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RATIONALE AND METHOD OF THE STOP*,** STUDY - STUDY ON TREATMENT BEHAVIOUR AND OUTCOMES OF TREATMENT IN PEOPLE WITH POSTTRAUMATIC STRESS FOLLOWING CONFLICTS IN EX-YUGOSLAVIA

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* STOP - Seeking, Treatment, Outcomes, Posttraumatic

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Abstract: *Background:* The collapse of Yugoslavia in the early 1990s precipitated the worst armed conflict in Europe since World War II. Ten years on, a significant number of people still suffer from posttraumatic stress and the majority of them have not requested or received any type of specialised psychiatric help. In order to better understand these phenomena, empirical results are needed about both barriers to treatment and treatment outcomes in specialised psychiatric services. *Objective:* To describe the rationale and method of the STOP study (the full title is "Treatment seeking and treatment outcomes in people suffering from posttraumatic stress following war and migration in the Balkans"), a multi-centre study funded by the European Commission. *Method:* Description of the study protocol as developed in collaboration of six centres in the UK, Germany, Croatia, Bosnia-Herzegovina and Serbia. *Results:* We have developed a combined quantitative-quantitative method in order to:

a) identify barriers to treatment and coping strategies of people with posttraumatic stress that have not asked for help, both of the ones that took refuge outside the post war area and of those who stayed in the region;

b) assess treatment outcomes in people already engaged with services.

Discussion: The STOP study has been designed as an ambitious collaborative project and as such carries certain risks. The first results of this study will be available in 2005.

Key words: *posttraumatic stress, barriers to treatment, treatment outcomes*

Conflict in the Balkans

The collapse of Yugoslavia in the early 1990`s precipitated the worst armed conflict in Europe since the end of World War II. The war and its consequences caused traumatic experiences in great parts of the population (1, 2). These experiences include combat, loss of relatives and friends, witnessing other people being killed, persecution, rape, being shot at and wounded and forced migration. Throughout the former Yugoslavia, as many as two million people remain uprooted and more than 100.000 are staying in European member states, having being granted or seeking residency (3).

Posttraumatic Stress

There is extensive literature suggesting that traumatic experience can lead to severe and long-lasting psychological distress (4, 5). Posttraumatic stress disorder (PTSD) may occur as a result of traumatic experience and is characterised by unwanted recollections of the event (e.g. in nightmares), emotional numbing and avoidance of any situation reminding of the event, and signs of hyper-arousal (e.g.

sleeplessness, irritability). It is often associated with impaired social functioning. Different types of traumatic events are likely to lead to different types of PTSD (6). War and migration usually pose on-going and repeated traumatic situations and tend to cause more complex and difficult to treat forms of PTSD, called Type II PTSD (7).

Numerous publications have shown that PTSD is a frequent (8, 9), but not the only mental sequelae of traumatic experience. Other disorders, such as depression, somatisation disorder, generalised anxiety and personality change, may also develop as a result of psychological trauma alongside PTSD or on its own (10, 11, 12). Thus the term posttraumatic stress, encompassing all these potential consequences following traumatic events is a much wider phenomenon then solely the concept of PTSD.

The direct and indirect costs for the care of people suffering from posttraumatic stress are high, partly because many people concerned are either inappropriately treated or do not receive any treatment at all.

Treatment seeking and treatment receiving

Appropriate care for patients suffering from posttraumatic stress is a special challenge to health services. A significant number of people with posttraumatic stress do not seek treatment (13, 14), which may partly be due to symptoms of the disorder itself. Mistrust towards institutions and social withdrawal may prevent them from seeking treatment that would be available (15, 16, 17). The stigma of being a psychiatric patient may be another factor. In addition to that, individuals that ask for treatment may not receive it due to various practical obstacles. Some of the non treatment seekers that have experienced psychological difficulties might have developed successful coping strategies or have found alternative sources of help (as opposed to professional psychiatric help) which might be relevant considering specificity of the cultural context. Since most studies have been carried out on treatment seekers, it remains poorly understood why so many people do not seek or receive treatment despite a high degree of suffering.

