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The influence of acute arousal and anxiety reduction on the prevention of PTSD in injured trauma patients

A randomised controlled trial

of a brief Internet-based early intervention

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Abstract

Internet-based interventions have been shown acceptable, viable and efficacious in the treatment of several mental health problems. The present study assessed a brief, Internet-based, early intervention for the prevention of post traumatic stress disorder (PTSD) in injured trauma patients of two level 1 trauma units of medical centres in Amsterdam, The Netherlands. Besides overall effectiveness, the influence of reduction of acute arousal and anxiety on the effectiveness was investigated, in compliance with recent guidelines for the prevention of PTSD. Of 300 adult patients, 151 were randomly assigned to the intervention group and 149 to a control group. The intervention incorporated elements of CBT, such as psychoeducation, cognitive restructuring, stress management and instructions for relaxation exercises. Levels of arousal and anxiety are measured prior and after the intervention with visual analogue scales. Using clinical interviews and self-report questionnaires a baseline and follow-up (at 1 and 3 months) of psychopathology is assessed. Preliminary linear mixed model results showed a main effect of time for symptoms of hyperarousal and a main group effect for depressive symptoms. The results showed a trend favorable for patients that were assigned to the intervention group. No effect was found of alleviation of arousal and anxiety shortly after the experience of a traumatic incident on PTSD, depression and anxiety at follow-up**.** The preliminary results presented in this study are promising for future development of preventive interventions, since it was shown to be feasible, easy to implement, well accepted by the patient. Some ideas for improving preventive interventions for trauma survivors are presented, and methodological suggestions for future research are given.

Contents

Introduction

Research in the USA, Israel and Australia has shown that sizeable percentages of injured trauma victims develop psychiatric symptoms as a result of their experience. Four to six months after the trauma approximately 10% to 19% are diagnosed with posttraumatic stress disorder (PTSD), 10% to 17% with depression, and 13% to 37% with another anxiety disorder (Yehuda, McFarlane, & Shalev, 1998; O'Donnell, Creamer, Pattison, & Atkin, 2004).

The substantial risk of developing psychiatric symptoms resulting from trauma is alarming for several reasons. PTSD and associated psychopathology, such as depression and anxiety disorders, represent a significant clinical problem that may persist for years. Mayou, Tyndel and Bryant (1997) reported that approximately 10% of their study sample was still diagnosed with PTSD five years after the trauma. The clinical as well as the societal burden of disorders related to posttraumatic stress is high. The impact of the loss of health and the economic burden affects not only those who experience the disorder, but also their families and society as a whole. Its effects extend far beyond the individual patients; the reduced quality of life affects the ability to function socially as well as occupationally (McCrone, Knapp & Cawkill, 2003). Moreover, risk of suicide attempts is relatively high among people with PTSD; altogether it is clear that PTSD is a highly impairing condition (Kessler, 2006). Besides, a recent study showed that currently only a minority of people with PTSD obtains treatment (Kessler, 2006). Available scientific evidence suggests that the prevalence of PTSD and the adverse emotional and psychological consequences of PTSD are even greater in the many countries around the world that are in the midst of armed conflicts involving political, racial, or ethnic violence (Desjarlais, Eisenberg, Good & Kleinman, 1995). The findings above indicate there is a clear need for effective, easily applicable interventions to prevent the development of post trauma psychopathology.

Early interventions to prevent the onset of PTSD could help reduce the individual burden as well as societal costs of this disorder (Kessler, 2006). In the last decades, various forms of early interventions for prevention of PTSD have been developed. One such early intervention is psychological debriefing. Psychological debriefing is a brief, usually single-session, psychological intervention that involves conversation on the traumatic experience, linked to expression of the emotional responses (Rose, Bisson, Churchill & Wessely, 2002). The rationale is that reducing acute emotional distress through emotional expression will prevent onset of chronic PTSD symptoms. Although psychological debriefing is an exceptionally widespread form of prevention (Rose, Bisson, Churchill & Wessely, 2002), which is being applied in many different forms (Van Emmerik, Kamphuis, Hulsbosch & Emmelkamp, 2002;

Rose, Bisson, Churchill & Wessely, 2002), its efficacy in preventing onset of PTSD is not empirically supported. Many studies failed to show any evidence of actual preventive qualities of psychological debriefing (e.g. Rose, Bisson, Churchill & Wessely, 2009; Litz et al., 2002). Perhaps even more worrying are the findings that in some cases debriefing may even aggravate the symptoms of distress (Sijbrandij, Olff, Reitsma, Carlier & Gersons, 2006; Bisson, Shepherd, Joy, Probert & Newcombe,2004; Hobbs,1996) and increase the development of PTSD (Mayou, Ehlers & Bryant 2002).

Based on current randomised clinical trial evidence, more benefits may be expected from early interventions that include cognitive behavioural techniques (CBT). Evaluation of the efficacy of a video-based intervention to ameliorate post-traumatic stress by reducing the level of arousal in a sample of 140 female victims of sexual assault (Resnick, Acierno, Waldrop, King, King et al., 2007) showed promising results. The intervention was implemented within 72 hours after the sexual assault. At six weeks follow-up, this intervention was associated with a reduction of symptoms of PTSD among those women with a prior rape history relative to PTSD symptoms among women with a prior rape history, compared to women with a prior rape history in the control group. However, for women without a history of rape, the frequency with which they reported symptoms of PTSD, was higher for those in the video condition than for the control condition. Recently, two randomised controlled trials assessed the efficacy of providing self-help information, which is a form of psycho-education, to trauma patients. Turpin, Downs and Mason (2005) evaluated the efficacy of an early intervention providing self-help information to patients who recently had experienced trauma. Results showed that post-traumatic stress disorder, anxiety and depression decreased with time but there was no significant effect of the intervention. In this study controls were even less depressed at follow-up and there was a non-significant trend that controls had less diagnoses of PTSD at follow-up than the intervention group. These results were supported by findings of Scholes, Turpin and Mason (2007), who assessed the efficacy of providing self-help information to patients with a high risk of developing post-trauma psychopathology. PTSD, anxiety and depression decreased with time but there were no group differences in measures or quality of life. Both trials failed to support the efficacy of providing self-help information as a preventative strategy for the onset of PTSD. However, subjective ratings of the usefulness of the self-help information were high in both studies. New insights based on scientific evaluation of the changing responses of professionals to people who have been in a traumatic event suggest that perhaps the information provided should have had a different focus or means of delivery (Wessely, 2008). The above mentioned studies led to consensus among experts that there is a need for single session early interventions which promote a sense of safety, sense of self- and community

efficacy, connectedness and hope (Hobfoll, Canetti-Nisim, Johnson, Palmieri, Varley et al., 2008).

Systematic reviews of trials of CBT based early interventions after trauma, have shown that CBT can be effective in the prevention of chronic PTSD symptoms (Ehlers &Clarke, 2003; Bisson & Andrew, 2005). An early intervention of four or five sessions CBT was shown beneficial for preventing chronic PTSD in trauma victims who are selected on symptoms of Acute Stress Disorder (ASD; DSM-4, American Psychiatric Association, 2000; Bryant, Sackville, Dang, Moulds, and Guthrie, 1999; Bisson, Shepherd, Joy, Probert and Newcombe, 2004). Cognitive behavioural techniques in this intervention included psychoeducation about individual reactions to traumatic events, stress management such as relaxation exercises, exposure and cognitive restructuring. Other studies showed that brief early cognitive behavioural therapy is efficacious in the treatment of ASD in civilian trauma survivors (Bryant, Harvey, Dang, Sackville, & Basten, 1998; Bryant, Moulds, Guthrie, & Nixon, 2003), in victims with mild traumatic brain injury (Bryant et al., 2003) and in the treatment of acute symptoms of PTSD in physically injured trauma victims (Bisson et al., 2004).

