RESEARCH PROTOCOL

The effect of humor on emotion regulation in people vulnerable to depression. Differential effectiveness of different types of humor.

DATE	01/01/2015
PROJECT TITLE	The effect of humor on emotion regulation in people vulnerable to depression. Differential effectiveness of different types of humor.
PRINCIPAL INVESTIGATOR name and contact information	Dr Anna Braniecka, PhD SWPS University of Social Sciences and Humanities; Chodakowska Street 19/31, PL - 03815 Warsaw, Poland; <u>abraniecka@swps.edu.pl</u> ; Tel: +48 696232981
FUNDING ORGANIZATION	National Science Centre (NCN) - Poland
NUMBER OF SITE	1 – SWPS University of Social Sciences and Humanities, Warsaw, Poland
STUDY DESIGN	experimental: 3 conditions
PRIMARY OBJECTIVE	Determining whether humor is an effective emotion regulation strategy for people with remitted depression. Specifying what kind of humor is the most effective in emotion regulation for people with remitted depression: stress- related or stress-unrelated humor.
SECONDARY OBJECTIVE(S)	Examining the mediating effect of selective attention impairment on the relation between the type of humor and the effectiveness of emotion regulation in remitted depression. Determining the costs of humor-based emotion regulation in remitted depression in terms of invested effort and subsequent performance.
NUMBER OF PARTICIPANTS	120
PARTICIPANT SELECTION CRITERIA	 Inclusion criteria: Participants (aged 18-65) with a psychiatric diagnosis of remission after a depressive episode, confirmed via a Structured Clinical Interview (SCID I) administered by a clinical psychologist blind to the psychiatric diagnosis. Self-reported depressive symptoms - BDI II score above a cut-off of 16. Exclusion criteria History of manic or psychotic episodes, head injury, or neurological disorder Current presence of eating disorders, anxiety disorders, intellectual disability, psychoactive substance use, pregnancy, or suicidal ideation
DURATION OF EXPERIMENT PARTICIPATION	45-60 minutes

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1. STUDY TEAM AND SITE(S)

- Anna Braniecka, PhD; Institute of Psychology, SWPS University of Social Sciences and Humanities, Chodakowska Street 19/31, PL - 03815 Warsaw, Poland; Email: <u>abraniecka@swps.edu.pl</u>; Tel: +48 696232981
- Anna Orylska, PhD; Institute of Psychology, SWPS University of Social Sciences and Humanities, Chodakowska Street 19/31, PL – 03815 Warsaw, Poland; Email: <u>aorylska@swps.edu.pl</u>
- Anna Z. Antosik-Wójcińska, PhD; Department of Affective Disorders, Institute of Psychiatry and Neurology, Sobieskiego 9, PL – 02957, Warsaw, Poland; Email: <u>aantosik@ipin.edu.pl</u>
- Agnieszka Chrzczonowicz-Stępień, PhD; Institute of Psychology, SWPS University of Social Sciences and Humanities, Chodakowska Street 19/31, PL – 03815, Warsaw, Poland; Email: <u>achrzczonowicz-stepien@swps.edu.pl</u>
- Iwona Wołkowicz, MA; Institute of Psychology, SWPS University of Social Sciences and Humanities, Chodakowska Street 19/31, PL – 03815 Warsaw, Poland; Email: <u>iwolkowicz@st.swps.edu.pl</u>
- Ewelina Bolek, MA; Institute of Psychology, SWPS University of Social Sciences and Humanities, Chodakowska Street 19/31, PL – 03815, Warsaw, Poland; Email: <u>ebolek@swps.edu.pl</u>

2. STUDY OBJECTIVES

Primary Objective

Determining whether humor is an effective emotion regulation strategy for people with remitted depression. Specifying what kind of humor is the most effective in emotion regulation for people with remitted depression: stress-related or stress-unrelated humor?

Hipothesis:

In remitted depression, stress-related humor is more effective than stress-unrelated humor and more effective than non-humorous emotion regulation in relation to negative and positive emotions experienced distress, and intrusive thoughts immediately after recalling personally stressful event and after a 20 minute delay.

Secondary Objective(s)

Examining the mediating effect of selective attention impairment on the relation between the type of humor and the effectiveness of emotion regulation in remitted depression.

Determining the costs of humor-based emotion regulation in remitted depression in terms of invested effort and subsequent performance.

