Attending support groups to reduce the prevalence of Anxiety Disorders in parents who have suffered a perinatal loss

FINAL DEGREE PROJECT

Author: Marina Rosado Hidalgo
Tutor: Dra. María Fe Martín Pérez
Girona, November 2019
Con cada amor
volvemos a nacer,
y con cada amor
que termina se nos
abre una herida.
Estoy llena de orgullosas
cicatrices.

Isabel Allende
ACKNOWLEDGEMENTS

I dedicate this study to my family, for all the support and love received.

I want to thank the staff of the mother and child area of the Josep Trueta hospital for treating me as part of the team.

I want to make a special mention to Dra. María Fe Martín and Natàlia Artigas for giving me the opportunity to learn more about the perinatal grieving process and for teaching me so much during this project.

To Alejandro, for his immense patience.

To Judit, for her necessary and useful advice.
INDEX

1. ABSTRACT .......................................................................................................................... 7
2. ABBREVIATIONS ................................................................................................................ 8
3. INTRODUCTION .................................................................................................................. 9
   3.1. GRIEF IN TODAY’S SOCIETY .................................................................................... 9
   3.2. NON-PATHOLOGICAL GRIEF .................................................................................. 10
   3.3. PATHOLOGICAL GRIEF .......................................................................................... 12
   3.4. PERINATAL LOSS ...................................................................................................... 14
      3.4.1. Definitions of gestational, perinatal and neonatal death .................................... 14
      3.4.2. Current situation ............................................................................................... 16
      3.4.3. Etiology and risk factors .................................................................................... 16
      3.4.4. Perinatal death and its grief .............................................................................. 18
4. JUSTIFICATION .................................................................................................................. 22
5. HYPOTHESIS AND OBJECTIVES OF THE STUDY ......................................................... 24
6. MATERIAL AND METHODS .............................................................................................. 25
   6.1. STUDY DESIGN ........................................................................................................... 25
   6.2. STUDY SETTING .......................................................................................................... 25
   6.3. STUDY POPULATION ................................................................................................. 25
      6.3.1. Inclusion criteria ................................................................................................. 25
      6.3.2. Exclusion criteria ............................................................................................... 25
   6.4. SAMPLE ...................................................................................................................... 26
      6.4.1. Sample selection ................................................................................................. 26
      6.4.2. Sample size ......................................................................................................... 26
   6.5. VARIABLES AND METHODS OF MEASUREMENT .................................................. 26
      6.5.1. Main variables ..................................................................................................... 27
      6.5.1.1. Dependent variable ....................................................................................... 27
      6.5.1.2. Independent variable .................................................................................... 27
      6.5.2. Covariates .......................................................................................................... 27
   6.6. METHOD OF DATA COLLECTION .............................................................................. 30
7. STATISTICAL ANALYSIS ................................................................................................... 31
   7.1. DESCRIPTIVE ANALYSIS ......................................................................................... 31
   7.2. BIVARIATE ANALYSIS .............................................................................................. 31
   7.3. MULTIVARIATE ANALYSIS ....................................................................................... 31
8. STUDY LIMITATIONS ......................................................................................................... 32
9. ETHICAL CONSIDERATIONS ............................................................................................ 34
10. CLINICAL AND HEALTHCARE IMPACT ...................................................................... 35
11. WORK PLAN ..................................................................................................................... 36
12. BUDGET ............................................................................................................................ 38
13. BIBLIOGRAPHY AND REFERENCES ............................................................................. 39

ANNEXES ................................................................................................................................. 43

ANNEX 1. TRYPIC WITH RECOMMENDATIONS: WHAT CAN YOU EXPECT AFTER THE DEATH OF YOUR CHILD? ................................................................. 43
ANNEX 2. REMEMBRANCE CARDS.................................................................44
ANNEX 3. GRIEF GROUP “BRESSOLS” AND “ESPAI DE PARAULA”........................45
ANNEX 4. TRAIT STATE ANXIETY QUESTIONNAIRE [STAI], FORM Y-1................46
ANNEX 5. TRAIT STATE ANXIETY QUESTIONNAIRE [STAI] FORM Y-2.................47
ANNEX 6. QUESTIONNAIRES FOR TOBACCO CONSUMPTION (FAGERSTRÖM AND RICHMOND TESTS)........................................................................................................48
ANNEX 7. QUESTIONNAIRES FOR ALCOHOL CONSUMPTION (CAGE AND AUDIT TESTS)..................................................................................................................49
ANNEX 8. DATA COLLECTION SHEET. ........................................................................50
ANNEX 9. INFORMED CONSENT AND STUDY INFORMATION FOR THE PATIENT......51
  9.1. Informed consent .................................................................................................51
  9.2. Study information for the patient..........................................................................52
FIGURE INDEX

Figure 1. Stages of grief..................................................................................................................11
Figure 2. Pregnancy outcome definitions......................................................................................15
Figure 3. Perinatal Mortality rate by Autonomous Region and by gender (2012-2018).
INE source 2019.................................................................................................................................16
Figure 4. Risk factors for perinatal death........................................................................................18

TABLE INDEX

Table 1. Manifestations of grief (adapted from (9))........................................................................12
Table 2. Possible complications of grief (adapted from (9)).............................................................13
Table 3. Summary presentation of the central clinical features for the different Anxiety Disorders included in the DSM-5 (adapted from (23))..................................................20
Table 4. Distribution of State Trait Anxiety Inventory (STAI) scores in each subscale (27). ..........................................................27
Table 5. Variables of the study. ID: identity document...................................................................29
1. ABSTRACT

Introduction

Nowadays, live in a tanatophobic society in which there is no place to express negative emotions or unpleasant thoughts, much less talk about death.

Grief must be understood as a normal process after the loss of a loved one. Pathological grief can appear in some situations and lead to physical, psychological or psychiatric disorders.

Perinatal death occurs from the 22nd week of gestation to the first 7 days from birth. Perinatal grief is generally unauthorized, so parents are at risk of developing a complicated grief disorder. Another underestimated aspect is the early detection of psychiatric disorders in these parents, such as Anxiety Disorder.

Justification

Most hospitals in Spain do not have a protocol for perinatal death. Therefore, medical personnel are not trained in this area. In addition, many parents mention not having received the necessary information at the time of the loss and not having had support from society. The support groups that have been created for these families, as well as the mental health of these parents should be studied.

Objective

This study aims to evaluate if the patients who have suffered a perinatal death and attend a support group have less at risk of developing an Anxiety Disorders than patients who do not attend these groups.

Methodology

This study is designed as a prospective observational study.

This study is designed to be multicentre and will be carried out in 3 health centres in Catalonia.

The sample will consist of 2 groups of parents who have suffered a perinatal death: a group that will attend support groups for perinatal grief (case group) and another group that will not attend these groups (control group).

Finally, the prevalence of Anxiety Disorder will be compared between the two groups.

KEYWORDS: Death, grief, perinatal loss, Anxiety Disorder, taboo.
2. ABBREVIATIONS

**DSM-V**: Diagnostic and Statistical Manual of Mental Disorders, 5th edition

**HBP**: High blood pressure

**PTSD**: Post-traumatic Stress Disorder

**SUD**: Substance use disorder

**WHO**: World Health Organization

**ICD**: International Classification of Disease

**ICD-PM**: International Classification of Disease-Perinatal Mortality

**FIGO**: International Federation of Gynecology and Obstetrics

**UNICEF**: United Nations Children’s Fund

**INE**: Instituto Nacional de Estadística

**IUGR**: Intrauterine growth restriction

**SEGO**: Sociedad Española de Ginecología y Obstetricia

**DM**: Diabetes Mellitus

**SLE**: Systemic lupus erythematosus

**THC**: Tetrahydrocannabinol
3. **INTRODUCTION**

3.1. Grief in today’s society

Since the industrial revolution, technological advances have made a big progress in all aspects of our daily life. We have moved away from fear and hardships to begin with a life full of opportunities to enjoy and to be successful. Hence, in a society which is completely focused on living just a satisfying moment all the time, there is no place for any negative emotion or unpleasant thought, and even less to talk about death.