Although the existent early interventions with elements of CBT have been shown to be effective in preventing onset of PTSD symptoms, a limitation is the fact that for most interventions it is still compulsory for the patient to take the initiative to seek treatment. This need for the patient to take initiative implies that the samples on which such interventions have been tested are by definition selective samples; consistent of patients who already report any form of psychopathology in anticipation to the intervention. As a consequence, most existing CBT interventions are rather curative than preventive. Another limitation is the fact that cognitive behavioural techniques are usually delivered to trauma survivors in the form of individual face-to-face psychotherapy consisting of at least four to five sessions. However, preliminary clinical trial results suggest that cognitive behavioural techniques could also be useful in very brief interventions, consisting of only one or two sessions (Somer, Tamir, Maguen, & Litz, 2005). Moreover, in the aftermath of some traumatic incidents, e.g. environmental disasters, it might be impossible for social workers to provide face to face care to trauma victims. Internet could be a resolution in circumstances of geographical isolation.

There are a number of significant other potential advantages of the Internet as a way of providing information and interventions for trauma survivors. These include ease of access (including access at home) with a unique capability of reaching large numbers of trauma survivors, which can reduce certain critical barriers to delivery of mental health assistance (e.g., cost, lack of familiarity with mental health services; Stuber, Galea, Boscarino, & Schlesinger, 2006). The increased ease of access may also facilitate early intervention for

trauma survivors. Potentially, Internet delivery can help to reduce social stigmatization associated with mental health help-seeking, increase delivery of best intervention practices via well-crafted materials, assist with education of practitioners, and facilitate research (Marks et al., 2007).

In their extensive review, Marks et al. (2007) reported on 175 randomised controlled trials (published and unpublished) of Internet-aided psychotherapy and found encouraging results related to the effectiveness of programs addressing a number of mental health problems, including phobia/panic disorder, depression, and alcohol abuse. The research on Internet interventions for trauma survivors has received a limited amount of attention to date. However, several online treatments for PTSD are evidence –based (Lange, Rietdijk, Hudcovicova, van de Ven, Schrieken et al., 2003;Hirai & Clum, 2005; Litz, 2008). The importance of critical evaluation of existent, non-evidence based, Internet-based traumatic stress interventions was recently made abundantly clear by Bremner et al. (2006), who reported that out of 80 identified sites targeting trauma survivors, 42% provided inaccurate or harmful information and only 18% of the sites provided any scientific references for the information provided. Almost half were not authored by mental health professionals at all. The available research support for Internet-based interventions for trauma survivors, although limited, provides some important and encouraging initial findings.

The guideline for PTSD of the National Institute of Clinical Excellence (NICE, 2005) recommends provision of general practical and social support and guidance to anyone following a traumatic incident. Acknowledgement of the psychological impact of traumatic incidents should be part of healthcare and social service workers' responses to incidents. Support and guidance are likely to cover reassurance about immediate distress, information about the likely course of symptoms, and practical and emotional support in the first month after the incident, (NICE, 2005). The major objective of the intervention is to reduce the risk of developing symptoms of PTSD, anxiety, or depression by alleviating acute symptoms of hyperarousal and anxiety. It must be noted, the NICE guidelines do not recommend this as generally appropriate practice, not necessarily as being a part of clinical practice.

The brief, Internet based, early intervention which is evaluated in this study incorporates evidence-based techniques for preventing the development of PTSD. The intervention is designed with a focus on accessibility, low-threshold, and ease of performance. The intervention consists of techniques of psychoeducation, cognitive restructuring, stress management and instructions for exposure exercises. One of the characteristics of the intervention is that it is being offered to all trauma patients within two weeks post trauma, irrespective of the presence of symptoms of psychological distress. This is in line with

recommendations for the development of preventive interventions delivered by the NICE guideline (2005).The design of the intervention is such that the frequency of sessions can vary from a single session to multiple sessions, dependent on the preference of the patient.

Studies performed in various countries report that psychological symptoms of acute arousal and anxiety immediately after experiencing a traumatic incident are good predictors for the development of post traumatic stress syndrome (PTSD, DSM-4, American Psychiatric Association, 2000). Harvey and Bryant (1998) investigated the relationship between Acute Stress Disorder (ASD) and PTSD. Their results showed that specific symptoms of ASD, inter alia feelings of distress and a sense of reliving the trauma had strong predictive power. These findings are in line with the results of a study by Ehlers, Mayou and Bryant (1998). Their study focused on predicting psychological factors of PTSD in victims of motor vehicle accidents. It was shown that negative interpretations of intrusions, perceived threat and rumination were enhancing factors for the prediction of chronic PTSD in combination with objective measures such as trauma severity. Classen et al. (1998) examined whether the acute psychological effects of being a witness of a violent crime predicted later posttraumatic stress symptoms. Known acute stress symptoms as dissociation and high peritraumatic emotions were found to be excellent predictors of the subjects' posttraumatic stress symptoms 7–10 months after the traumatic experience, (Ozer, Weiss, Best & Lipsey, 2003). These results suggest that being a bystander to violence is highly stressful not only on the short term, but as well that acute stress reactions to such an experience further predict later posttraumatic stress symptoms. Similar findings were presented by Johansen et al. (2007). They examined the predictive value of symptoms of post-traumatic stress for the quality of life in victims of non-domestic violence over a period of one year. The presence of PTSD symptoms predicted lower quality of life, established 1 year post trauma.

Moreover, recent studies have identified some biological symptoms of acute arousal and anxiety to be of predictive value for the onset of PTSD as well. The role of acute psychophysiological arousal in the development of posttraumatic stress disorder (PTSD) was assessed by Bryant, Harvey, Guthrie and Moulds (2003). They found that in hospitalized motor vehicle accident survivors, patients who were diagnosed with PTSD 2 years posttrauma, had higher heart rates at hospital discharge than those without PTSD. These findings suggest that, though caution is required, acute elevated heart rate can be predictive of longer-term PTSD following trauma.

The objectives of the present study were twofold. The primary aim was to assess the overall effectiveness of the intervention as a means to prevent onset of future PTSD symptoms. In the clinical practice, there is a shortage, to date, of effective, brief, low-

threshold, easily accessible and inexpensive, early interventions for the prevention of PTSD. Both for the interest of the individual patient as for society as a whole, it is important to develop and evaluate such interventions. The second aim was to assess whether alleviation of acute arousal and anxiety shortly after the experience of a traumatic event can act as a protective factor for the onset of future PTSD. Therefore, the following three hypotheses are being tested. Firstly, it is hypothesized that people in the experimental condition will report a significantly lower level of anxiety immediately after having received the intervention compared to the level of anxiety which is reported before receiving this intervention (cf**.** Figure 1) Secondly, it is hypothesized that people in the experimental condition will report a significantly lower level of arousal immediately after having received the intervention compared to the level of arousal which is reported before receiving this intervention. (cf. Figure 1). Thirdly, it is hypothesized that reduction of anxiety and arousal, achieved by means of the intervention, will be a protective factor for future development of post trauma psychopathology. As a consequence, people in the experimental condition will report less psychopathology at one month follow-up and at three months follow-up (cf. Figure 2).

