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Cognitive functioning and creativity in the face of personal stress in previously-depressed people

Submission date
12/09/2021

Recruitment status
No longer recruiting

Registration date
20/09/2021

Overall study status
Completed

Last Edited
18/07/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Stressful situations are part of everyday life, and most people recover from them quite quickly. However, people with depression have more difficulties in this regard, and this also applies to previously depressed people, which makes them more vulnerable to future depression. Therefore, it is important to determine what ways of regulating negative emotions are particularly effective for them.
This study aims to examine different emotion regulation strategies related to creativity and, more specifically, to writing scenarios of future events. Besides, since creativity requires cognitive skills, the research also considers the importance of attention and memory. This study aims to recruit 120 people diagnosed with remitted depression to participate in two meetings in our lab. The goal is to find the most effective emotion regulation strategy among the three strategies studied compared in terms of improving emotional state. The study's findings should help to improve the therapeutic methods for enhancing dealing with distress and increasing resilience to depression in previously-depressed people.

Who can participate?
Adults aged 18 to 65 years, diagnosed with remission after depression, living in Poland.

What does the study involve?
Participants meet with a clinician to complete questionnaires assessing their emotions and cognitive skills. Next, within a week, they participate in an individual meeting in the lab, where they are handed a printed packet containing all materials. The researcher will be present in the room. According to the instructions they are asked to recall any of their currently stressful issues to be addressed later in the study and reflect on them. In the next step, the participants are randomly allocated to one of three groups and asked to write a scenario in the form of a sequence of events. Both of these tasks (recalling the stressful event and writing a scenario) will be accompanied by examples. Next, the participants view a nature video (15 min.) and answer a few short questions. Also, they are rating their emotions and experienced stress several times during the study. The entire lab meeting lasts about 45-60 minutes.

What are the possible benefits and risks of participating?
There is a risk that recalling a personally stressful event can cause negative emotions.
A possible benefit of participating in this study is contributing to the new scientific knowledge, which in the future can help previously depressed people. Participating in this study may also provide an opportunity to see how contemporary research is conducted in the area of clinical psychology, and then to learn about the overall results of this study. Also, as a thank you for taking part in the study, each participant receives 12 euros in the form of a gift card or a guide on depression prevention.

Where is the study run from?
The study is being run by the SWPS University of Social Sciences and Humanities (Warsaw) and takes place in the Institute of Psychiatry and Neurology (Warsaw, Poland)

When is the study starting and how long is it expected to run for?
January 2015 to May 2021

Who is funding the study?
The National Science Centre - NCN (Poland)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
In people with remitted depression, is stress-related humor more effective than stress-unrelated humor in regulating negative emotions? What is the role of selective attention deficits in humor-based emotion regulation?

Acronym
Humor and emotion regulation in depression

Study objectives
Stress-related humor is more effective than stress-unrelated humor would be effective in relation to emotions and experienced distress immediately and after a brief delay.
Participants with deficient selective attention have difficulties in the application of humor and benefit more from non-humorous regulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2015, The USSH Ethics Committee on Ethics of Empirical Research Involving People as Research Subjects (Chodakowska Street 19/31, PL - 03815 Warsaw; +48 022 5179911; komisja_etyki_badan@swps.edu.pl), ref: 1/2015; G:2014/15/D/HS6/04991

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Determining effective emotion regulation strategies (stress-related humor, stress-unrelated humor, non-humorous strategy) in patients with remitted depression.

Interventions
Participants will take part in a double-blind laboratory experiment; it will consist of stress induction (recalling any current personally stressful issue) and emotion regulation manipulation, which will involve the use of one of the three strategies corresponding to the three conditions: stress-related humor, stress-unrelated humor, and non-humorous regulation.

To induce stress, the participant will be asked to recall any of his/her own currently stressful issues (they will be presented with an example).
In the next step, the participants will be randomly assigned to experimental conditions (by a computer generated random number list) and asked to produce a scenario in the form of a sequence of events. In the stress-related humor condition, the scenario will be humorous and related to one's own stress-inducing issue; in the stress-unrelated humor condition, it will be humorous and unrelated to one's own stressful issue; and in the non-humorous condition, it will be rational and related to one's own stressful issue. The experimental manipulation is derived from stress management techniques. The participants will be provided with detailed guidelines and led step-by-step through the process of writing scenarios.

Intervention Type
Procedure/Surgery

Primary outcome measure
Positive emotions, negative emotions, and experienced distress are measured using single self-report scales, from 0 ("not at all") to 6 ("as strong as possible").
Negative emotions and positive emotions are assessed four times: at baseline (T1), after stress induction (T2), after the emotion regulation manipulation (T3), and after 20 minutes (T4).
The experienced distress is measured in T2, T3 and T4.

Secondary outcome measures
1. Selective attention measured using the d2 Test of Attention (Brickenkamp & Zillmer, 1998) at the introductory stage (before experiment)
2. Invested effort measured using single self-report scale, which specifies the effort exerted for the task, from 0 ("none") to 6 ("as much as possible") immediately after the emotion regulation manipulation (T3)
3. Subsequent performance measured using a multiple-choice knowledge test (with eight questions about the video content) at the end of the neutral nature video the participants watched (T4).

4. Intrusive thoughts measured using self-report - how many times they thought about their stressful situation during the film.
5. manipulation check, the participants answered two questions, one about the subjective funniness of the scenario (“Does this scenario seem funny to you?”) and one about its rationality (“Does this scenario seem rational to you?”), by choosing “yes,” “sort of,” or “no.” They also specified how funny/rational the scenario was, from 0 (“not at all”) to 6 (“as funny/rational as possible”). Then, the participant reported the effort exerted for the task, from 0 (“none”) to 6 (“as much as possible”). A single assessment was conducted to measure invested effort (T3), subsequent performance (T4) and intrusive thoughts (T4).

Overall study start date
01/01/2015

Completion date
04/05/2021

Eligibility

Key inclusion criteria
1. Participants from outpatient psychiatric clinics (aged 18-65) with a diagnosis of remission after a depressive episode
1.1. The diagnosis is made by a psychiatrist and confirmed via a Structured Clinical Interview (SCID I) administered by a clinical psychologist blind to the psychiatric diagnosis.
1.2. Depressive symptoms: An additional inclusion criterion is a BDIII score above a cut-off of 16.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

Total final enrolment
122

Key exclusion criteria
1. History of manic or psychotic episodes, head injury, or neurological disorder
2. Current presence of eating disorders, anxiety disorders, intellectual disability, psychoactive substance use, pregnancy, or suicidal ideation

Date of first enrolment
05/06/2015

Date of final enrolment
19/04/2021

Locations

Countries of recruitment
Poland

Study participating centre
Institute of Psychiatry and Neurology
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Sponsor information

Organisation
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Sponsor type
Government

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ROR
https://ror.org/03ha2q922

Funder(s)

Funder type

Government

Funder Name
Narodowe Centrum Nauki

Alternative Name(s)
National Science Centre, NCN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Poland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request and approval from the SWPS University of Social Sciences and Humanities (abraniecka@swps.edu.pl)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			20/09/2021	No	Yes
Protocol file		01/01/2015	20/09/2021	No	No
Results article		13/05/2022	18/07/2022	Yes	No