Stressors, coping and symptoms of adjustment disorder in the course of the COVID-19 pandemic – study protocol of the European Society for Traumatic Stress Studies (ESTSS) pan-European study

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STUDY PROTOCOL

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ABSTRACT

Background: During the current COVID-19 pandemic, the people in Europe are exposed to self-isolation, quarantine, job loss, risk of contracting COVID-19, or grief of loved ones. Such a complex array of stressors may lead to symptoms of adjustment disorder or posttraumatic stress disorder. This research protocol describes a study launched by the European Society of Traumatic Stress Studies (ESTSS) to investigate the impact of the COVID-19 pandemic on symptoms of adjustment disorder across European countries.

Objective: The longitudinal online cohort study aims (1) to explore psychosocial reactions to the COVID-19 pandemic across ten European countries; (2) to examine the relationships between risk and resilience factors, stressors and symptoms of adjustment disorder during the pandemic; and (3) to investigate whether these relationships are moderated by coping behaviours.

Method: In ten countries (Austria, Croatia, Georgia, Germany, Italy, Lithuania, Netherlands, Poland, Portugal, and Sweden), between 1,000 and 2,000 participants will be recruited, depending on the size of the country. Participants will be assessed at two timepoints with a six-month interval. Following a conceptual framework based on the WHO's social framework of health, an assessment of risk and resilience factors, COVID-19 related stressors and pandemic-specific coping behaviours will be measured to estimate their contribution to symptoms of adjustment disorder. The Adjustment Disorder New Module 8 (ADNM-8) will be used to assess symptoms of adjustment disorder. As a secondary measure, symptoms of posttraumatic stress disorder will be measure using the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5).

Data analysis: The relative contribution of risk factors, resilience factors, and stressors on symptoms of adjustment disorder or symptoms of posttraumatic stress disorder will be estimated using multilevel analysis. To determine the moderating effects of different types of coping behaviours on these relationships, a multilevel mediation analysis will be carried out.

Estresores, afrontamiento y síntomas de trastorno de adaptación en el curso de la pandemia de COVID-19 - protocolo de Estudio de la Sociedad Europea de Estudios de Estres Traumático (ESTSS) estudio pan-europeo

Antecedentes: Durante la actual pandemia de COVID-19, las personas en Europa están expuestas a autoaislamiento, cuarentena, pérdida de empleo, riesgo de contraer COVID-19 o duelo de sus seres queridos. Un conjunto tan complejo de factores estresantes puede provocar síntomas de trastorno de adaptación o trastorno de estrés postraumático. Este protocolo de investigación describe un estudio lanzado por la Sociedad Europea de Estudios de Estrés Traumático (ESTSS) para investigar el impacto de la pandemia COVID-19 en los síntomas del trastorno de adaptación en países europeos.

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Objetivo: El estudio longitudinal de cohorte en línea tiene como objetivo (1) explorar las reacciones psicosociales a la pandemia de COVID-19 en diez países europeos; (2) examinar las relaciones entre los factores de riesgo y resiliencia, estresores y síntomas de trastorno de adaptación durante la pandemia; e (3) investigar si estas relaciones son moderadas por comportamientos de afrontamiento.

Método: En diez países (Austria, Croacia, Georgia, Alemania, Italia, Lituania, Países Bajos, Polonia, Portugal y Suecia) serán reclutados entre 1,000 y 2,000 participantes, dependiendo del tamaño del país. Los participantes serán evaluados en dos momentos con un intervalo de seis meses. Siguiendo un marco conceptual basado en el marco social de salud de la OMS, una evaluación de los factores de riesgo y resiliencia, factores estresantes relacionados con COVID-19 y el comportamiento de afrontamiento específico de la pandemia serán medidos para estimar su contribución a los síntomas de trastorno de adaptación. El nuevo módulo de trastorno de adaptación 8 (ADNM-8) se utilizará para medir los síntomas del trastorno de adaptación. Como medida secundaria, se evaluarán síntomas de trastorno de estrés postraumático usando el cribaje de TEPT en atención primaria para DSM-5 (PC-PTSD-5).