Nowadays, we live in a thanatophobic society (1) which tries to refuse and hide the idea of the death as much as possible. People do not talk about it but if they do it, they verbalize phrases such as “he was at the end of his life”, “he passed away”, “now he is in Heaven” ...

To avoid expressing sad feelings, funerals are lived as most intimate and private as possible. Leaving the tradition of sharing our saddest moments with our community behind and trying to hide our weakness as much as we can.

It is remarkable how, in the past, homes had a central role in funerals, sheltering families and friends during this event with affection and tenderness. Nevertheless, after the hospital’s institutionalization, which has been instigated in the last decades, the hospital has become an antiseptic and anaesthetic place where death occurs.

All the technical vocabulary, medical procedures and the lack of information, combined with paternalistic model of interaction between doctor and patient, has created the ideal atmosphere to deny the obvious, the death.

This supports the idea that death has become one of the biggest taboos in western world, described by some authors, like Salvador Pániker i Alemany, as the “retroprogres” or “evolutionary retroprocess” (2). This theory is based on the idea that our society is going towards more immature stages of the evolutionary process of death.
The loss of funeral ceremonies that served as cultural patterns to develop a physiological grief results in repressed feelings, which increase the risk of pathological grief.

3.2. Non-pathological grief

Grief should be understood as a normal adaptive process to the death of a loved one according to DSM-V (3). It is a universal human experience, not necessarily harmful, and many people can cope with their own means (4). Elizabeth Kübler-Ross described in her 1969 book *On death and dying*, that there are five stages of grief:

1. **Denial**: Shock may occur as a reaction and it can be shown with emotions of disbelief, denial of what has happened, relief from death and emotional insensitivity (4). The first task of grief is to accept the fact that the loved one has died and will not return. To accept it, it is recommended to repeat phrases that prove their death and talk about the loss. Good emotional contact is essential. This task will be more complicated to perform in cases of sudden and unexpected deaths (5).

2. **Anger**: Anger, guilt and hostility can appear towards the whole environment. It also includes self-directed anger or hostility. Being able to incur self-destructive risk behaviors. It is important to recognize what the subject feels and comfort them, without judging (4).

3. **Bargaining**: It is a way of dealing with guilt and engages with those towards whom the anger was directed. Any self-destructive behavior is abandoned and begins to commit to recovery (6).

4. **Depression**: The pain of loss is experienced with greater intensity. The griever loses the meaning of their life and feels that the loss of the loved one takes meaning away from everything. Physical symptoms are common, often secondary to anxiety (anorexia, weight loss, insomnia or loss of libido). Problems with concentration and recent memory retention are frequent too. Over time, the intensity and frequency of pain are decreasing. But it returns frequently when important dates coincide like anniversaries or burial date (4). A remarkable task in this stage is to insist that the person expresses their pain and feelings, not be repressed and tell how they live and feel their emotions, without censorship (5). Active listening and emotional support are really essential (7).

---

1. It is remarkable in the anger process of perinatal grief that the feeling of guilt is very present. Parents review each of the things that were done, trying to find a reason that explains what happened.
5. **Acceptance**: In this stage the griever finally accepts the loss (4). The next step will be to assume all the roles performed by the deceased, learn to live alone and make decisions without the other. To achieve this, it is necessary to reinforce that the detachment of the loved one does not mean giving up their memory. To solve the grief is to be able to think about the deceased without feeling pain, guilt or anger; considering that it is normal to feel sad from time to time (5).

![Figure 1. Stages of grief.](image)

It is not necessary that all phases of grief take place, or follow the same order, or have the same duration, since grief is totally subjective and unique to each person. However, normal and non-pathological grief must end with the acceptance of loss (8).

Moreover, it is also really important to know which signs and symptoms could appear as a part of the normal process of grief (Table 1), such as intense sadness, anxiety, rumination about loss, insomnia, dysphoric dreams (upon awakening they follow
introspection and insight, rather than discomfort), hallucinations like the hypnagogic, concentration problems, recent memory retention problems, loss of libido, anorexia and weight loss can be some of them. Cultural norms, personal history and age must always be considered (3).

**Table 1. Manifestations of grief (adapted from (9)).**

<table>
<thead>
<tr>
<th>Physical</th>
<th>Empty stomach, chest and chest tightness, choking, palpitations, sighs, insomnia, nightmares, lack of libido, anorexia, weight loss, dry mouth, indigestion, headache, noise sensitivity, somatic complaints.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional</td>
<td>Insensitivity, daze, sadness, guilt, reproach, anger, despair, hostility, irritability, anhedonia, loneliness, emptiness, helplessness, longing, relief.</td>
</tr>
<tr>
<td>Behavioral</td>
<td>Automatic operation, absent mind, social isolation, crying crisis, search or avoidance behavior, attachment objects, consumption of toxins, hyperactivity, mummification.</td>
</tr>
<tr>
<td>Psychological</td>
<td>Disbelief, denial, rumination about the deceased, confusion, unreality, ideas of suicide / substitution, sense of presence, idealization, hallucinations and illusions, lack of concentration / memory</td>
</tr>
<tr>
<td>Spiritual</td>
<td>Search for meaning, awareness of mortality, rethinking beliefs.</td>
</tr>
</tbody>
</table>

### 3.3. Pathological grief

According to DSM-V (3), pathological grief occurs when the person has experienced the death of someone with whom they had a close relationship. Certain symptoms that occur, for at least 12 months in adults (6 months in children) and the vast majority of days, causes clinically significant discomfort or dysfunction in social, labor or other important areas of functioning. Furthermore, the grieving reaction is disproportionate or inconsistent with cultural, religious, or age-appropriate norms. It is necessary to specify if there is a traumatic grief because, in this case, times and intensities of reactions significantly increase (10).
The differentiation between a non-pathological grief and pathological grief is not always simple. When physical or psychiatric disorders clearly appear (Table 2) like major depressive disorder or a psychotic break, the diagnosis and treatment are usually immediate. However, it is more difficult when complicated grief appears without obvious symptoms.

**Table 2. Possible complications of grief (adapted from (9)).**

<table>
<thead>
<tr>
<th>Physical</th>
<th>Psychological/Psychiatric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune response modifications, adrenocortical activation (ulcers, HBP), increase in serum prolactin (with menstrual disorders), growth hormone elevation (with diabetes, HBP), mortality due to heart problems.</td>
<td>Depression / mania, schizophreniform reaction, anxiety and phobia symptoms, PTSD, behavioral disorders, SUD.</td>
</tr>
</tbody>
</table>

Pathological or complicated grief disorder can be classified in five different types (10):

- **Anticipatory grief**: It is a kind of grief in which the debtor has already begun to elaborate the pain of loss without it having occurred yet. It is a way to anticipate the loss that will inevitably occur in a short period of time. This type of grief is relatively frequent when the loved one is in a terminal situation.
- **Chronic grief**: It has an excessive duration, never reaches a satisfactory conclusion and the person who suffers it is very aware that they cannot finish it.
- **Delayed grief**: Also called inhibited, suppressed or postponed. The person has an insufficient emotional reaction at the time of the loss, which may be due to lack of social support, the need to be strong for someone else or for something, or in agony over the amount of losses. At some point in the future the person may experience the symptoms of grief, sometimes for a subsequent loss; and the symptoms may be disproportionate regarding the loss.
- **Exaggerated grief**: The person experiences the intensification of a normal grief, feels overwhelmed and resorts to maladaptive behavior. The person is aware that their symptoms are related to a loss. They include major psychiatric
disorders that arise after a loss such as depression, anxiety in the form of panic attacks or phobic behaviors, substance abuse and posttraumatic stress disorder.

- **Masked grief:** The person experiences symptoms and behaviors that cause them difficulties but do not realize or recognize that they are related to the loss. They may appear as physical symptoms (psychosomatic diseases, ...), or maladaptive behaviors (unexplained depression, hyperactivity, ...).

In relation with risk factors for developing a pathological grief, the risk of presenting it increases in cases of greater dependence on the deceased person before death, and if the one who dies is a child. About genetic and environmental factors, the risk of presenting it increases if the grieving individual is a woman (3). There are also circumstantial risk factors, amongst which single out unauthorized or silent grief (10).

