Internet therapy of complicated grief and chronic rumination after the loss of a loved one: an intervention study

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The primary goal of this study is to compare the effectiveness of an exposure therapy module with a behavioral activation module and a control group in reducing rumination and complicated grief symptoms. A secondary goal of this study is to compare…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Adjustment disorders (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON38564

Source
ToetsingOnline

Brief title
An internet therapy of complicated grief and chronic rumination

Condition

- Adjustment disorders (incl subtypes)

Synonym
Complicated Grief, Problematic grief

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Zon-Mw TOP subsidie

Intervention

Keyword: Grief, Internet, Rumination, Therapy

Outcome measures

Primary outcome

Primary study parameters are (grief) rumination and complicated grief symptoms.

Secondary outcome

Secondary outcome measures are depressive rumination and symptoms of anxiety, depression and posttraumatic stress disorder. Control variables are demographic variables (i.e. age, gender, education level), loss-related variables (time since loss, relationship with deceased, gender deceased, expectations about the loss) and medication use. Moreover, the therapist(s) will fill out a registration form on therapeutic adherence and motivation of the participant.

Study description

Background summary

The loss of a loved one is one of the most stressful events a person can experience. Although most people adjust to the loss of a loved one without professional intervention, some people develop physical and mental problems and or grief complications. An important, potentially changeable risk factor in the development of grief complications is rumination. Rumination has been defined as recurrent, self-focused thinking about negative events and/or negative feelings. Rumination after bereavement has been associated with, and is a predictor of, complicated grief symptoms. Because rumination is a risk factor in the grief process, therapeutic treatment for complicated grief can focus on altering levels of rumination. By lowering levels of rumination, a reduction of grief symptoms can be achieved.
Chronic rumination is presumed to be maladaptive because it plays a role in avoidance processes. First, continuous rumination may serve to avoid painful aspects of the reality of the loss and the emotions linked with it, thereby interfering with the acceptance of, and adjustment to, the loss. Second, chronic rumination may play a role in stimulating inactivity, because it takes

up time and strengthens the idea that all is hopeless after the loss and nothing can be done to change this situation. As a consequence, bereaved ruminators have less positive experiences that could invalidate their negative thoughts, thereby fueling negative mood.
Because rumination in the context of bereavement appears to be inherently linked with anxious avoidance of the reality of the loss and depressive avoidance of activities, rumination could be reduced by influencing these avoidance processes. First, exposure techniques could be used to confront bereaved ruminators with the reality of the loss, which could increase the acceptance of the loss and the integration of the loss in the autobiographical knowledge base. Exposure could also diminish rumination, because confronting the painful aspects of the reality of the loss would reduce the need to rely on rumination to avoid this reality. Second, behavioral activation could be used to reduce inactivity. Behavioral activation could also reduce rumination, because bereaved individuals who are more active have less time to ruminate. Furthermore, they may also have less reasons to ruminate, because negative affect, an important cause of rumination is the experience of negative affect. Since exposure therapy has repeatedly been found effective in the treatment of complicated grief , while there is currently no conclusive evidence that behavioral activation may be effective in reducing complicated grief symptoms, we expect exposure to be a more effective treatment of rumination and complicated grief symptoms than behavioral activation.
In the proposed intervention study the effects of short, internet based exposure and behavioral activation will be compared with each other and an internet control group. We expect that exposure and behavioral activation will reduce rumination and symptoms of complicated grief more strongly than the control group. Furthermore, we expect exposure to be more effective than behavioral activation in reducing rumination and symptoms of complicated grief. Finally, we expect that decreases in rumination and complicated grief symptoms in the exposure condition will be more strongly associated with reductions in anxious avoidance of the loss-reality, when compared with the behavioral activation condition. Furthermore, we expect that decreases in rumination and complicated grief symptoms in the behavioral activation condition will be more strongly associated with reductions in depressive avoidance of activities, when compared with the exposure condition.

Study objective

The primary goal of this study is to compare the effectiveness of an exposure therapy module with a behavioral activation module and a control group in reducing rumination and complicated grief symptoms. A secondary goal of this study is to compare the association between reductions in rumination and complicated grief symptoms and reductions in anxious and depressive avoidance between treatment groups.

Study design

A randomised controlled trial (RCT) in which two internet-based treatments for chronic rumination and grief complications will be compared with each other and a control group.

Intervention

Participants will be randomly assigned to one of three conditions: an exposure module of 6 weeks, a behavioral activation module of six weeks or a waiting list control group. Participants who are assigned to the waiting list control group will receive the most effective of both treatments after their initial waiting period.

Study burden and risks

The treatment participants receive can be emotionally taxing, because participants are confronted with the reality of their loss (exposure condition) or aversive situations (activation condition). However, participation is completely voluntary. Furthermore, the treatment is based on effective existing treatments or treatments for which preliminary evidence of its effectiveness exists. The treatment will be implemented by qualified therapists. Participants will do 6 homework assignments over 6 weeks and fill out questionnaires at 4 time-points. All questionnaires are valid and frequently used in scientific research. The relevance of the study is great, because it provides new insights into the effectiveness of intervention modules in reducing rumination and symptoms of complicated grief. This is important, because it can improve existing psychological treatments of grief. See also Paragraph 9.3.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) The participant is 18 years or older
2) The participant has been bereaved of a partner, child, parent or sibling at least 6 months ago.
3)The participant expresses a need for psychosocial help with dealing with his or her loss.
4) The participant has elevated scores on grief rumination (>42) measured with the Utrecht Grief Rumination Scale
5) The participant has elevated scores (>25) on symptoms of complicated grief measured with the short version of Inventory of Complicated Grief (ICG);See paragraph 4.2 of the research protocol for details on inclusion criteria.

Exclusion criteria

1) The participant has no or limited access to internet.
2) The participant currently suffers from a severe depressive episode
3) The participant currently suffers from suicidal ideation
4) The participant has recently experienced dissociation or psychotic symptoms
5) The participant is physically disabled, in the sense that he or she is limited in physical mobility;See paragraph 4.3 of the research protocol for details on exclusion criteria.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2013
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43072.042.12