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## STUDY OF LONG-TERM CLINICAL AND SOCIAL OUTCOMES AFTER WAR EXPERIENCES IN EX-YUGOSLAVIA – METHODS OF THE ‘CONNECT’ PROJECT\*

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### Abstract:

**Background:** The CONNECT study investigates long-term clinical and social outcomes of people with war experience in countries of Ex-Yugoslavia and in refugees in Western Europe, and aims to identify the impact of social and health care interventions on these outcomes.

**Objective:** To describe the rationale and methods of the CONNECT study (full title: Components, organization, costs and outcomes of health care and social interventions for people with posttraumatic stress following war and conflict in the Balkans).

**Method:** Description of the study protocol as developed in collaboration of eight centres in the United Kingdom, Germany, Italy, Serbia and Montenegro, Croatia, Bosnia-Herzegovina, and FYR Macedonia.

**Results:** In each country, a survey will be conducted in community populations with a high risk to have experienced potentially traumatic events (N=640 in each country in Ex-Yugoslavia and 250 in each Western European country). Current social and clinical characteristics will be obtained, and social and health care interventions received in the past will be assessed. Moreover, a total sample of 900 people with persistent symptoms of posttraumatic stress will be identified and followed-up over a one year period.

**Discussion:** This large scale project aims to provide evidence on the relative impact of social and health care interventions on long-term sequelae of war related traumatic events, and puts particular emphasis on people with persistent symptoms of posttraumatic stress. The results should help to develop models to predict long-term service needs in future populations that experience traumatic events and either take refuge in other countries or stay in the area of conflict.

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## **HISTORICAL BACKGROUND**

The collapse of former Yugoslavia in the early 1990s precipitated the worst armed conflict in Europe since 1945. For several million people the conflict was associated with various extremely stressful and potentially traumatic experiences (1, 2). During and following the war, more than two million people were uprooted and left the area they used to live in. Whilst most of these displaced people stayed in countries of Ex-Yugoslavia, large numbers sought residence in Western European states (3).

### **Posttraumatic stress and other mental sequelae of traumatic events**

A large body of literature shows that stressful experiences occurring in war situations may lead to short-term and long-term mental disorders (4, 5). A common feature of these disorders is posttraumatic stress as characterized by unwanted recollections of the traumatic event(s), avoidance of situations reminding of the event, emotional numbing, and signs of hyper-arousal. Other sequelae, however, such as depression, phobias, and addictive behaviour also frequently follow traumatic experiences, either in combination with specific symptoms of posttraumatic stress or on their own (6, 7, 8).

Despite significant publications on the epidemiology of posttraumatic stress in community samples (9, 10, 11, 12), systematic studies on long-term outcomes are rare and little is known about: a) the frequency of mental disorders in populations that have been exposed to war related stressful events ten or more years after the war, b) the social outcomes in these populations, and c) the predictors of more or less positive long-term outcomes.

### **Impact of social and health care interventions**

Randomised controlled trials have provided evidence that specific treatment of Posttraumatic Stress Disorder (PTSD), in particular psychological treatment with trauma focused cognitive-behavioural work and exposure, can be effective in alleviating symptoms and preventing relapse (13, 14, 15, 16). Yet, it has been argued that provision of such treatments is less important for helping people with war related mental health distress, and most notably refugees, than social and material support (17, 18). Summerfield (18) has suggested that the people concerned would prefer social interventions to psychological treatment and benefit more from it in terms of social outcomes. This debate is of obvious relevance for health and social policies, but for the time there have been hardly any systematic empirical studies addressing the issue.

### **People with persistent symptoms**

There is a consensus in the literature that treatment of people with posttraumatic stress is less successful once the symptoms have lasted for several years and become chronic (19, 20). In many treatment studies patients

with such persistent disorders are excluded because of their poor prognosis (21). This patient group poses a special challenge to social and health services. Because of the dearth of research evidence on what factors, if any, influence symptoms and quality of life in these patients effective care is difficult to plan and deliver. As a consequence, the often severely distressed and persistently suffering patients are not only excluded from research studies, but also from receiving targeted interventions.

