

BMJ Open Family bereavement and organ donation in Spain: a mixed method, prospective cohort study protocol

Maria Victoria Martinez-Lopez ¹, Elisabeth Coll ²,
Francisco Cruz-Quintana ³, Beatriz Dominguez-Gil ², Ivar R Hannikainen ¹,
Ramón Lara Rosales ⁴, Alicia Pérez-Blanco ², Maria Nieves Perez-Marfil ³,
Jose Miguel Pérez-Villares ⁵, David Uruñuela ², David Rodríguez-Arias ¹

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¹Department of Philosophy I, Faculty of Philosophy, University of Granada, Granada, Spain

²Organización Nacional de Trasplantes, Madrid, Spain

³Department of Personality, Assessment and Psychological Treatment, Faculty of Psychology, University of Granada, Granada, Spain

⁴Coordinación Sectorial de Trasplantes de Granada, Granada, Spain

⁵Coordinación Autonómica de Trasplantes de Andalucía, Sevilla, Spain

Correspondence to

Maria Victoria Martinez-Lopez; mvmartinez@ugr.es

ABSTRACT

Introduction There is a discrepancy in the literature as to whether authorising or refusing the recovery of organs for transplantation is of direct benefit to families in their subsequent grieving process. This study aims to explore the impact of the family interview to pose the option of posthumous donation and the decision to authorise or refuse organ recovery on the grieving process of potential donors' relatives.

Methods and analysis A protocol for mixed methods, prospective cohort longitudinal study is proposed. Researchers do not randomly assign participants to groups. Instead, participants are considered to belong to one of three groups based on factors related to their experiences at the hospital. In this regard, families in G1, G2 and G3 would be those who authorised organ donation, declined organ donation or were not asked about organ donation, respectively. Their grieving process is monitored at three points in time: 1 month after the patient's death, when a semistructured interview focused on the lived experience during the donation process is carried out, 3 months and 9 months after the death. At the second and third time points, relatives' grieving process is assessed using six psychometric tests: State-Trait Anxiety Inventory, Beck Depression Inventory-II, Inventory of Complicated Grief, The Impact of Event Scale: Revised, Posttraumatic Growth Inventory and Connor-Davidson Resilience Scale. Descriptive statistics (means, SDs and frequencies) are computed for each group and time point. Through a series of regression models, differences between groups in the evolution of bereavement are estimated. Additionally, qualitative analyses of the semistructured interviews are conducted using the ATLAS.ti software.

Ethics and dissemination This study involves human participants and was approved by Comité Coordinador de Ética de la Investigación Biomédica de Andalucía (CCEIBA) ID:1052-N-21. The results will be disseminated at congresses and ordinary academic forums. Participants gave informed consent to participate in the study before taking part.

BACKGROUND Context

In most countries, families play a decisive role in the decision about organ recovery from

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study assesses the impact of organ donation on donor family members' bereavement using multiple outcome measures, including personal growth and resilience.
- ⇒ By including two control groups, the study dissociates the effects of authorisation (relative to refusal) and the opportunity to donate (relative to the absence of opportunity) on family members' grief.
- ⇒ Whether the results of this study can be generalised to various cultures with different worldviews (religious beliefs or social customs) is uncertain.
- ⇒ Possible confounds have been controlled (characteristics of the deceased, circumstances of death, etc), but the complexity of factors involved is such that other factors cannot be excluded.

deceased individuals. They may act as surrogate decision-makers when the wishes of the deceased are unknown or even override their preferences in some cases.^{1 2} In Spain, the country with the highest donation rates in the world,³ although donor transplant coordinators ask relatives whether the deceased had expressed any preference regarding donation, the final decision on organ recovery is often based on the family's wishes or on what they believe the deceased would have wanted.⁴

The family interview involves a complex decision-making process characterised by a great emotional burden,^{5 6} which could have a notable impact on the subsequent grieving process. In the existing literature, there is a discrepancy as to whether relatives' decision to authorise donation can have an impact on the grieving process after the death of a loved one. Many studies have examined the factors that influence family members in deciding to donate or refuse.⁷ However, few have addressed the possible postdonation psychological sequelae experienced by these

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families.⁸ The extent to which the donation process (both application, authorisation and rejection) influences the family's well-being in the months after their loss is also unknown. Some variables have already been identified as factors influencing the decision to authorise or decline donation: cause of death, age, relationship with the deceased or expectation of death.⁹ These variables may also influence subsequent grief processing. Understanding whether and how the donation process affects grief processing among donor families may be the first step to tailoring and improving the care they are offered.

