

Study Protocol (based on SPIRIT checklist)**Descriptive title**

English:

Resilience and Stress in Covid Times Study (ReST): A survey to longitudinally assess psychological wellbeing of employees of the University of Bremen and further institutions during the COVID-19 pandemic

German:

Resilienz- und Stresserleben in COVID-Zeiten: Eine längsschnittliche Befragung zum psychischen Wohlbefinden von MitarbeiterInnen der Universität Bremen und weiterer Institutionen während der COVID-19 Pandemie

Trial identifier and registry name.

Not applicable

Protocol version:

No. 3 21.04.2020

Funding:

No additional funding, the investigators are doing this as part of their position at the Department of Psychology (University of Bremen) or the Leibniz Institute for Prevention Research and Epidemiology.

Roles and Responsibilities:

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Name and contact information for the trial sponsor

no funding

Background & Rationale:

The COVID-19 pandemic has fundamentally changed the life of the population in affected countries all over the world. Responses of policies and health care systems varied between countries in intensity and rapidity. However, experiences from previous epidemics (e.g., the SARS outbreak) demonstrate that these restrictions, such as quarantine, have a negative impact on the population's well-being (Brooks et al., 2020). Psychological symptoms may include anxiety, depression, stress, nervousness, sleep problems, reduced work performance and increased alcohol abuse (for a review see Brooks et al., 2000). It is quite likely that the current situation may lead to similar impacts (Brooks et al., 2020). This would not be surprising given the challenges individuals are faced with (e.g., social isolation, potential financial problems due to job uncertainty, cramped living situations). At the same time, coping strategies to reduce stress such as going to the gym or meeting friends, are not available.

The increased level of individual stress could in turn lead to dysfunctional individual coping strategies such as alcohol misuse, more aggressive behavior and thereby spillover conflicts into close relationships (spillover effect). This is specifically likely to happen within close relationships, including partners and children, respectively.

Moderators/predictors of individual well-being. Several factors that might influence the effect of the public restrictions on the well-being of individuals have been identified. For example, Brooks et al., 2000 showed that understanding the situation, effective and rapid

communication, availability of medical and other supplies were protective factors during the SARS outbreak (Brooks et al., 2000). In addition, social support can be a protective factor for mental health problems (e.g., Wang et al., 2018). People that feel socially supported (although alone at home) during the current pandemic might therefore experience less stress compared to people that do not feel socially supported. Other possible protective factors that could act as health resources are a strong resilience, sufficient physical activity levels, and the use of relaxation techniques can also help to counteract possible quarantine-related stressors, also be means of digital technologies (e.g., Klaperski, 2017), while eHealth literacy is a necessary precondition to make use of digital technologies for physical activity and relaxation (Koopman et al., 2014). Furthermore, a well-known risk factor for mental health problems, and violent behavior specifically, include cramped living conditions, which could make the current quarantine even more challenging (Cluver et al., 2020).

Moderators/predictors of family, couple and child well-being. Since the schools and kindergartens are closed, families are faced with additional challenges during the quarantine. Parents have to handle isolation, day care and working remotely from home at the same time. Accordingly, Giray et al. (2020) suggested that school closure may increase the risk for child maltreatment for children of abusive parents (e.g., because the child is more often at home and children have less contact with potential reporters of CM such as teachers). In line, a study assessing the impact of the Ebola epidemic reported more family conflicts and a negative impact on child mental health (Plan international, 2015; Cluver et al., 2000). Parental behaviors are consistently related to child mental health indicators. Creating a safe, stable, and nurturing environment for children has been shown to increase their resilience and help them thrive. Adults are often in the role of a primary caregiver for a child and therefore their mental health is also key to raising healthy and strong children. Finally partners usually turn to each other for support when they are facing a major stressor. However, this process is only maintained for a short period of time and if a stressor, such as the comprehensive regulations emerged in response to the pandemic situation, the macro-stressor (being faced with a pandemic) now turns into a longer-term sequence of micro-stressors (e.g., coping with smaller but enduring daily challenges such as working at home with everyone around) and daily hassles. Couple relationships may then be affected by more tension and partners may not turn to each other any longer for support but instead demonstrate more dysfunctional relationship behavior. While men and women provide similar levels and quality of support to each other when not stressed men tend to provide lower-quality support when they are stressed (Bodenmann, et al., 2015).