### 3.4. Perinatal loss

In relation to perinatal loss, in recent years, there is some sensitivity in this item and a few sanitary centres in Spain have offered specific training and are following a protocol. The need to give visibility to perinatal deaths, through medical training, due to the fact that during decades these deaths have been underestimated, causing inadequate treatment and follow-up of affected families.

This section describes the concept of perinatal loss, the epidemiological characteristics in Spain, specifically in Catalonia, the main causes of perinatal loss and a summary of different aspects that should be validated and studied.

#### 3.4.1. Definitions of gestational, perinatal and neonatal death

The definition of gestational, perinatal and neonatal death has changed in the last years and it varies depending on the context. According to the WHO (World Health Organization), it was used the weight, length and weeks of gestation to compare these deaths internationally (11). Furthermore, ICD (International Classification of Disease) incorrectly assumed equivalence between birthweight and gestation age (12).
As there were variations between these parameters depending on gender and region that hindered the capacity of comparation, the WHO Working Group on Perinatal Death Classification developed the document *The WHO application of ICD-10 to deaths during the perinatal period: ICD-PM* (13). This recommends the use of weeks of gestation as the principal parameter because is considered the best predictive viability factor (12).

Therefore, the classification of death according to gestational age has defined different entities (7,11,14,15):

- **Gestational death or abortion**: Expulsion or removal of a foetus or embryo <500g or <22 weeks of live or dead pregnancy spontaneously or caused.
- **Perinatal death**: According to FIGO, it includes from 22 weeks until the first 7 days after birth or ≥500g. A practical and programmatic grouping of prenatal deaths consists in differentiating between:
  - Antepartum death: Before the start of labor.
  - Intrapartum death: After the start of labor and before birth.
- **Neonatal death**: First 28 days of life.
  - The early neonatal period: First seven days after birth.
  - The late neonatal period ranges from the seventh to the twenty-eighth full day.

*Figure 2. Pregnancy outcome definitions.*
3.4.2. Current situation

According to UNICEF (16), globally 2.5 million children died in the first month of life in 2018, approximately 7,000 neonatal deaths every day.

In Spain, according to the latest data available from INE, during the last decades there has been a reduction in perinatal mortality rate, associated with social and health improvements until being 4.2‰ live births. In Catalonia, there were 3.98‰ live births in 2018 (INE, 2019).

Nevertheless, it is believed that there is a lower record regarding the number of real cases.

![Figure 3. Perinatal Mortality rate by Autonomous Region and by gender (2012-2018). INE source 2019.](image)

3.4.3. Etiology and risk factors

It is recommended to conduct the necropsy or to study the body in pathological anatomy in all cases that a perinatal death occurs. Placenta, umbilical cord and mother studies are also important. To know the etiology of the perinatal death can be helpful to elaborate the grief and to understand why death has occurred, as well as to provide useful information for future gestations. However, in high number of cases these causes cannot be identified, causing parents desperation and frustration (17).

The main causes of pregnancy loss in the 1st trimester are fetal causes due to chromosomal or genetic abnormalities, in the 2nd trimester they are infectious causes
and in the 3rd trimester they are umbilical cord alterations and antepartum hemorrhages (17). From the etiological point of view, fetal causes represent 25-40% of fetal deaths, placental causes between 25-35% and maternal causes 5-10%. Between 25-35% of deaths are of unknown etiology (SEGO, 2008).

The result of the interaction of several pathophysiological processes that can occur in foetus, mother, placenta/cord/membranes and labour can be just risk factors or the cause of perinatal death (13,17–19). The following is a summary of the main and most relevant items that can cause perinatal loss.

**Mother**

- Previous perinatal death
- Multiple pregnancy
- Early maternal age (≤18 years of age) and advanced maternal age (> 35 years)
- Incompetent cervix or uterine rupture
- Prolonged pregnancy (over 42 weeks)
- Pre-eclampsia, eclampsia
- Uncontrolled and chronic maternal diseases (DM, SLE, HBP...)
- Maternal overweight or obesity
- Infectious and parasitic disease
- Tobacco/alcohol/drugs of addiction
- Nutritional or environmental chemical substances and maternal medication
- Low socioeconomic level

**Foetal**

- Congenital malformations, deformations and chromosomal abnormalities
- Disorders related to foetal growth like IUGR
- Prematurity

**Placenta, cord and membranes**

- Placenta dysfunction, infarction, insufficiency
- Prolapsed cord, other compression of umbilical cord
- Oligohydramnios/polyhydramnios
- Preterm rupture of membranes

**Labour and delivery**

- Malpresentation, malposition and disproportion during labour and delivery
- Preterm labour and delivery
- Emergency caesarean section
3.4.4. Perinatal death and its grief

Unauthorized or silent grief is not openly recognized in society. It is hidden for fear of discrimination, contempt for humiliation or shame (10). When the loss is socially recognized, the person is allowed to express their feelings openly, and share their pain, which facilitates its healthy and constructive process. Consequently, people who have lived this kind of experiences have more probabilities to develop pathological grief.

A perinatal death is a clear case that could be presented as an unauthorized grief where neither mother nor father can express their feelings to their environment or if they do it, they are not understood (14). That is why these parents are at risk of developing a complicated grief disorder.

Some risk factors for developing a pathological grief when a perinatal loss occur are (9) previous psychiatric problems, not having children, not having relatives, social or partner support, scarce information about the loss, no explanation for what happened, recurrent losses, current history of depression or coincidence with other important vital problems.
Preventing perinatal grief from becoming a pathological process is a function of healthcare professionals, who must be trained to face the grieving process, focusing not only on the expression of feelings but on helping to overcome each of the phases that appear in the person suffering the grief. It is important to keep in mind as a professional, that the intervention must be careful not to intervene in the normal human process (5,7,20,21).

Some recommendations and useful information given to families in HUJT (Hospital Universitari Josep Trueta) are provided in the Annex 1.

The communication of the news is a very important moment and families will always remember the treatment received by health professionals, at this time and throughout the process. That is why it is essential to offer empathetic attention, good communication with signs of affection and respect, availability for their questions and acceptance of their feelings (7). Appropriate vocabulary should be used, as well as actions that validate the loss such as the collection of memories of the deceased child (7,14,17,21). The Remembrance cards used in HUJI are shown in Annex 2.

The lack of social support is very common in this situation. Recently in some hospitals, support groups were created such as grief group “Bressols” in Girona and “Espai de Paraula” in Barcelona. These groups are formed by parents and qualified professionals in order to help during the grieving process. In the group, an appropriate environment is created to speak clearly about feelings and ideas and what the loss represents in their life, in a safe and trustful environment, because no one will judge their negativity, but they will be accepted and included (7,14,21). Further information about grief groups is provided in Annex 3.
Another undervalued aspect is the early detection of psychiatric disorders. Anxiety Disorder is very common in a working society with 4.18 on average \(^2\) (INE, 2018). This could be an important risk factor that could alter the normal grieving process, especially for women in reproductive age\(^{(22)}\). DSM-5 classifies Anxiety Disorder into 11 different types (Table 3).