Current knowledge

The impact of the family interview

Memories of the brain death of a loved one and decisions about organ donation can lead to anxiety and conflict¹⁰ or even trigger post-traumatic stress disorder, characterised by intrusive thoughts, nightmares, avoidance of memories of the trauma, hypervigilance and sleep disturbances.¹¹ These elements may trigger complicated grief. Complicated grief can be understood as those manifestations that cause 'the person to become overwhelmed, to resort to maladaptive behaviours or to remain endlessly in this state without progressing in the grieving process towards resolution'.¹² Despite this, family members can experience the organ donation request positively, regardless of what their final decision was.¹³

The decision to donate and bereavement

The claim is often made that organ donation may positively impact families' grieving process. Yet existing research on this question has yielded mixed evidence. Some research points towards a beneficial effect of organ donation on the coping process after a loved one's death (see Merchant *et al.*⁸). That claim is partially supported by family members' reports that organ donation has helped them with their grief,¹⁴ perhaps by providing meaning to their loved one's death.¹⁵ Some families even spontaneously suggest donation after learning of the diagnosis of brain death.¹⁶ Organ donation can be experienced as a form of comfort during bereavement, as long as family members remain convinced that their decision was correct.¹³ Relatedly, in a study conducted by Siminoff and Mercer, most donor families (70.2%) believed that organ donation helps family bereavement. A statistically smaller proportion of the families who had refused donation (42.0%) held that belief. The authors interpret that difference as an indication that families who authorise organ recovery experience some benefits as a result.¹⁷

Other studies have found an absence of evidence that donation affects families' grieving process. In a study by Pearson & Zuryski¹⁸ relatives were interviewed. The relatives belonged to the following three groups according to whether they: authorised donation, declined donation or were not approached about donation in the first place. The results revealed non-significant differences in the resolution of grief when comparing relatives between these three different groups, despite 'a slightly higher

probability of grief resolution among donor families" than among relatives in the other two groups. Similarly, Cleiren and Van Zoelen¹⁹ found that consenting to donation does not hinder or favour the grieving process. In the same vein, Tavakoli *et al.*²⁰ concluded that organ donation does not have a significant effect on the course of grief and subsequent depression among relatives in cases of brain death. Similarly, Smudla *et al.*²¹ found that levels of grief and depression were not associated with the authorisation of organ recovery. More recently, in a study conducted in Switzerland,²² in which 147 relatives who had faced the donation process answered a *post hoc* questionnaire on issues including organ donation and its impact on grief, the majority of relatives denied that facing organ donation had played a role in their bereavement.

Thus, on the basis of existing empirical studies, it is unclear whether the opportunity to donate and the decision to authorise or refuse donation ameliorates families' grieving processes.

Communication process, brain death and bereavement

In addition to the impact that the decision to donate may have on subsequent coping, the quality of communication between professionals and relatives, and the understanding of the diagnosis of brain death may also be associated with the bereavement process. Relatives of non-donors who perceive lower quality communication experience greater difficulty in bereavement, while a better understanding of the diagnosis of brain death is associated with non-pathological bereavement.⁷ Similarly, Smudla *et al.*²¹ concluded that relatives who were not confident about brain death had more intense grief and more severe depressive symptoms.

A recent systematic review²³ aimed at identifying relatives' psychological and financial support needs during the donation process showed that they express ambivalence and prolonged distress for weeks after organ donation, possibly associated with the perceived ambiguity of brain death. Some relatives were unhappy when approached for a conversation about organ donation and were not always able to cope with the difficulties following their decision. The researchers conclude that health professionals should provide ongoing care and up-to-date information to family members.

However, it is important to note that misunderstanding brain death does not prevent families from consenting.⁷ Siminoff²⁴ found that 145 out of 232 donor families agreed to donation, even though they considered that the patient was alive when brain death was diagnosed. These findings may suggest that some family members authorise organ recovery while distrusting the diagnosis of death—a circumstance which could conceivably aggravate their grieving process.

Follow-up of relatives

Both in Spain, a country in which donation rates greatly exceed the European and international averages²⁵ as in other countries, there are no formal protocols to follow-up

on families who have confronted the decision, whether they have authorised or declined donation.¹¹ Instead, in Spain, a supportive relationship is established between donor transplant coordination teams and relatives, which is maintained even when families declined organ recovery. Some Spanish donor transplant coordinators²⁶ state that this supportive relationship could be 'key to help them in their bereavement'. Families are provided with a contact number and those who have authorised donation receive a personalised thank you letter.⁴ According to Guillem,⁴ some families maintain contact with the coordination team for many years, probably with unresolved bereavements. One of the likely impediments to a posteriori follow-up of the bereavement process is that most relatives who authorise donation remain anonymous. Thus, there is no information available to guide health professionals in caring for the relatives of potential organ donors.¹⁴

In Spain, it is common for donor families to request professional support to help them cope better with bereavement. Research has shown that the incidence of complicated bereavement among these families requesting help exceeds 50%.²⁷ In contrast, none of the families of the 14 deceased who refused organ removal sought help. Subsequent studies have pointed to the need for further follow-up with relatives to answer their questions and process their grief.⁶

Therefore, there is a clear need to update and expand what we know about the psychological impact that organ authorisation requests (as well as the outcome of organ authorisation) have on family members involved in the organ donation process. Due to high authorisation rates, analysing the donation experience of potential donors' relatives in Spain is of particular importance.

To contribute towards this objective, this study aims to uncover the impact that the interview has on the relatives of potential donors. It also provides the possibility to identify longitudinal associations between a relative's decision

to authorise or decline organ recovery for transplantation and their subsequent mourning of the loss. The evolution of relatives' mourning process is documented through self-reported measures of anxiety, depression, complicated grief, post-traumatic stress, personal growth or resilience.

