⁴⁶	Family-focused information package
Duchemin ⁴⁷	Staff-directed mindfulness program
De Lucio ⁴⁸	Nurse-focused communication training program
Garrouste Orgeas ⁴⁹	Nurse participation in family conferences
Garland ⁵⁰	Physician staffing models
Halm ⁵¹	Family-focused support groups
Harris ⁵²	Family-focused psychologic support
Johnson ⁵³	Family-focused telephone intervention
Kitchens ⁵⁴	Family-focused pre-transfer brochure
Kowal ⁵⁵	Nurse-focused peer support program
Krupa ⁵⁶	Educational video
Lewis ⁵⁷	Family-focused web-based education program
Lickiewicz ⁵⁸	Family-focused communication algorithm
Maillet ⁵⁹	Family-focused transfer support services
Mitchell ⁶⁰	Family-focused support services
Moreau ⁶¹	Family-focused information
Reider ⁶²	Family-focused support services
Ricou ⁶³	Nurse-focused psychology services
Rudnick ⁶⁴	Family-focused information package
Schooley ⁶⁵	Family-focused teaching
Singh ⁶⁶	Family-focused educational video
Outcomes of interest not addressed	
Black ⁶⁷	Family participation in psychologic care of the patient. Outcome – patient cognition
Van den Bulcke ⁶⁸	Music. Outcomes – patient anxiety, sedation, and physiologic variables
Combe ⁶⁹	Diaries. Outcomes – patient and family perceptions

Table 2 continued

Study ID	Intervention
Cook ⁷⁰	Three wishes. Outcomes – quality of end-of-life care
Egerod ⁷¹	Diaries. Outcomes – how they helped patients construct the illness narrative and affected relatives' subjective feeling of support
Lee ⁷²	Music and aromatherapy. Outcomes – effects on patient anxiety and physiologic variables
Koohi ⁷³	Family participation in care. Outcomes – pain and anxiety among burn ICU patients
Mitchell ⁷⁴	Flexible visiting. Outcomes – family and staff satisfaction
Tracey ⁷⁵	Music. Outcomes – patient and family experiences
Twibell ⁷⁶	Family presence. Outcomes – family coping strategies
Gemunden ⁷⁷	Music. Outcomes – patient stress and anxiety
Huynh ⁷⁸	Diaries. Outcome – family satisfaction
Fumagalli ⁷⁹	Liberal visitation. Outcomes – patient anxiety and depression and family stress and change in role function
Blair ⁸⁰	Diaries. Outcome – family and staff feedback
Locke ⁸¹	Diaries. Outcome- patient, family, and staff perceptions of usefulness

ICU = intensive care unit

Burnout among healthcare professionals and relatives

Two studies addressed burnout among healthcare professionals; none addressed burnout among relatives.^{86,87} Both studies used the Maslach-Jackson Burnout Inventory (MBI) to measure burnout.⁹⁴ Gianni studied liberal visitation (a minimum of eight hours a day).⁸⁷ Locally organized staff training sessions were provided at each centre before the change. Burnout among healthcare professionals was measured before and at six and 12 months after the policy change. Baseline levels of burnout were higher among nurses than physicians. A small but significant increase in burnout levels was seen in the year following the policy change, with the increase being greater for nurses than physicians. Of note, staff perceptions of liberal visitation reflected burnout levels with those with high burnout scores expressing more negative opinions than those with low burnout scores.

Quenot also used a before-and-after cohort study to examine the effects of an 'intensive communication strategy' that included unrestricted visiting hours, greater family involvement in basic patient care, educational sessions, more frequent family meetings, staff debriefing, role playing, and working groups.⁸⁶ The strategy was designed to improve communication among healthcare professionals, patients, and families and was designed in

Table 3 Characteristics of included studies

Liberal Visitation							
Study ID	Design	Setting	Participants	Exclusion Criteria	Number Enrolled	Outcomes	Number Followed up
Holl ⁸⁸	Before and after cohort study	Single-centre cardiac critical care unit, USA	Family members of patients who had undergone open heart surgery admitted to cardiac critical care	Not fluent in English Age < 18 yr	90	Unclear outcome priority Patient and family satisfaction and anxiety (Spielberger, Gorsuch, and Lushene Revised Scale)	Not reported Non-significant decrease in anxiety levels among family members in liberal visitation group
Giannini ⁸⁷	Before and after cohort study	8 Critical care units, Italy	Medical professionals	None	235	Unclear outcome priority Burnout and anxiety pre- and 12 months post-intervention (Maslach-Jackson Burnout Inventory Anxiety; State-Trait Anxiety Inventory)	198 Burnout levels – Pre- vs 12 months post-intervention 34.5 vs 42.6% ($P = 0.001$) Anxiety scores – No significant difference
Orlen ⁸⁹	Prospective controlled cohort study (control group had important baseline differences)	Single-centre cardiac surgical critical care and medical coronary care unit, USA	Wives of patients admitted to each unit	Not fluent in English	53	Unclear outcome priority Satisfaction and anxiety among wives (State-Trait-Anxiety Inventory)	53 Anxiety levels among patients' wives at 48 hr Unlimited visiting hours vs limited visiting hours 47 vs 37 ($P = 0.02$)