Hipotheses:

Remitted depressed patients with deficient selective attention (based on the d2 test score) have difficulties in the application of humor-based emotion regulation strategies, and thus benefit more from non-humorous regulation in terms of positive emotions, negative emotions, intrusive thoughts, and experienced distress.

Humor-based emotion regulation strategies involve greater effort (self-reported) and lower subsequent performance (scores in a multi choice knowledge test) than non-humorous emotion regulation.

3. BACKGROUND

Depressive disorders are among the most common and the most severe common mental health disorders. Research demonstrates that depressive episodes can be the consequence of dysfunctional negative emotion regulation, and there is the need for determining effective emotion regulation strategies for people at high risk of depression, more specifically, for previously-depressed individuals.

Despite growing research efforts in this area, the results are inconclusive, which seems to be due to a predominant focus on examining emotion regulation strategies aimed at decreasing negative emotions and related symptomatology without addressing positive emotions and well-being. Whereas, the positive affect system is recognized as a significant treatment target for patients with remitted depression as it plays a key role in building their resilience and buffering against future episodes. Therefore, one promising emotion regulation strategy seems to be humor, and there is some preliminary evidence for its effectiveness in remitted depression.

In fact, basic mechanisms of humor, like reinterpretation of the distressing situation, distancing from stressful stimuli, distraction from negative thinking, and eliciting positive emotions, have been proven to be highly effective in reducing negative mood. It is unclear, however, what type of humor is most effective in people with past depression. Indeed, humor is a heterogeneous phenomenon which takes many different forms, each with a distinct set of emotional consequences. This study compared two distinct humor-based strategies: stress-related humor and stress-unrelated humor.

Considering that vulnerability to depression is usually "triggered" in the face of a stressful experience, it can be assumed that distinguishing different types of humor based on their relationship to the stressor is most relevant. Accordingly, this study is aimed the compare the effectiveness of two humor types: stress-related humor and stress-unrelated humor, as emotion regulation strategies in remitted depression. It also includes a control strategy, which is a non-humorous emotion regulation. In addition, the purpose of this study is to investigate whether, as indicates previous research, humor imposes some cost, such as requiring immense effort and compromising subsequent performance.

The study also considers the importance of selective attention deficits which often persist in remitted depression, impairing emotion regulation ability, for the effectiveness of humorous regulation. Producing humor is cognitively demanding, especially in distressing situations, when it requires the simultaneous processing of both humorous and stressful stimuli. In this context, selective attention is pivotal, as it allows one to ignore or inhibit irrelevant (e.g., distressing) material and attend to relevant (e.g., funny) material. Therefore, this study is intended to examine whether humor is an effective emotion regulation strategy for remitted depressed individuals, what type of humor is optimal for them, and what are potential limitations of humor resulting from its cognitive demands.

4. STUDY DESIGN

The introductory stage was followed by a neuropsychological assessment of selective attention, and the participants completed two additional questionnaires for a different research project. Then, within a week, they took part in a double-blind laboratory experiment; it consisted of stress induction (recalling any current personally stressful issue) and emotion regulation manipulation, which involved the application of one of the three strategies corresponding to the three experimental conditions: stress-related humor, stress-unrelated humor, and non-humorous regulation.

There were also repeated measures of the dependent variables. Negative emotions and positive emotions were assessed four times: at baseline (T1), after stress induction (T2), after the emotion regulation manipulation (T3), and after a delay (T4). The experienced distress was measured in T2, T3 and T4. A single assessment was conducted to measure invested effort (T3), subsequent performance (T4) and intrusive thoughts (T4). The sequence of the experiment is illustrated in Figure 1.

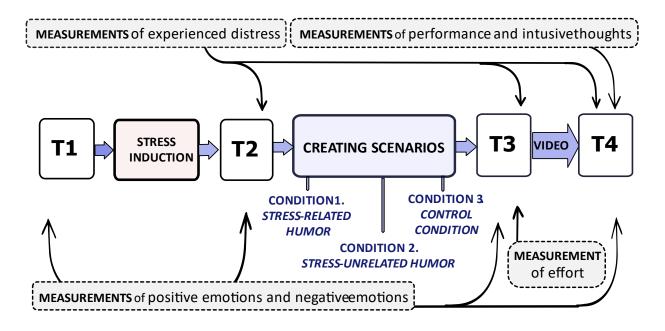


Figure 1. Flow diagram of the experimental part of the study.