It has recently been pointed out that further study of the donor family's experiences and subsequent satisfaction is needed.²⁸ There are factors related to the family members' experience that are closely related to the elaboration of their bereavement, irrespective of the decision on organ donation (being together as a family, disagreements in the decision making, a meaningful good-bye, etc).²⁹ Our findings can help clinicians to improve communication at the time of request and to offer actions, follow-up and intervention programmes that may improve care for this specific population. Exploring the impact of the family's decision on their bereavement will help understand whether or not the organ recovery process benefits the families of deceased individuals with the capacity to donate, beyond the benefits obtained by the eventual recipients of these organs.

Study aims

Research hypothesis and aims

We hypothesise that there are a number of aspects that may affect the bereavement of family members such as: the opportunity to donate, authorisation for donation, perceived quality of communication, understanding of the diagnosis of death, conditions of death, kinship and age of the deceased (see table 1). The ultimate aim of this work is to understand which factors positively influence the quality of grief among family members involved in donation and the extent to which they do so.

Table 1 Hypothesis

H1	H1.1. The opportunity for family members to authorise donation *group 1, G1 and group 2, G2, relative to the control group, G3) reduces their psychological distress (measured in terms of anxiety, depression, impact of stressful event, manifestations of complicated grief) in the medium and long term (3 and 9 months, respectively) and increases psychological well-being (measured in terms of resilience and personal growth in the long term—9 months), favouring a more adaptive grief processing.	
	H1.2. Authorisation for donation by relatives *group 1, G1, relative to refusal, group 2, G2) reduces psychological distress (measured in terms of anxiety, depression, impact of stressful event, manifestations of complicated grief) in the medium and long term (3 and 9 months, respectively) and increases psychological well-being (measured in terms of resilience and personal growth in the long term—9 months). It is related to lower symptomatology of complicated grief.	
H2	H2.1. Relatives who authorise organ recovery *group 1, G1) perceive communication with professionals to be of higher quality than those who reject organ recovery (group 2, G2) and than those whose deceased relatives is not considered potential donor (control group, G3).	
	H2.2. Perceived higher quality of communication with professionals is correlated with lower symptomatology of complicated grief.	
H3	H3.1. A greater understanding of the diagnosis of death is associated with less complicated grief symptomatology.	H3.1.1. The diagnosis of death by circulatory criteria is better understood than the diagnosis of death by neurological criteria.
H4	The cause of death of the deceased is related to the quality of grief. In other words, rapid, traumatic deaths and deaths following long and uncontrolled illness processes are associated with more complicated grief symptoms.	
H5	The kinship relationship is related to the quality of grief. Deaths of immediate descendants are associated with greater symptomatology of complicated grief than deaths of immediate ancestors.	
H6	The age of the deceased is related to the ease/difficulty of grief processing. In other words, the deaths of young people are related to a greater symptomatology of complicated grief.	
*See Box 1 for details of group composition.		

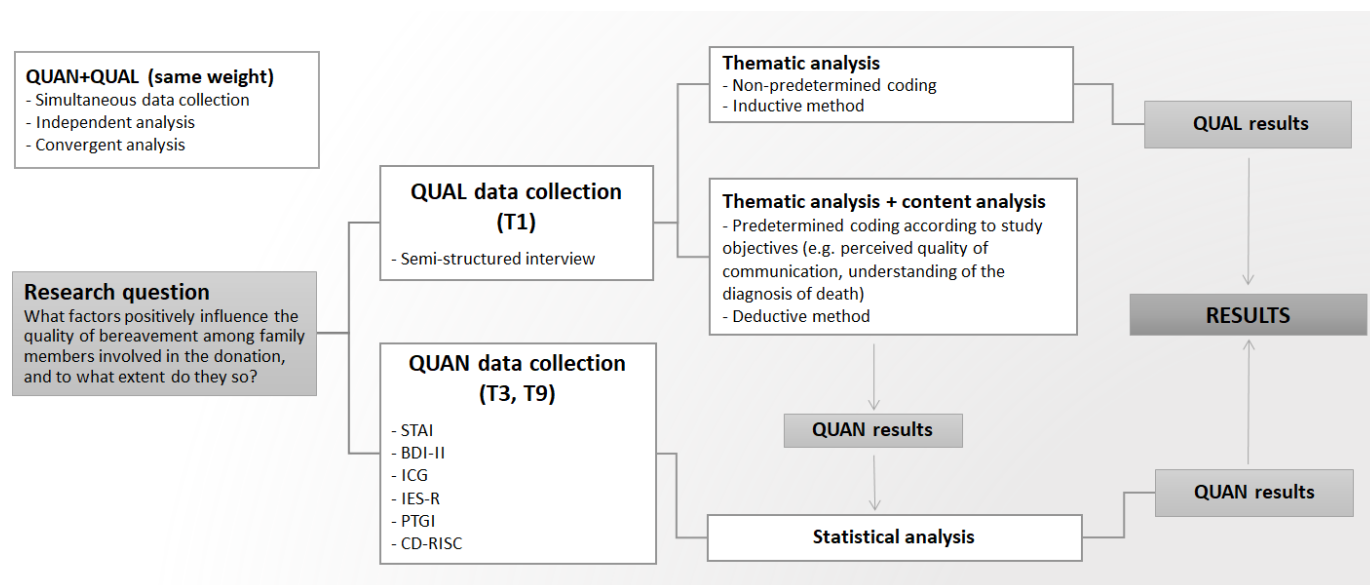


Figure 1 Mixed methods methodology. BDI-II, Beck Depression Inventory-II; CD-RISC, Connor-Davidson Resilience Scale; ICG, Inventory of Complicated Grief; IES-R, The Impact of Event Scale: Revised; PTGI, Posttraumatic Growth Inventory; STAI, State-Trait Anxiety Inventory; QUAN, Quantitative; QUAL, Qualitative.

