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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?
Dr Maša Vukčević Marković, masa.vukcevic@f.bg.ac.rs

Dr Jovana Bjekić, jovana.bjekic@imi.bg.ac.rs
Dr Stefan Priebe, s.priebe@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Maša Vukčević Marković

ORCID ID
https://orcid.org/0000-0002-1884-9948

Contact details
Čika Ljubina 18-20
Belgrade
Serbia
11000
+38 1637234658
masa.vukcevic@f.bg.ac.rs

Type(s)
Scientific

Contact name
Dr Jovana Bjekić

ORCID ID
https://orcid.org/0000-0001-7413-0324

Contact details
dr Subotica 4
PO BOX 39
Belgrade
Serbia
11129
+38 1646344895
jovana.bjekic@imi.bg.ac.rs

Type(s)
Scientific

Contact name
Dr Stefan Priebe

ORCID ID
https://orcid.org/0000-0001-9864-3394

Contact details

Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 20 7540 4210
s.priebe@qmul.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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
Psychosocial Innovation Network

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