Table 3 Characteristics of included studies

Diaries						
Study ID	Design	Setting	Participants	Exclusion Criteria	Number Enrolled	Outcomes
Garroute-Orgeas ⁸⁴	Before and after cohort study comparing pre-diary, diary, and post-diary periods	Single-centre critical care unit, France	Family members of patients admitted to critical care for 4 or more days	Not fluent in English Family members of patients who died on day 4 Family unavailable on day of patient discharge Patient had dementia	216	Unclear outcome priority Patient and family anxiety, depression, and post-traumatic stress at ICU discharge and at 3 months (Anxiety prevalence was measured as a score > 8 on the State-Trait Anxiety Inventory)
Kloos ⁸³	Randomized-controlled trial	Single-centre cardiothoracic critical care unit	Families of these patients	Not fluent in English Age < 18 yr Relatives of patients who developed major complications	160	State Anxiety among family members on the 3 rd postoperative day (State-Trait Anxiety Inventory)
					91	Anxiety pre- vs post-intervention 45 vs 40 Control group Anxiety pre- vs post-intervention 46.5 vs 39
Family Involvement in Basic Care						
Study ID	Design	Setting	Participants	Exclusion Criteria	Number Enrolled	Outcomes
Rodriguez-Martinez ⁹⁰	Prospective controlled cohort study	Single-centre critical care unit, Spain	Family members of these patients	Family members of patients who were not able to communicate verbally No family available Family of patients on the unit for < 3 days	117	Unclear outcome priority Cognitive state of patient, anxiety among family members Opinions of nurses (Anxiety was measured using the State-Trait Anxiety Inventory)
					56	Anxiety levels of families Intervention vs Control 23.5 vs 31.2 ($P = 0.002$)

Table 3 continued

Diaries						
Study ID	Design	Setting	Participants	Exclusion Criteria	Number Enrolled	Outcomes
Skoog ⁸⁵	Before and after cohort study	Single-centre cardiac critical care unit, United States	Family members of patients admitted to critical care who had heart surgery in the preceding 12 hr	Families who were not fluent in English Age < 18 yr < 6 th grade reading and writing skills	64	Anxiety levels among family members before versus after the intervention (State-Trait Anxiety Inventory)
					56	Anxiety levels before and after the intervention 53.6 vs 40.6 ($P = 0.001$)
Pritchard ⁹¹	Prospective controlled cohort study	Single-centre critical care unit	Family members of these patients	Family members not fluent in English, pregnant, or who were children	30	Mean change in anxiety levels in both groups (Hospital Anxiety and Depression Scale)
					30	Mean change in anxiety scores on day 3 Intervention vs Control 3.87 vs 0.4
Witnessed Resuscitation						
Study ID	Design	Setting	Participants	Exclusion Criteria	Number Enrolled	Outcomes
Robinson ⁸²	Randomized-controlled trial	Emergency Department, United Kingdom	Family members of patients requiring resuscitation for major trauma	Family members unavailable None of 3 specific senior staff available, successful resuscitation (survival to follow-up)	25	Unclear outcome priority Post-traumatic stress, anxiety, depression, grief Adverse psychological effects (Anxiety was measured by Hospital Anxiety and Depression Scale and Beck's Anxiety Inventory)
					16	Anxiety score Intervention vs Control 9 vs 7 at 3 months 6.5 vs 3 at 9 months No significant difference at either time point Adverse psychological effects – None Note – Study was stopped early because of lack of clinical equipoise

Table 3 continued

Family Involvement in Basic Care						
Study ID	Design	Setting	Participants	Exclusion Criteria	Number Enrolled	Outcomes
Pasquale ⁹³	Retrospective cohort study	Single-centre level 1 trauma centre, United States	1 Family members of patients who were successfully resuscitated after major trauma	Families who were not fluent in English Family members of patients who were children, prisoners, had burns or self-inflicted injuries	50	Anxiety Satisfaction Adverse psychologic effects (Anxiety was measured using the State-Trait Anxiety Inventory)
Leske ⁹²	Prospective controlled cohort study	Single-centre level 1 trauma centre, United States	1 Family members of patients who were successfully resuscitated after major trauma	Families not fluent in English Families who had more than one trauma victim or where the patient was a child, had sustained burns, was a prisoner, or victim of domestic violence Combative or intoxicated families	250	Unclear outcome priority Measured anxiety, acute stress, wellbeing, satisfaction (Anxiety was measured using the State-Trait Anxiety Inventory)
					140	Anxiety Intervention vs Control 43.5 vs 48.1 ($P = 0.43$)
Mixed Intervention (liberal visitation, involvement of families in basic care, improved family communication, staff support workshops, staff debriefing, etc.)						
Study ID	Design	Setting	Participants	Exclusion Criteria	Number Enrolled	Outcomes
Quenot ⁸⁶	Before and after cohort study	Single-centre critical care unit, France	Medical professionals	None	62	Prevalence of severe burnout (Maslach-Jackson Burnout Inventory) Depression
					49	Prevalence of severe burnout Pre- and post-intervention 15 vs 7 ($P < 0.01$) Severe burnout was defined as a score > 30 on the emotional exhaustion subscale, or a score > 12 on the depersonalization subscale, or a high total score)