5. SUBJECT INCLUSION AND EXCLUSION CRITERIA

Participants are recruited from outpatient psychiatric clinics. The sample will consist of 122 participants; women and men aged 18 to 65.

The inclusion criterion is a diagnosis of remission after a depressive episode, made by a psychiatrist and confirmed via a Structured Clinical Interview (SCID I) [1] administered by a clinicians blind to the psychiatric diagnosis. An additional inclusion criterion is low or most intensity of depressive symptoms, which will be reported by participants by completing the scale BDI-II [2]; score above a cut-off of 16 will be an inclusive criterion.

Exclusion criteria involved the following: (a) history of manic or psychotic episodes, head injury, or neurological disorder and (b) current presence of eating disorders, anxiety disorders, intellectual disability, psychoactive substance use, pregnancy, or suicidal ideation.

- 1. First, M. B. et al. Structured Clinical Interview for DSM-IV-TR Axis I Disorders (New York State Psychiatric Institute, 2007).
- 2. Beck, A.T., Steer, R.A. & Brown, G.K. Manual for Beck Depression Inventory-II (Psychological Corporation, 1996).

6. STUDY ENROLLMENT PROCEDURES

After being recruited for the study by a psychiatrist, each participant will be assigned an individual code that they will be labeled with in the further stages of this study. The recruited individuals will provide written consent after careful explanation of the study. They will be informed that they were participating in a study on cognitive functioning and creativity in the face of personal distress.

After the study, there will be a debriefing session with a clinician, who will explain the purpose of the study and attempt to identify and minimize any harm to the participants.

7. STUDY INTERVENTION

Experimental part of the study:

Upon arrival at the lab, a participant will be handed a printed packet containing all experimental materials. They will be asked by an experimenter to read it carefully and follow the instructions without skipping any portions. The experimenter will be present in the room throughout the study. In order to induce stress, the individual will be instructed to recall any of his/her own currently stressful issues to be addressed later in this study and to write down one statement describing the selected issue. First, the participant will be presented with an example of stressful issue: a short description of a stressful situation involving an individual matched for gender, age, and past experience of depression. Then, to enhance their negative mood, the dysphoric mood induction procedure of Nolen-Hoeksema and Morrow will be adapted, in which the person is asked to focus on the causes, meanings, and consequences of their problem and related feelings (for about 8 minutes) by reflecting on a series of questions (e.g., "Why do things turn out the way they do for me?", "What might my current feelings mean?").

In the next step, the participants will be assigned to experimental conditions and asked to write a scenario in the form of a sequence of events in the space provided. 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 (see Supplementary Material 2) is derived from stress management techniques and involves an exaggeration-based construction based on the sequence of questions "And then what?".

In the stress-related humor condition, the person will start by writing down what they feared could happen because of the stressful issue and then answered a series of questions ("And then what?") in an increasingly negative, exaggerated manner until the outcome became ridiculous. Then the participant will move on to an exaggerated positive continuation, responding in an increasingly positive way, and finishes with an absurdly optimistic outcome. In the stress-unrelated humor condition, the procedure will be the same except that the humorous scenario concerned the stressful situation of an unknown fictional person. To do this, the participant will receive one of six descriptions of someone's situation. To avoid the person identifying with that example, he/she will be of a different gender and worked in a gender-stereotyped profession. In the control condition (non-humorous regulation), the scenario will concern the participant's stressful issue; however, it will be as realistic as possible. The participants will be instructed that the positive and negative parts of the scenario should be plausible. In each experimental condition, the task will be accompanied by an example from a pilot study.

Manipulation check: after completing the scenario of events, the participant will be asked to answer two questions, one about the 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." The patients will also specify how funny/rational the scenario was, from 0 ("not at all") to 6 ("as funny/rational as possible"). Then, the person will report the effort exerted for writing the scenario, from 0 ("none") to 6 ("as much as possible").

Then, there will be a delay period (about 20 minutes), during which the participants will view an emotionally neutral video (showing birds living in the forest) and will be asked to watch it carefully (15 minutes). Subsequently, they will report how many times they thought about their stressful issue during the video (measurement of intrusive thoughts) and complete a multiple-choice knowledge test (measurement of subsequent performance) with eight questions about the video content (about 5 minutes). Finally, the last measurement of emotions and subjective distress was taken. The experiment is estimated to last 45-60 minutes. Materials showing the experimental manipulation are presented in Appendix 1.