Treatment outcome

Intervention studies demonstrated that debriefing directly following a traumatic event is likely to be ineffective, or even detrimental (18), whilst different forms of psychotherapeutic and pharmacological treatment at a later stage have been found to be effective in terms of symptom reduction, as demonstrated in randomised controlled trials (19). However, most studies evaluated well-defined treatments, whilst in real clinical practice most patients with Type II PTSD need combinations of different treatment interventions in a more complex fashion (12, 20), which does not lend itself to being evaluated in randomised controlled trials. Thus, relatively little is known about what treatment outcomes are to be expected in patients following war experience, what patient characteristics predict a more or less favourable outcome, and what treatment elements are associated with different outcomes in those patients. Also, there is a gap in research on how PTSD is intertwined with the reduction of quality of life, and how quality of life indicators and social functioning change during treatment.

There are some special difficulties for conducting research on posttraumatic stress following war experience resulting in a comparatively small number of systematic studies. In most post-war situations, there were neither special institutions for treating and investigating patients nor sufficient funding for research. Also, clinicians are often reluctant to collaborate in studies on their patients, possibly feeling that traumatised people should be protected from becoming subjects in institutionalised research (21). Therefore, there is a paucity of research on posttraumatic stress in war regions, whilst most of the published research studies in these areas have included people from war affected areas that sought refuge in Western countries. The Western countries have an established research tradition, infrastructure and funding, but it remains unclear to what extent results gained in these refugee groups apply to people who stayed in the post-war area.

Treatment centres

Over the last 10 years, several centres specialising in treatment of patients suffering from posttraumat

ic stress have been established in Bosnia-Herzegovina, Croatia and Serbia. Whilst there are some common elements across all centres, there are also major differences in treatment components and therapeutic orientation (22, 23, 24). These centres have so far seen several thousand patients and accumulated an almost unique expertise in the care for patients in post-war regions suffering from posttraumatic stress. What might be missing is systematic research on assessing and comparing outcomes of treatments, identifying predictors of outcomes, benchmarking outcomes for subgroups and analysing treatment elements that are associated with more or less favourable outcomes across all centres.

The STOP study

In the light of these issues, we present the rationale and method of the STOP study. The full title is “Treatment Seeking and Treatment Outcomes in People Suffering from Posttraumatic Stress Following War and Migration in the Balkan”. This is a multi-centre study funded by the European Commission being conducted in the Balkan countries - Bosnia-Herzegovina (Sarajevo), Croatia (Zagreb and Rijeka) and Serbia (Belgrade) as well as in two member states of the European Community - United Kingdom (London) and Germany (Dresden).

Chance for research

We hope that the proposed project will bring together the expertise developed in different treatment centres in countries of ex-Yugoslavia and the research background of university departments working on posttraumatic stress in the United Kingdom and Germany. The participating treatment centres in ex-Yugoslavia have been consolidated over the last years and are now in a position to engage in systematic collaborative research. The project will address two very

important issues for improving the care of millions of people in post-war region suffering from posttraumatic stress: 1) what are the barriers to seeking and receiving treatment and what are relevant coping strategies, and 2) how are treatment components and costs associated with outcomes in different subgroups.

Work plan

The work plan has been divided into two parts, i.e. the investigation of non-treatment seekers in ex-Yugoslavia and member EC states (Part A), and the evaluation of outcomes of treatment programs in specialised centres in ex-Yugoslavia (Part B).

In order to simplify the language, in further text we will use the term "non treatment seekers" to refer both to people that did not seek treatment and to people that sought treatment for posttraumatic stress but have not received it regardless of the specific causes (detailed assessment of previous treatment behaviour is part of the interview procedure).

Research questions and method

Part A is a cross-sectional mainly exploratory study. It will yield results on the barriers to treatment and coping strategies, compare non-treatment seekers with patients in specialised treatment centres where possible – i.e. Belgrade and Zagreb, and compare non-treatment seekers in Germany and the UK (Dresden and London) with those who stayed in Croatia and Serbia (Belgrade and Zagreb).