In sum, there are a number of risk and some protective factors known which threaten or rather maintain mental health in individuals, couples and families during such challenging times. On the individual level, temperament, poor physical health, intellectual disability, and poor coping strategies increase dysfunctional response to stressors. On the family level, contributors to

increased risk include developmental outcomes of the caregivers (e.g., maternal depression) or the spill over into their close relationships (e.g., via increased parental stress into the parent child relationship) or via increased conflicts with partners to more exposure to intimate partner violence.

The current research team hypothesizes that the government and university-level measures will have a significant impact on the well-being of university staff. In line with the framework on the psychological impact of quarantine (Brooks et al., 2020) and the extension of the framework from the individual to dyadic as well as family level variables, the current study will be able to monitor psychological adaption to the different measures taken across time (shutdown, quarantine, loosening, re-opening) and it may also capture re-lapses if another shutdown would be announced within the next couple of months.

Objectives

The aim of this study is to measure the effects of the COVID-19 pandemic as a major stress event that hits everyone, adults and children alike, as well as families and the associated restrictions which impose a number of daily micro stressors especially to adults in their different roles (as professionals, as parents, as partners) and therefore threaten on the well-being of the population. In order to monitor the course of these developments and how the mental health might be affected when public restrictions are modified, we aim to administer the survey several times. The longitudinal design also allows to identify predictors for increased mental health problems as well as resilience during these times. Thus, the results may help to enhance support systems during enduring crisis, such as COVID-19.

This general research is translated into the following research objectives:

- RO 1 Assess how the individual well-being is changing during the COVID-19 outbreak
- RO 2 Assess how the couple well-being is changing during the COVID-19 outbreak
- RO 3 Assess how children's well-being is changing during the COVID-19 outbreak
- RO 4 Evaluate if the spillover effect is occurring and indeed originates from the individual distress level and spreads from there into the couple and / or parent-child relationship.
- RO 5 Monitor the course of psychological well-being across 16-20 weeks; we assume that lowering the restrictions will increase individual well-being in general; however, we expect a subsample of individuals to not improve due to their experiences during the quarantine and therefore:
- RO 6 Identify risk and protective factors regarding psychological vulnerability, adaption, and stress related to COVID-19.

Trial design:

Cross-sectional baseline assessment, and longitudinally (repeated) survey

An online survey will be used to collect data among the staff population of the university and associated institutions. We expect the sample to be representative for university staff populations in high education. We plan to repeatedly invite participants (altogether 4 times, approx. every 4 weeks) to monitor the adaptation process. Sampling participants through the internet is preferred as it allows people to participate anonymously and with little effort. In addition, it is currently one of the only possible methods of data collection in times of quarantine.

Domains and Measures

We plan to assess the following domains:

- Living situation before and during COVID-19 outbreak and currently (20 questions)
- Health behavior, COVID-19 diagnosis, symptoms, knowledge, and perceived worries (28 questions)
- eHealth literacy (15 questions)
- Stressors, informal support, mental well-being, and health resources on an individual level (CES-D, GAD-7, AUDIT, BIFL, RS-13, PRE-HIT, self-esteem, basic needs, resilience - 60 questions)
- If a partner is present: dyadic well-being and partner violence screening (dyadic level: ADAS, HITTS - 17 questions)
- If a child between 3-16 years is present: child well-being and parent-child relationship, including screening for family violence (child and family level: SDQ externalizing, pro-social, SCAS 4 subscales, PS brief, PDS - 78 questions)

All questions are attached to the ethics application (Attachment C). We outline each measure in the following section:

Individual Adult Level Variables

CES-D 8: The Center of Epidemiological Studies-Depression (CES-D) scale (Radloff, 1977) is a self-report measure to assess depression in the general population. The CES-D 8 is an 8-item version of the original scale with items rated on a 4-point scale ranging from 1 = (almost) never to 4 = (almost) always, leading to total scores ranging from 8 to 32 with higher scores indicating more severe depressive symptoms. The 8-item version has been included and evaluated in the 3rd, 6th, and 7th round of the European Social Survey (ESS).