METHODS AND ANALYSIS

Study design

This is a protocol for prospective cohort longitudinal study throughout several hospitals in Andalusia. A convergent mixed-methods design³⁰ is used, combining quantitative and qualitative results with the same weight³¹ via concurrent triangulation with data integration in the results and analysis.

A mixed methods approach is valuable for studying the factors that influence the grief of family members facing a donation process because of the need to consider all aspects, including the evolution of their grief (assessable using quantitative instruments) and the subjective experiences of family members about the process (which are better understood with a qualitative design). The results obtained from these two approaches will be integrated to provide a more complete view of the reality studied.³² For further clarification on the methodology, see figure 1. Researchers do not randomly assign participants to groups. Instead, participants are considered to belong to one of three groups: relatives who authorise donation (group 1, G1) (In this study, donors are defined as those patients from whom an organ and/or tissues are removed for transplantation purposes (not research and teaching).), relatives who refuse donation (group 2, G2) and relatives who are not offered the option to donate (eg, because the deceased is deemed medically unsuitable for donation; group 3, G3). For this purpose, at least one family member is recruited from all patients who die in an intensive care unit (ICU) and who meet the inclusion criteria (see box 1).

The target sample size is calculated using a sensitivity power analysis, conducted in the GPower programme. We establish a medium effect (Cohen's $d=0.60$) as the smallest effect size of interest and set our desired

power (ie, $1-\beta$, or the false-negative rate) to 80% and significance level (or α) to 0.05. On the basis of these values, we conducted a statistical power analysis and concluded that a sample size of 45 participants per group would suffice to reliably detect a medium effect of group assignment on any of the outcome measures in our study. Thus, we established our target sample size to be 135 participants distributed across three groups (G1, G2 and G3).

The study is being carried out in collaboration with the Spanish Organización Nacional de Trasplantes and the Regional Transplant Coordination in Andalusia, which contacted all sector donor transplant coordinators in each of the regions. Since the aim is to include the maximum number of hospitals in Andalusia and to maintain a systematic recruitment process, sector coordinators are encouraged to invite all hospital coordinators with an organ-generating capacity to assist with the study. So far the hospitals included are: Hospital Universitario Virgen de las Nieves (Granada), Hospital Universitario Virgen del Rocío (Sevilla), Hospital Universitario Puerta del Mar (Cádiz), Hospital Universitario Reina Sofía (Córdoba) and Hospital Universitario Virgen de la Victoria (Málaga). Start of study: November 2021.

This study has been designed in accordance with the guidelines of the Declaration of Helsinki³³ and the study was approved on 28 September 2021 by the Coordinating Committee on Biomedical Research Ethics of Andalusia (CCEIBA), with reference number: 1052-N-21. This is a collegiate institution responsible for research ethical assessment. The approval process by the committee requires an authorisation signed by the hospital manager to ensure that the study complies with the ethical requirements of each hospital.

Box 1 Inclusion and exclusion criteria

Inclusion criteria

General (G1, G2 and G3): Relatives of patients 18 ≥ years of age diagnosed dead by neurological or circulatory death (candidates for controlled donation after the circulatory determination of death (DCD)) who agree to participate in the study.

Specific:

G1. Relatives who have participated in the interview and have authorised the recovery of organs for transplantation. Two subgroups are distinguished:

- G1A. Relatives of patients who have been declared dead by neurological criteria.
- G1B. Relatives of patients who have been declared dead by circulatory criteria.

This includes:

- Relatives of patients who are able to donate organs and/or tissues.
- Relatives of patients who were initially considered potential donors but, at some point, donation was frustrated for some clinical or logistical reason. In this case, the fact that actual donation did not take place will be recorded.

G2. Relatives who have participated in the interview and have refused organ recovery for transplantation. Two subgroups are distinguished:

- G2A. Relatives of patients who have been declared dead by neurological criteria.
- G2B. Relatives of patients who have been declared dead by circulatory criteria.

G3. Relatives who have not been offered the opportunity to authorise or refuse the recovery of organs for transplantation. For the sampling of this group, relatives of persons who died in the intensive care unit (ICU) under analogous conditions to those of the candidates for donation will be included. For this purpose, a matching procedure will be followed that consists of considering the last inclusion in G1 and looking for the next death in the ICU in similar conditions, that is, in regard to the time of admission to the ICU and the patient's age.

This includes:

- Relatives of patients who died in hospital ICUs and who, due to logistical problems, were not offered donation.