### **The CONNECT study**

Against this historical and scientific background, the CONNECT study has been designed as a multi-centre project. Its full title is: „Components, organization, costs and outcomes of health care and social interventions for people with posttraumatic stress following war and conflict in the Balkans“. It is funded by Commission (Research Directorate) of the European Community within the Framework Programme 6. It builds on and complements the STOP project, which has also addressed issues of posttraumatic stress following war in Ex-Yugoslavia (22). STOP has two parts. In the first part barriers to treatment and coping strategies are assessed in samples in Croatia, Serbia and Montenegro, Germany and the United Kingdom. In the second part, outcomes of treatment in specialized centres in Belgrade, Rijeka, Sarajevo and Zagreb are obtained and linked to treatment components and costs. CONNECT investigates related, but distinct issues, in terms of methodology represents an even more ambitious project, and widens the research network that has already been established for STOP in countries of Ex-Yugoslavia, focusing on university departments for psychiatry and psychology. It will be conducted in seven countries, i.e. the United Kingdom (centre in London), Germany (centre in Dresden), Italy (centre in Modena), Serbia and Montenegro (centre in Belgrade), Croatia (centres in Rijeka and Zagreb), Bosnia-Herzegovina (centre in Sarajevo), and FYR Macedonia (centre in Skopje). Another centre in Pristina is likely to be included at least for parts of the study, although this will not be funded by the project grant. The study is co-ordinated in London, and the design has been developed and finalized involving all partners.

### **Study objectives**

The project has the following research aims:

1. To assess the components and organisation of health care and community based social interventions for people with posttraumatic stress.
2. To develop a model predicting long-term service use and clinical, as well as social, outcomes in people who experienced potentially traumatic events.

3. To assess components, costs and subjective outcomes of health care and community based interventions in people with persistent posttraumatic stress.
4. To identify factors influencing change in people with persistent posttraumatic stress.
5. To estimate whether and, if so, to what extent, results gained in refugee populations can be generalised to people who stayed in the area of the conflict, and *vice versa*.

## **METHODS**

To achieve these objectives, the methods include two related parts of data collection:

- A) A survey will be conducted in each country to identify and study people who experienced potentially traumatic events related to war in the Balkans.
- B) Within the survey people with persistent symptoms of posttraumatic stress will be identified, who will be re-interviewed after a one year follow-up period. In case the survey will not identify a sufficient number of people with persistent symptoms in one or more countries, additional people will be recruited through specialized treatment centres as necessary.

### **A) Survey**

#### *Sampling and recruitment*

A random sample of people who had been exposed to potentially traumatic events in the Balkans will be investigated in each country. The size of these samples will be a minimum of 640 in each participating Balkan country and a minimum of 250 in each member state. In each Balkan country, the sampling procedure will follow the random walk approach, i.e. trained researchers will go to areas with populations that were subjected to war (armed conflicts) and interview people, approaching a random selection of households and people within households.

In Italy, Germany and the UK there are no areas with sufficient density of suitable interviewees so that the random walk approach cannot be used. Thus, the sampling will preferably follow a random selection of people in resident registers or respective community centres. In case this does not yield a sufficient number of participants, recruitment can be done via lists of general practitioners. Only if this is also impossible, a snowballing approach will be used.

#### *Inclusion criteria*

The inclusion criteria for interviewees in the survey are

- Born within the territory of former Yugoslavia
- Age between 18 and 65 years
- Having experienced a potentially traumatic event related to war (armed conflict) or migration on the Balkans, which will be confirmed through screening questions
- No mental retardation; no severe mental disorder as a result of brain injury or other organic illness

#### *Interviews and instruments*

Researchers will approach potential interviewees, explain the aims and nature of the study and ask for written informed consent. If consent has been obtained, researchers will interview participants and use the following instruments (the whole interview is assumed to take about an hour on average):

- A short screening list (23) to check whether the interviewee has experienced potentially traumatic events related to war (armed conflict) and migration on the Balkans; the experience of any of the events on the list of war stressors will be sufficient for inclusion.
- The Life Stressor Checklist-Revised (24) to assess potentially stressful events before, during, and after the war in the Balkans.
- The Manchester Short Assessment of Quality of Life (MANSA) (25) to obtain basic socio-demographic characteristics as well as objective and subjective indicators of quality of life.
- The MINI International Neuropsychiatric Interview (MINI) (26), supplemented by an additional short section on somatisation disorders and with questions on all symptom clusters of PTSD (even if the diagnosis is not fulfilled), to assess current psychiatric disorders of the interviewee.
- The Brief Symptom Inventory (BSI) (27) to assess the degree of self rated mental health symptoms, including the level of symptoms on subscales.
- The Impact of Event Scale-Revised (IES-R) (28) to assess more specifically the level of current symptoms of posttraumatic stress.
- A short new instrument on health care and social interventions that has been developed in a Delphi-process within the CONNECT project. Table 1 shows the categories in the instrument.