Análisis de datos: La contribución relativa de los factores de riesgo, factores de resiliencia y los estresores sobre los síntomas de trastorno de adaptación o síntomas de trastorno de estrés postraumático se estimará mediante análisis multinivel. Para determinar los efectos moderadores de diferentes tipos de conductas de afrontamiento en estas relaciones, se llevará a cabo un análisis de mediación multinivel.

COVID-19大流行过程中的应激源、应对方式和适应障碍症状–欧洲创伤应激研究学会（ESTSS）泛欧洲研究的研究方案

背景:在当前COVID 19大流行期间, 欧洲人民面临自我隔离, 隔离, 失业, 感染COVID-19的风险或丧亲之痛。如此复杂的一系列应激源可能导致适应障碍或创伤后应激障碍症状。本研究方案描述了由欧洲创伤应激研究学会 (ESTSS) 发起的一项研究, 以研究COVID-19大流行对个欧洲国家的适应障碍症状的影响。

目的:纵向线上队列研究旨在 (1) 探查10个欧洲国家对COVID-19大流行的心理社会反应; (2) 考查大流行期间风险与适应力因素, 应激源与适应障碍症状之间的关系; (3) 研究这些关系是否被应对行为所调节。

方法:将在10个国家 (奥地利, 克罗地亚, 乔治亚州, 德国, 意大利, 立陶宛, 荷兰, 挪威, 波兰, 葡萄牙和瑞典) 招募1,000至2,000名参与者, 具体取决于国家的规模。将在间隔六个月的两个时间点对参与者进行评估。根据以世界卫生组织健康社会框架为基础的概念框架, 将评估风险和适应力因素, COVID-19相关应激源和针对大流行的应对行为, 以评估其对适应障碍症状的影响。《适应障碍新模块8》 (ADNM-8) 将用于测量适应障碍症状。作为二级测量, 将使用《DSM-5初级PTSD筛查》 (PC-PTSD-5) 评估创伤后应激障碍症状。

数据分析:风险因素, 适应力因素和应激因素对适应障碍症状或创伤后应激障碍症状的相对贡献将通过多水平分析进行估计。为确定不同应对行为类型对这些关系的调节作用, 将进行多水平调节分析。

1. Introduction

With the global COVID-19 pandemic, Europe faces one of the most significant challenges in many years. Population-wide public health measures to reduce the spread of COVID-19 have disrupted social and economic systems. As in other regions of the world, the European populations are exposed to a variety of persistent stressors that can lead to mental health problems. These include social isolation, lack of childcare, loss of employment, having COVID-19, and loss of loved ones (Brooks et al., 2020; Fiorillo & Gorwood, 2020; Galea, Merchant, & Lurie, 2020). Given the psychological, social and economic burden placed on entire populations, the impact of the pandemic on mental health is a critical issue to be addressed (Holmes et al., 2020).

Subgroups of the general populations might be particularly vulnerable to develop mental health problems. People with a low socio-economic position may experience greater social and economic burden due to unemployment, low financial reserves and precarious working conditions (van Dorn, Cooney, & Sabin, 2020). Frequent consumption of news about COVID-19 in social media seems to increase the perceived distress (Gao et al., 2020).

Elderly persons might be more distressed by measures of self-isolation than younger person due to fewer social contacts (Armitage & Nellums, 2020). Previous or current mental or physical health conditions (Liu, Chen, Lin, & Han, 2020) and previous trauma exposure (Frewen, Zhu, & Lanius, 2019) may be additional factors that may place people at greater risk. People who have COVID-19, or who have personal contact with people who may have COVID-19, are prone to mental health problems. Frontline health care workers may experience distress related to moral injury if they are unable to provide appropriate treatment due to a lack of needed resources (Greenberg, Docherty, Gnanapragasam, & Wessely, 2020; Kang et al., 2020; Lai et al., 2020).

When facing stressful situations, most individuals may cope in a resilient manner and react with strength to personal and social adversity (Kitson, 2020). However, during the current uncertain and acute crisis of the COVID-19 pandemic, the accumulated stressors may disrupt mental health (Rajkumar,

2020). Based on findings from earlier pandemics, one out of four individuals suffered from clinical symptoms (Mihashi et al., 2009). A study conducted in Italy at the beginning of the current COVID-19 pandemic showed that many individuals experienced psychological distress, particularly women (Rossi et al., 2020).