Exclusion criteria

General (G1, G2 and G3): to be excluded from the study:

- Relatives of patients who died out-of-hospital, on the ward or in the emergency department, whether or not they are candidates for uncontrolled DCD.
- Family members who are unable to communicate in Spanish because the assessment tools cannot be performed adequately.

Specific (G3): Patients whose death occurred in circumstances very different from the prototypical ones that eventually lead to donation will be excluded.

Measurement of exposures and confounders

The choice of grief measurement instruments draws inspiration from a previous study.⁷ In addition, new indicators have been added: Post-traumatic Growth Inventory (PTGI) and Connor-Davidson Resilience Scale (CD-RISC). This timing is also based on a previous study⁷ and according to the scientific literature^{34 35} on bereavement, 3 and 9 months are relevant times for the evolution of adaptive or complicated bereavement. Participants in all three groups (G1, G2 and G3) are administered every measure.

Initial interview

This semistructured interview, based on a questionnaire of Kentish-Barnes's research,⁷ is conducted by telephone or video call 1 month after the patient's death. Relatives are asked 39 questions concerning: health professionals' care of the deceased at the end of life, the request and process of organ donation, decision-making and general aspects related to their perceived experience. This interview also collects sociodemographic information such as participants' gender, age, relationship to the deceased, nationality, employment status and religious beliefs. This interview is group specific, with slight variations depending on the group to which it is administered (group 1, group 2 or group 3). The original questionnaire⁷ has been adapted to the Spanish context by the team's researchers with expertise in the field and includes novel questions exploring the lived experience of relatives of patients who have been declared dead by circulatory criteria. The audio is recorded for its subsequent transcription. Estimated duration: 20 min.

State-Trait Anxiety Inventory

The *State-Trait Anxiety Inventory* (STAI)^{36 37} consists of 40 items and two subscales: state anxiety and trait anxiety. The inventory exhibits good psychometric properties, with coefficients of internal consistency around 0.90 for both subscales.³⁷ Additionally, test-retest reliability is high ($\alpha=0.81$) for the trait anxiety subscale and, as expected, low for the state anxiety subscale ($\alpha=0.40$). The STAI captures transient shifts in state anxiety among patients undergoing therapy and in reaction to different types of stressors. Estimated duration: 15 min.

Beck Depression Inventory-II

The *Beck Depression Inventory-II*^{38 39} measures the severity of depression using 21 items, with higher scores reflecting higher levels of depression. Psychometric studies support the reliability, with $\alpha=0.81-0.89$, and concurrent validity of 0.41.³⁹ It is administered to all three groups. Estimated duration: 10 min.

Inventory of Complicated Grief

The *Inventory of Complicated Grief* (ICG)^{40 41} is composed of 19 items rated on 5-point Likert scales (from 0 to 4). The items inquire about the main symptoms that characterise complicated grief: a longing for the deceased, ruminations, emotional aspects or hallucinations. Internal consistency has been shown to reach values of $\alpha=0.94$.⁴¹ Estimated duration: 5 min.

The Impact of Event Scale

The Impact of Event Scale: Revised (IES-R). The IES-R^{42 43} consists of 22 items and three subscales: seven measure intrusion, eight measure avoidance and seven measure hyperarousal. Psychometric studies support reliability, with $\alpha=0.86$ for the total scale, $\alpha=0.87$ for the intrusion subscale and $\alpha=0.85$ for the avoidance subscale, and $\alpha=0.79$ for the hyperarousal subscale.⁴³ Estimated duration: 5 min.

Post-traumatic Growth Inventory

The PTGI^{44 45} consists of 21 items that assess the positive changes that people can experience after having suffered a traumatic or adverse event. It includes a total score and five scales indicating different dimensions of growth: relationships with others, new possibilities, personal strengths, spiritual changes and appreciation of life. High scores on this questionnaire indicate a higher degree of perceived post-traumatic growth with the maximum score being 105. High internal consistency values have been found for the five subscales as well as for the total score. Estimated duration: 5 min.

Connor-Davidson Resilience Scale

The CD-RISC^{46 47} is a self-administered questionnaire of 25 items that assess how the participant has felt in the last month. The maximum score is 100. Higher scores reflect higher resilience. This scale addresses, among others, the concepts of locus of control, commitment, defiance, action-oriented behaviour, self-efficacy, resistance to distress, optimism, adaptation to stressful situations and spirituality. Regarding its psychometric characteristics, studies confirm high reliability ($\alpha=0.90$) and validity for use in caregivers with a situation of chronic stress.⁴⁷ Estimated duration: 5 min.

Confounds

In this study, group assignment is determined by non-random variables: whether the opportunity to donate arises and whether participants agree to organ recovery. This opens up the possibility for extraneous differences in group composition to confound the primary relationship between donation and grief.⁴⁸ To this end, we consulted the existing literature⁹ and identified a number of covariates that could determine participants' inclusion in one of the groups (eg, their predisposition to donate) and/or their subsequent experience of grief. For this purpose, the structure of relationships and interactions contained in the *Integrated Psychosocial Model of Relatives' Decision on Deceased Organ Donation*⁹ is used. The groups are matched on the main variables related to the decision by including them in the initial interview (table 2).