Table 1: Categories for the assessment of health care and social interventions

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**1) Primary Care***(for mental and physical health problems)***2) Mental health care**

- a) Care of community mental health services (e.g. psychosocial treatment and care for various groups with mental health problems provided for individuals or groups; this may include counselling, supportive therapy, psycho-education, social skills training, programmes for perpetrators and support for victims of domestic violence).
- b) Outpatient mental health treatment (e.g. specialist consultations; individual and group psychotherapy; pharmacotherapy; addiction programmes).
- c) Inpatient mental health treatment (including day hospital care).
- d) Specialised tertiary treatment for post-traumatic stress (in inpatient or outpatient setting).
- e) Self-help groups for mental health problems (e.g. alcoholics anonymous and similar groups).

**3) Specialist physical health care**

- a) Care of health care services in the community.
- b) Outpatient specialist treatment (e.g. rehabilitation for physical disability or cardi-ological problems; physiotherapy; specialist consultations).
- c) Inpatient specialist treatment (including day hospital care and in-patient rehabilita-tion units).

**4) Housing**

- a) Fully provided (e.g. sheltered home; collective refugee centres; refugee accommo-dation in hotels or temporary homes).
- b) Support and allowances in independent accommodation (e.g. support for rents or special rents; materials for building houses; houses rebuilt by authorities; equipment and furniture).

**5) Employment and training**

- a) Sheltered employment (e.g. specialised companies for disabled staff or run by vet-erans).
- b) Support in regular employment.
- c) Training schemes (e.g. retraining programmes and training for work schemes).
- d) Other support (e.g. for finding jobs).

**6) Leisure and social support**

- a) Mutual support groups (non-health treatment, possibly supported by voluntary or-ganisations or individuals).
- b) Leisure time, social support and contacts (e.g. organised sport activities and events; commemorations; concerts, arts workshops and exhibitions; drop-in, day care and social centres; cultural clubs; specific initiatives of political parties and churches; language courses).

**7) Pensions and financial benefits***(e.g. compensation for disability; veterans pension; allowances for carers, transport, vi-sas, medical assessments, medication, clothing, and education; coupons for food; provi-sion of telephone; tickets for public transport).***8) Legal support***(e.g. advice on property issues, citizenship, visas, and legal status)***9) Information and advocacy***(e.g. through special interest groups; interpreters; organised information visits to re-gional surroundings, offices and services)*

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- The instrument will be used to ask interviewees about the inter-ventions that they have received since the war because of post-traumatic stress and other psychiatric disorders. The instrument

may be further amended depending on the results of a piloting phase and is harmonised with the Client Service Receipt Inventory (29) so that costs of interventions can be estimated.

- A question on medication (prescribed and self-medication) taken for mental health problems since the war.
- Open questions on the effects of interventions, which will include:
  - 1) Which of the interventions you received have been helpful and, if there have been any, why and how have they helped?
  - 2) Which of the interventions you received have been detrimental and, if there have been any, why and how have they harmed?
  - 3) Which other interventions would you have wished to receive?These general questions will be complemented by specific probes.

## **B) Longitudinal assessment of people with persistent posttraumatic stress**

### *Sampling and recruitment*

Within the above survey or – if not enough people are identified within the survey – through specialised treatment centres people with persistent symptoms of posttraumatic stress will be identified in each country. The sample size will be a minimum of 160 in each Balkan country and a minimum of 90 in each member state.

### *Inclusion criteria*

The same inclusion criteria as in the survey plus:

- Symptoms of posttraumatic stress in line with the definition of full or partial PTSD for a minimum of one year prior to the interview; this will be assessed on the MINI (with the additional question on whether symptoms have been persistent for a year or more). Partial PTSD will be defined as the presence of the PTSD Criteria B and C, or B and D, even if other symptoms are not present.