Symptoms of adjustment disorder or posttraumatic stress disorder (PTSD) were most often reported (Rossi et al., 2020). Given the psychological burden during the COVID-19 pandemic (Lima et al., 2020), the relationships between the cumulative risk and resilience factors, stressors, and stress-related symptoms should be investigated.

The COVID-19 pandemic characteristics and its development are not well understood. The course of the pandemic is unpredictable, although the most likely scenario is that COVID-19 will continue to spread (Cyranoski, 2020). Previous research has shed light on risks and mitigating factors of trauma and stress-related disorders; such knowledge could be helpful to design timely prevention strategies. At present, knowledge of the risk factors and stressors that contribute most to the psychological burden in the general population across different countries in Europe is still sparse.

According to the WHO's multilevel social framework of health (Solar & Irwin, 2010), both social determinants of health inequalities and social determinants of health impact on mental health and disorders. Such determinants include risk factors and stressors on the individual, community and country level nation. The COVID-19 pandemic may have an impact on many, if not all, of these risk factors and stressors (see Figure 1).

Determinants of adverse mental health may include biological factors (e.g. having COVID-19 or chronic illness), psychosocial factors (e.g. fear of contracting COVID-19, feeling isolated, perceived lack of social support, having Intensive Care Unit treatment, death of loved ones, severe COVID-19 infection of loved ones, working in health care), and material circumstances (e.g. financial and job loss, restricted housing conditions). Behavioural factors, i.e. behaviours to cope with the stressors of the pandemic (e.g. physical exercise or substance use) may buffer or heighten the impact of pandemic-related stressors on mental health (Allen, Balfour, Bell, & Marmot, 2014).

Determinants of mental health inequalities during the COVID-19 pandemic comprise socioeconomic characteristics (e.g. loss of job, access to financial support), culture and societal values (e.g. stigmatization of vulnerable groups, limitation of individual rights), social and health policies (e.g. short-term work, access to health services), and public policies (e.g. physical distancing, restriction of free movement, quarantine, enforcing surveillance of individuals).

Tackling the COVID-19 pandemic has placed immense pressure on healthcare systems around the world, health care workers are at increased risk of extreme stress and trauma exposure (Greenberg et al., 2020; Williamson, Murphy, & Greenberg, 2020).

Different European countries enforce different public policies to respond to and manage the COVID-19 crisis. Some apply more restrictive and less participatory public policies (e.g. Georgia, Italy), while others decided upon less restrictive and more participatory approaches (e.g. Sweden). European countries also differ in terms of socioeconomic factors, onset of the outbreak, social security, healthcare system, and in the extent to which supportive social policies are planned and implemented. Moreover, European countries have different cultural values which not only shape the perception of the stressors,
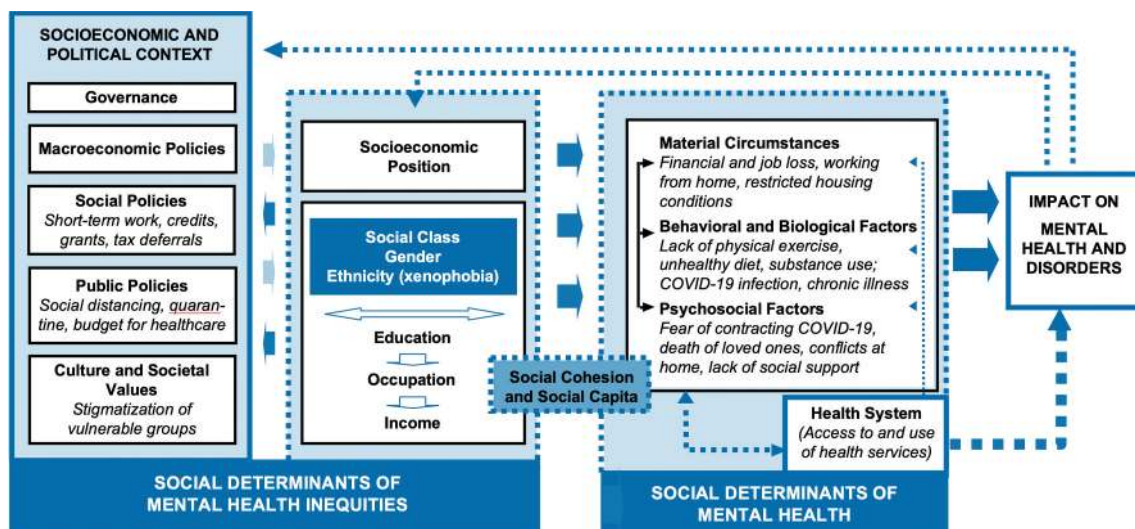