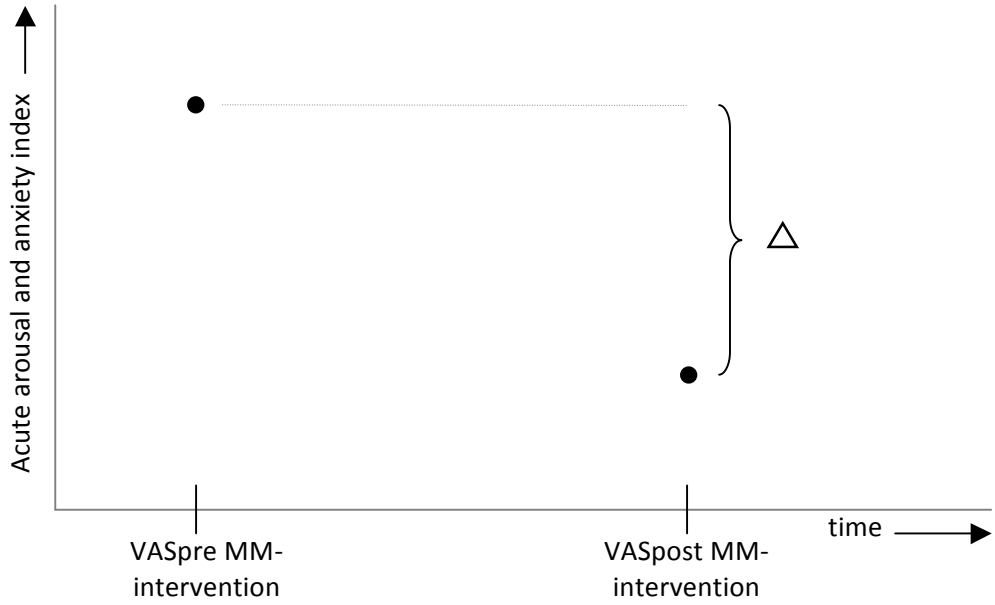

Figure 1.

An illustration of hypothesis 1 and hypothesis 2: Level of self-reported acute arousal and anxiety will drop after the reception of MM-intervention.

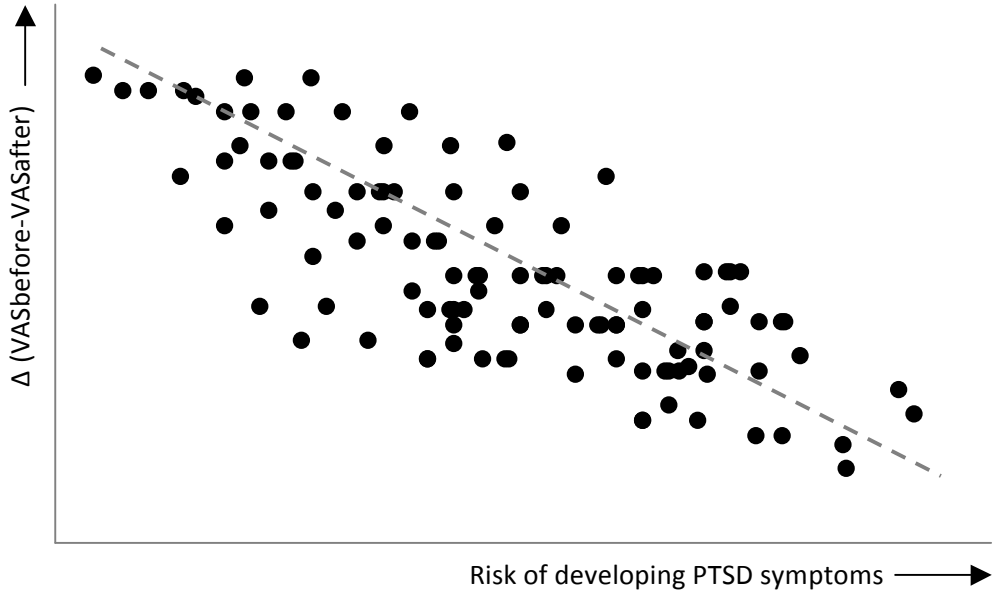

Figure 2.

An illustration of hypothesis 3: Levels of arousal and anxiety are negatively correlated to the risk of developing PTSD (illustrative graph showing N=50 measures).

Methods

Subjects

This study is part of a larger ongoing trial, called Trauma TIPS, on the incidence and prediction of trauma-related psychopathology in adult injury patients of Level I trauma centres (Academic Medical Centre and VU Medical Centre) in Amsterdam, the Netherlands. In the period from September 2007 to February 2009 adult patients of the trauma centres, who experienced an accident or assault, and had a trauma mechanism according to the A1-criterion for PTSD (DSM-IV-R) were invited to participate in the study. Participation was on voluntary basis. Excluded from the study are patients: 1) under the age of 18 years, 2) with suicidal ideation, 3) with psychotic symptoms or disorder, bipolar disorder, or organic disorders, 4) with depressive disorder with psychotic characteristics, 5) with a Glasgow Coma Score < 13 at the time of the intervention, 6) who are physically unable to perform the intervention.

Procedure

After written and oral informed consent, an extensive interview with the patients takes place in which demographic characteristics; trauma related characteristics and the history of medical and psychological pathology are investigated. Baseline measures of psychopathology are assessed by means of clinical interviews and self-report questionnaires at the same occasion. Consecutively, patients are randomised into either the intervention group or the control group. Patients in the intervention condition are provided with personal log-in names for the web-based Intervention. Patients in the control group receive care as usual. Incidental, non-structured, non-protocollised, talks with trauma unit staff, social workers, general practitioners or other trauma related care providers take place. If the patient is already dismissed from hospital at the time of the intervention, the patient will be given the website's address to perform the intervention at home. Patients who are still hospitalized are visited by a research assistant with a laptop to practice the intervention at bedside. Immediately prior to and after the intervention, the participants complete an online assessment of acute anxiety and arousal. At 1 month post-trauma and at 3 months post-trauma the patients complete a follow-up investigation of PTSD symptoms, consisting of self-report questionnaires and clinical interviews. All clinical assessments are performed by advanced master students in clinical psychology, who are personally trained by the principal researcher J. Mouthaan and the professionals who were involved in the development of the multi media intervention.