**Table 3. Summary presentation of the central clinical features for the different Anxiety Disorders included in the DSM-5 (adapted from \((23))\).**

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Central clinical features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Separation Anxiety Disorder</td>
<td>Intense fear/anxiety (≥6 months in adults) relative to have to separate from a dear person. ≥3 clinical manifestations with concern, distress, refusal to stay home alone / move to other places, nightmares or physical symptoms.</td>
</tr>
<tr>
<td>Selective mutism</td>
<td>Persistent (≥1 month) inability to speak or respond to others in a specific social situation in which it is expected to be done. It is done without problems in other situations.</td>
</tr>
<tr>
<td>Specific phobia</td>
<td>Appearance of intense fear/anxiety and persistent (≥6 months), almost immediate and invariable with respect to a specific object/situation, which is avoided or endured at the expense of intense fear-anxiety.</td>
</tr>
<tr>
<td>Social Anxiety Disorder</td>
<td>Intense fear/anxiety that usually appears in social situations in which the person is exposed to possible scrutiny by others. The person fears to act in a certain way or show anxiety symptoms. Duration ≥6 months.</td>
</tr>
<tr>
<td>Distress Disorder</td>
<td>Presence of unexpected recurrent crises of distress. At least one of them is followed by a month of persistent concern or concern about the emergence of new crises or their consequences, and/or a significant and maladaptive change in behaviour related to distress crises.</td>
</tr>
</tbody>
</table>

\(^2\) The level of stress at work is measured on a scale of 1 (not stressful) to 7 (very stressful).
<table>
<thead>
<tr>
<th>Disorder</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agoraphobia</strong></td>
<td>Fear/anxiety usually appears regarding prototypical agoraphobic situations (public transport, open places, closed places, queuing or being in the crowd, and / or being alone outside). The person fears or avoids these situations for fear of having difficulty escaping or being helped. Duration ≥6 months.</td>
</tr>
<tr>
<td><strong>Generalized Anxiety Disorder</strong></td>
<td>Excessive anxiety/worry, persistent (≥6 months) and with difficulty controlling various events or activities that are associated with ≥3 symptoms of physiological overactivation.</td>
</tr>
<tr>
<td><strong>Substance / medication induced Anxiety Disorder</strong></td>
<td>Symptoms (presence of anxiety or anxiety crisis) develop during or shortly after poisoning or withdrawal of a substance. They do not occur exclusively during delirium.</td>
</tr>
<tr>
<td><strong>Due to another medical illness</strong></td>
<td>Presence of anxiety/anxiety crisis, with evidence that this is a direct pathophysiological consequence of another medical condition. They do not occur exclusively during delirium.</td>
</tr>
<tr>
<td><strong>Other specified Anxiety Disorder</strong></td>
<td>Presence of clinically significant symptoms characteristic of an AD that do not meet all the diagnostic criteria of any of these disorders. The specific reason why not all diagnostic criteria are met can be specified.</td>
</tr>
<tr>
<td><strong>Not specified Anxiety Disorder</strong></td>
<td>Presence of clinically significant symptoms characteristic of an AD that do not meet all the diagnostic criteria of any of these disorders. The specific reason why not all diagnostic criteria are met cannot be specified.</td>
</tr>
</tbody>
</table>
4. JUSTIFICATION

Perinatal grief, despite having a prevalence to consider in our environment, is an under-studied topic. This is because it integrates different taboo issues (16,23): death of a child, women sexuality and mental health.

It is considered that the causes of the losses are underdiagnosed and many of them are not registered (17,20). Some causes are that they occur outside the health field and the Spanish Civil Registry (BOE-A-2011-12628) only allows the inclusion of perinatal deaths if they are >180 days of gestation. Therefore, the available data may not show the real prevalence of the event.

Nowadays, the vast majority of hospitals in Spain have a lack of perinatal death protocols (14,15,17,24). For this reason, medical staff is not sufficiently well trained and experienced in this area and they cannot correctly carry out different aspects that must be addressed when a perinatal death occurs (14,20).

Families who have suffered it usually mention that they did not receive the necessary information at the moment of loss (20,25). This makes many of them feel desolate and not knowing how to handle the grief. They explain that due to lack of information they could not make right decisions in that moment. For example, seeing the body, asking for the necropsy or burying their child.

In addition, they do not feel socially supported, so some grieving groups have been created (7,15,21). The effectiveness of these groups in the grieving process are not currently studied, as well as the mental health of the parents who go through this process.

Anxiety Disorder is increasingly prevalent in our environment (INE, 2018) and may be a potential risk to develop a complicated grief disorder in these cases (1,4,9,10,17).
This situation encourages to improve diagnose, follow-up care, and treatment of pathological grief in families who have suffered a perinatal death, especially in the field of mental health. It is also carried out to raise awareness about the importance of performing protocols for perinatal death and for its correct application.
5. HYPOTHESIS AND OBJECTIVES OF THE STUDY

HYPOTHESIS

Patients who have suffered a perinatal death and attend support group during the grieving process suffer from less Anxiety Disorder than patients who do not attend these groups.

OBJECTIVES

Main objective

This study aims to evaluate if the patients who have suffered a perinatal death and attend a support group have less at risk of developing an Anxiety Disorders than patients who do not attend these groups.

Secondary objectives

1. To study the prevalence of Anxiety Disorder in patients who have suffered a perinatal death in total and by gender.
2. To describe the type of Anxiety Disorder according to the kind of loss and weeks of gestation.
3. To describe the causes of perinatal deaths.
4. To study the consumption of toxics in parents who suffered a perinatal loss.
5. To give visibility to perinatal death.
6. MATERIAL AND METHODS

6.1. Study design

This study is designed as a prospective observational study.

6.2. Study setting

This study is designed to be multicentre.

The study will be implemented in the hospitals that have a perinatal death protocol and support groups that collaborate with Mémora Funeral Services.

In Girona, these hospitals will be Hospital Universitari Josep Trueta (HUJT) and Hospital Santa Caterina (HSC). In Barcelona, the only hospital that meets these requirements is the Hospital Universitari Vall d’Hebron (HUVH).

The estimated time of recruitment is approximately 1 year, in order to achieve an adequate sample size which results represent the population. The next 2 years of the study will be used to perform the rest of the procedures.

6.3. Study population

The study population will be all patients who have suffered a perinatal death admitted in HUJT, HSC and HUVH, that fulfill the following requirements:

6.3.1. Inclusion criteria

1. Parents who have suffered at least 1 perinatal death.
2. Age ≥18 years old.

6.3.2. Exclusion criteria

1. Parents who have not suffered any perinatal death.
2. Patient diagnosed with anxiety disorder before suffering perinatal loss.
3. Age <18 years old.
4. Patients transferred from another medical centre.
6.4. Sample

6.4.1. Sample selection

The sample selection technique is based on non-probabilistic sampling. The sample will be composed by 2 groups:

- **Case group**: The sample that have suffered a perinatal loss and attends support groups in the health centres of Girona (HUJT and HSC) or Barcelona (HUVH).
- **Control group**: The sample that have suffered a perinatal loss and does not attend groups in the health centres of Girona (HUJT and HSC) or Barcelona (HUVH).

Cases and controls will be matched by the mother’s age or father’s age with a range of 2 years.

6.4.2. Sample size

The sample size is performed through a bilateral contrast with a level of alpha significance of 5% and a power of 80%, assuming a prevalence of 3.98‰ live births in Catalonia’s registration (INE, 2019).

345 cases and 345 controls will be needed. Assuming a 10% withdrawal would result in a sample of 380 cases and 380 controls.

Computations were carried out with the Prof. Dr. Marc Saez’s software based on the power library of the free statistical environment R (version 3.6.2).

6.5. Variables and methods of measurement

The data for the 2 study groups, case and control groups, will be collected prospectively by completing different questionnaires (Annexes 4-7) and data collection sheet (Annex 8).

The case group will consist of patients who assist perinatal loss groups. Controls will be obtained from those patients who accept participation in the study but do not attend support groups during the data collection process.
6.5.1. Main variables

6.5.1.1. Dependent variable

It is “Anxiety Disorder”. It will be studied with Trait State Anxiety Questionnaire [STAI] (26). The questionnaire consists of 2 parts, one to study Anxiety Disorder as a state and the other as a trait. Each part has 20 questions. The questionnaire is attached in Annexes 4 and 5.

To facilitate the interpretation of the STAI scale results, some authors have submitted the score in each subscale:

Table 4. Distribution of State Trait Anxiety Inventory (STAI) scores in each subscale (27).

<table>
<thead>
<tr>
<th>State-STAI or Trait-STAI Scores</th>
<th>Equivalents in percentiles</th>
</tr>
</thead>
<tbody>
<tr>
<td>High level anxiety &gt; 65</td>
<td>94–99</td>
</tr>
<tr>
<td>Moderate high anxiety 56–65</td>
<td>70–93</td>
</tr>
<tr>
<td>Medium anxiety 46–55</td>
<td>32–69</td>
</tr>
<tr>
<td>Minor anxiety 36–45</td>
<td>8–31</td>
</tr>
<tr>
<td>Low level anxiety &lt; 35</td>
<td>1–7</td>
</tr>
</tbody>
</table>

To simplify the results, these numerical values will become dichotomous values (Absence/Presence) being:

- **Absence**: <35-45 points
- **Presence**: 46- >65 points

The results will be expressed as percentages.