Referral and contact with relatives

The time of referral and the person responsible for it may vary depending on the type of death of the potential donors (G1 and G2) and the place and circumstances of death for G3.

Once donation has been discussed and the decision has been made, families in groups 1 and 2 are informed of the study by the Donor Transplant Coordination Team at the hospital. Relatives in group 3 are informed of the study by the ICU team once the patient's death has been certified.

Initially, families are handed an informed consent form, asking whether they would like to be contacted by a researcher 'to follow-up on their experience in the hospital'. Within the coming days, relatives who consent

Table 2 Covariates and candidate confounds*

Characteristics of the deceased	Age Socio-economic and cultural background Religious beliefs Communication of desire to donate to family members
Characteristics of the deceased person's relatives	Age Socio-economic and cultural background Religious beliefs Information received about donation and transplantation Experience with donation and transplantation Attitudes towards donation Number of decision-makers and relationship between them Social support
Perceptions of bereaved family members	Satisfaction with the medical team Satisfaction with personal treatment Satisfaction with information received
Circumstances of death	Cause of death Determination of death by neurological or circulatory criteria Duration of process Expectancy of death
Behaviour of the health professional	Care and communication with the patient and relatives (death, diagnosis of brain death, information and request for donation).
*Based on variables affecting the decision to donate. ⁹	

then receive a phone call from the main researcher (MVML) with detailed information about the purpose and procedure of the study. The gap between the donation interview and the beginning of the study was thought to promote participants' sense of the study as unrelated to clinical procedure and unaffiliated with the Donor Transplant Coordination Team. This perception, in turn, may foster participants' exercise of consent and facilitate sincere responses.

For all groups, both the information sheet and the consent form are provided electronically to the relatives who have given their prior written consent to contact them. These documents are read over the telephone and the principal investigator clarifies any questions about the study. Consent to participate in the study is obtained verbally.

The interviews are conducted by one researcher (MVML) since November 2021. She is a female PhD researcher full-time contracted at the University of Granada. She has a degree in Nursing and a degree in Philosophy and is a specialist in Bioethics, Gender, and Health and Care Management. She has training and experience in caring for people in highly vulnerable situations. The interviewer had no previous relationship with any of the participants, who received no remuneration for their participation. In the consent to contact that the coordinators provide to family members, as well as in the information and consent to participate in the study, participants are informed of the researcher's credentials. Her contact address is also provided.

Contacts are arranged with the relatives at three points in time, the first session (T1) consisting of a telephone or video call interview 1 month after the death of their loved one. A time is agreed with the participant when they can be in a quiet place for the interview. Subsequent contacts (T3 and T9) are carried out by telephone or online,

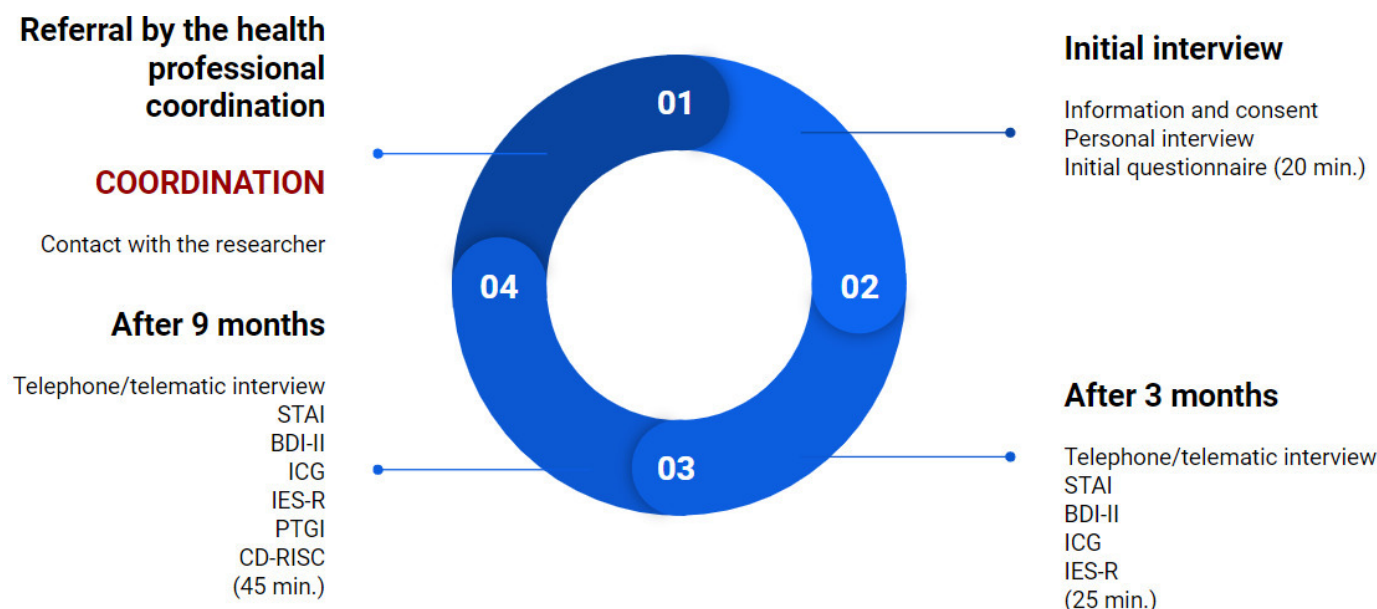


Figure 2 Procedure (legend) 1. Recruitment of the sample, 2. initial interview (T1). 3 months after death (T3) 4.9 months after death (T9). BDI-II, Beck Depression Inventory-II; CD-RISC, Connor-Davidson Resilience Scale; ICG, Inventory of Complicated Grief; IES-R, The Impact of Event Scale: Revised; PTGI, Posttraumatic Growth Inventory; STAI, State-Trait Anxiety Inventory.