Intervention

The intervention is an Internet programme (which can be found at www.traumatips.nl) of about 30 minutes duration with interactive elements and visual and auditory materials. The intervention consists of the following six consecutive steps:

1. Introduction: Written explanation of the aim of the intervention and operating instructions.
2. Questions: A brief pre-test of arousal and anxiety using two visual analogue scales, which the user can set by dragging and dropping a slider (cf. Figure).
3. Trauma: This module consists of three sections:
    a. Trauma Unit: A video clip in which a trauma unit professional explains the procedures at the unit and briefly introduces the trauma unit staff;
    b. Experiences: In this section participants can choose to click and see one of three videos. In each of these videos, a patient of the Trauma Unit briefly tells about his or her experiences after the accident. Three different patients are presented, to enable participants to choose the story that most closely fits their own story, so that they can identify with it. Based on the records of the trauma registry, three of the more frequently occurring types of accidental injuries are depicted. a) a male survivor of an industrial accident (50 years); b) a male survivor of a motor vehicle accident (28 years); and c) a female survivor of an assault (35 years). Two males and 1 female are shown, as this represents the sex distribution of accident victims in the trauma records. In each of the three video clips instructions to the cognitive behavioural procedures are given. These include: psychoeducation about commonly occurring physiological reactions during and right after accidental injuries and information about the relation between thoughts and resulting emotions. Also, instructions to use adaptive self-talk and to replace anxiety-producing thoughts with ones of a pleasant situation (e.g. a pleasant place, a favourite activity) are given. Participants are instructed to practice the technique whenever an unpleasant or anxiety provoking thought occurs. Further, other possible adaptive strategies for responding to stress symptoms are discussed such a seeking social support or finding distraction. Next, information about repeated exposure exercises that can be used to counteract avoidance and withdrawal is provided. The exercises are specifically tailored to injured patients since many of them will have temporal or permanent physical disabilities.

c. Tips: a summary list of five tips for coping with common physical and psychological reactions after a traumatic event is presented. The tips are derived from the examples and instructions provided in the three video features of the Trauma Unit patients. An example of a tip is 'Often it is helpful to seek support with other people, both in sharing your emotional concerns as in sharing your practical questions'.

4. Exercises: two audio features of approximately 7 minutes duration each with instructions for stress management techniques are presented: (a) "Muscle relaxation" focuses on progressive muscle relaxation through breathing retraining; (b) "Safe place" is an exercise that focuses on decreasing stress or tension levels by imagining a safe and secure place while retraining breathing. The exercises are developed by external experts and staff members of the Amsterdam Academic Medical Center;
5. Questions: A brief post-test of arousal and anxiety using two visual analogue scales, identical to step 2. (cf. Figure 3).
6. The end: Information about other sources of help available is provided, including the email address and telephone number of the psychosocial worker of the Trauma Unit, who can be contacted in case the participant wishes to obtain further assistance. The first time the patients log on, they are to complete all steps of the program, including the pre-test and post-test of state anxiety. If they choose to undergo the intervention a second time, or additional times, they may skip any sections they wish. By assigning each client a login name and password in advance, the components of the intervention of each single patient can be traced.

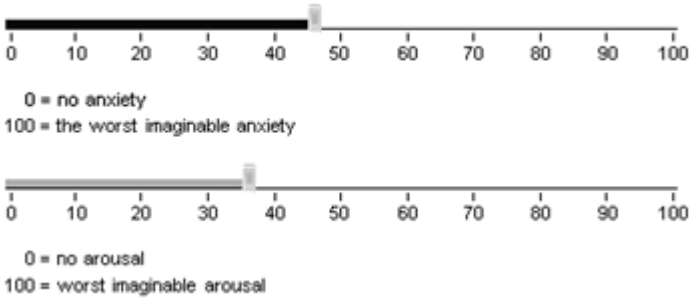

Figure 3

Intervention, steps 2 and 5: Users are asked to score their current state of anxiety and arousal on a visual analogue scale.

Instruments

Clinical Interviews

The Dutch translation of the Mini-International Neuropsychiatric Interview 5.0 (MINI-Plus; Van Vliet & De Beurs, 2007), a structured diagnostic DSM-IV-based interview, is used to diagnose participants with anxiety and mood disorders. An additional item is constructed to assess symptoms of Acute Stress Disorder, since this is absent in the MINI-Plus. The MINI-Plus is a more extensive version of the MINI. The MINI has good psychometric characteristics and is suitable for research purposes (Van Vliet & De Beurs, 2007). The psychometric characteristics of the MINI-Plus have not been studied so far, but they are expected to be similar or better than those of the original MINI. In the current study, participants are coded as having no anxiety disorder (0) or having at least one anxiety disorder (1). The same categorisation is used for mood disorders; subjects are coded 0 (no mood disorder) or 1 (at least one mood disorder).

The Clinician-Administered PTSD Scale for DSM-IV (CAPS-DX; Blanchard, Hickling, Taylor, Forneris, Loos, & Jaccard, 1995) is used to assess PTSD symptoms. The CAPS-DX is a structured interview which can be used for diagnosing PTSD and determining the frequency, intensity, and severity of PTSD symptoms. The psychometric characteristics of the CAPS-DX are good (Hovens, Van der Ploeg, Klaarenbeek, Bramsen, Schreuder, et al., 1994). The total severity of the PTSD symptoms is determined by using the CAPS-DX total score. This score is calculated by summing frequency and severity scores of all symptoms (range: 0-136). For diagnosing PTSD, the rule advised by Weathers, Ruscio, and Keane (2001) is used, who suggest a cut-off score of 45 points on the CAPS-DX. For determining whether there has been a significant improvement on PTSD symptoms, the rule advised by Weathers, Keane, and Davidson (2001) is used. According to this rule, a significant clinical improvement is present in case of a decline of 15 points or more on the CAPS-DX.

Self-report questionnaires

As additional assessments of subjective distress, participants complete self-report questionnaires on each assessment occasion. The Dutch version of the Hospital Anxiety and Depression Scale (HADS; Zigmund & Snaith, 1983; in Spinhoven, Ormel, Sloekers, Kempen, Speckens et al., 1997) is used to assess anxiety and depressive symptoms. The HADS can be divided into two scales: the anxiety (HADS-A) and the depression (HADS-D) scale, both consisting of seven items. All items are scored on a scale from 0 to 3. The range of scores on both scales is 0 - 21, the range for the total score is 0-42. High scores indicate higher symptom

levels of anxiety or depression. The test-retest reliability coefficients of the two scales are high (Spinhoven et al., 1997).

The Dutch version (translation by the Centre for Psychological Trauma of AMC de Meren, 2005) of the Impact of Event Scale-Revised (IES-R; Weiss & Marmar, 1997; in Creamer, Bell, & Failla, 2003) is used to assess PTSD symptoms. The IES-R was developed by Horowitz, Wilner, and Alvarez (1979) to assess the frequency of intrusive and avoidant symptoms after a variety of traumatic experiences. The Dutch IES-R consists of three subscales: intrusion (8 items), avoidance (8 items) and hyperarousal (6 items). For every item, the respondent answers on a 5-point scale whether the symptom was present (0 = not at all; 1 = rarely; 2 = sometimes; 3 = somewhat much; 4 = often) during the past seven days. In the current study, only the total score is used, which consists of 22 items. The range of the summed total score is 0-88. The IES-R has good psychometric properties (Creamer et al., 2003).