GAD 7: The **GAD-7 is part of the** Patient Health Questionnaire (PHQ; Spitzer, Kroenke, Williams & Patient Health Questionnaire Primary Care Study Group, 1999) and assesses general

anxiety problems. It consists of 7 items, participants rate on a 4-point scale ranging from 0 = *not at all* to 3 = *nearly every day*. The questionnaire measures the key symptoms of General anxiety disorder. For the total score, the items are summed up. Thus, the total score ranges from 0 to 21. Good internal consistency and re-test reliability as well as validity have been demonstrated (Spitzer et al., 2006).

AUDIT: The Alcohol Use Disorders Identification test (AUDIT, Babor, Higgins-Biddle, Saunders, & Monterio, 2001) is a brief screening instrument for alcohol consumption and misuse developed by the World Health Organization (WHO) in order to identify individuals with hazardous and harmful patterns of alcohol consumption. The self-report version measures the domains of hazardous alcohol use, dependence symptoms and harmful alcohol use with 10 questions rated on a five-point scale. The WHO recommends a total score of 8 or more as indicator of hazardous and harmful alcohol use (Babor et al., 2001). As German version, the translation “AUDIT Münster” (Mann, Hoch, & Batra, 2016) was used. For the survey, the AUDIT was adjusted by not asking symptoms within the last 12 months, but only within the last 4 weeks. The total score reliability shows values between good and excellent ($\alpha = .84-.95$, see de Meneses-Gaya, Zuardi, Loureiro, & Crippa, 2009).

BIFL: The Bielefelder Instrument to assessment quality of life uses 18 items relating to various aspects of life and assesses the satisfaction as well as the relevance of the specific aspect. The combination of both results in a total score for Quality of life. In addition, there is also a 19th item asking for a global estimate of life satisfaction. This item may be used for validation purposes if the instrument is used in new contexts. The instrument has been validated across a heterogenous clinical group seeking psychotherapy due to their mental health problems.

Self-Esteem: The German version of the single-item self-esteem scale (SISE-D; Brailovska & Margraf, 2018; English version: Robins, Hendin, & Trzesniewski, 2001) is used to measure the global self-esteem level. The one item of the SISE-D is rated on a 5-point Likert scale from 1 = strongly disagree to 5 = strongly agree. The measure (English and German version) has been evaluated in different settings and was found to be a valid and reliable tool. It is recommended as an economic measure for self-esteem, especially for online surveys and longitudinal designs (e.g., Brailovska & Margraf, 2018; Robins, Hendin, & Trzesniewski, 2001).

Basic Needs: According to consistency theory (Grawe, 2003), individuals strive for need satisfaction by realizing their goals. These psychological needs can be categorized into the four domains attachment, appreciation / self-esteem, control / autonomy and pleasure / enjoyment. We will assess the satisfaction of these four needs with 8 items formulated for this survey by the applicants. The questions are rated on a four-point scale and a total score can be calculated.

Resilience: Resilience is the ability to manage crises and use them as an opportunity for development through recourse to personal and socially mediated resources. As such, resilience might also play a crucial role in coping with a pandemic-level virus outbreak and its consequences (e.g., lockdown, unemployment, etc.). We will assess resilience by using the German resilience scale in its short form with 13 items (Leppert, Koch, Brähler, & Strauß, 2008).