Despite the exploratory nature, there are several specific hypotheses:

I. Non-treatment seekers have – on average - a lower level of posttraumatic stress than patients in treatment centres, but scores in the two groups overlap.
II. When the overall degree of posttraumatic stress is controlled for, non-treatment seekers have more symptoms of withdrawal and avoidance than patients in treatment centres.
III. Non-treatment seekers report more successful coping strategies and a higher degree of social support. The level of posttraumatic

stress in non-treatment seekers is associated with the report of less successful coping strategies and of less social support.

The investigation of barriers to treatment and coping strategies is purely explanatory and partly qualitative.

Recruitment

Considering local circumstances, approx. 150 non-treatment seekers will be recruited in each of four centres, i.e. in Croatia, Germany, Serbia, and the UK. People that have experienced war and/or forced migration related to the conflicts in ex-Yugoslavia are contacted through community organisations, social services, other professional organisations and personal networking. We have to contact and screen a larger number in each centre to recruit a minimum of 150 people that have experienced significant level of posttraumatic stress because of war/migration and have not sought/received any specific psychiatric treatment.

Due to the larger number of potential participants in Serbia and Croatia, recruitment procedure in these centres is different, i.e. we are aiming at recruiting people from high risk groups (refugees, internally displaced persons or war veterans) in a randomised way.

Once potential participants are contacted, the inclusion criteria will be the following: Balkan origin, aged between 18 and 65 years, have experience of war and/or forced migration related to the conflicts in ex-Yugoslavia, have not sought/received specific psychiatric treatment which is defined as formal psychotherapy, have no severe mental impairment due to organic causes and are capable of giving written informed consent. If all inclusion criteria are fulfilled, interviewees are asked for written informed consent to participate in the study.

In the next step, we ask seven screening questions (25) on symptoms of posttraumatic stress since war/migration. Participants reporting two or more symptoms are asked to complete the full interview. Approximately thirty of the participants in each centre will be asked to do an additional in-depth qualitative interview. Content of the research interview is shown in Table 1

All interviews are conducted face-to-face and open questions are tape recorded.

The open questions will be subjected to content analysis using a posteriori developed categories. Inter-rater reliability on the categories will be established. The open questions cover coping strategies with psychological difficulties, effect of those strategies and barriers to treatment.

Table 1. Assessment instruments for Part A

Constructs/ criterion	**Assessment instruments**
Screening for PTSD symptoms	Short Screening Scale
Stressful events *PTSD and impact on social functioning*	List of Stressors CAPS (26) plus extended question on impact on social functioning
General psychopathology	Brief Symptom Inventory BSI (27)
Posttraumatic stress	*Impact of Event Scale-Revised 22 (28)*
Socio demographic data	
Quality of life	Manchester Short Assessment of Quality of Life (MANSA)(29)
Costs of health service utilisation and other support	Client Socio Demographic and Service Receipt Inventory (CSRI) (30)
Psychiatric history	Structured questions
Physical health	Structured questions
Alcohol and substance abuse	CAGE questionnaire (31)
Current stress, migration stressors and acculturation	Structured questions
Wishes for compensation *(In Belgrade and Zagreb)*	Structured questions
Coping strategies and barriers to treatment	Open questions **tr**

tr - a semi-structured interview with defined open questions and possible further probes is tape recorded

A more in depth qualitative interview is conducted with approximately 30 participants per centre. The sampling is theoretical, possibly based on levels of posttraumatic stress and coping strategies as identified in the aforementioned interview. The in depth interviews aim to explore processes in coping and treatment seeking over time, and

identify major themes that characterise successful and less successful coping without treatment. Interviews are tape recorded, transcribed and analysed using a framework for categorising contents and themes. An adjusted form of grounded theory is applied to analyse results at each centre and compare findings from different sites, in particular between Germany/UK (with refugee populations in new cultures) and Croatia/Serbia (with people in their culture of origin).