Acute peritraumatic reactions are assessed using two short inventories. First, the Peritraumatic Distress Inventory (PDI; Brunet, Weiss, Metzler, Best, Neylan et al., 2001) is a 13-item self-report measure, the Peritraumatic Distress Inventory, to obtain a quantitative measure of the level of distress experienced during and immediately after a traumatic event. Items assess the level of terror, horror, grief, helplessness, anger and panic. Scores are ranging from 1(completely false) to 5 (completely true). The PDI is scored as mean item response. The PDI has been demonstrated to be internally consistent, with good test-retest reliability and good convergent and divergent validity. The PDI has been shown to be correlated with measures of posttraumatic stress symptoms (Brunet al., 2001). Second, the Dutch version of the Peritraumatic Dissociative Experience Questionnaire (PDEQ; Marmar, Weiss & Metzler, 1997), which is a 10-item scale that assesses the level of dissociative experiences during and / or immediately after trauma exposure (depersonalisation, derealisation, amnesia, out of body experience, and altered time perception). Responses reflect the extent to which a dissociative phenomenon has been experienced, with scores ranging on a scale from 1 (not at all) to 5 (extremely true). The PDEQ is scored as mean item response. The PDEQ has been demonstrated to be internally consistent and strongly associated with other measures of traumatic stress response, dissociation and level of stress exposure (Marmar et al., 1997). Reliability and validity of the Dutch PDEQ has been demonstrated elsewhere (Sijbrandij, Olff, Opmeer, Carlier, & Gersons, 2006).

Table 1.

Instruments that were administered on assessment occasions during this study

Instruments	Assessment occasions			
	T1	T2	T3A	T3B
Clinical interviews				
MINI-Plus		×	×	×
CAPS-DX			×	×
Self-report questionnaires				
PDEQ		×		
HADS		×	×	×
IES-R		×	×	×
PDI		×		
Other				
GCS	×			
ISS	×			
Demographic information		×		
Trauma-related details		×		

Note. MINI-Plus: Mini-International Neuropsychiatric Interview 5.0, CAPS-DX: Clinician-Administered PTSD Scale for DSM-IV, PDEQ: Peritraumatic Dissociative Emotions Questionnaire, HADS: Hospital Anxiety and Depression Scale, IES-R: Impact of Event Scale-Revised, PDI: Peritraumatic Distress Inventory, GCS: Glasgow Coma Scale, ISS: Injury Severity Score.

T1: in trauma unit, T2: one week after the accident, T3A: one month after the accident, T3B: three months after the accident.

Demographic, accident-related, and work-related information

During the first clinical interview, patients are asked about their demographics; gender (0 = man, 1 = woman), nationality (0 = Dutch, 1 = other than Dutch), country of origin (0 = the Netherlands, 1 = other than the Netherlands), marital status (0 = not married nor living with partner, 1 = married or living with partner), children living at home (0 = no children living at home, 1 = at least one child living at home), level of education (1 = primary school, 2 = lower secondary, 3 = medium secondary, 4 = higher secondary, 5 = other), and work status (0 = unemployed, 1 = employed). Furthermore, during the first interview a detailed description of the accident is provided by the participants. Information regarding the number of days spent in the hospital is collected from a database of the academic hospital.

Injury severity

The Injury Severity Score (ISS; Baker, O'Neill, Haddon, & Long, 1947) is a measure of the severity of the physical injury. The ISS is an anatomical scoring system that provides an overall score for patients with multiple injuries. In the trauma unit or shock room (T1), a physician assigns a score to each injury using the Abbreviated Injury Scale (AIS; Kühn, Ehlert, Rumpf, Backhaus, Hohagen et al., 2006), for six specific body parts (head, face, chest, abdomen, extremities, external). The three most severely injured body regions have their AIS score squared and added together to produce the ISS score. The range of the ISS is 0 to 75. In case of an injury with AIS of six (fatal), the ISS score is automatically assigned to 75. The ISS correlates linearly with mortality, morbidity, and hospital stay.

Glasgow Coma Scale

The Glasgow Coma Scale (GCS; Teasdale & Jennet, 1974) is a neurological scale which aims to give a reliable, objective way of recording the level of consciousness of an individual. The GCS is composed of three parameters: Best Eye Response (four grades), Best Verbal Response (5 grades), Best Motor Response (6 grades). Resulting scores are between 3 (indicating deep unconsciousness) and 15. In general, brain injury is classified as: Severe, which is generally accepted as a definition of a coma, (GCS ≤ 8), Moderate (GCS 9 – 12) and Mild, corresponding with a GCS of 13 or higher.

Statistical analyses

Statistical analyses are performed using SPSS 15.0 for Windows. For tests of significance for categorical variables we use chi square tests. In testing the differences between groups on continuous variables we use paired samples *t*-tests, independent samples *t*-tests in case of two groups, and one-way ANOVA's are performed for comparing the two groups. Repeated measurement analyses are used to study the changes over time in IES-R score, and in HADS Anxiety and Depression scores between the two groups. We applied mixed linear models to take into account that measurements within the same individual are correlated (Litell, Pendergast, & Natarajan, 2000).

The mean scores for each outcome, at 1 month follow-up and at 3 months follow-up, are modelled as a function of the intervention given (two levels), time since intervention (as a categorical variable with two levels), the baseline measurement (continuous), and the interaction between time and intervention. This interaction term is added to the model to allow the treatment effect to be different at 1 month and at 3 months of follow-up.

Reduction on the VAS scales are measured by scoring the differences on arousal and anxiety prior to and after the intervention (VAS scores before – VAS scores after). Delta scores are tested using paired *t*-tests and one-way ANOVA's are used to compare the subgroups which are constructed.

Results

Patients

The final sample for the current study consisted of 300 trauma patients. 151 Patients were randomly assigned to the intervention group and 149 patients were assigned to the control group. There were no significant differences found regarding the demographic profiles of the intervention group and the control group (see table 2). The greater part of the sample consisted of men (*n* = 180, 60%). Average age of the total group was 43.5 years (*SD* = 16.0). A majority of the sample had the Dutch nationality (*n* = 286, 96.3%), was from Dutch origin (*n* = 248, 83.8%), had an education level of five to six years of high school, or had had lower continuing education after elementary school (*n* = 134, 45.1%), was married or living with a partner (*n* = 196, 65.6%), had children (*n* = 170, 56.9%) and was working or going to school (*n* = 240, 80.8%).

Table 1

Demographic characteristics of the patients in the sample.

	Control	Intervention	Total
Age M(*SD*)	43.49 (16.0)	44.19 (15.8)	43.84 (15.9)
Gender			
Male	91 (61.1%)	89 (58.9%)	180 (60%)
female	58 (38.9%)	62 (41.1%)	120 (40%)
Country of origin			
The Netherlands	122 (83.0%)	126 (84.6%)	248 (83.8%)
Other than the Netherlands	25 (17.0%)	23 (15.4%)	48 (16.2%)
Nationality			
The Netherlands	143 (97.3%)	143 (95.3%)	286 (96.3%)
Other than the Netherlands	4 (2.7%)	7 (4.7%)	11 (3.7%)
Educational level			
elementary school/up to 4 yrs high school	42 (28.4%)	41 (27.5%)	83 (27.9%)
5-6 yrs high school/lower continuing education	63 (42.6%)	71 (47.7%)	134 (45.1%)
college/university	43 (29.1%)	37 (24.8%)	80 (26.9%)
Marital status			
Married or living with partner	95 (63.8%)	101 (67.3%)	196 (65.6%)
Not married nor living with partner	54 (36.2%)	49 (32.7%)	103 (34.4%)
Children			
Yes	85 (57.0%)	85 (56.7%)	170 (56.9%)
No	64 (43.0%)	65 (43.3%)	129 (43.1%)
Pre trauma work status			
No work nor school	26 (17.4%)	31 (20.9%)	57 (19.2%)
(un) paid work or school	123 (82.6%)	117 (79.1%)	240 (80.8%)

With only one exception, there were no significant differences between the intervention group and the control group on trauma related characteristics. It was shown that the control group reported significantly more intrusive thoughts of dying at the moment of trauma, compared to the intervention group. In the control group 40 patients (28%) reported they had thought they were going to die, compared to 20 patients (14.4%) in the intervention group, (χ^2 (1) = 7.76, p < .01). The intervention matched the control group on all other trauma-related variables (see table 2).