according to participants' preferences, 3 and 9 months after the patient's death. The content of each session is summarised in figure 2. At a broad level, the first session (T1) serves as an opportunity to record information about the participants and interview them about their recent experience at the hospital. Then, in subsequent sessions (T3 and T9), we repeatedly administer assessments of participants' grief, except for PTGI and CD-RISC which are added to T9.

The interviews of T1 are recorded in audio format and transcribed by the researcher who performed them with NVIVO Transcription. The duration of T3 is 25 min and T9 is 45 min. These questionnaires (T3 and T9) are both conducted through the Qualtrics platform.

Patient and public involvement

Patients are not involved in the design.

The research team must take into account the seriousness of the situation in which family members may find themselves. They must also be aware of the additional effort that family members are required by responding at the three points in time when they will be contacted. Therefore, additional protective measures are taken to preserve respect for the participants such as: (1) waiting a month before the first contact, so that they have time to arrange their affairs, (2) accommodating family members' preferences, the option of face-to-face, telematics or telephone interviews is offered, (3) respect their response times during the interview.

Participants are reminded at all times that they may choose not to answer certain questions or even to withdraw from the research without any consequences for themselves. Participants are also reminded that their participation in the study is entirely voluntary.

Study participants can inform other family members of the existence of the study and facilitate contact with the principal investigator. This is done as long as the family member agrees and in the case of groups G1 and G2, it is essential that he/she has been involved in the decision-making process for the donation.

By default, no personalised feedback of results will be provided. Participants will have access to the overall results of the study, which is explained in the participant information sheet. It is also stipulated how to contact the researcher to request this information. If, as a result of the data obtained for the study, any participant is found to have signs of pathological grief, they will be advised to contact their doctor of reference or the mental health team at their health centre.

Data analysis

Qualitative analysis plan

Following Braun and Clarke,⁴⁹ once the interviews have been transcribed and anonymised, the transcriptions are provided to three members of the team (MVML, M-NP-M and DR-A) for thematic analysis. This process is conducted with Atlas.ti V.7 (Scientific Software Development GmbH, Berlin, Germany). Specifically, coding is performed in an inductive manner, where categories are not predetermined but agreed on between three experts in qualitative analysis. For that process, categories are established by grouping codes according to their characteristics, where main categories and subcategories are identified (axial coding): a series of initial codes are obtained and progressively refined and integrated into larger codes (inductive approach).⁵⁰ In cases of doubt or disagreement, the researchers discuss them to ensure that each new code is as close as possible to the participants'

experience. Group codification is reviewed and discussed until sufficient intercoder reliability (Cohen's kappa >0.7) is reached. The analysis concludes when theoretical saturation is reached. This process is done by the researchers in an iterative and reflective manner⁵¹.

In order to establish that the findings of the study comply with key trustworthiness requirements—that is, transferability, dependability, confirmability⁵²—the research design incorporates elements such as triangulation of data collection and the researcher, detailed descriptions of the processes, checking that the process is logical, traceable and clearly documented and, finally, comparing the results with those of other similar studies”.

Statistical analysis plan

Matching (pairing by propensity score): group assignment is determined by non-random variables. Therefore, participants and patients may differ on several dimensions or characteristics that are relevant to the study. In particular, there is a risk that certain psychological or demographic characteristics of relatives and/or patients may confound the relationship between group assignment and bereavement outcomes. For example, there is evidence that religious belief is associated with favourable bereavement outcomes^{53 54} and may conceivably be associated with the decision to donate as well. In such a circumstance, group differences in religiosity would result in group differences in grief, which would not be attributable to the decision to donate per se. As such, it is important to reduce the imbalance between groups on various covariates of interest. For this purpose, we apply a *matching* method once the data have been obtained, of which we point out two alternatives: (1) propensity score matching⁵⁵ and (2) coarsened exact matching.⁵⁶ In both cases, the aim is to select or reweight participants in each group in a way that maximises homogeneity in the distribution of multiple covariates across groups, thereby emulating a key property of random assignment.

Based on the existing work,⁵⁷ we consider the following covariates and risk factors for complicated bereavement: (1) socioeconomic status of the relative, (2) age of the deceased, (3) communication of the wish to donate by the deceased, (4) religious beliefs of the relative, (5) attitudes towards donation, (6) experience with donation and transplantation, (7) relationship, (8) criteria to determine death (neurological or circulatory) and (9) cause of death.