6.5.1.2. Independent variable

It is “Attend support groups for families who have suffered a perinatal loss”. It will be studied as a dichotomous variable (Yes/No).

It will be expressed as a percentage.

6.5.2. Covariates

- **Age**: It is a continuous quantitative variable. It will be collected from patient’s ID card or other valid documents during admission, such as medical history. It will be expressed in years, calculating its mean and standard deviation.
• **Gender:** It is a nominal qualitative variable (Male/Female/Unknown). It will also be collected from patient’s ID card or another valid document. It will be expressed as a percentage.

• **Approximate socioeconomic status by educational level and employment:** It is a qualitative ordinal polytomous variable (28,29). The information will be collected from the Pregnant card, for both women and men. It will be expressed as a percentage for each category (High, Medium and Low).

• **Number of children:** It is a discrete quantitative variable. It will be collected from the family book and will be expressed as “Number of children alive”. It will be expressed as a mean and standard deviation.

• **Gestation age:** It is a discrete quantitative variable. It will be collected from the Pregnant card. It will be expressed as a mean and standard deviation.

• **Cause of perinatal loss:** It is a nominal qualitative variable. Information will be collected from fetal necropsy, fetal genetic study, anatomopathological study of the placenta and gynecological (30) and obstetric history of the mother during pregnancy (clinical history or Pregnant card). It will be expressed as a percentage.

• **Recurring perinatal deaths:** It is a discrete quantitative variable. It will be collected from gynaecological and obstetric records of women or pregnant card. It will be expressed as a mean and standard deviation.

• **Toxic consume (tobacco and alcohol):** It is a nominal dichotomous qualitative variable (Yes/No). The consumption of these 2 drugs will be collected through validated questionnaires:
  - Questionnaires for **tobacco** consumption: Fagerström test and Richmond test (Annex 6).
  - Questionnaires for **alcohol** consumption: CAGE test and AUDIT test (Annexes 7).

It will be presented as a percentage for each of these 2 substances.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Type</th>
<th>Categories</th>
<th>Measure instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dependent variable</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Anxiety Disorder | Nominal dichotomous qualitative | Absence/Presence | Trait State Anxiety Questionnaire [STAI]:  
- **Absence**: <35-45 points  
- **Presence**: 46- >65 points |
| **Independent variable** | | | |
| Attend support groups for families who have suffered a perinatal loss | Nominal dichotomous qualitative | Yes/No | Attendance lists |
| **Covariables** | | | |
| Age | Continuous quantitative | Numbers of years | ID card or other valid documents |
| Gender | Nominal qualitative | Male/Female/Unknown | ID card or other valid documents |
| Approximate socioeconomic level for educational level and employment | Qualitative ordinal polytomous variable | High, Medium and Low | Pregnant card |
| Number of children | Discrete quantitative | Number of children alive | Family book |
| Gestation age | Discrete quantitative | Weeks of gestation | Pregnant card |
| Cause of perinatal loss | Nominal qualitative | Foetus cause/ Maternal cause/ Placental cause/ Delivery’s causes/ Unknown | Foetal necropsy, foetal genetic study, anatomopathological study of the placenta, women’s medical history or Pregnant card |
| Recurring perinatal deaths | Discrete quantitative | Number of perinatal deaths | Gynaecological and obstetric records of women or Pregnant card |
| Toxic consume (tobacco and alcohol) | Nominal dichotomous qualitative | Yes/No |  
- **Tobacco**: Fagerström test and Richmond test  
- **Alcohol**: CAGE test and AUDIT test. |
6.6. Method of data collection

The data of case group and control group will be collected prospectively by a multidisciplinary team during a maximum period of time of 12 months.

The data collection sheets and questionnaires will be distributed among the HUJT, HSC and HUVH interviewers.

Potential patient will be obtained for the study when a perinatal death occurs.

The maternal-child clinical psychologist (or the expert nurse if there is no maternal-child clinical psychologist in the centre, as in HSC) will inform the patient about the study. If there is interest in the participation of the study, the psychologist will contact the centre interviewer. The interviewer will give the necessary information and ask for consent (Annex 9).

In the case of accepting participation in the study, a visit will be made with the interviewer to collect data and to fill the questionnaires. The questionnaires will be filled at the time of perinatal loss, 1 month later, 3 months later and 6 months later.

An identification code will be assigned to each patient which will remain constant throughout the process.

It is important that the patient is informed about the existence of support groups for perinatal loss. Assistance to support groups for perinatal losses allows classification as group cases. Not attending these groups allows classification as control group.

It is essential that interviewers do not know if participants are part of the control group or case group. Therefore, the only person responsible for collecting group attendance sheets and classifying patients into the 2 groups, will be the principal investigator.

The interviewer will follow the evolution of the patient during these 6 months. If Anxiety Disorder is detected by the STAI questionnaires, the patient must be referred to a psychiatrist. If the diagnosis is verified, the type of Anxiety Disorder should be specified.

All the data of the members of the study will be registered in a particular database of each centre. Then, the principal investigator of the study will obtain all the data and analyse it.
7. STATISTICAL ANALYSIS

This study is a descriptive analysis that will summarize the relationship of the dependent variable (Anxiety Disorder) and the independent variable (assistance to support groups for families who have suffered perinatal loss) using contingency tables.

Secondary objectives will also be summarized with proportions.

7.1. Descriptive analysis

The dependent variable “Anxiety Disorder” will be summarized in a table of contingency, stratifying by the groups of the independent variable “Attend support groups for families who have suffered a perinatal loss”, by means of proportions. This table will be also stratified by the covariables. When the covariable was quantitative it would be categorized in quartiles.

Although “number of children” and “number of perinatal losses” are discrete variables, they have a very small range and therefore I will treat them as qualitative variables.

7.2. Bivariate analysis

The relationship between the dependent variable and the independent variable will be assessed with chi-square ($x^2$) test and Fisher's exact test, if the expected frequencies in any cell were less than 5.

This analysis will be also stratified by the covariables. When the covariable was quantitative it would be categorized in quartiles.

7.3. Multivariate analysis

The relationship between the dependent and the independent variables will be adjusted in a logistic regression controlling for all covariables.

IBM SPSS® Statistics will be the software package that will be used for statistical analysis. To manage the calculated data, the Microsoft Excel tool will be used.

It will be considered all the statistically significant variables if the value of $p<0.05$. 
8. STUDY LIMITATIONS

This study is not based on a random sample, it is a non-probabilistic study. The optimal strategy to overcome this problem would be to randomize the sample. However, since perinatal death is a rare event, this cannot be done. To avoid random biases, a multicentre study will be carried out even though this increases the cost.

In relation to control group, it will be composed by those patients who have suffered a perinatal death but have decided not to attend support groups. It must be explained that once the decision to not to participate in the support groups, it should be maintained throughout the data collection process, otherwise this could lead to a sample selection bias. This selection bias could lead to some errors in the analysis and discussion of the results.

Withdrawal and losses during follow-up may cause selection bias. They will be registered. To avoid this bias, the sample size has been calculated with expectations of future losses and withdrawals. In addition, the importance of continuing to participate in the study will be explained to the participants. Proper follow-up of people through visits with the interviewer and calls could avoid abandoning the study.

In order to avoid the interviewer’s bias, only the responsible investigator will know which group each participant belongs to, since she/he will be the only one who will collect and review the attendance lists to the support groups.

An information bias related to the diagnosis of Anxiety Disorder could be established, so if there is a suspicion of this possible diagnosis after completing the STAI questionnaire, the patient must be referred to a psychiatrist.

Data loss could occur because the interviewers do not introduce it in the data base system. Therefore, it will be explained that all data must be introduced in the system after finishing the visits with the participants.
Multiple confounding factors may influence association between dependent and independent variables. Confusions will be trying to prevent by a multivariate analysis.