Table 2

Trauma related characteristics of the patients in the sample.

	Control	Intervention	Total
Trauma mechanism			
Traffic related accident	103 (69.1%)	97 (64.2%)	200 (66.7%)
Physical abuse	5 (3.4%)	2 (1.3%)	7 (2.3%)
Work-related accident	18 (12.1%)	15 (9.9%)	33 (11.0%)
Fall from height	15 (10.1%)	29 (19.2%)	44 (14.7%)
Other	8 (5.3%)	8 (5.3%)	16 (5.3%)
Glasgow Coma score (GCS) M(*SD*)	14.67 (1.47)	14.64 (1.43)	14.66 (1.46)
Glasgow Coma score (GCS) <13	4 (3.6%)	6 (5.36%)	10 (4.5%)
Injury Severity Score (ISS) M(*SD*)	9.11 (8.75)	11.04 (8.76)	10.04 (8.78)
Injury Severity Score (ISS) = >16	20 (18.5%)	28 (27.72%)	48 (23.0%)
Clear memories of trauma			
Yes	63 (42.6%)	74 (50.0%)	137 (46.1%)
No	86 (57.7%)	74 (50.0%)	160 (53.9%)
Did you think you were going to die?*			
Yes	40 (28.0%)	20 (14.4%)	60 (21.3%)
No	103 (72.0%)	119 (85.6%)	222 (78.7%)
Time spent in hospital (days) M(*SD*)	5.87 (11.5)	5.44 (8.1)	5.66 (9.9)
Were others injured			
Yes	37 (26.6%)	37 (26.2%)	75 (26.4%)
No	105 (73.4%)	104 (73.8%)	209 (73.6%)
Did others die?			
Yes	5 (3.5%)	8 (5.7%)	13 (4.6%)
No	137 (96.5%)	132 (94.3%)	269 (95.4%)

* $p < .01$

History of psychopathology

Group comparison of the history of psychopathology prior to the traumatic event revealed a significant difference between the intervention and the control group. The intervention group included significantly more patients with a history of mood disorder than the control group, (χ^2 (1) = 4.219, p = .04). Both groups reported a comparable level of the current negative influence of prior psychological or psychiatric problems. Table 3 shows the prior history of psychopathology of the patients in the intervention and in the control group.

Table 3

History of psychopathology.

	Controls	Intervention	Total
Prior anxiety disorder (MINI)			
Yes	11 (7.6%)	11 (7.8%)	22 (7.7%)
Prior mood disorder* (MINI)			
Yes	35 (24.3%)	44 (31.4%)	79 (27.8%)
Current negative effect of prior psychological trauma			
Yes	9 (34.6%)	13 (30.2%)	22 (31.9%)

* p <.05

Dropout

The dropout rate after randomization did not differ significantly between the intervention group and the control group. In both groups 13 subjects (8.6 % respective 8.7%) dropped out after randomization. Non-completers differed significantly from completers on several demographic background characteristics. Dropout rate was significantly higher among females compared to males, (χ^2 (1) = 7.64, p = .006). The ratio of dropout was significantly higher for people with a nationality other than Dutch, (χ^2 (1) = 4.90, p = .003), or did not have the Netherlands as country of origin, (χ^2 (1) = 18.8, p < .001). With regard to the traumatic incident of the patients there was a significant relation between the severity of injury and the likelihood of dropping out after randomization. Non-completers were significantly less severely injured than completers (F (1, 207) = 4.08, p < .05). Patients who dropped out also reported more peritraumatic distress, as reported in the PDI, (F (1, 210) = 6.28, p < .05). Non-completers patients also reported more symptoms of feelings of anxiety and depression (F (1,213) = 7.59, p < .05). Non-completers reported a significantly bigger impact of the traumatic event, as measured with the total score of IES-R, (F (1, 214) = 21.55, p < .001). Patients who dropped out reported more PTSD symptoms like avoidance (F (1, 214) = 15.95, p < .001), and intrusion (F (1, 214) = 19.20, p <.001), and hyperarousal (F (1, 214) = 17.81, p < .001).

Effectiveness of multimedia intervention

Baseline

There were no significant between-group differences on any baseline measurement of psychopathology (see Table 4).

1 Month follow-up

At 1 month follow-up, analysis of variance between the control group and the intervention group showed significant differences on the HADS-D, subscale for depression. The control group reported significantly more symptoms of depression than the intervention group, (F (1, 144) = 4,005, p = .047). Similarly, on the IES-R total score of the impact of the traumatic event, a significant difference was revealed between the groups. The control group experienced a significantly higher impact of the event than the intervention group, (F (1, 146) = 4,863, p = .03). Exclusively on the IES-R avoidance subscale, (F (1, 145) = 4.864, p = .03) and on the IES-R hyperarousal subscale this difference was significantly apparent (see table 4).

3 Months follow-up

At 3 months follow-up, significant differences between the control group and the intervention group were once more found on the total score of the IES-R. The control group then still reported significantly more negative impact of the traumatic event than the intervention group. (F (1, 100) = 6.101, p = .02). It was shown that, at 3 months, the intervention group scored significantly lower on both the IES-R hyperarousal subscale, (F (1, N = 100) = 6.085, p = .02) as on the IES-R intrusion subscale, (F (1, *99*) = 5.709, p = .02) (see table 4).

Table 4

Incidence of psychopathology at baseline, 1 month follow-up and three months follow-up.

