ISRCTN40400582 https://doi.org/10.1186/ISRCTN40400582

Systematic early intervention for bereaved (SEIB) with families who suddenly lose a partner /parent

Submission date
02/03/2016

Recruitment status
No longer recruiting

Registration date
10/03/2016

Overall study status
Completed

Last Edited
03/05/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The loss of a parent or partner is a major life event for their family. It often changes the way that the family unit functions and can also be linked with mental health problems for both bereaved parents and their children. When this death is unexpected, especially if it is an unnatural or violent death, it can be a particularly traumatic and difficult time. Norwegian studies show that bereaved people often seek help very immediately when they lose a loved one in this way, however there is a lack of services available to provide early support for families in the first days after a sudden and potentially traumatic loss. The systematic early intervention for bereaved (SEIB) is a program that has been specially designed to help families to adjust after the sudden death of a partner/parent and to lower the risk of complicated grief (long-lasting grief which makes it more difficult to accept the loss and move on). The aim of this study is to find out whether this program is able to reduce the risk of complicated grief and help children and parents to adjust to their new personal circumstances after a sudden death of a parent or partner.

Who can participate?
Families with children under the age of 18 who have suddenly and unexpectedly lost a partner or parent within the last three weeks.

What does the study involve?
Participating families are randomly allocated to one of two groups. Those in the first group take part in the SEIB program. This involves taking part in a minimum of five sessions, lasting for around two hours each, starting in the first days after their loss. The program is tailored to each family's individual needs and aims to provide a supportive environment to teach them coping skills so they are better able to deal with their situation, such as advice about returning to school or work and securing social support. Those in the second group receive SEIB three months after their loss. The sessions that these participants take part in involve less advice about how to cope with the immediate effects of their loss and how to handle them, and prioritize talking about the traumatic aspects surrounding the death. The advice that they are given is adapted to the emotions usually experienced some time after a traumatic loss, when the situation feels more

real and there is less social support available. At the start of the study and then again after three, six and nine months, participants in both groups complete a number of questionnaires designed to assess how well they are coping and whether they are showing signs of complicated grief.

What are the possible benefits and risks of participating?
Participants may benefit from being able to shorten and optimise the grieving process, allowing them to better adjust after the death of a partner/parent. There is a risk that completing the questionnaires and intervention sessions may be distressing for participants.

Where is the study run from?
Center for Crisis Psychology, Bergen (Norway)

When is the study starting and how long is it expected to run for?
November 2014 to November 2017

Who is funding the study?
1. Statoil ASA (Norway)
2. The Norwegian Research Council (Norway)

Who is the main contact?
Dr Mariana Pereira

Contact information

Type(s)
Scientific

Contact name
Dr Mariana Pereira

Contact details
Center for Crisis Psychology
Fortunen 7
Bergen
Norway
5013

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Intervention effects of Systematic Early Intervention for Bereaved (SEIB) with families who suddenly lose a partner/parent: A stepped wedge randomized controlled trial

Study objectives
The aim of the study is to optimize families' normal grieving process and adjustment after a sudden death of a partner/parent, and to decrease the risk for complicated grief in both bereaved children and their surviving parents. Based on the study's aims and the relevance of SEIB's intervention components for complicated grief in the aftermath of a potential traumatic loss, the following hypotheses are proposed:
1. SEIB will be effective in decreasing complicated grief and traumatic stress symptoms in both bereaved partners and their children
2. SEIB will be effective in enhancing psychological wellbeing, daily functioning, and social support in both bereaved partners and their children
3. SEIB will be effective in enhancing parental capacity, positive parenting, and the quality of family relations

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Committee of Research and Ethics in Western (REK West) Norway; ref: 2015/556 /REK vest

Study design
Single-centre stepped wedge randomized controlled trial

Primary study design
Interventional

Secondary study design
Stepped wedge randomized controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Grieving following bereavment

Interventions
Families are randomised to one of two study arms, the early SEIB intervention arm (receiving SEIB in the aftermath of the loss) and the delayed SEIB intervention arm (receiving SEIB 3 months post-loss).

Early SEIB intervention arm: Participants receive a minimum of five sessions (lasting for approximately two hours), starting in the first days after a sudden and traumatic loss. The SEIB is tailored to each individual's and family's needs.

Intervention sessions :
Session 1 is to take place within the first three days after the loss, whenever possible (no later than three weeks post-loss). The initial aim is to reduce bodily activation and stimulate the perception of being cared for. In addition, it focuses on the children needs'. Finally, it provides concrete advice on sleep, work/school, use of medication, participation in rituals, and how to maximize support from the social network.
Session 2 takes place within two to four weeks post-loss. The initial aim is to share factual information, securing open and direct communication. In addition, psychoeducational information concerning common grief reactions is combined with concrete advice for dealing with school/work re-entry. Finally, it discusses how family members interact with each other, and how they can effectively support and take care of each other.
Session 3 takes place within five to seven weeks post-loss. The initial aim is to address and process trauma aspects of the loss. In addition, an emphasis is placed on living with grief over time. Finally, parents receive information for learning more about children's reactions.
Session 4 takes place within three to six months post-loss. The initial aim is to address and process trauma aspects of the loss. A special emphasis is placed on living with grief over time and recovering daily functioning. Finally, it continues to stimulate family communication and discuss how they support each other.
Session 5 takes place around or following the first anniversary of the death (12-13 months after death). A special emphasis is placed on living with grief over time and recovering daily functioning, particularly in the social and work spheres of life.