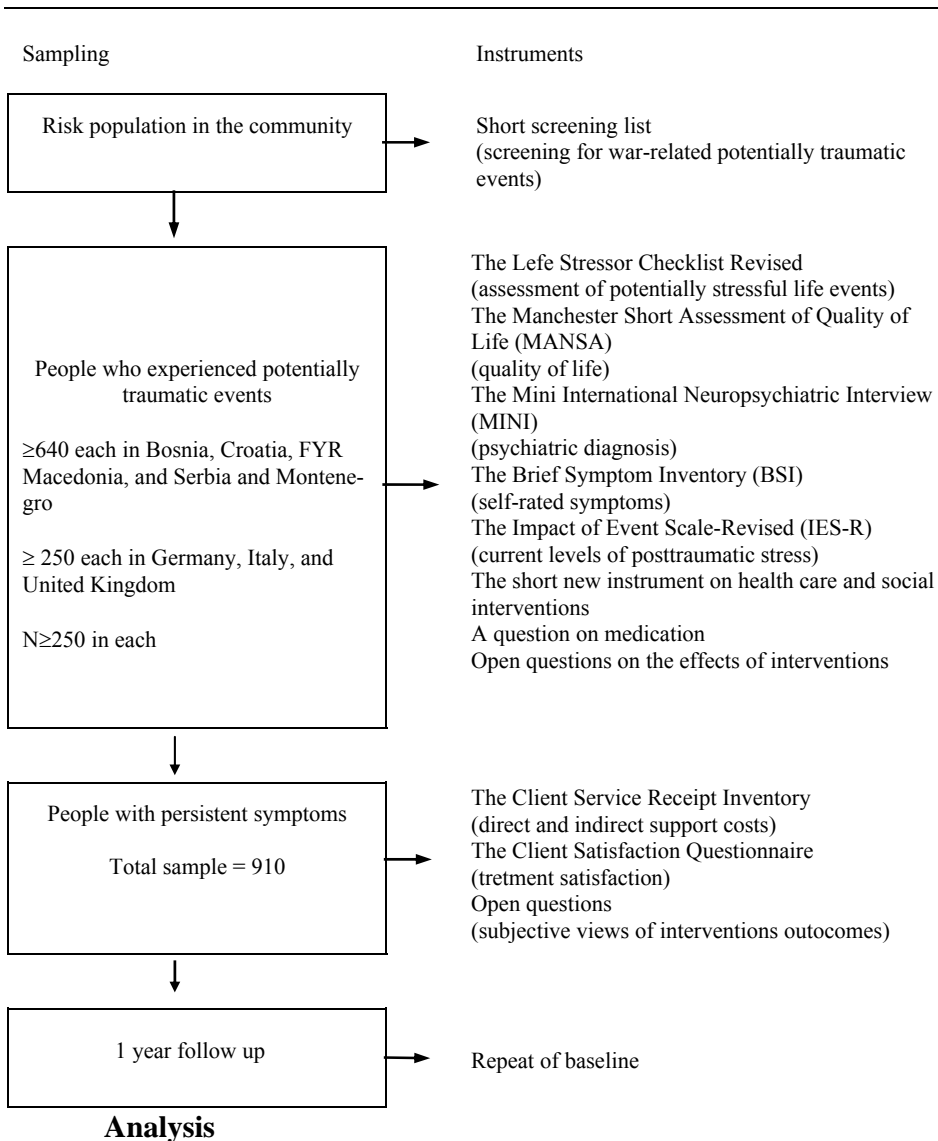
### *Interviews and instruments*

Researchers will approach potential interviewees, explain the aim and nature of the longitudinal assessment and ask for written informed consent. At baseline, interviewees will be asked about service utilisation and other support within the three months prior to the interview using an adopted version of the Client Service Receipt Inventory. Otherwise there will be no questions in addition to the ones asked as part of the survey.

The participants will be reinterviewed one year after the baseline interview. They will be asked about stressful events (using the same check list that was used in the Life Stressors Check List) and received interventions (using the new instrument) within the follow-up period. Also, the MANSA, BSI, IES-R, MINI, CSRI (for last three months) and open questions will be readministered.

Figure 2 summarises the approach of the whole study.