ICU = intensive care unit

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Garrouste-Orgeas 2010	⊖	⊖	⊖	?	⊖	⊖	⊖
Giannini 2013	⊖	⊖	?	?	⊖	?	⊖
Holl 1992	⊖	⊖	⊖	?	⊖	⊖	⊖
Kloos 2008	?	⊖	⊖	?	⊖	+	⊖
Leske 2017	⊖	⊖	⊖	?	⊖	?	?
Martínez 2003	?	⊖	⊖	?	⊖	?	⊖
Orlen 1993	⊖	⊖	⊖	?	+	?	⊖
Pasquale 2010	⊖	⊖	⊖	?	+	+	+
Prichard 2015	⊖	⊖	⊖	?	+	+	⊖
Quenot 2012	⊖	⊖	⊖	?	⊖	+	⊖
Robinson 1998	+	+	+	?	?	?	?
Skoog 2016	⊖	⊖	⊖	?	+	+	⊖

Fig. 2 Risk of bias in included studies.

response to information obtained by psychologists, who interviewed staff beforehand to identify specific areas for intervention and who remained available for consultation during the study period. The prevalence of severe burnout and depression among staff decreased significantly after the intervention, with all three components of the MBI (emotional exhaustion, depersonalization, and personal accomplishment) showing a significant change. As both studies had an overall high risk of bias and investigated interventions with important differences in their content, a pooled estimate of effect was not calculated.

Anxiety among relatives of the critically ill

Ten studies addressed this outcome.^{82-85,88-93}

Of these ten studies, two measured the effects of liberal visitation on anxiety among relatives,^{88,89} using the State-Trait Anxiety Inventory.⁹⁵ Only one reported the actual figures for this outcome and the timing of outcome measurement.⁸⁹ One study found a significant decrease⁸⁹ and the other a non-significant decrease in anxiety.⁸⁸

Two studies evaluated the effects of family-maintained diaries on anxiety among relatives.^{83,84} One measured the prevalence of anxiety at three months after patient discharge from critical care, using a score of > 8 on a self-administered questionnaire as an indicator of anxiety.⁸⁴ The other measured mean anxiety levels on the third postoperative day, using the State-Trait Anxiety Inventory.⁸³ Both found a non-significant decrease in anxiety in the diary groups.

Three studies measured the effects of family involvement in basic patient care on anxiety among relatives.^{85,90,91} Two used the State-Trait Anxiety Inventory,^{85,90} and one used the Hospital Anxiety and Depression Scale.⁹¹ Timing of outcome measurement was reported by only one study.⁹¹ All reported significant results.

Three studies investigated the effects of family presence during resuscitation on anxiety among relatives.^{82,92,93} Two used the State-Trait Anxiety Inventory,^{92,93} and one used the Hospital Anxiety and Depression Scale and Beck Anxiety Inventory.⁸² Timing of outcome measures ranged from 48 hr to nine months. None reported significant results.

No pooled estimates of effect were calculated for this outcome as no two studies (each with less than a high risk of bias) of any of the included interventions measured the same outcome using comparable scales at comparable time points.

Adverse events

No adverse events were reported by the two studies that sought them; hence, no pooled estimate of effect was calculated.^{82,93}

Overall quality of evidence

The overall quality of the available evidence was poor with evidence being either low or very low quality. Details and reasons why the evidence was downgraded are provided (summary of findings in Table 5).

Table 4 Risk of bias in individual studies

Domain	Risk	Rationale
Holl⁸⁸		
Random sequence generation	High	Not randomized and no control group
Allocation concealment	High	None
Blinding of participants	High	No mention of blinding of those accessing outcome and, although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Blinding of outcome assessors	Unclear	Not clear from the report whether all participants were followed up; also the authors state that no baseline measures of anxiety levels were made for family members as many were not available at the time the investigator intended to make these measurements
Incomplete outcome data	High	No mention of blinding of those accessing outcome and, although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Selective reporting	High	Outcome priorities were not stated and multiple analyses of variables were made, raising the possibility of selective reporting bias
Other bias	High	No sample size calculation so difficult to know if the study was adequately powered
Giannini⁸⁷		
Random sequence generation	High	Non-randomized study. All staff working in the eight participating units received the intervention (liberalization of visitation). Without a control population who were not exposed to a visitation policy change, it is impossible to accurately quantify the effect of the policy change on burnout levels
Allocation concealment	High	None
Blinding of participants	Unclear	The term 'burnout' was not mentioned to the participants but it is possible that some of them may have guessed what was being measured when they completed the questionnaire
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants
Incomplete outcome data	High	37 participants were lost to follow-up; the absence of these participants may have distorted the effect size
Selective reporting	Unclear	Outcomes priorities were not pre-specified
Other bias	High	No sample size was provided; also the authors acknowledge that confounding factors including other unmeasured changes occurring in participating units may have influenced staff burnout levels
Orlen⁸⁹		
Random sequence generation	High	No randomization. Patient populations in the two groups were different, one group being patients admitted to the surgical cardiac critical care and the other being those admitted to the medical coronary care unit
Allocation concealment	High	None
Blinding of participants	High	No mention if participants were blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their responses
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Incomplete outcome data	Low	No losses to follow-up
Selective reporting	Unclear	Outcomes priorities were not pre-specified
Other bias	High	No sample size was calculated so it is difficult to know if the study was adequately powered
Garrouste-Orgeas⁸⁴		
Random sequence generation	High	Not randomized. Consecutive patients admitted to the Critical Care unit were enrolled. No baseline measures of anxiety were made.
Allocation concealment	High	None
Blinding of participants	High	No, and if families were aware of the outcomes being measured it may lessen or exacerbate their anxiety