Physical Activity and Relaxation: Sufficient levels of physical activity and the use of relaxation techniques might help to buffer stress and therefore might also help in times where lockdown and quarantine become an ever-present stressful situation (Klaperski, 2017). Additionally, individuals might turn to digital technologies to be physically active or use relaxation techniques as some forms of activity cannot be performed during lockdown or quarantine (e.g., going to the gym). Therefore, we will assess current levels of physical activity as well as current levels of physical activity and relaxation realized with help of digital technologies before the COVID-19 outbreak and the current levels (3 items; Milton, Bull, & Bauman, 2010). Furthermore, we will also ask individuals regarding their self-efficacy in using digital technologies for physical activity and relaxation (2 items; based on: Milton et al., 2010 and Reinwand et al., 2013).

eHealth Literacy: Technology-based aids for lifestyle change are becoming more prevalent. Important “digital divides” remain, as well as concerns about privacy, data security, and lack of motivation. As a result, researchers need a way to characterize participants’ readiness to use health technologies for adjusting and changing lifestyles (e.g., increasing physical activity). To do so, four subscales of the PRE-HIT instrument will also be included: (1) Computer/Internet Experience, Expertise, (2) Computer Anxiety, (3) Preferred Mode of Interaction, and (4) Internet Privacy Concerns (15 items, Koopman et al., 2014).

Dyadic Adult Level Measures

ADAS: To assess couple relationship satisfaction, the German short version of the Dyadic Adjustment Scale (Sharples, & Rogers, 1984; German: Fragebogen zur Beurteilung einer Zweierbeziehung; FBZ-K; Köppe, 2001) will be used. This instrument assesses relationship satisfaction and the degree to which couples agree on matters of importance to the relationship with six items rated on a six-point Likert scale (5 = always agree to 0 = always disagree or 0 = never to 5 = more often) as well as one global item assessing the degree of happiness with the relationship on a seven-point Likert scale. All seven items can be added up to a total score. Results from a German sample show good values of internal consistency ($\alpha = .82$).

HITS: In order to assess Intimate Partner violence (IPV), we use an adaption of the screening tool Hurt, Insult, Threaten, and Scream (HITS; Sherin, Sinacore, Li, Zitter, & Shakil, 1998). The original version of the HITS consists of four items to assess physical abuse, emotional abuse,

and threats against self (e.g., *How often does your partner physically hurt you?*). Respondents rate on a 5-point scale from 1 (*never*) to 5 (*frequently*). This tool has been evaluated in different outpatient settings and showed acceptable internal reliability and concurrent validity (Chen, Rovi, Vega, Jacobs, & Johnson, 2005; Chen et al., 2007; Shakil, Donald, Sinacore, & Krepcho, 2005; Sherinet al., 1998). For the purpose of this study, the HITS was translated (and back-translated) into German language. Moreover, we adapted the original version by assessing frequencies within the last year and within the last month, as well as by adding one item on sexual abuse. This item was based on the caregiver version PedHITSS (Shakil, Day, Chu, Woods, & Bridges, 2018). Score values of the adapted version can range from 5 to 25, with higher scores indicating more frequent IPV victimization.

Child and Family Level Measures

Parenting Scale Brief (PS). The PS (Arnold et al., 1993) assesses dysfunctional parenting behavior with 13 items. The parenting scale has been widely used and has shown adequate reliability and validity (e.g., Prinzie et al., 2007). Confirmatory factor analyses suggested a 13 items short version (Rhoades & O’Leary, 2007). Parents report on their discipline practices in typical parenting situations. They report on a 7-point Likert scale on their discipline practices in typical parenting situations. For the total score, the items are averaged. Higher scores indicate more dysfunctional parenting.

Parental Distress Tolerance Scale (PDTS): The PDTS is an adapted version of the Distress Tolerance Scale (Simons & Gaher, 2005). The questionnaire contains 33 items, however, for the present study only 2 subscales will be used: Expectation of Child Coping & Interaction (13 items). Each item will be rated on a 5-point likert scale from 1 = completely agree to 5 do not agree at all. A higher score indicates a stronger parental distress tolerance. The measure has been developed in a pilot study with experts and parents together and the present version is currently under investigation for reliability and validity.