Part B: Treatment seekers are recruited in specialised treatment centres in Bosnia-Herzegovina, Croatia, and Serbia. In addition to the comparison between characteristics of patients and non-treatment seekers (see Part A) this part of the study addresses the following questions:

- What outcomes in changes of symptoms, treatment satisfaction, social functioning and quality of life are to be expected for different sub-groups of patients in specialised treatment centres?
- What baseline characteristics and treatment components are consistently associated with a more favorable outcome across treatment centres?
- What are the treatment and support costs for patients suffering from posttraumatic stress and how are costs linked to outcome?

Part B is a longitudinal mainly exploratory study. It assesses treatment processes and outcomes of patients in specialised treatment centres in Belgrade, Rijeka, Sarajevo and Zagreb. Patients are interviewed at baseline (i.e. pre-treatment), after 3 and after 12 months. In addition to the hypothesis mentioned in part A, we predict that patients reporting a lower level of social support, less successful coping strategies and wishes for compensation at baseline have a poorer outcome. Investigation link between treatment elements and outcome is exploratory.

Recruitment

All patients referred to treatment in specialised treatment centres are assessed for eligibility for the study. The same inclusion criteria are applied as in part A (apart from obvious omission of the criterion “have not sought/received specific psychiatric treatment”). In addition the patient must score above the required threshold score on the Impact of Events Scale Revised. The required threshold is based

on the method applied by Gavrilovic et al. (32) for 'low intensity' posttraumatic stress and is scoring 6 or more both on the intrusion and on the avoidance scale. This inclusion criterion is important as a 'filter' for including patients with symptoms of posttraumatic stress as opposed to these who might be in treatment for other reasons.

Altogether, 375 newly admitted patients at the treatment centres will be recruited and assessed at baseline. To participate in the study patients are asked for written informed consent.

All patients are interviewed at baseline and will be followed up after 3 and after 12 months, independently of their treatment adherence and outcome (and independently of the duration of treatment). All interviews are conducted face-to-face by an interviewer who is not directly involved in the treatment of the given patient.

Content of the research interview is shown in Table 2.

Table 2. Assessment instruments for Part B

Constructs/ criterion	Assessment instruments	*Baseline*	*3 months*	*12 months*
Stressful events *Posttraumatic stress*	*List of Stressors* *Impact of Event Scale-Revised 22*	+	+	+
PTSD and impact on social functioning	CAPS plus extended question on impact on social functioning	+		+
General psychopathology	Brief Symptom Inventory BSI	+	+	+
Socio demographic data		+		
Quality of life	MANSA	+	+	+
Personality traits	NEO Five Factor Inventory (33)	+		
Costs of health service utilisation and other support	Client Socio Demographic and Service Receipt Inventory	+	+	+
Therapeutic relationship	The Helping		+	+

	Alliance Scale (34)			if in treatment beyond 3 months
Psychiatric history	Structured questions	+		
Physical health	Structured questions	+		
Alcohol and substance abuse	CAGE questionnaire	+		+
Current stress, migration stressors and acculturation	Structured questions	+		
Wishes for compensation	Structured questions	+		
Coping strategies	Open questions	+ **tr**		+ **tr**
Motives/expectations concerning treatment	Open questions	+ **tr**		
Experiences with/ views of the given treatment	Open questions		+ **tr**	+ **tr**
Documentation on treatment input and treatment adherence	Open questions	Every 3 months as long as in treatment (at 3, 6, 9 and 12 months)		

tr - a semi-structured interviewed with defined open questions and possible further probes is tape recorded

A semi-structured interview with defined open questions and possible further probes covering coping strategies, motives concerning treatment and experience with given treatment is tape recorded and subjected to content analysis using a posteriori developed categories. Inter-rater reliability on the categories will be established.

Outlook

It will take several years before the final results of the STOP study are available. Over these years the STOP study will hopefully initiate collaboration and establishment of a research infrastructure bringing together expertise from different areas. Designed as an ambitious collaborative project, as such it carries certain risks (e.g.

under-recruitment, ineffective or insufficient communication etc.). Once the final results are yielded, the STOP study will provide an empirical basis for designing adequate care programmes for people suffering from posttraumatic stress that reach people who currently do not seek or receive help, and for improving treatment programmes for those patients who are cared for in specialised treatment centres.

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