Being a prospective case study and control, associations and prevalence can be calculated. The passage of time can introduce changes in the methods and criteria of the study.
9. ETHICAL CONSIDERATIONS

This study will be carried out in accordance with the four basic ethical principles (respect, justice, no maleficence and beneficence) and with the requirements expressed in the Helsinki Declaration of Ethical Principles for Medical Research in Human Beings signed by the World Medical Association in 1964 and last revised in October 2013. The study will also be submitted to the Clinical Research Ethics Commission (CEIC) of each of the participating centres.

Before beginning any study procedure and for a patient to enter the study, they must have been informed correctly, have time to contemplate participation and freely read and sign the informed consent (Annex 8).

The patient’s autonomy must be respected, not only before entering the trial, but at all times.

Patient data anonymity will be guaranteed to preserve patient confidentiality. Patient anonymity and rights will be based on the Organic Law 3/2018, 5th of December, protection of Personal Data and guarantee digital rights. It will also be regulated by the order the Basic Law 41/2002 on the autonomy of the patient and rights and obligations with regard to clinical information and documentation and the Royale Decree 1090/2015, of the 24th of July, on Biomedical Research.

The patient’s confidentiality will be preserved using codes to identify the patient instead of their names. Only the principal investigator will know the relation between the inclusion codes and the patient’s name. Content of the database will be encrypted.

All investigators of this study will have to declare conflict of interest if they exist.
10. CLINICAL AND HEALTHCARE IMPACT

The death of a child is an emotionally very difficult process that families will remember throughout their lives. It is unacceptable that parents have to suffer this situation feeling alone and unprotected, since in many health centres attention is not provided to parents who go through this process. In addition, today's society does not usually understand the grief for the death of a baby and therefore, the perinatal grief can be unauthorized.

To provide adequate assistance to these families during grief, it is essential that health personnel be familiar with the normal grieving process. It must be transmitted that grief is a normal, personal and non-transferable process (14,17). Giving the necessary advices and show the availability of the team to answer doubts or concerns is highly recommended.

There must also be taken into account the signs, symptoms and complications that this process may present. Being able to detect, diagnose, treat and follow-up correctly these complications can prevent the development of a pathological grief, which can lead to psychiatric disorders such as AD or SUD.
11. WORK PLAN

The research team will be coordinated by the responsible investigator. This team will be formed by the maternal-child clinical psychologist, an expert nurse of HSC, psychiatrists and interviewers. The study will be carried out in 8 phases:

- **Stage 0 “Study design” (September-November 2019):** Time spent for performing the protocol. It took 3 months, from September to November 2019. It has been done for the responsible investigator.

- **Stage 1 “Ethical evaluation” (December 2019-January 2020):** The protocol will be presented for evaluation to Clinical Research Ethics Committee (CEIC) of every hospital (HUJT, HSC and HUVH). It will be carried out in 2 months.

- **Stage 2 “Meeting, instruction and purchase of material” (February-April 2020):** This period will last 3 months. Multidisciplinary meetings will be held with the responsible investigator and mother-child psychologists, as well as the expert nurse, to explain the study and how to inform potential patients of the study. The responsible investigator will also explain to the interviewers the work methodology and how to enter the data into the program.

  As for the material, the necessary photocopies of the questionnaires, the data collection sheets, the informed consents and the information sheets for the patients and for the interviewers must be delivered.

- **Stage 3 “Patients recruitment” (May 2020-May 2021):** For 12 months, potential patients will be recruited to be members of the study. The mother-child clinical psychologist (or the expert nurse in HSC) will inform the parents about the study. If there is interest in the participation of the study, the interviewer will explain the study and ask for consent. During the visits data will be collected and the questionnaires will be carried out.

- **Stage 4 “Data compilation” (June -July 2021):** Interviewers should enter the data collected at the end of each visit. The responsible researcher must collect the information of the 3 participating centres in a single database. It will last 2 months.
• **Stage 5 “Statistical analysis” (August-September 2021):** The statistical analysis of the study will be carried out by a qualified statistic and with the proper software. This process will last 2 months.

• **Stage 6 “Interpretation of the results” (October-December 2021):** The research team will meet to analyze, interpret and discuss the results. These procedures will last 3 months.

• **Stage 7 “Dissemination of the results” (January-March 2022):** The study information will be disseminated. This period will last 3 months. It is proposed to attend congresses related to Anxiety Disorder. Some of the most relevant are:
  - Perinatal Mental Health Day of the Marcé Spanish Society
  - 13th International Congress and 18th National of Clinical Psychology

• **Stage 8 “Publication of the results” (April-June 2022):** For the publication of the results it will be used 3 months.

Some journals of interest where it could be published are:

- Annals of Psychology
- Spanish Psychiatry Acts
- Anxiety and Stress journal (SEAS)
12. **BUDGET**

The following table details the estimated budget for the study:

<table>
<thead>
<tr>
<th>ITEMS</th>
<th>CATEGORY</th>
<th>COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel costs</td>
<td>Project manager (4h/week x 12 months)</td>
<td>48 € x 52 weeks x 25 € = <strong>5200 €</strong></td>
</tr>
<tr>
<td></td>
<td>3 Interviewer (one of each centre) (4h/week x 12 months)</td>
<td>63 € x 52 weeks x 6 € x 3 interviewers = <strong>5616 €</strong></td>
</tr>
<tr>
<td></td>
<td>Statistical consultant (4h/week x 2 months)</td>
<td>48 € x 8 weeks x 35 € = <strong>1120 €</strong></td>
</tr>
<tr>
<td></td>
<td>Translator</td>
<td>150 €/Article = <strong>150 €</strong></td>
</tr>
<tr>
<td>Resource cost</td>
<td>Paperwork (information sheet, informed consent printing and questionnaires)</td>
<td>30 photocopies x 850 ppl x 0,05 € = <strong>1275 €</strong></td>
</tr>
<tr>
<td>Dissemination of the results</td>
<td>Perinatal Mental Health Day of the Marcé Spanish Society</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Incription fee</td>
<td>65 € x 2 = <strong>130 €</strong></td>
</tr>
<tr>
<td></td>
<td>-Travel</td>
<td>40 € x 2 = <strong>80 €</strong></td>
</tr>
<tr>
<td></td>
<td>-Food expenses</td>
<td>90 € x 2 = <strong>180 €</strong></td>
</tr>
<tr>
<td></td>
<td>13th International Congress and 18th National of Clinical Psychology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Incription fee</td>
<td>300 € x 2 = <strong>600 €</strong></td>
</tr>
<tr>
<td></td>
<td>-Travel</td>
<td>400 € x 2 = <strong>800 €</strong></td>
</tr>
<tr>
<td></td>
<td>-Food expenses</td>
<td>300 € x 2 = <strong>600 €</strong></td>
</tr>
<tr>
<td></td>
<td>-Accommodation</td>
<td>300 € x 2 = <strong>600 €</strong></td>
</tr>
<tr>
<td>Publication of the results</td>
<td>-Annals of Psychology</td>
<td>1000 € (for each publication) x 3 = <strong>3000 €</strong></td>
</tr>
<tr>
<td></td>
<td>-Spanish Psychiatry Acts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Anxiety and Stress journal (SEAS)</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>19351 €</strong></td>
</tr>
</tbody>
</table>

Responsible investigator, mother-child clinical psychologists, expert nurse and psychiatrists will not receive any financial compensation for the participation in the study.
13. BIBLIOGRAPHY AND REFERENCES


18. Lawn JE, Kinney M. Muerte fetal intrauterina. Lancet Glob Heal [Internet].


ANNEXES

ANNEX 1. TRYPIC WITH RECOMMENDATIONS: WHAT CAN YOU EXPECT AFTER THE DEATH OF YOUR CHILD?

Desitgem que aquesta informació us ajudi a comprendre el que esteu vivint i que el nostre acompanyament us permeti fer un procés natural del vostre dol.

Si esteu llegint aquesta publicació, probablement hagueriu sortit recentment del vostre nadiu. L’esperem profundament aquesta perda.

Volem explicar-vos que el que sentiu ara mateix es comprehénsible en una situació com la vostra. Sentir dolor, estar en un del per un efecte d’un béi és molt natural i, a mesura que paseu els dies, un poc semblar que això es va sentir a un somni, quedar-se assolit o culpa envoltat podria tenir estances d’una enorme tensió i games de pilar.