Table 4 continued

Domain	Risk	Rationale
Blinding of outcome assessors	Unclear	Investigators performing the follow-up telephone interviews were unaware of which patients and families had received diaries; however, the authors mention that investigator blinding may have been compromised as some participants may have mentioned the diary during the interviews
Incomplete outcome data	High	Family members who were not present on the day of ICU discharge were excluded. Their omission may have distorted the anxiety profile of the study population
Selective reporting	High	Outcome priorities were not predefined and they calculated <i>P</i> values for 21 different outcomes, without statistical adjustment for multiple testing of data, increasing the risk of a false-positive results
Other bias	High	No primary outcome was specified and no sample size was calculated so it is difficult to know if the study was adequately powered
Kloos ⁸³		
Random sequence generation	Unclear	Participants were assigned to either the treatment group or the no-treatment group according to week (e.g., odd weeks = no intervention; even weeks = intervention) so participants were not truly randomly assigned
Allocation concealment	High	None
Blinding of participants	High	No mention if participants were blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their responses
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' response
Incomplete outcome data	High	High losses to follow-up (69/160) without details of the reasons raises the possibility of more or less anxious family members being less likely to complete the study
Selective reporting	Low	Outcomes were reported as specified
Other bias	High	No sample size was calculated so it is difficult to know if the study was adequately powered. It is also likely that either group's responses may be influenced by knowing that there was another group
Rodriguez-Martinez ⁹⁰		
Random sequence generation	Unclear	Participants were not randomly selected; however they had similar baseline anxiety levels, which partially mitigated the risk of selection bias
Allocation concealment	High	None
Blinding of participants	High	No mention if participants were blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their responses
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Incomplete outcome data	High	High losses after enrolment with a lack of data as to which group these losses were from and why
Selective reporting	Unclear	Outcomes priorities were not pre-specified
Other bias	High	No sample size was calculated so it is difficult to know if the study was adequately powered
Skoog ⁸⁵		
Random sequence generation	High	No randomization and no control group
Allocation concealment	High	None
Blinding of participants	High	Participants were not blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their responses
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Incomplete outcome data	Low	No losses to follow-up
Selective reporting	Low	Outcomes reported as specified
Other bias	High	Small study and no sample size calculation provided so difficult to determine if the study was adequately powered
Prichard ⁹¹		

Table 4 continued

Domain	Risk	Rationale
Random sequence generation	High	No randomization and the groups had significant differences in the baseline prevalence of anxiety with significantly greater anxiety prevalence in the control group 93% vs 67%, $P = 0.03$
Allocation concealment	High	None
Blinding of participants	High	Participants were not blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their responses
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Incomplete outcome data	Low	No losses to follow-up
Selective reporting	Low	Outcomes reported as specified
Other bias	High	Small study and no sample size calculation provided so difficult to determine if the study was adequately powered
Robinson ⁸²		
Random sequence generation	Low	Sealed envelopes; the unit of randomization was the patient
Allocation concealment	Low	Allocations were concealed by sealed envelopes
Blinding of participants	Low	The senior nurse in charge of the resuscitation was aware of the allocations but participants were blinded to the outcomes being measured
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' response
Incomplete outcome data	Unclear	Even though total losses to follow-up were small (7 participants), they were a high percentage (28%) of the overall study cohort and unevenly distributed between the groups, with 5 being lost from the intervention group and 2 from the control group.
Selective reporting	Unclear	Outcomes priorities were not pre-specified
Other bias	Unclear	Small study that was stopped early as staff became convinced of the benefits of giving relatives the option of witnessing resuscitation, risking compromise of the randomization process
Pasquale ⁹³		
Random sequence generation	High	Not randomized. Compared family members who were present during resuscitation because they opted to be present and were deemed suitable for presence by the trauma team with family members who were not present because of their absence at the time of enrolment, their choice not to be present, or the trauma team's recommendation that they not be present. Potentially these populations have important baseline differences in their anxiety profiles, which may have introduced selection bias
Allocation concealment	High	None
Blinding of participants	High	No mention if participants were blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their responses
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Incomplete outcome data	Low	No losses to follow-up
Selective reporting	Low	Outcomes reported as specified
Other bias	Low	None identified
Leske ⁹²		
Random sequence generation	High	Since there was no randomization and the control group was chosen on the basis of their own choice, their physical absence at the time, or the trauma team's judgement, they were potentially a very different population from the intervention group, which may have led to selection bias
Allocation concealment	High	None