Delayed intervention arm: For these participants, the first sessions contain less advice on the acute handling of the situation (including children in rituals, return to work and school, securing social support) and less focus on reducing bodily activation by calming family members. They prioritize the traumatic aspects surrounding the death, and psychoeducation is adjusted to the reactions usually seen at this time point (around three months following the loss), when the unreality has abated and the social network is often less active in their support.

Family functioning is measured using self-reporting at baseline, 3, 6, and 9 months

All participants are asked to fill in a set of questionnaires at the start of the study, and after 3, 6 and 9 months. Data on mental health, daily functioning, parental capacity, family functioning, and social support is also collected.

Intervention Type
Behavioural

Primary outcome measure
Primary outcome measures for parents:
1. Complicated grief is measured using Inventory of Complicated Grief at 3, 6, and 9 months
2. Traumatic stress symptoms are measured using Impact of Event Scale-Revised at baseline, 3, 6, and 9 months

Primary outcome measures for children:
1. Complicated grief is measured using Inventory of Prolonged Grief for Adolescents at 3, 6, and 9 months

2. Traumatic stress symptoms are measured using Children's Impact of Event Scale at baseline, 3, 6, and 9 months

Secondary outcome measures
Secondary outcome measures for parents:
1. Psychological wellbeing is measured using General Health Questionnaire at baseline, 3, 6, and 9 months
2. Daily functioning is measured using Work and Social Adjustment Scale at 3, 6, and 9 months
3. Social support is measured using Crisis Support Scale at 3, 6, and 9 months
4. Parental capacity is measured using Parenting Coping Scale at 3, 6, and 9 months
5. Parenting practices is measured using Alabama Parenting Questionnaire at 3, 6, and 9 months
6. Family functioning is measured using Family Assessment Device at 3, 6, and 9 months

Secondary outcome measures for children:
1. Psychological wellbeing is measured using Strengths and Difficulties Questionnaire at baseline, 3, 6, and 9 months
2. Daily functioning is measured using the supplement focusing on functional impairment of Strengths and Difficulties Questionnaire at 3, 6, and 9 months
3. Parenting practices is measured using Alabama Parenting Questionnaire at 3, 6, and 9 months
4. Family functioning is measured using Family Assessment Device at 3, 6, and 9 months

Overall study start date
17/11/2014

Completion date
17/11/2017

Eligibility

Key inclusion criteria
1. Bereaved families with children below 18-years-old, who suddenly and unexpectedly lose a partner or parent
2. Criterion for unexpectedness - The loss shall occur following an accident, a suicide, a murder, or a disease, as well as situations where people are missing (presumed dead).
3. Criterion for suddenness - The loss shall occur shortly, or within the same day as the event /disease happened or started. This period can be extended up to five days for people who do not regain consciousness after the incident (e.g., illness/accident/suicide, etc).
4. All family members must speak Norwegian
5. Death has occurred within the past three weeks

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants

80 bereaved families

Key exclusion criteria
1. Families with severe medical conditions for both the bereaved partner and their children such as:
1.1. Serious physical impairment
1.2. Intellectual deficit
1.3. Severe child developmental problems
1.4. Borderline personality disorder
1.5. History of psychosis (e.g., schizophrenia, bipolar disorder)
1.6. Current substance use disorder (in the past 6 months)
1.7. Severe suicidal risk, or dementia
2. Families receiving other psychotherapeutic intervention for problems concerning loss and/or trauma

Date of first enrolment
17/08/2015

Date of final enrolment
17/09/2016

Locations

Countries of recruitment
Norway

Study participating centre
Center for Crisis Psychology
Fortunen 7
Bergen
Norway
5013

Sponsor information

Organisation
Center for Crisis Psychology

Sponsor details
Fortunen 7
Bergen
Norway
5013
+47 55 59 61 80
email@krisepsyk.no

Sponsor type
Research organisation

Website
www.krisepsyk.no

Organisation
Regional Committee of Research and Ethics in Western (REK-West) Norway

Sponsor details
University of Bergen, Faculty of Medicine, 7804
Bergen
Norway
5020

Sponsor type
University/education

Organisation
Senter for Krisepsykologi

Sponsor details

Sponsor type
Not defined

Website
http://www.krisepsyk.no/

ROR
https://ror.org/04wb8fh44

Funder(s)

Funder type
Industry

Funder Name
Statoil ASA

Funder Name

SkatteFUNN (The Norwegian Research Council)

Results and Publications

Publication and dissemination plan

1. Planned publication of a study protocol and results paper in a peer reviewed journal
2. Planned dissemination of results both nationally and internationally via conferences/seminars /courses, scientific and popular scientific article writing

Intention to publish date

17/11/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/08/2016	03/05/2019	Yes	No