8. STUDY PROCEDURES

Study Evaluation Schedule

ASSESSMENT	Preliminary stage	VISIT 1	VISIT 2
Psychiatric Diagnosis	x		
Diagnosis Confirmation (SCID II and BDI II)		x	
Demographics		x	
Selective Attention Assessment		x	
Lab experiment			x
Debriefing Session			x
Reward for participating in the study			X

Selective Attention Assessment:

The d2 Test of Attention is a widely used neuropsychological tests of selective attention. It is a cancellation test, it involves crossing out as many target letters as possible among similar non-target letters. The items are presented in 14 lines with 47 letters in each line. The person is permitted 20 seconds per line.

Brickenkamp, R. & Zillmer, E. (1998). The d2 Test of Attention, Hogrefe & Huber Publishers.

9. SAFETY ASSESSMENT

Recalling a personally stressful event (distress induction) can cause negative emotions in the participants. In order to mitigate this negative effect, two elements are included in the study:

- 1) When selecting the stressful issue, the participant will be informed that she/he is supposes to deal with later in the study. Therefore, the participants can choose a stressor that he/she will be able to confront for longer.
- 2) After the study, there will be a debriefing session with a clinical psychologist, who in addition to explaining the purpose of the study, will attempt to identify and minimize any harm to the participants. In particular, the clinician will encourage the participants to report any problems they may have with their stress recovery and provide them with professional assistance in doing so.

10. INTERVENTION DISCONTINUATION

The participants have the right to refuse participation, refuse any question and withdraw at any time without any consequence whatsoever. Besides, the experiment will be discontinued if the experimenter notices signs of severe stress in the participant.

11. STATISTICAL AND ANALYTICAL CONSIDERATIONS

Statistical analysis will be conducted with the aid of SPSS 22 (PS IMAGO) software for Windows. The mixed version of variance analysis will be applied with the intergroup factor (experimental condition: the use of one of three emotion regulation strategies: stress-related humor, stress-unrelated humor, non-humorous regulation) and the intragroup factor (subsequent variable measurement on IV levels). In the analyses determining which test the moderation of individual factors (selective attention) the level will be determined (high vs low. The chi-square test will be used for analyzing some demographic characteristics.

12. DATA COLLECTION

The research will follow ethical and legal practice. All the information about the participants will be kept strictly confidential. Any data collected about the participants will be stored in our laboratory at the SWPS University of Social Sciences and Humanities in Warsaw, where it will be locked in a secure location. Data collected may be shared in an anonymised form to allow reuse by the team and other third parties. These data will not allow any individuals to be identified or identifiable.

13. QUALITY ASSURANCE

All staff will consist of certified clinicians. They will receive training from the project manager: one group meeting and two individual meetings.

The study will be conducted in accordance with the principles established in the 1975 Declaration of Helsinki, as revised in 2008, and is approved by the local ethics committee (The USSH Ethics Committee on Ethics of Empirical Research Involving People as Research Subjects; No 1/2015). The entire research will be performed in accordance with relevant guidelines and regulations. Informed consent will be obtained from all participants (see: Appendix 2).

14. PUBLICATION

Results of this study will be published. The participants will not be identified in any report or publication. If a person wishes to be given a copy of reports resulting from the research, they will be asked to put her/him on the circulation list.

15. APPENDIX 1

Experimental manipulation of emotion regulation strategy - materials for three groups / conditions (translated from Polish).

CONDITION 1: STRESS-RELATED HUMOR

(female version)

Creativity Task: Transform Your Stressful Issue into Humor

Transform your fears related to the selected stressful issue into humorous fantasies by following these seven steps:

1) Start by admitting again what you fear could happen:

2) Next ask, "And then what?"	
3) Take your worry to the extreme by responding with an even worse outcome, mmediately followed by, "And then what?"	
'And then what?":	
4) Continue this process, exaggerating increasingly negative, even preposterous outcom	es.
'And then what?":	
'And then what?":	
Continue for as long as you wish.	
'And then what?":	
'And then what?":	
'And then what?":	

5) Finish by stating a final positive outcome

"And then what?" For example, you could write something similar to this: I'm afraid that my company might downsize and I could lose my job. "And then what?" ... I would receive unemployment benefits while I look for another job. "And then what?" ... I won't find a job and my benefits will run out. "And then what?" ... I won't be able to pay my mortgage and will get evicted. "And then what?" I will have to ask my parents if I can move back home? "And then what?" ... They will say no and I will have to live in my car. "And then what?" ... I'll have no gas money and my car will get towed away with me inside. "And then what?" ... The towing company needs an office manager and they hire me!