Figure 1. Social determinants of mental health during the COVID-19 pandemic. Framework adapted from the WHO's Conceptual Framework for the Social Determinants of Health (Solar & Irwin, 2010).

but have an impact on individual, family and collective coping strategies to deal with them.

This study protocol describes a study launched by the European Society for Traumatic Stress Studies (ESTSS). The study was planned with a specific focus on stress- and trauma-related disorders. An ESTSS Task Force on Psychosocial Responses to COVID-19 identified the need for such studies to fill the gap of knowledge about stress- and trauma-related mental health problems during the COVID-19 pandemic (Javakhishvili et al., 2020). The study will examine the relationships between these complex risk and resilience factors, stressors, coping behaviour and stress-related symptoms during the COVID-19 pandemic across ten European countries.

2. Research objectives

The cohort study aims (1) to explore psychosocial reactions to the COVID-19 pandemic across ten European countries; (2) to examine the relationships between risk and resilience factors, stressors and symptoms of adjustment disorder during the COVID-19 pandemic; and (3) to investigate whether the relationships between risk factors, resilience factors, stressors and symptoms of adjustment disorder are moderated by different types of coping behaviours. It is assumed that the selected risk factors, resilience factors and stressors are significantly associated with severity of adjustment disorder symptoms at T1 and T2.

3. Methods

3.1. Design

The study was planned to be an online cohort survey involving the general population. The study will be conducted in ten European countries: Austria, Croatia, Georgia, Germany, Italy, Lithuania, Netherlands, Poland, Portugal, and Sweden. Participants will be assessed at baseline (T1) and will be reassessed 6 months later (T2) (Figure 2).

3.2. Eligibility

The study will recruit participants from the general population who have access to internet. The inclusion criteria require all participants to be at least 18 years old and to be willing to take part in the survey. In accordance to ethics standards, all participants are requested to provide an informed consent before taking part in the study.

3.3. Sample size

The countries involved in this study differ by population size. In light of this, the sample sizes will be N = 1,000 for countries with less than 15 Mio. inhabitants (Austria, Croatia, Georgia, Lithuania, Portugal, Sweden), and N = 2,000 participants for countries with more than 15 Mio. inhabitants (Italy, Germany, Netherlands, Poland).
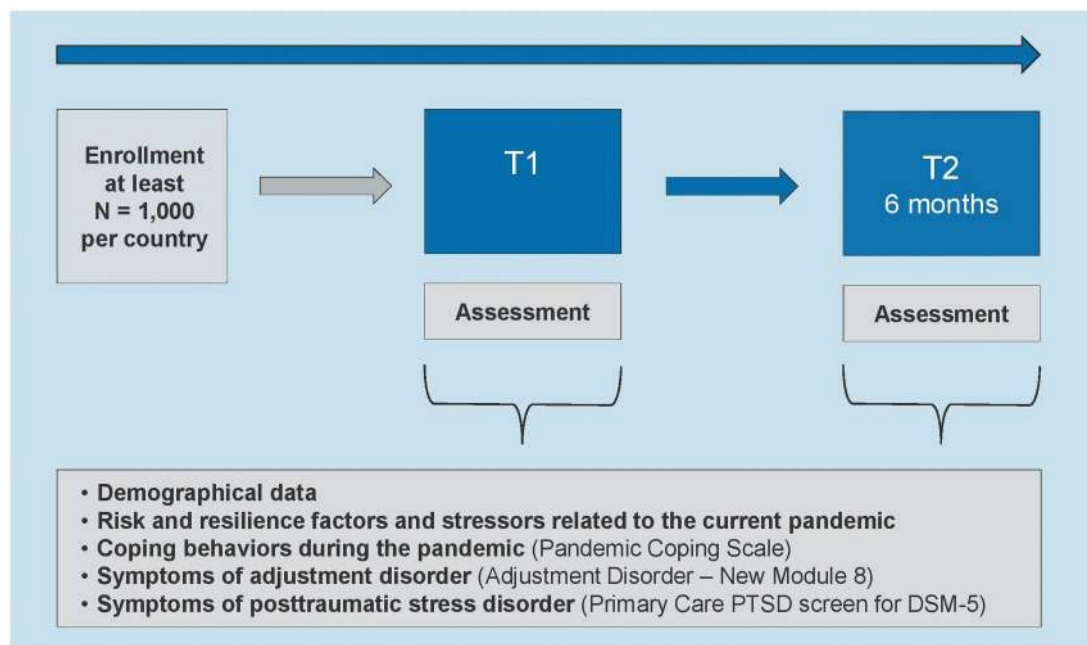