	Baseline			1 Month Follow -up			3 Months Follow -up		
	Control	Intervention	Total	Control	Intervention	Total	Control	Intervention	Total
Anxiety									
Anxiety disorder (MINI)	17 (11.5%)	21 (14.2%)	38 (12.8%)	6 (5.4%)	4 (3.5%)	10 (4.4%)	6 (8.5%)	4 (4.7%)	10 (6.4%)
HADS Scale A M (*SD*)	4.95 (4.4)	4.39 (4.0)	4.66 (4.2)	4.51 (4.3)	3.33 (3.1)	3.87 (3.7)	4.16 (4.1)*	2.98 (3.5)*	3.5 (3.8)
Depression									
Mood disorder (MINI)	12 (8.1%)	14 (19.5%)	26 (8.8%)	9 (8.0%)	8 (7.1%)	17 (7.6%)	1 (1.4%)	4 (4.7%)	5 (3.2%)
HADS Scale D M(*SD*)	4.11 (4.2)	3.83 (3.8)	3.96 (4.0)	3.99 (4.2)*	2.66 (3.5)*	3.27 (3.9)	3.69 (4.1) *	2.39 (3.6)*	2.97 (3.8)
PT*SD*									
IES-R Total M (*SD*)	21.00 (18.4)	17.30 16.7)	19.04 (17.8)	15.64 (16.7)*	10.4 (12.0)*	12.8 (14.6)	13.49 (13.4)*	7.77 (10.0)*	10.29 (11.9)
IES-R Hyperarousal M (*SD*)	5.84 (5.5)	5.26 (5.2)	5.54 (5.3)	5.10 (5.1)*	3.4 (4)*	4.2 (4.6)	3.82 (4.3)*	2.17 (2.5)*	2.91 (3.5)
IES-R Intrusion M (*SD*)	9.64 (8.7)	7.52 (7.1)	8.52 (7.9)	5.87 (6.6)	4.3 (5.1)	5 (5.9)	5.82 (5.7)	3.30 (4.7)*	4.41 (5.3)
IES-R avoidance M (*SD*)	5.51 (6.4)	4.52 (6.0)	4.99 (6.2)	4.81 (6.1)*	2.7 (4.1)*	3.7 (5.2)	3.84 (4.8)	2.38 (3.8)	3.02 (4.3)
CAPS DX total score M (*SD*)	- -	- -	- -	18.47 (17.8)	19.2 (18.9)	20.8 (18.9)	18.47 (17.8)	16.10 (17.0)	17.16 (17.4)
CAPS DX PT*SD*	- -	- -	- -	9 (7.9%)	6 (5.3%)	15 (6.6%)	4 (5.6%)	3 (3.5%)	7 (4.4%)

* p <.05, ** p <.01

Linear mixed-model analysis

Mixed-model analysis on main outcome measure IES-R Hyperarousal showed a significant main effect of Time, (F (1,299) = 8.99, p < .01). The mixed-model analysis on main outcome measure HADS-D showed a significant main effect of Group, (F (1,299) = 4.15, p < .05) (see table 5).

Table 5

Main effects of the multimedia intervention.

Measure	**Group effect (F)**	**Time effect (F)**	**Group x Time Effect (F)**
IES-R Total	1.61	3.72	1.23
IES-R Intrusion	.72	.43	2.95
IES-R Avoidance	1.94	2.22	.02
IES-R Hyperarousal	.14	**8.99****	.31
HADS-A	1.64	.24	.10
HADS-D	**4.15***	.22	.14

All mixed models controlled for baseline assessments

* p <.05, ** p <.01

Influence of acute arousal and anxiety on the effectiveness of the intervention

The visual analogue scales of arousal and anxiety were filled out by 69 patients (45.6%) during their first login to the intervention. As illustrated by table 6, the decrease of patients who logged in more than once and completed the VAS scales was very high. Only 29 patients (19.2%) filled out the scales for a second time or more. This fraction would not represent the intervention group as a whole. Therefore, only the scores of the first log were used in the statistical analysis.

Mean reduction of arousal after the first log in to the multimedia intervention (arousal pre.intervention - arousal post.intervention) was 5.38 (SD = 17.76) on a scale from zero to hundred. A paired sample t-test between pre- and post measurements of arousal revealed this difference was significant, (t (68) = 2.51, p = .01). Mean reduction of anxiety after the first log in to the multimedia intervention (anxiety pre.intervention - anxiety post.intervention) was 2.80 (SD = 15.82) on a scale from zero to hundred. Analysis revealed this reduction was not significant (see table 6).

Table 6

Reduction of anxiety and arousal on visual analogue scales (pre.intervention – post.intervention) M (SD).

Number of logins	Anxiety reduction		*n*	Arousal reduction		*n*
1	2.8	(15.81)	69	5.38	(17.78)	69
2	-2.07	(22.12)	29	-2.64	(22.43)	28
3	-11.5	(30.89)	14	-3.36	(14.04)	14
4	7.14	(17.25)	7	0.86	(2.04)	7
5	0	(0)	3	-2.5	(5)	4
6	11	(0)	1	17	(0)	1
7	1	(0)	1	-6	(0)	1
8	-49	(0)	1	-66	(0)	1
9	0	(0)	1	0	(0)	0
10	-5	(0)	1	2	(0)	1
11	-1	(0)	1	-4	(0)	1
12	-2	(0)	1	0	(0)	1
13	0	(0)	0	-2	(0)	1

Two subgroups were constructed to compare the patients who reported a decrease in anxiety and or arousal with the patients who did report no reduction of arousal and or anxiety. This subgroup analysis on the reduction of anxiety within the intervention group showed that patients who experienced a decreased level of anxiety after the intervention, reported a significantly higher total PTSD score at baseline (assessed with the IES-R) compared to patients who reported no reduction, (F (1, 68)= 5.353, p = .03). Besides, on the IES-R intrusion subscale, the same significant difference was found at baseline, (F (1, 68) = 5.327, p = .03). The analysis on the reduction of arousal by means of the intervention showed that patients who had reported a decreased level of arousal after the intervention did not significantly differ from patients who reported no decrease of arousal, on any of the measures of psychopathology at baseline (see tables 7a and 7b).

At 1 month and at 3 months follow-up, no significant differences were found in the incidence of psychopathology between patients who had reported a reduction of anxiety or arousal compared to patients who had not reported a decreased level of arousal or anxiety after having completed the intervention (see tables 7a and 7b).

Table 7a.

Subgroup analysis (high reduction of anxiety vs. no reduction of anxiety) of incidence of psychopathology.

	Baseline		1 Month Follow-up		3 Months Follow-up	
	no reduction of anxiety	reduction>0	no reduction of anxiety	reduction>0	no reduction of anxiety	reduction>0
Anxiety						
Anxiety disorder (MINI)	7 (13.7%)	2 (11.1%)	1 (2.7%)	0 (0.0%)	0 (0%)	0 (0%)
HADS Scale A M(SD)	3.92 (3.7)	4.33 (3.7)	3.29 (3.3)	2.91 (2.3)	3.69 (4.3)	4.56 (4.1)
Depression						
Mood disorder (MINI)	5 (9.8%)	2 (11.1%)	4 (10.8%)	1 (18.3%)	2 (9.1%)	1 (10%)
HADS Scale D M(SD)	3.03 (3.1)	4.73 (3.7)	2.75 (3.8)	2.09 (2.2)	3.62 (4.9)	4.22 (4.7)
PTSD						
IES-R Total M (SD)	11.67 (11.5)*	20.7 (15.7)*	7.86 (9.1)	7.18 (6.8)	11.1 (13.2)	7.22 (6)
IES-R Hyperarousal M (SD)	3.66 (3.9)	6.2 (5.3)	2.79 (3.5)	3.00 (2.3)	2.46 (3.2)	2.11 (1.7)
IES-R Intrusion M (SD)	5.36 (5.3)*	9.33 (6.6)*	3.39 (3.8)	3.18 (4.1)	5.54 (7)	3.22 (3.2)
IES-R avoidance M (SD)	2.64 (3.6)	5.13 (5.4)	1.68 (2.5)	1.00 (1.7)	3.08 (4.4)	1.89 (1.8)

* $p < .05$

Table 7b.