Figure 2: Summary of recruitment and instruments in the CONNECT study





The data will be managed and analysed in each country as well as centrally for the total sample and international comparisons. The analysis will develop statistical models for predicting: a) long-term use of health care and community based interventions including their costs, b) outcomes in terms of persistent posttraumatic stress and other psychiatric morbidity, and c) current quality of life including objective social outcomes. Three sets of predictor variables will be considered, i.e. first, socio-demographic characteristics and details of stressful events, second, utilisation and costs of interventions received, and third, current levels of posttraumatic stress and other psychiatric symptoms. A comparison between findings in countries of Ex-Yugoslavia and western European states will suggest whether and, if so, to what extent results gained in refugee populations in member states can be generalised to populations that stayed in the area of conflict and *vice versa*. The predictor models will identify the relative contribution of different types of interventions to long-term outcome. For the cost analysis, service utilisation will be linked to costs as estimate costs will be attributed to different types of interventions and specified for each country. For the assessment and analysis of costs, the Centre for the Economics of Mental Health at the Institute of Psychiatry (Kings College, University of London) has been subcontracted.

Results of open questions will be subjected to content analysis with a posteriori developed categories. The findings will be linked to the quantitative analysis, and categories with sufficient discriminative ability will be entered as variables in the statistical analysis.

In people with persistent posttraumatic stress, we will test which baseline variables and intervening factors within the follow up period predict costs of treatment and changes of clinical and social outcomes within the follow-up period. Additionally, a cost-consequences-analysis will be conducted.

## **DISCUSSION**

When the rationale and methods of the STOP study were first published in this journal in 2002, the hope was expressed that the project would initiate further collaboration and help to establish an infrastructure for mental health service research in countries of Ex-Yugoslavia. To some extent, those plans have materialized with the inception of CONNECT, an even larger and, in some ways, more ambitious study involving more partners. CONNECT alone does not provide a research infrastructure, but it might be another important step towards a growing network of research groups in academic institutions across countries of former Yugoslavia. It addresses issues of far reaching significance for mental health service research, in particular the relative contribution of health care and social interventions to recovery from mental disorders. Thus, it might indirectly be of relevance and linked to wider initiatives for mental service development in the participating coun-

tries. In particular, the project may – indirectly – benefit the initiative to establish community mental health services as part of the Stability Pact for South Eastern Europe (30). That initiative promises to be a first major step towards modern community mental care across countries of Ex-Yugoslavia and beyond. The establishment of new services would be supported by appropriate evaluation and specific research evidence. To provide this evaluation and research evidence sufficient expertise and a robust research infrastructure in South East Europe are needed. CONNECT might be helpful to develop expertise and infrastructure as well as international collaborative links.

On a scientific level, the importance of the findings is supposed to go beyond the studied groups. The intention of the survey is to develop models to predict long-term outcomes and service needs of populations following war, including refugee groups. The comparison of the models between countries will yield hints as to how stable outcomes and the predictive value of baseline features and interventions is across different contexts. Yet, although the detailed characteristics of groups in the different participating countries will vary, they all fulfill the same inclusion criteria and share a similar cultural background. Populations after war in other regions and refugee groups in other countries may have different features, expectations, experiences and responses to interventions. Thus, the predictive models developed in this study may have to be amended and adjusted. Nevertheless, the findings of CONNECT should be a basis for more specific surveys in future groups and help to specify what data should be collected and analyzed to predict service needs.

The results of both the survey and the naturalistic longitudinal assessments of people with persistent symptoms of posttraumatic stress should inform future intervention studies which might experimentally vary health care and social interventions to identify the most effective – and cost-effective – ways to help the people concerned. This applies in particular to patients with chronic distress who are often treated with an attitude of helplessness amongst clinicians. It is a challenge for researchers and clinicians to develop effective intervention strategies for this group, and the findings of CONNECT will hopefully contribute to this.

The implementation of a complex study like CONNECT is not without risks. There are the potential pitfalls of under-recruitment, an inconsistency of the quality of interviewers and interviews, an inconsistent sampling procedure, and problems of data management in eight centers some of which are without experience of studies of this nature and scale. However, there also is the expectation that the study will have positive effects beyond the delivery of the findings according to the study protocol. As already suggested, the investigators hope that expertise in mental health service research will be further developed in the participating centres and help to initiate high

quality research on issues of posttraumatic stress and – more general – development of mental health services based on outcome assessments and evidence.

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