Figure 2. Study design.

3.4. Recruitment

Recruitment strategy complies with the need of having a fast data collection; therefore, most of the participants will be recruited via social platforms (e.g. Facebook, Twitter, Instagram, WhatsApp, LinkedIn). Additional strategies will include recruitment through universities, stakeholders and professional organizations, and advertisements in television, newspapers and magazines. A range of different methods will be used to increase variability of the sample in terms of gender, age, education, and regions of the countries (e.g. posting on interest groups and websites that address different age, gender, and education groups). Participants may or may not receive incentives, depending on the financial resources of the participating countries.

3.5. Measures

The core set of instruments includes sociodemographic characteristics (e.g. age, gender, nationality, relationship status, education, income and work situation), risk and resilience factors and stressors related to the COVID-19 pandemic, coping behaviours during the pandemic, symptoms of adjustment disorder, and symptoms of posttraumatic stress disorder.

4. Risk and resilience factors and stressors during the COVID-19 pandemic

For the selection of risk and resilience factors and stressors, a conceptual framework on the determinants of mental health during the COVID-19 pandemic has been developed (Figure 1), based on the WHO framework for social determinants of health (Solar & Irwin, 2010). Individual risk factors include age, gender, single-parent status, migration status, health worker (e.g. nurse, care assistant, front-line health worker), being at work with frequent personal contact, education, previous or current mental illness, and childhood trauma exposure, among others. Childhood trauma exposure will be assessed using the first five items of the Adverse Childhood Experiences (ACE) Questionnaire (Felitti et al., 1998). Respondents are asked ('yes' vs. 'no') whether they experienced five different types of ACEs before age of 19 (emotional, physical, and sexual abuse; emotional and physical neglect). The ACE Questionnaire has been validated in nonclinical and clinical samples and demonstrated satisfactory internal consistency and evidence for its convergent validity with the Childhood Trauma Questionnaire (Schmidt, Narayan, Atzl, Rivera, & Lieberman, 2020). The remaining risk factors will be assessed by self-constructed items.

Perceived cognitive, behavioural, and emotional burden of COVID-related stressors will be assessed with 4-point scales (0 = not at all burdened, 1 = somewhat burdened, 2 = moderately burdened, 3 = strongly burdened) during the last month. More specifically, we will assess stressors related to health (e.g. fear of contracting COVID-19, having COVID-19; severity of COVID-19; loved ones having COVID-19; severity of COVID-19 of loved ones, death of loved ones); public-life restrictions (e.g. restricted leisure activity, being at home most of the time); social relations (e.g. perceived lack of social support; restricted personal contact to loved ones; stigmatization); home (e.g. difficulties with combining work with childcare, conflicts at home; restricted housing conditions); work (e.g. financial and job loss, reduced working hours); and social media (e.g. consumption of social media coverage of the pandemic).

Risk and resilience factors and stressors on the country level, e.g. population demographics (density, age structure), public policies to respond to the COVID-19 pandemic, the time of the outbreak, social security, healthcare system characteristics, and social policies will be collected from publicly available data sources (e.g. John Hopkins Coronavirus Resource Centre, Centre for Health Security).