Subgroup analysis (high reduction of arousal vs. no reduction of arousal) of incidence of psychopathology

	Baseline		1 Month Follow-up		3 Months Follow-up	
	no reduction of anxiety	**reduction>0**	**no reduction of anxiety**	**reduction>0**	**no reduction of anxiety**	**reduction>0**
Anxiety						
Anxiety disorder (MINI)	4 (8.7%)	5 (21.7%)	0 (0%)	1 (7.7%)	0 (0%)	0 (0%)
HADS Scale A M(SD)	3.92 (3.7)	4.33 (3.7)	3.45 (3.2)	2.4 (2.1)	3.85 (4.2)	4.33 (4.3)
Depression						
Mood disorder (MINI)	4 (8.7%)	3 (13%)	2 (5.6%)	3 (23.1%)	1 (4.8%)	2 (18.2%)
HADS Scale D M(SD)	3.02 (3.1)	4.73 (3.7)	2.86 (3.7)	1.7 (2.4)	3.69 (4.8)	4.11 (4.8)
PTSD						
IES-R Total M (SD)	11.95 (11.7)	19 (15.6)	8.79 (9.2)	4.40 (4.2)	12.54 (13.1)	5.11 (3.9)
IES-R Hyperarousal M (SD)	3.62 (4.0)	6.00 (5.0)	3.00 (3.5)	2.40 (2.5)	2.69 (3.2)	1.78 (1.6)
IES-R Intrusion M (SD)	5.76 (5.5)	8 (6.7)	3.93 (4.2)	1.60 (1.9)	6.38 (6.9)	2.00 (1.6)
IES-R avoidance M (SD)	2.57 (3.5)	5 (5.4)	1.86 (2.5)	0.40 (1.0)	3.46 (4.3)	1.33 (1.5)

Discussion

Early interventions that facilitate mental health recovery in the aftermath of a traumatic event are potentially of great value for individual patients as well as for society as a whole. Brief, Internet-based interventions are of particular interest because they are inexpensive, highly transportable, easily accessible and standardized, as well as easily tailored to the needs of specific individuals.

This paper presents the rationale and preliminary results of the effectiveness of a brief Internet-based multimedia intervention for preventing the onset of PTSD, and other symptoms of psychopathology, in traumatic injury survivors.

The research questions which were investigated in this paper were twofold. The first aim was to assess the overall impact of a brief Internet-based intervention for the prevention of PTSD in a sample of trauma unit patients of academic hospitals. We found a main effect of time for symptoms of hyperarousal and a main effect of group for depression. However, no significant interaction effects (group x time) could be established. Considering that the results of this study are preliminary, interactions might be significant after inclusion of the final data. This is supported by the promising results of single analyses of the incidence of psychopathology, at baseline and at follow-up on one and on three months. At one month and three months follow-up, multiple self report measures of symptoms are improved for the intervention patients compared to controls. At one-month follow-up there are significant between-group differences for depression and for PTSD and its specific symptoms, except for symptoms in the cluster intrusion. At three-month follow-up more significant between group-differences are found. All psychopathology scores are lower in the intervention group except for the PTSD symptoms in the cluster avoidance. Despite the limited main effects these results are of importance for future development and implementation of early Internet-based interventions. Results show a favorable trend for patients who were assigned to the intervention group; possibly, inclusion of the final data will reveal more significant results. Not less important is the conclusion that no harmful effects of the intervention were found.

Our second aim addressed the influence of reduction of anxiety and arousal shortly after a traumatic event. We expected that reduction of acute anxiety and arousal would be a protective factor for the onset of future psychological sequelae in the survivors of traumatic injury (cf. Figure 2). No general influence of the reduction of arousal on the incidence of

psychopathology at follow-up was found. Possibly, methodological problems account for these results. It was found that the visual analogue scales in the intervention were not filled out well (see table 6). Many patients exclusively filled out the scales at the beginning of the intervention, which made it impossible to measure a difference (before minus after) of arousal and anxiety. Moreover, only at first log in a reasonable amount of patients (*N* = 69, 45.7%) used the VAS scales. As a consequence, the analysis of the influence of the reduction of anxiety and arousal lost statistical power. It is suggested that close attention should paid to improving the online instructions of the interventions for the patients, in future development of comparable interventions. Emphasizing the personal interest patients have in filling out the scales, namely to enhance insight in their emotional states, could be effective, since in the current intervention it was not explicated what the importance was of completely filling out the scales of anxiety and arousal at every login, before as well as after the intervention. Although, it should be noted a significant reduction of arousal was found after the intervention (cf. Figure 1).

Subgroup analysis (of patients who did report significant reduction of arousal and anxiety compared to patients who did not report any reduction) of the intervention found that higher initial levels of symptoms of PTSD, mainly intrusion, were related to higher reduction of anxiety by means of the intervention. This might be an indication that there is a significant influence of baseline symptoms of PTSD on the effect of the intervention on the reduction of arousal and anxiety. It is possible that this result can be explained by the fact that patients with many PTSD symptoms at baseline can relatively reduce more arousal and anxiety. In the remainder of the TRAUMA TIPS study, growth curve analyses will be performed, which is expected to provide more information on this topic. Another factor might be that, for some reason, the intervention is more appealing for people with more symptoms of PTSD.

In the subgroup analysis, no significant influence of the reduction of arousal and anxiety on the development of future psychopathology was found. Compared to 'non-reduction-patients', patients with significant reduction of arousal and anxiety, are not diagnosed less often with PTSD or any mood or anxiety disorder, nor do they develop significantly less symptoms of PTSD, anxiety and depression at one month or three months follow-up. The lack of influence of the reduction of anxiety and arousal on the development of psychopathology can possibly be due to some content limitations. In future interventions, the instruction of the intervention should be optimized. Another explanation for the lack of effect could be the limited power, as a result of the small number of people who filled out the visual analogue scales.

Several other explanations could account for the overall lack of effect of the intervention. Since the development of Internet-based interventions is relatively new, the intervention materials themselves may have content limitations. The process of recovery following trauma might as well be so strong that the intervention is not intensive enough to have additional impact. Another option might be that the general absence of benefit seen in this study is due to the lack of the caring, supportive therapeutic alliance that is an integral part of in vivo psychotherapy.

With regard to the drop-out patients, drop-out rate was low compared to similar randomised controlled trials (Mayou, Ehlers & Bryant, 2002; Turpin, Mason & Downs, 2005). It was found that less than 10 percent dropped out after randomisation. This is encouraging, since it supports the objectives of the intervention to be low-threshold, it should be noted, that especially those who dropped out have high scores on psychopathology. This is a common, though unwanted finding. It seems the intervention is not so well applicable for patients with more severe psychopathology, despite the fact they probably need it the most. An important issue for future development of early intervention will be directed on the question how to reach the patients with severe psychopathology.

The current study suffers from several limitations. The patient sample in this study was relatively healthy. This complicates finding significant effects, because little progress can be expected. Moreover, it should be noted that there was a lack of cultural diversity since most of the participants are from Dutch origin; this is probably related to the inclusion criterion that participants needed to speak Dutch fluently. Another limitation is that we lack information on the mental health of the patients refusing participation in the study. This means the participating patients could introduce a bias. Also drop out patients could introduce a bias since drop out patients were shown to score high on psychopathology. This will be investigated in the remainder of the TRAUMA TIPS study, in which non-response research will be performed.

These data provide some promising preliminary initial results for the efficacy of providing an early Internet-based intervention to injury patients of Level I trauma Centres. If this approach of interventions proves to be useful for a significant number of those who receive it, and since it is shown to be not harmful, this may have important implications for public health adaptation and for use with other populations exposed to traumatic events.

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