Table 4 continued

Domain	Risk	Rationale
Blinding of participants	High	No mention if participants were blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their response
Blinding of outcome assessors	Unclear	No mention if participants were blinded to the outcomes being measured; if they were aware that anxiety was being measured then this may have influenced their responses
Incomplete outcome data	High	Very high losses to follow-up in the control group (104/174) may have distorted the true results
Selective reporting	Unclear	Outcomes priorities were not pre-specified
Other bias	Unclear	Outcomes were measured any time during the first 72 hr, creating potential for differences in anxiety levels due to differences in the time course of the patients' illness rather than the intervention being studied
Quenot ⁸⁶		
Random sequence generation	High	Not randomized and as the study was conducted over a two-year period other changes in the conditions that the staff were exposed to may have influenced the results
Allocation concealment	High	None
Blinding of participants	High	Participants were not blinded to the outcomes being measured; if they were aware that burnout was being measured then this may have influenced their responses
Blinding of outcome assessors	Unclear	No mention of blinding of those accessing outcome and, although outcomes were measured by participant-completed questionnaires, investigator knowledge of outcomes being assessed may have influenced participants' responses
Incomplete outcome data	High	22 of 62 participants lost to follow-up without explanation
Selective reporting	Low	Outcomes reported as specified
Other bias	High	No sample size calculation provided, two-year gap between study periods, and multiple interventions tested at the same time make it difficult to know if the study was adequately powered and if the observed differences in outcome were due to time bias or confounding effects of other interventions

ICU = intensive care unit

Discussion

Summary of main results

We found insufficient evidence to make any quantitative assessment of the effect of any of the included humanizing interventions on empathy among healthcare professionals, anxiety among relatives, or risk of burnout and compassion fatigue in either group. We observed a trend towards reduced anxiety among family members who participated in basic patient care, liberal visitation, and diary keeping. Nevertheless, the quality of the data was low and although the trend was consistent it was not consistently significant. We found conflicting effects of liberal visitation on burnout among healthcare professionals again with the limitation of low data quantity and quality.

Agreements and disagreements with other studies or reviews

To our knowledge, this is the first systematic review that aimed to measure the effects of a range of interventions with potential to humanize care of the critically ill on the

psychologic wellbeing of healthcare professionals and relatives. This limits the scope for comparison with similar studies. There are however studies that have addressed similar but more focused aspects of this question. Considering these in terms of individual interventions:

Diaries

Ullman and colleagues reviewed the effect of diaries on critically ill patients and their relatives.⁹⁶ They found only three eligible studies, only one of which addressed psychologic outcomes in relatives. This single study showed a reduced risk of post-traumatic stress in relatives of patients in the diary group.⁹⁷ They found no eligible studies addressing other psychologic outcomes. Their review differs from ours in that they focused on diaries alone and only included randomized-controlled studies. Aiken *et al.* did not limit inclusion criteria to randomized-controlled studies and found 11 eligible studies examining the effects of diaries on psychologic outcomes.⁹⁸ The majority of these studies reported open-ended patient perceptions and were not designed to

Table 5 Study quality – Newcastle–Ottawa quality assessment scale for cohort studies

Selection									
	Are participants representative of the wider population?*	Were intervention and control groups drawn from the same population?	Can we be sure that the intervention group actually received the intervention ?	Can we be sure that the outcome of interest was absent at baseline or if not that it was adequately adjusted for in the analysis?†	Comparability		Outcome		
					Did the study control for severity of illness of the patient population?‡	Did the study control for participants' psychologic or psychiatric history?	Was outcome assessor blinded to group assignment?	Was follow-up long enough for the outcome of interest to occur?§	Was follow-up complete?
Holl ⁸⁸	-	★	□□□□□□□★	-	-	-	-	-	-
Giannini ⁸⁷	★	★	□□□□□□□□-	★	-	★	-	★	-
Orlen ⁸⁹	-	-	□□□□□□□★	-	-	-	-	★	★
Garrouste-Orgeas ⁸⁴	-	-	□□□□□□□★	★	★	★	-	★	-
Rodriguez-Martinez ⁹⁰	★	★	□□□□□□□□-	★	★	-	-	★	-
Skoog ⁸⁵	-	★	□□□□□□□□★	★	-	★	-	★	-
Prichard ⁹¹	★	-	-	-	-	-	-	★	★
Pasquale ⁹³	★	-	□□□□□□□★	-	★	-	-	★	★
Leske ⁹²	★	-	□□□□□□□★	-	-	-	-	★	-
Quenot ⁸⁶	★	-	□□□□□□□★	★	★	-	-	★	-