Les reactions al dolor són molt diferents. És probable que caigui experiència d’alts o baixs formen les emocions i els sentiments davant d’aquesta situació.

La mort d’un fill és sempre perdua, el temps no l’elimina. El vostre nadiu és el seu i sempre ho serà, és part de la vida vostè. Però el dolor tan fort que podiu sentir durant els primers dies deixar pàs a moments més suaus i, encara que fuguessin sempre present el vostre nadiu, un dia, no saber quan, podreu tornar a sentir plers per les coses senceres de la vida.

Naixement del vostre fill
- La llavora i la morta estaràn amb vosaltres durant el procés del part i el naixement. Els va explicar què estau passant en tot moment i les vostres explotaran els dubtes que poguem anar surgint.
- La psicologia us rellotarà emocionalment si ho desitguen.
- La majoria de vegades s’hi troben el naixement al matí, al qual podria afegir-se un estat del matí.
- És important que sigui aconseguida. Si no és possible, podreu haver-hi un moment més curt.
- Si voleu, és possible que un familiar us acompanyi en aquest moment.
- L’experiència de les famílies que han passat per aquesta situació i els estudis científics reconeixen veure i acompanyar-vos del vostre fill i crear records.

Pujada de la llit
- Comença a tornar tot després del naixement del seu fill i segueix l’estat gestacional. Existeixen diferents opcions:
  - Pujar la pujada de la llit: medicació o means no farmacològiques.
  - No anar la pujada de la llit: donació de llit materna o anar l’admetre en cas d’estar allant altres fills.
- La llavora us orientarà sobre això que podeu fer en el vostre cas.

Quan arribau a casa
- No és el moment de decidir qui fer amb això que havíeu preparat per a l’arribada del seu fill. Aquesta decisió podria prendre la més endavant.
- Eliminar els records no ajudarà a l’elaboració del vostre fill. S’arrela la decisió tot com està i quan us veureu amb prou forces, vosaltres decidireu què veureu amb les coses del vostre fill. És un moment dur, però us ajudarà a aconseguir en el procés del dol.

Amistats i familiars
- És possible que us sembi que el seu entorn no us comparteixi o no us adhiu prou. De vegades, podreu intentar minimitzar el procés que estueu vivint. És convenient que els siguiu com veueu que us ajudin o quines coses no us agraden perqué, podre, no saben com ho ho.
- A nivell social es un dels poc reconeguts. Tot i així, per a vosaltres, és un dels més importants i que veureu ser elaborat.
ANNEX 2. REMEMBRANCE CARDS.
ANNEX 3. GRIEF GROUP “BRESSOLS” AND “ESPAI DE PARAULA”.

**grup de dol “Bressols”**

Aquest és un espai on poden expressar les emocions que desperta la pèrdua i poder compartir-les amb altres marxes i pares que han passat pel mateix.

Amb l'esperança de integrar-les i simplificar-les per poder adequar el dol de la millor manera.

Professional responsable:

Natàlia Artigas, psicòloga

**Horaris d'obertura:**
- Dies: El primer divendres del mes de 17:00 a 19:00 hores.
- El tercer divendres del mes de 18:30 a 20:00 hores.
- Lloc: Espai de Suport Mèmora Girona
  
  
  **Insepció pòstum:**
  
  Per correu electrònic: natatiaartigas@espc.cat

Per telèfon 049 112 198

---

**mémora**

**Compromesos amb la salut**

**ESPAI DE PARAULA**

"Espai de Paraula" és un projecte que neix amb l'objectiu de crear espais de reflexió on poder expressar i compartir les emocions que desperta el dol perinatal, derivat de la mort durant la gestació o els primers 28 dies de vida. Aquest programa es desenvolupa a l'Hospital Universitari Vall d'Hebron pels Serveis de Ginecologia i Obstetrícia i Neonatologia, amb el suport de Mémora.

Actualment hi ha dos grups, un per als professionals i un altre per a pares i marxes. El primer, està format per professionals de les Units d'Obstetrícia i Neonatologia, els que atanenc cases de maternitat agudes, molt grans, croniques o limitants, alguns dels quals morien durant el seu ingerés. Compartir amb aquest espai de reflexió i suport psicològic els permet compartir experiències, començar les seves vivències en grup i aprendre per afrontar futures situacions i millorar l'atenció per a les marxes i famílies. En el cas dels pares i famílies, després de la defunció, viuen el que és començament del perinatal, necessiten parlar amb altres pares i compartir el seu dolor amb altres persones que es trobin en la seva mateixa situació que amb freqüència se senten poc compresos pel seu entorn habitual.

- El projecte Espai de Paraula d'atenció al del perinatal guanyat al Premis Humanitzant la Sanitat de Teva. Lligar nota de premsa i veure vídeo.
**ANNEX 4. TRAIT STATE ANXIETY QUESTIONNAIRE [STAI], FORM Y-1.**

**SELF-EVALUATION QUESTIONNAIRE [STAI Form Y-1]**

Please provide the following information:

<table>
<thead>
<tr>
<th>Name</th>
<th>Date</th>
<th>S</th>
</tr>
</thead>
</table>

**Age | Gender (Circle) | M | F | T |
|------|----------------|----|----|----|

**DIRECTIONS:**
A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

1. I feel calm
2. I feel secure
3. I am tense
4. I feel strained
5. I feel at ease
6. I feel upset
7. I am presently worrying over possible misfortunes
8. I feel satisfied
9. I feel frightened
10. I feel comfortable
11. I feel self-confident
12. I feel nervous
13. I am jittery
14. I feel indecisive
15. I am relaxed
16. I feel content
17. I am worried
18. I feel confused
19. I feel steady
20. I feel pleasant

© Copyright 1968, 1977 by Charles D. Spielberger. All rights reserved.

SELF-EVALUATION QUESTIONNAIRE
STAI Form Y-2

Name_________________________ Date____________________

DIRECTIONS
A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

21. I feel pleasant................................................................. 1 2 3 4
22. I feel nervous and restless .................................................. 1 2 3 4
23. I feel satisfied with myself.................................................. 1 2 3 4
24. I wish I could be as happy as others seem to be.................... 1 2 3 4
25. I feel like a failure............................................................. 1 2 3 4
26. I feel rested................................................................. 1 2 3 4
27. I am "calm, cool, and collected"........................................ 1 2 3 4
28. I feel that difficulties are piling up so that I cannot overcome them 1 2 3 4
29. I worry too much over something that really doesn’t matter. 1 2 3 4
30. I am happy................................................................. 1 2 3 4
31. I have disturbing thoughts.................................................. 1 2 3 4
32. I lack self-confidence...................................................... 1 2 3 4
33. I feel secure ................................................................. 1 2 3 4
34. I make decisions easily .................................................... 1 2 3 4
35. I feel inadequate............................................................. 1 2 3 4
36. I am content ................................................................. 1 2 3 4
37. Some unimportant thought runs through my mind and bothers me 1 2 3 4
38. I take disappointments so keenly that I can’t put them out of my mind 1 2 3 4
39. I am a steady person...................................................... 1 2 3 4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests 1 2 3 4

© Copyright 1969, 1977 by Charles D. Spielberger. All rights reserved.
Published by Mind Garden, Inc., 1690 Woodside Rd, Suite 202, Redwood City, CA 94061
www.mindgarten.com

STAI-A0 Test Form Y
ANNEX 6. QUESTIONNAIRES FOR TOBACCO CONSUMPTION (Fagerström and Richmond tests).

**Fagerstrom Test for Nicotine Dependence**

| PLEASE TICK (✓) ONE BOX FOR EACH QUESTION |  
|------------------------------------------|---|
| How soon after waking do you smoke your first cigarette? | Within 5 minutes □ 3  
6-30 minutes □ 2  
31-60 minutes □ 1  
After 60 minutes □ 0  
| Do you find it difficult to refrain from smoking in places where it is forbidden? e.g. Church, Library, etc. | Yes □ 1  
No □ 0  
| Which cigarette would you hate to give up? | The first in the morning □ 1  
Any other □ 0  
| How many cigarettes a day do you smoke? | 10 or less □ 0  
11 - 20 □ 1  
21 - 30 □ 2  
31 or more □ 3  
| Do you smoke more frequently in the morning? | Yes □ 1  
No □ 0  
| Do you smoke even if you are sick in bed most of the day? | Yes □ 1  
No □ 0  

**SCORE**

1-2 = low dependence  
3-4 = low to mod dependence  
5-7 = moderate dependence  
8+ = high dependence

Add up the scores from the questionnaire.