To apply *propensity score matching*, group assignment is predicted by entering the covariates of interest as predictors in a logistic regression model (where 1=experimental group ‘G1’ and 0=control group, ‘G3’). This regression model estimates a propensity score for each participant, that is, the predicted probability that the participant will be ‘assigned’ to the experimental group (and not the control) as a function of the values of its nine covariates. If, for example, religiosity is greater among participants in G1 than in G3, consequently the propensity score will be higher among religious participants than among

non-believers. As the last step, pairs of treatment–control participants are selected whose propensity scores are equivalent or nearly equivalent (by the *nearest neighbour method*). Alternatively, the inverse probability of treatment is calculated and responses are weighted according to this value. These methods reduce the imbalance between groups *a posteriori*, mitigating the effects of possible confounds (provided that the selection of covariates is correct) and improving estimation of the treatment effect (ie, donation vs non-donation).⁵⁵

For the quantitative analysis, descriptive statistics are calculated (means, SDs and frequencies), summarising key variables in each group. Inferential analyses will evaluate whether there are significant differences between groups by using parametric and/or non-parametric tests, depending on the distribution of the data.

For instance, to assess whether the evolution of grief differs between the two groups, a split-plot analysis of variance (ANOVA) with two factors is performed: (1) group, the between-subject factor and (2) time, the within-subjects factor, plus (3) the interaction between group and time. The interaction effect between group and time would indicate that the trajectory of grief differs between groups. If such an interaction is observed, simple slope analyses (ie, of the change over time) will be carried out for each group. Critically, these analyses will weight responses according to the inverse probability of treatment—to preclude confounding, as previously explained. In the analysis, the psychopathological part and the personal growth part will be distinguished. The statistical package SPSS version number 29 is used.

In parallel to the qualitative and quantitative analysis, and having coded the qualitative interview responses, we explore whether various qualitatively coded variables (eg, communication with professionals, a meaningful good-bye) predict the evolution of grief. For instance, in moderation analyses, we enter (1) the qualitatively coded variable of interest, (2) time, the within-subjects factor, (3) the interaction between group and time, while controlling for (4) group, the between-subject factor. Additionally, in a series of ANOVAs, we enter (1) group, the between-subject factor as a predictor of the qualitatively coded variable of interest—in order to investigate whether there are group differences, for example, in communication with professionals, a meaningful good-bye.

Methodological issues

It is recognised that it is difficult to reach the necessary sample (n=45) of the G2 group (family members who oppose recovery). Annually, in Andalusia, the number of families refusing donation is estimated at between 20 and 30.⁵⁸ This difficulty is mitigated by the fact that the protocol allows several members of each family to be recruited, as long as they have participated in the decision-making of the donation process. However, it is to be expected that this is a particularly reluctant population to participate in the research. The study is feasible even if the minimum *n* in this category is not achieved.

To this end, it is proposed: (1) extend the study to other autonomous regions even if this would mean increasing the n in other groups, (2) extend the recruitment period until the minimum n is achieved for G2, (3) in the event of not achieving uniformity in the three groups (difficulty in reaching the minimum of 45 participants in G2), we could seek to achieve statistical power by compensating with a greater number of participants in G1 or G3 and, ultimately, renounce the verification of the hypotheses that require analysis of this subgroup.

Data management and oversight

Main risks and potential benefits associated with participation

Participation in this study presents no demonstrated risks to participants. However, the participation of family members follows a potentially painful event, and the memory of the loss of a loved one may be uncomfortable.

Although this study is not designed to provide participants with individual or direct benefits, there is also the possibility that the follow-up of family members in this study may help them to express themselves and to perceive continuity of care.

However, there is the possibility that secondarily and incidentally, the study may help the participant.⁵⁹ This may happen because the interview process itself is interesting or beneficial to the participant, or because the research is conducive to a diagnosis of complicated bereavement but is not intended to be so.

All interviews and completed questionnaires will be anonymised by coding. No one except the main investigator of this research (MVML) has access to the personal data. The rest of the researchers can access them once they have been anonymised. All documents related to a participant have the same code and their safekeeping is the responsibility of the principal investigator both during and after the research process. Recordings will be destroyed once they have been transcribed. The data files will be kept for 5 years after the relevant analyses have been carried out to meet the objectives set. Once this time has elapsed, they will be destroyed deleting the files.

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ORCID iDs

Maria Victoria Martínez-Lopez <http://orcid.org/0000-0002-1101-1413>
 Elisabeth Coll <http://orcid.org/0000-0001-6876-7476>
 Francisco Cruz-Quintana <http://orcid.org/0000-0001-9805-5939>
 Beatriz Domínguez-Gil <http://orcid.org/0000-0002-5695-8993>
 Ivar R Hannikainen <http://orcid.org/0000-0003-0623-357X>
 Ramón Lara Rosales <http://orcid.org/0000-0001-8718-3839>
 Alicia Pérez-Blanco <http://orcid.org/0000-0002-8552-4094>
 Maria Nieves Perez-Marfil <http://orcid.org/0000-0001-6329-8770>
 Jose Miguel Pérez-Villares <http://orcid.org/0000-0002-9860-3891>
 David Uruñuela <http://orcid.org/0000-0002-9486-6205>
 David Rodríguez-Arias <http://orcid.org/0000-0002-4555-5259>

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