*Points were not given for studies performed in specialized units such as cardiac or coronary care units, studies that did not clearly define inclusion and exclusion criteria, and studies that excluded large numbers of eligible participants

† Points were only given if baseline measures of the outcome of interest were made and were either similar or any inequality was adequately adjusted for in the analysis

‡ Severity of illness of the patient population and participants' previous psychiatric history were thought to be likely confounding factors for psychologic outcomes among healthcare professionals and relatives

§ Points were only given if length of follow-up was reported and if follow-up was at least 48 hr for anxiety and empathy and at least one month for burnout and compassion fatigue

measure specific psychologic outcomes. Our own finding of a non-significant trend towards reduced anxiety among family members of critically ill patients is supported only by the two included studies that addressed this outcome^{83,84} and should be interpreted in the light of the substantial limitations in both quality and quantity of the contributing data (Table 6).

Liberal visitation

In their review of the benefits of flexible visitation in intensive care, Errasti-Ibarrondo *et al.*⁹⁹ found 15 studies describing positive responses from families including increased satisfaction, reduced stress, and reduced anxiety. Their review aimed to identify themes rather than quantify effects. Flexible visitation appears to be well received by relatives,⁹⁹⁻¹⁰¹ but the evidence tends to be observational, exploratory, and limited by substantial bias, making it impossible to be sure of its effects in terms of measurable, reliable outcomes. There is a paucity of research regarding the effects of liberal visitation on healthcare professionals. We found only one study addressing the effects of liberal visitation alone on the risk of burnout among medical professionals; this study reported a small but significant increase in risk of burnout when visiting hours were increased to a minimum of eight hours.⁸⁷ Interestingly, another study of a multifaceted program that included, among other things, more liberal visitation showed a lower prevalence of severe burnout among critical care professionals.⁸⁶ The potentially important difference was that liberal visitation here was only one aspect of a comprehensive quality improvement program designed in response to issues raised by healthcare professionals, benefited from psychologic expertise from the outset, and included comprehensive staff training and support sessions with a focus on improved communication between healthcare professionals and relatives. This may explain why this study showed a decrease in burnout levels while the other showed an increase. It is both logical and plausible that certain new practices, no matter how desirable, bring with them ‘change stress’ and that unless introduced thoughtfully and with a change support structure may have unanticipated undesirable consequences. It may well be that it is not liberal visitation per se that increases the risk of burnout among healthcare professionals but rather inadequately supported liberal visitation.

Family participation in care

The three studies included in our review showed a consistent trend towards reduced anxiety among family members who had the opportunity to participate in the

basic care of their critically ill relative.^{85,90,91} A narrative review of the literature identified an overall theme of increased satisfaction and reduced anxiety among relatives who participated in care. Nevertheless, this review was exploratory and did not attempt to define outcomes or synthesis effects.¹⁰²

Witnessed resuscitation

The three studies included in our review showed no significant effect of witnessed resuscitation on anxiety among family members.^{82,92,93} A Canadian Critical Care Society position paper on family presence during resuscitation based on a literature search of the topic found that in general family members were supportive of the opportunity to be present during the resuscitation of their loved ones and physicians and nurses were largely supportive of the practice.¹¹ The summary recommendation was that the practice was ethically sound and should be considered an important component of patient- and family-centred care. The review upon which this recommendation is based differs from our review in that it included randomized-controlled studies only and included family members of patients resuscitated in a pre-hospital setting and family members of pediatric patients.¹⁰³ The primary outcomes were patient mortality and quality of resuscitation with family psychologic outcomes being secondary.

What this review adds to the current state of knowledge

Our review highlights the current lack of knowledge regarding the effects of humanized care of the critically ill on empathy and compassion fatigue and provides some potentially useful observations regarding its effects on anxiety and burnout. We found a consistent trend towards reduced anxiety among family members who were allowed more time to visit or were involved in diary keeping or basic patient care.^{83-85,88-91} Although these studies were small and had a high risk of bias, the consistent direction of their results may well imply a true effect. Interestingly, witnessed resuscitation did not reduce anxiety,^{82,92,93} which makes sense considering the acute emotional turmoil one is likely to experience when watching vigorous attempts to bring a loved one back to life.