Information about scoring the Test is on the next page.

**TEST DE RICHMOND**

Este cuestionario valora la motivación para dejar de fumar

Nombre:

Por favor, conteste a las siguientes preguntas, con la máxima sinceridad

1. ¿Quiere dejar de fumar?

0 No □  
1 Sí □

2. ¿Con qué ganas quiere dejarlo?

0 Nada □  
1 Poca □  
2 Bastante □  
3 Mucha □

3. ¿Intentará dejarlo en las próximas semanas?

0 No □  
1 Dudo □  
2 Probable □  
3 Sí □

4. ¿Cree que dentro de 6 meses no fumará?

0 No □  
1 Dudo □  
2 Probable □  
3 Sí □

Puntuación total:

**Interpretación del resultado:**

- Motivación máxima: 7-10
- Motivación moderada: 4-6
- Motivación baja: ≤ 3
ANNEX 7. QUESTIONNAIRES FOR ALCOHOL CONSUMPTION (CAGE AND AUDIT TESTS).

CAGE Questionnaire

- Have you ever felt you should cut down on your drinking?
- Have people annoyed you by criticizing your drinking?
- Have you ever felt bad or guilty about your drinking?
- Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover (eye opener)?

**Scoring:**

Item responses on the CAGE are scored 0 or 1, with a higher score an indication of alcohol problems. A total score of 2 or greater is considered clinically significant.

---

### The Alcohol Use Disorders Identification Test: Interview Version

Read questions as written. Record answers carefully. Begin the AUDIT by saying “Now I am going to ask you some questions about your use of alcoholic beverages during this past year.” Explain what is meant by “alcoholic beverages” by using local examples of beer, wine, vodka, etc. Code answers in terms of “standard drink.” Place the correct answer number in the box at the right.

<table>
<thead>
<tr>
<th>Question</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often do you have a drink containing alcohol?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) Never (1) Skip to Q6 (2) 1 or 2 drinks (3) 3 or 4 drinks (4) 5 or 6 drinks (5) 7, 8, or 9 drinks (6) 10 or more drinks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. How many drinks containing alcohol do you have on a typical day when you are drinking?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) 1 or 2 (1) 3 or 4 (2) 5 or 6 (3) 7, 8, or 9 (4) 10 or more</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. How often do you have six or more drinks on one occasion?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) Never (1) 1 time a month (2) 2 times a month (3) 3 times a month (4) 4 or more times a month</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. How often during the last year have you found that you were not able to stop drinking after a heavy drinking session?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### The Alcohol Use Disorders Identification Test: Self-Report Version

**PATIENT:** Because alcohol use can affect your health and can interfere with certain medications and treatments, it is important that we ask some questions about your use of alcohol. Your answers will remain confidential so please be honest. Place an X in one box that best describes your answer to each question.

<table>
<thead>
<tr>
<th>Question</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often do you have a drink containing alcohol?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) Never (1) Skip to Q6 (2) 1 or 2 times a week (3) 2-3 times a week (4) 4 or more times a week</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. How many drinks containing alcohol do you have on a typical day when you are drinking?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) 1 or 2 (1) 3 or 4 (2) 5 or 6 (3) 7, 8, or 9 (4) 10 or more</td>
<td>1 or 2</td>
<td>3 or 4</td>
<td>5 or 6</td>
<td>7 to 9</td>
<td>10 or more</td>
</tr>
<tr>
<td>3. How often do you have six or more drinks on one occasion?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) Never (1) 1 time a month (2) 2 times a month (3) 3 times a month (4) 4 or more times a month</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. How often during the last year have you found that you were not able to stop drinking after a heavy drinking session?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(0) Never (1) Less than monthly (2) Monthly (3) Weekly (4) Daily or almost daily</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

10. Has a relative, friend, doctor, or another health care worker been concerned about your drinking or suggested you cut down? | No | Yes, but not in the last year | Yes, during the last year | Yes, during the last year | Yes, during the last year | Yes, during the last year |

---

If total is greater than recommended cut-off, consult User’s Manual.
## ANNEX 8. DATA COLLECTION SHEET.

### DATA COLLECTION SHEET

<table>
<thead>
<tr>
<th>Basic patient data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name and surname</strong></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>☐ Male</td>
</tr>
<tr>
<td>☐ Female</td>
</tr>
<tr>
<td>☐ Unknown</td>
</tr>
<tr>
<td><strong>Place of birth</strong></td>
</tr>
<tr>
<td><strong>Date of birth</strong></td>
</tr>
<tr>
<td><strong>Age</strong></td>
</tr>
<tr>
<td><strong>ID/CIP number</strong></td>
</tr>
<tr>
<td><strong>Home address</strong></td>
</tr>
<tr>
<td><strong>Telephone</strong></td>
</tr>
<tr>
<td><strong>Email address</strong></td>
</tr>
<tr>
<td><strong>Language</strong></td>
</tr>
<tr>
<td>☐ Catalan</td>
</tr>
<tr>
<td>☐ Spanish</td>
</tr>
<tr>
<td>☐ English</td>
</tr>
<tr>
<td>☐ French</td>
</tr>
<tr>
<td>☐ Others</td>
</tr>
<tr>
<td>☐ Language barrier</td>
</tr>
<tr>
<td><strong>Education level</strong></td>
</tr>
<tr>
<td><strong>Profession</strong></td>
</tr>
<tr>
<td><strong>Current job</strong></td>
</tr>
</tbody>
</table>

### Information about perinatal loss

<table>
<thead>
<tr>
<th>Incident date</th>
<th>__ / __ / _____</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gestation age</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Cause of perinatal death</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Health Center</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Recurrent perinatal deaths</strong> (number)</td>
<td></td>
</tr>
<tr>
<td><strong>Number of children alive</strong> (number)</td>
<td></td>
</tr>
</tbody>
</table>
9.1. Informed consent

Title of the study:

Attending support groups to reduce the prevalence of Anxiety Disorder in parents who have suffered a perinatal loss

I (first and last name), ............................................................
I confirm that:

- I have received and read the information sheet for the patient that has been delivered to me
- I have been able to ask questions about the study and my doubts have been resolved
- I have received enough information about the study
- I understand that my data will be treated in a strictly confidential manner
- I understand what my role will be as a participant in the study
- I understand that my participation is voluntary and that I can withdraw from the study at any time, without this affecting my future healthcare

Consequently, I agree to participate in the study: "Attending support groups to reduce the prevalence of Anxiety Disorder in parents who have suffered a perinatal loss".

Signature of the participant:  
Signature of the researcher:

---------------------------------------------  ---------------------------------------------

Date: ___ / ___ / ___  
Date: ___ / ___ / ___
9.2. Study information for the patient

Patient information sheet:

Main researchers: Marina Rosado Hidalgo, María Fe Martín Pérez.

Project Code: _______________

1. Project Overview: The project is carried out by 3 hospitals in Catalonia in collaboration with Mémora Funeral Services, with an approximate duration of 30 months. As a participant, you must authorize the collection of personal and clinical data of interest.

2. Objectives and purpose of the study: The purpose of the study is to assess whether attending support groups decreases the risk of suffering from Anxiety Disorder in parents who have suffered a perinatal death.

3. Participation: Your participation is completely voluntary. The participant is free to leave the study if they wish, without the need to justify themselves and with the guarantee that this will not affect their health care. Participation in the study does not entail financial compensation.

4. Confidentiality and data protection: In compliance with the Organic Law of Protection of Personal Data, measures have been taken to guarantee confidentiality. Your data will be treated anonymously and exclusively for research purposes.

5. Task of the study participant: The participant will authorize the collection of personal and clinical data for use for research purposes.

6. Results and benefits of the investigation: The participant can request to be informed of the results of the investigation. The results derived from the investigation will be used to improve the prehospital care of patients suffering from perinatal death.

Thank you for your participation.