Child Maltreatment (PedHITTSS): The Pediatric Hurt-Insult-Threaten- Scream-Sex (PedHiTTS) is a screening instrument for parents or guardians of children aged 12 years or younger. The instrument is an adaption of the HiTS (screening for intimate partner violence, see below) and measures emotional, physical and sexual child abuse with 5 items. The response format is a 5-point Likert scale ranging from 0 “never” to 4 “frequently”. For the total score, all items are summed up. The total score varies between 0 and 20, while higher scores indicate more frequent abuse. Reliability was good ($\alpha = .85$; Shakil et al., 2018). The PedHitts was highly correlated with the more comprehensive Conflict Tactics Scale: Parent-Child Version (CTSPC, 24 items, $r = .70$; Shakil et al., 2018). Sensitivity and Specificity analysis showed that the optimal cut-off point to detect abuse is 1 or higher (Shakil et al., 2018).

Spence Children’s Anxiety Scale (SCAS): The parent report of the SCAS will be used to assess anxiety of children aged between 6 and 18 years (Spence, 1998). This instrument consists of 38 items with six subscales. All symptoms will be rated on a four-point scale (0 = never; 3 = always) and a total score can be calculated. In the present study, we will only assess four subscales (the ones deemed most relevant for the research questions): separation anxiety, fear of physical injury, obsessive-compulsive behavior, general anxiety.

Strengths and Difficulties Questionnaire (SDQ). We will use the subscales externalizing (consisting of hyperactivity and conduct problems, 10 items) as well as the prosocial scale (5 items). For the SDQ, parents report on a three-item Likert Scale (ranging from 0 “not true” to 2 “certainly true”) about their child’s behavior. The questionnaire has been widely used with large samples; reliability of the subscales was adequate (e.g., Goodman et al., 2010). Validity: the hyperactivity and conduct problems scales predicted the presence of an externalizing disorder (measured via a clinical interview). Also, factor analysis supported the externalizing subscale. The externalizing score ranges from 0 to 20 with higher scores indicating more problems. For the prosocial subscale the items are summed up (total score: 0 to 10), with higher scores representing more prosocial behavior.

Methods: Participants, interventions, and outcomes

Study setting	9	University of Bremen and associated institutions, potentially open to City of Bremen, Germany
Eligibility criteria	10	<p>In order to be eligible to take part in the study, study participants must meet the following criteria:</p> <ul style="list-style-type: none"> • Currently enrolled as staff in the University of Bremen or an associated institution • aged 18 years or above • willing and able to provide digital informed consent • accepting to answer the study questionnaire <p>Potential participants meeting any of the following criteria will not be enrolled in the study:</p> <ul style="list-style-type: none"> • Not understanding the language in which the survey is being conducted.
Interventions	11	Na

Outcomes	12	<p><u>Developmental outcomes across time:</u></p> <p>Mental Health of adults and children (depressive, anxiety symptoms in adults, externalizing and anxiety symptoms in children, relationship satisfaction in couples) as well as Quality of Life in adults/pro-social behavior in children</p> <p><u>Risk factors on an individual level</u></p> <p>Coping</p> <p>Self-esteem: SISE-D</p> <p><u>Risk factors on a dyadic level:</u></p> <p>Violence experiences (partner-partner, parent-child),</p> <p>Dysfunctional parenting behavior</p> <p>Parental Distress Tolerance Scale</p> <p><u>Predictors at Baseline:</u></p> <p>Knowledge about COVID-19</p> <p>Perception of political and institutional procedures to cope with the virus</p> <p>Resources on an individual level:</p> <p>Physical activity</p> <p>Using digital technology for physical activity and relaxation</p> <p>eHealth literacy</p>
Participant line	time- 13	<p>The study is intended to start as soon as possible.</p> <p>Timescale: 04/05/2020 – 31/01/2021</p> <p>Data collection: 30/04/2020 – 07/08/2020</p> <ul style="list-style-type: none">• T0: after having received ethics approval (approx. End of April) data collection for 1 week;• T1: 4 weeks after T0 (approx. end of May); data collection for 1 week• T2: 4 weeks after T1 (approx. End of June) data collection for 1 week;• T3: 4 weeks after T2: (approx. End of July) data collection for 1 week