4.1. Coping behaviours

To address all COVID-related coping behaviours, a brief questionnaire on coping behaviour was specifically developed (Pandemic Coping Scale, PCS; Lotzin, 2020). The first set of items was developed by the University of Hamburg, based on the recently published recommendations on how to cope with the COVID-19 pandemic (AMA, 2020; CDC, 2020; CSTS, 2020; WHO, 2020), and on a review of studies about coping during previous pandemics. The resulting questionnaire includes 13 items representing coping behaviour in six areas: Preventive action (e.g. 'I have been following the recommendations to limit the spread of the coronavirus'); Health lifestyle (e.g. 'I have been paying attention to a healthy diet.'); Rest (e.g. 'I have been paying attention to take enough breaks.'); Meaningful activities (e.g. 'I have been doing something that I enjoy.'); Daily structure (e.g. 'I have been paying attention to maintain my daily routine.'); and Social support (e.g. 'I have been spending a good time with loved ones, friends, or my pet.'). Respondents rate on a 4-point-scale ranging from 0 to 3 (0 = I have not been doing this at all; 1 = I've been doing this a little bit; 2 = I've been doing this a medium amount; 3 = I've been doing this a lot) what best applies to them. Items were constructed by a clinical psychologist with expertise in traumatic stress research and psychological treatment of posttraumatic stress disorders (first author of this

protocol). Items were then reviewed, refined and selected by consensus of an expert group of professionals in the field of traumatic stress (authors of this protocol). Use of supportive services (telephone consultation, online coaching, psychotherapy or self-help group; personal coaching, psychotherapy or self-help group) during the pandemic will be also assessed.

4.2. Mental health-related measures

Symptoms of adjustment disorder will be assessed with the Adjustment Disorder – New Module 8 (ADNM-8; Kazlauskas, Gegieckaite, Eimontas, Zelviene, & Maercker, 2018). The ADNM-8 measures adjustment disorder symptoms with eight items ranging from 1 to 4 (1 = never, 2 = rarely, 3 = sometimes, 4 = often). A total score (ranging from 8 to 32) can be calculated by summing up the item scores. The measure has been psychometrically evaluated in help-seeking individuals with symptoms of adjustment disorder, where it has indicated factorial validity (Kazlauskas et al., 2018).

Symptoms of posttraumatic stress disorder will be assessed using the Primary Care PTSD Screen for DSM-5 (PC-PTSD-5; Prins et al., 2015). The PC-PTSD-5 is a brief 5-item screening measure for PTSD according to DSM-5. Respondents rate on dichotomous items whether the respective PTSD symptom was experienced within the last month (0 = no, 1 = yes). The total PC-PTSD-5 score is obtained by summing the scores of the five items. The PC-PTSD-5 has been developed from the PTSD-4, a widely used screening measure for PTSD that showed reasonable performance characteristics in community settings (Spoont et al., 2015). The PC-PTSD-5 has demonstrated strong preliminary results for its diagnostic accuracy (Prins et al., 2015).

4.3. Optional measures

In addition to the core set of measures described above, each participating country may include optional instruments to assess the following constructs: resilience, coping behaviours, symptoms of depression, and positive consequences of the COVID-19 pandemic.

Resilience will be assessed using the Resilience Evaluation Scale (RES; van der Meer et al., 2018). The scale comprises nine items tapping self-confidence and self-efficacy. The participants indicate how they think about themselves and the way in which someone usually responds to difficult situations on a 5-point scale (from 0 = completely disagree to 4 = completely agree).

In addition to the Pandemic Coping Scale that measures the pandemic-specific coping behaviour, coping behaviours can be assessed using the Brief COPE (Carver, 1997). The Brief COPE is a multidimensional inventory to assess coping with distress. Fourteen types of behaviours (Self-Distraction, Active Coping, Denial, Substance Use, Use of Emotional Support, Use of Instrumental Support, Behavioural Disengagement, Venting, Positive Reframing, Planning, Humour, Acceptance, Religion, Self-Blame) are measured by 28 items on 4-point rating scales (1 = I have not been doing this at all to 4 = I've been doing this a lot).