The other interesting observation was the opposite directions of effect we found in the two studies that reported burnout among healthcare professionals,^{86,87} which may speak to the importance of change support strategies when introducing any new initiative no matter how ‘right’ it feels. Taking these results to the bedside of the critically ill person, it’s probably fair to say that involving families and providing comprehensive support

Table 6 Summary of findings for reported outcomes

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

Liberal visitation					
Patient population: Critically ill patients. Study population: Health care professionals caring for these patients and family members of these patients. Settings: In hospital. Intervention: Liberal visitation. Comparison: Restricted visitation					
Outcomes	Quantitative effect (95% CI)	Qualitative effect	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Burnout among health care professionals caring for critically ill patients	Not measured	No consistent trend identified	247 (2)	⊕⊕⊕⊕ Very low *	
Anxiety among relatives of critically ill patients	Not measured	Trend towards reduction of anxiety among relatives but not consistently significant	145 (2)	⊕⊕⊕⊕ † low	

* The evidence was downgraded by three levels due to an overall high risk of bias in both studies, inconsistency due to differences in study design and interventions and indirectness of the multifaceted intervention applied in one of the studies.^{87,88} † The evidence was downgraded by two levels due to overall high risk of bias in both studies and likely imprecision due lack of robust methodology and the lack of sample size calculations.^{89,90}

Diaries					
Patient population: Critically ill patients. Study population: Health care professionals caring for these patients and family members of these patients. Settings: In hospital. Intervention: Diary keeping. Comparison: No diary keeping					
Outcomes	Quantitative effect (95% CI)	Qualitative effect	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Anxiety among relatives of critically ill patients	Not measured	Non significant trend towards reduction in anxiety among relatives	234 (2)	⊕⊕⊕⊕ * low	

* The evidence was downgraded by two levels as one study had an overall high risk of bias,⁸⁴ and the other had an overall very high risk of bias.⁸⁵

Family involvement in basic patient care					
Patient population: Critically ill patients. Study population: Health care professionals caring for these patients and family members of these patients Settings: In hospital. Intervention: Family involvement in basic patient cares. Comparison: No family involvement in basic patient care					
Outcomes	Quantitative effect (95% CI)	Qualitative effect	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Burnout among health care professionals caring for critically ill patients	Not measured as only one potentially eligible study identified	Only one potentially eligible study was identified, this showed a significant decrease in burnout. However it involved a multifaceted intervention with several other components	62 (1)	⊕⊕⊕⊕ Very low *	
Anxiety among relatives of critically ill patients	Not measured	Consistent trend towards reduction in anxiety among relatives	184 (3)	⊕⊕⊕⊕ low †	

- The evidence was given a very low grading as it came from a single study of a bundle type intervention that had multiple components and an overall high risk of bias.⁸⁷

† The evidence was downgraded two levels as all three studies had an overall high risk of bias and the lack of robust methodology and lack of sample size calculations in any of the studies increases the risk of imprecise effect estimates.

Witnessed resuscitation					
Patient population: Critically ill patients. Study population: Health care professionals caring for these patients and family members of these patients Settings: In hospital. Intervention: Witnessed resuscitation Comparison: No witnessed resuscitation					
Outcomes	Quantitative effect (95% CI)	Qualitative effect	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Anxiety among relatives of critically ill patients	Not measured	Consistent trend showing no significant difference in anxiety levels	215 (3)	⊕⊕⊕⊕ * Low	

* The evidence was downgraded two levels as 140 of the participants came from a study with an overall very high risk of bias,⁹³ and another 50 came from a retrospective study.⁹⁴

for staff who facilitate greater family presence and participation are likely important contributors to humanized care.

Strengths

Novel and important area of research

First, this is a novel and important area of research. Evidence from psychologic studies is often not widely known to clinicians so their relevance to medical practice can be all too easily missed. When we think of translational research we often think of basic science studies, but translation can and should occur in multiple dimensions. Psychology, the study of human behaviour, has particular value as medicine, no matter how technologically advanced, is ultimately delivered by humans. Infrahumanization is well known to psychologists. This study helps to introduce it to medical clinicians and highlight its relevance to critically ill people and those who care for them.

While many studies have investigated various initiatives aimed at making care more person centred, few have identified these interventions as potentially humanizing, investigated a range of such interventions, or addressed quantitative outcome measures that are both clinically relevant and likely to be influenced by humanization.

Quantitative outcomes addressed

Second, although qualitative studies are ideal for exploring, describing, and understanding perceptions and behaviours, they tend to be less generalizable and are not designed to measure specific defined outcomes, magnitude, or directions of effect or to inform risk-benefit estimation.

Examining humanization through a quantitative lens allows important effects that may otherwise be missed to be captured and measured.

For example, some studies that measured quantitative patient outcomes when families were present during resuscitation found concerning results. A study of simulated codes where the relative present was displaying an overt grief reaction showed delayed time to defibrillation and fewer total shocks delivered.¹⁰⁴ A retrospective study of more than 300 patients in a medical intensive care unit showed significantly lower rates of return of spontaneous circulation and survival to hospital discharge for patients whose families were present during cardiopulmonary resuscitation.¹⁰⁵ Although these results are not consistent across studies, they do raise an important issue. While humanization is innately right, it

does not necessarily follow that all efforts to optimize it should be pursued without considering the risk-benefit balance. As for all interventions, we need to know which work best, what the effects are (good and bad), the size and direction of those effects, and for whom the benefits outweigh the risks. Quantitative data about clinically relevant outcomes can provide us with this information.

Robust methodology

Lastly, this review was conducted using a rigorous methodology in accordance with the PRISMA guidelines for systematic reviews.¹⁹ The search was not restricted on the basis of language, study date, or location, ensuring maximum retrieval of studies that met our inclusion criteria.