Sample size	14	Staff of Uni HB: approx. 3500; UBRA: approx. 800. We assume that approx. 30% would participate which would result in N = 1500 participants. In addition, we intent to open recruitment to additional participants from the general population in Bremen and around if the experiences with the survey are positive.
Recruitment	15	At the first measurement, the link to the online questionnaire is sent out by a central, university-wide e-mail distribution list. Participants are asked to voluntary share their e-mail address if they want to participate in the repeated assessment approx. 4, 8, and 12 weeks later. The indication of the email address is not compulsory. However, if the participants do not share their email address they cannot participate in the later assessments. Also, we will send a reminder email after 4 days. Additional recruitment strategies include post on website of KLIP and BIPS and through other formats (twitter/social media, etc.)

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcomes: Via an online survey. Reliability and validity of measures- see measure section and their respective descriptions.
	18b	Plans to promote participant retention: Send email-reminders, stress in the email that survey participation is anonymous and voluntary; The follow-up surveys are also conducted via an online questionnaire. Participants will receive the invitation to the follow-up survey and the link to the survey by e-mail.
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values) will be found in the data protection concept

- Statistical methods
- me- 20a Descriptive statistics, including means and standard deviations for continuous variables as well as counts for categorical variables will be calculated. The resulting data will allow the research team to describe the living conditions before and during the COVID-19 outbreak as well as levels of well-being on an individual, dyadic and family level during the COVID-19 outbreak among staff of the University of Bremen and related institutes as well as within the general population (if extension is feasible). Furthermore, the longitudinal data collection also allows structural equation modelling to test the risk factor models that will be specified in the detailed analysis plan finalized prior to statistical analysis. Descriptive and multilevel regression models will be used to study variations and associations of specific risk factors or risk profiles with staff' well-being.
- 20b 20a comprises planned analyses to investigate our study aims. Additional analyses may include a subgroup analysis regarding the employee status at the university of Bremen (versus other community members), and gender differences on specific measures. Additional/alternative tests will be considered after data is tested for normality, multicollinearity, and linearity.
- 20c Missing data will be examined by conducting a Little's MCAR test. In case that data is missing completely at random, we will impute missing data in our study.

Methods: Monitoring

Data monitoring	21a	A DMC is not needed. Data will be fully anonymized before processing in the team. No intervention will be administered. Also, study participants are not a vulnerable group but part of the general population. Study participants are asked to complete an online survey for about 20 minutes online. The survey includes sensitive items (e.g, with regard to intimate partner violence). However, we do not anticipate that answering these questions will increase the general levels of stress in participants.
	21b	Study participants can stop the survey at any time by closing the browser. We do not intend to have to terminate the study. However, if the study team finds that the survey is leading to harm or is not feasible to safely conduct the survey from a technical or health perspective, then there is an option to terminate the study, specifically those assessment points still open. The decision will be made by the PIs after consulting with the ethics committee. Only descriptive baseline analyses are planned. We will wait for the full data to be available for all longitudinal ROs
Harms	22	Not planned or expected. However, if we are made aware of any during the first survey round, we will either adapt the survey or stop the study
Auditing	23	<i>Not applicable</i>

Ethics and dissemination

Research ethics approval	24	We are submitting all documents to the IRB of the university.
Protocol amendments	25	If changes will occur, we will document these in an amendment.
Consent or assent	26a	See Informed Consent procedure in the data protection concept

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable <i>Not applicable</i>
Confidentiality	27	See data protection concept (Attachment E)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site None declared– see also Ethics application
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators See ethic application and data protection concept
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation None
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions Scientific publications (e.g., journal articles), reports, websites of the BIPS and the Department of Psychology at the University of Bremen
	31b	Authorship eligibility guidelines and any intended use of professional writers We will adhere to guidelines by the DFG. No professional writers will be involved.

- 31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

A strategy in line with open science requirements will be developed in due course, prior to the finalization of the study. We aim to make anonymous trial data and documentation available for secondary use by other researchers, while following data protection rules and regulations.

Appendices

- Informed consent materials 32 Model consent form and other related documentation given to participants and authorized surrogates
- See Attachments A and B to Ethics application
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