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

Submission date
21/04/2020

Recruitment status
No longer recruiting

Registration date
23/04/2020

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request participant information sheet

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

Secondary outcome measures
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)

Overall study start date
21/03/2020

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

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
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Sponsor information

Organisation
Psychosocial Innovation Network

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Sponsor type
Other

Website
https://psychosocialinnovation.net/en/

Funder(s)

Funder type
Other

Funder Name
Psychosocial Innovation Network

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

Results and Publications

Publication and dissemination plan
The results will be published in the peer-reviewed journal.
Furthermore, the results will be presented at scientific conferences and congresses.
In addition, the findings' summary for a lay audience will be created, circulated to local and international networks dealing with mental health interventions, and disseminated through social networks.

Intention to publish date
31/12/2021

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