The use of a blinded voting system to select studies minimized the risk of selection bias and the use evidenced-based criteria to define humanizing interventions allowed precise appraisal of the effects of interventions that were likely to have substantial potential in this regard.

Limitations and potential biases

This review has a number of limitations and potential biases

Outcome-based search strategy

Our search strategy was population and outcome rather than population and intervention focused. We chose this approach for two reasons. First, we felt that it allowed us to identify all interventions with humanizing potential that evaluated our outcomes of interest and reduced the risk of missing studies that evaluated interventions that we had not thought of as humanizing a priori. Second, it allowed us to identify a manageable number of studies to screen. Searching for the concept of 'humanization' using terms such as humaniz* or respect* retrieved over one third of OVID Medline's records, which is approximately 9 million citations (where * allows for any truncation of the word). While our choice of search strategy was both logical and feasible, we cannot exclude the possibility that we missed studies that measured our outcomes of interest but described them without using the specific labels of empathy, burnout, compassion fatigue, and anxiety. To mitigate this risk, for studies examined in full-text format and excluded on the basis that they did not report our outcome of interest, one author contacted study authors to see if they measured our outcomes of interest but expressed them in other ways. None were identified.

Focused definition of humanizing interventions

To get a clear view of the effect humanizing interventions on healthcare professionals and relatives, it was necessary to select interventions that had substantial potential to increase the awareness of others of the patient's humanity. For this reason, we only included studies that had substantial potential to increase patient-healthcare professional or patient-relative inter-group contact through increased physical or emotional proximity. We excluded studies of interventions that were broadly directed at enhancing the emotional or physical health of healthcare professionals or relatives without substantial potential to increase physical or emotional proximity to the patient. This meant excluding educational programs, resilience training, relaxation techniques, mindfulness training, general communication improvement strategies, stress management programs, and rearrangement of work patterns.

Defining humanizing interventions in this way meant that any humanizing potential of broader, more care provider- and relative-directed interventions is not captured in this review. While this may be a weakness in terms of measuring the effect of all interventions that may have any humanizing potential, it allowed a more precise appraisal of those with substantial potential in this regard.

Limited outcomes addressed

Humanization is a psychological concept and cannot be fully understood by quantitative methods alone, with both quantitative and qualitative research having important roles to play in furthering our understanding of this area. For this review, we chose to focus on selected quantitative outcomes, choosing to sacrifice breadth of knowledge to get a more focused and accurate view of the current state of knowledge in terms of definable, measurable, and reliable outcomes. This meant that research describing the feelings of patients, relatives, and healthcare professionals in descriptive or narrative terms was not captured in this review. We also excluded outcomes that had a plausible association with humanization but were not likely to fully manifest while the patient was still in hospital; we cannot say whether humanization influences late-occurring psychologic outcomes including complicated grief, depression, and post-traumatic stress. Identifying any association between humanization and more long-term psychologic outcomes quantitatively is subject to substantial distortion by confounding factors. Even if known confounders are adjusted for, there are likely to be many unknown confounders that may blur any real association. Qualitative methods may be much more appropriate for investigating those outcomes.

Moral distress was not evaluated by this review and, although there is no proven association, when we consider that moral distress arises in situations where one is required to act in a manner that conflicts with their own belief of what is morally correct, it is plausible that humanized patient care may lessen or exacerbate moral distress depending on the individual caregiver's perception. This would be worth investigating in future studies.

Conclusions

This review identifies a knowledge gap regarding the effects of humanizing interventions on clinically important quantitative psychologic outcomes among healthcare professionals and relatives. It does however suggest that relatives of the critically ill are less anxious when they feel more involved or are allowed more time at the bedside and that liberal visitation may have opposing effects on healthcare professional burnout dependant on the context in which it is introduced. One should be cautious, however, about basing practice change on the findings of a few, small, generally poor-quality studies. As we move towards increasing patient and family-focused care, it is important we consider the emotional impact on healthcare professionals and families. While the natural human assumption may be that only good things come of person-focused and family-inclusive care, we do not know to what extent that is true. To get an accurate picture of the broader effects of humanized care, we need to study its effects on patients, families, and healthcare professionals both qualitatively and quantitatively.

Differences between the protocol and the review

In response to expert peer review, we revised our original outcomes to include burnout and compassion fatigue among relatives of the critically ill. As our original search used all the terms needed to identify these studies, we did not repeat the search. Two authors rescreened the studies to identify any that might have measured these outcomes among relatives of the critically ill. None were identified.

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Authors contributions Imelda M. Galvin conceived the idea, prepared the protocol, selected studies, extracted and assessed the quality of the data, and drafted the manuscript. Jordan Leitch contributed to the development of the idea, selected the extracted studies, assessed the quality of the data, and provided input for manuscript refinement. Sandra McKeown assisted with refining the search strategy, conducted the searches, and wrote the search section of the manuscript. Rebecca Gill and Katherine Poser both screened and selected studies and assisted with manuscript preparation and refinement.

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