In addition to symptoms of adjustment disorder and posttraumatic stress disorder, symptoms of depression can be measured using the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). Respondents rate on nine items (0 = not at all to 3 = nearly every day) whether they experienced symptoms of fatigue, loss of appetite or negative thoughts related to depression within the last 2 weeks.

Positive consequences due to the coronavirus pandemic can be assessed by a set of items developed for the purpose of this study. They ask the participants to indicate whether they see that the COVID-19 pandemic may have had any positive aspects. The 14 items are designed in a 4-point response format, ranging from 'not at all positive' to 'strongly positive'. These items cover the potentially positive consequences in the following areas: social, health, job, learning, joyful time, reflection, and recovery.

5. Procedure

The study was registered in a study registry prior to its start (OSF registry, https://doi.org/10.17605/OSF.IO/8XHYG). Participants are expected to be recruited from end of May 2020 to November 2020. Potential participants will receive an invitation to participate in the survey by providing a website link to the study. All eligible participants will be included in the study. Participants will be asked to complete an online survey consisting of several questionnaires (see measurement section). Participants will be contacted again after 6 months and asked to participate in the survey for the second assessment point.

6. Data analysis

To explore psychosocial reactions to the COVID-19 pandemic across the ten European countries, descriptive statistics of the COVID-related stressors, symptoms of adjustment disorder and posttraumatic stress disorder will be computed, stratified by country and relevant risk groups (e.g. health workers, elderly, low income). Mean and standard deviation or median and interquartile range will be computed, as appropriate, for the continuous variables; absolute and relative frequencies will be computed for categorical

variables. The prevalence of adjustment disorder (ADNM-8 > 22) and posttraumatic stress disorder (PC-PTSD > 3) will be estimated for each timepoint with mixed logistic regression for the sample and for risk-groups (p-level 5%, two-sided).

For examining the impact of risk and resilience factors and stressors on symptoms of adjustment disorder, we will apply a longitudinal multilevel model with the adjustment disorder symptom score (ADNM-8) as dependent variable, all defined risk and resilience factors and stressors (see measures section) and time point (repeated measurement using a first-order autoregressive covariance matrix) as independent variable. If the data will not follow a normal distribution, the data will be transformed with appropriate data transformation methods (e.g. linear square, cube root or logarithmic transformation, depending on the distribution of the skewed data) prior to data analysis (Šimkovic & Träuble, 2019).

After a backward selection using a likelihood ratio test in each step, a final model with the most important determinants will be obtained. This model will be extended to a moderation model to examine the moderating effect of coping behaviour. To test the robustness of the results, missing values will be imputed using the full information maximum likelihood approach in a sensitivity analysis. The same procedure will be followed for examining the impact of risk and resilience factors and stressors on symptoms of posttraumatic stress disorder. In addition to the analysis described above using continuous scores, the presence (vs. absence) of adjustment disorder (ADNM-8 > 22) or posttraumatic stress disorder (PC-PTSD>3) will be used as a dependent variable for a secondary data analysis to examine the impact of risk and resilience factors and stressors on adjustment disorder.

7. Ethics, consent and permissions

The study will meet all ethical regulations as required by the regulations of the ethics committees which are responsible for the respective study sites. Each country will obtain ethical approval of the study on a national level. Informed consent to participate in the study will be obtained from all participants. Participants will be informed that they are under no obligation to participate and that they can withdraw at any time from the study without consequences.

8. Data protection and quality assurance

Data will be stored on a server of the coordinating Centre (Centre for Interdisciplinary Addiction Research, CIAR, at University of Hamburg), or on a secure server of the study site, depending on the country. Data handling will follow the EU General Data Protection Regulation (DSGVO); data will be stored for at least 10 years. We will follow the STROBE statement on good reporting practice. The results will be published in Open Access journals, following the Guidelines on Open Access to Scientific Publications and Research Data in H2020.

9. Data Sharing

Participant countries will retain the property and administration of their national data, and all countries will share the core dataset in order to enable analyses from the whole sample of the ten countries. After study completion and publication of the results of the primary study aims, data will be made available to the public.

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