

Expressive writing for the reduction of psychological difficulties during the COVID-19 pandemic

Submission date 21/04/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/04/2020	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/11/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Large body of evidence suggested that expressive writing can be beneficial for different conditions, including depression, suicidal ideation, trauma coping, etc.

The study aims to provide the evidence needed for the development and implementation of online expressive writing interventions (EW intervention) in the reduction of psychological difficulties among the general population during the COVID-19 pandemic.

Who can participate?

Adults over 18 years, fluent in Serbian, normal or corrected-to-normal vision.

What does the study involve?

Participants will be randomly allocated to either perform expressive writing five times over two weeks, for 20 minutes at a time, or to continue as normal. Participants will fill in mental health questionnaires at the start of the study and after two weeks.

What are the possible benefits and risks of participating?

The possible benefits include positive effects on one's psychological condition and wellbeing and there are no risks associated with the study.

Where is the study run from?

University of Belgrade (Serbia)

When is the study starting and how long is it expected to run for?

April 2020 to December 2020

Who is funding the study?

Psychosocial Innovation Network (Serbia)

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

2020-20

Study information

Scientific Title

Effectiveness of an expressive writing intervention in the reduction of psychological difficulties during the COVID-19 pandemic

Acronym

EWICOVID

Study objectives

Expressive writing intervention is more efficient in reduction of psychological difficulties in the general population during COVID-19 pandemic, in comparison to receiving treatment as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/04/2020, Institutional Review Board (IRB) of the Department of Psychology, Faculty of Philosophy, University of Belgrade, Serbia (no tel. provided; komocetis@f.bg.ac.rs), ref: #2020-20

Study design

Between-subjects pre-test post-test randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Depression, anxiety, and stress-related difficulties

Interventions

The participants are randomized across experimental and control groups and blinded for group allocation.

Following recruitment, the researcher who was blind to participants identities and baseline assessment results performed randomisation into groups using random number generating software.

Intervention: Expressive writing (20 minutes, 5 sessions during 2 weeks), participants are instructed to write about any experiences and thoughts on their life during the pandemic.

Control: Treatment as usual (TAU), i.e. informal support through families, friends, and networks (face-to-face, telephone and online) as well as support participants could get using available services in the community during the state of emergency (e.g. online counseling, hotlines, available self-help manuals)

Intervention Type

Behavioural

Primary outcome(s)

Severity of psychological difficulties assessed by DASS 21 - depression, anxiety and stress scale, short version at pre-test and post-test (2 weeks)

Key secondary outcome(s)

At pre-test and post-test (2 weeks):

1. Severity of depression-related psychological difficulties, assessed by DASS 21 depression subscale
2. Severity of anxiety-related psychological difficulties is assessed by DASS 21 anxiety subscale
3. Severity of stress-related psychological difficulties is assessed by DASS 21 stress subscale
4. Well-being, assessed by the WHO wellbeing index
5. Subjective perception of capacities for handling situations related to pandemic and state of emergency, assessed by a single item
6. Subjective perception of the quality of life, measured by SQOL, the mean score of the 12 satisfaction items from Manchester Short Assessment of Quality of Life (MANSA)

Completion date

20/12/2020

Eligibility

Key inclusion criteria

1. Over 18 years of age
2. Native, or fluent in Serbian
3. Normal or corrected-to-normal vision

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

120

Key exclusion criteria

1. A physical or mental disability, severe mental illness
2. No access to the internet and personal computer/mobile device

Date of first enrolment

07/04/2020

Date of final enrolment

14/04/2020

Locations**Countries of recruitment**

Serbia

Study participating centre

University of Belgrade

Studentski trg 1

Belgrade

Serbia

11000

Sponsor information**Organisation**

Psychosocial Innovation Network

Funder(s)**Funder type**

Other

Funder Name

Funder Name

Ministry for Education Science and Technological Development of the Republic of Serbia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Type of data: quantitative data - baseline and post-treatment assessment scores.

Data will become available three months post-study completion and will be available indefinitely.

Access criteria: the data will be shared with all interested researches or third parties who provide a reasonable explanation for the inquiry (replication, meta-analysis, etc.).

Consent from participants was obtained to share data anonymously.

Anonymization is ensured even at the data collection stage since all participants are taking part online using personalized passcode (the researchers are blind to participants personal information).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/11/2020	27/11/2020	Yes	No