6) Now, resume the question-and-answer session starting where you left off.

"And then what?"

.....

7) This time, respond with exaggerated positive outcomes, each one more outrageous than the previous one. Continue until you feel safe or happy or proclaim your wildest dream.

For example:

The towing company needs an office manager and they hire me!

"And then what?" ...

A client is impressed by my work and offers me a job in a corporate office! "And then what?" ...

My salary is tripled and I'm accepted into a management training program! "And then what?" ...

I'm promoted to CEO and earn a six-figure income!

"And then what?"

"And then what?"

"And then what?"
Continue for as long as you wish. Set no limitations on yourself. You can be whoever you wish and do whatever you desire.
"And then what?":

Thank you!

CONDITION 2: STRESS-UNRELATED HUMOR

(female version)

Creativity Task: Transform Someone's Stressful Issue into Humor

In a moment, you will be asked to create a humorous sequence of events regarding John's situation. Here is its description:

John, an IT specialist, is having a wedding next week. The day before, he had an accident and his legs were put in a cast. He worries about what will happen to the wedding ceremony.

	Other versions for females:
1.	Henry , an auto mechanic, decided to try working abroad. Upon arrival, he was waiting for hours for people arranging the job, and their phone was turned off. Henry worries he has been cheated
2.	James, a boy's boxing teacher, had to leave for a while during the last training, and one of the boys suffered an eye injury. The boy is almost fine now, but James fears getting into trouble
	Versions for males:
1.	Linda , a perfume shop worker, is having a wedding next week. The day before, she had an accident and her legs were put in a cast. Linda worries what will happen to the wedding ceremony
2.	Susan , a teacher of rhytmic gymnastics for girls, had to leave for a while during the last training, and one of the girls suffered an eye injury. The girl is almost fine now, but Susan fears getting into trouble

Now, imagine John's stressful situation and transform it into comical fantasies by following these seven steps:

1) Start by writing what John fears could happen:

.....

2) Next ask, "And then what?"

3) Take his worry to the extreme by responding with an even worse outcome, immediately following with, "And then what?"		
"And then what?":		
4) Continue this process, exaggerating increasingly negative, even preposterous outcomes.		
"And then what?":		
"And then what?":		
Continue for as long as you wish.		
"And then what?":		
"And then what?":		
"And then what?":		
"And then what?"		
5) Finish by stating a final positive outcome. "And then what?"		
An example:		
Situation: Henry, an auto mechanic, decided to try working abroad. Upon his arrival, he was waiting for hours for people arranging the job, and their phone was turned off. Henry worries he has been cheated		
For example, you could write something similar to this:		
Henry was cheated. No one showed up, the number to call was off. "And then what?" He started looking for another job. "And then what?"		
He did not find a job and his money ran out. "And then what?" Henry asked his wife if he could come home with nothing.		

"And then what?" ...
She said no.
"And then what?" ...
Henry had to ask his wife if she would transfer him some money.
"And then what?" ...
She said no, so he had to live in his car and eat very little.
"And then what?" ...
Henry lost weight, nothing left of his tummy or his double chin.
"And then what?" ...
A nearby nail salon needed a receptionist and they hired Henry!

6) Now, resume the question-and-answer session starting where you left off.

"And then what?"

.....

7) This time, respond with exaggerated positive outcomes, each one more outrageous than the previous one. Continue until you feel safe or happy or proclaim your wildest dream.

For example:

A nearby nail salon needed a receptionist and they hired Henry!

"And then what?" ...

A client was impressed by his ideal figure and offered him to pose for swimsuit photos! "And then what?" ...

His salary was tripled and he was accepted into a prestigious model agency! "And then what?" ...

Henry became a top model and started earning a six-figure income!

"And then what?"

.....

"And then what?"

.....

"And then what?"

.....

Continue for as long as you wish.

Set no limitations on John. You can create whatever you wish.

"And then what?":

"And then what?":

And then what?":	
And then what?":	
And then what?":	
	• • • • • • • • • • • • • • • • • • • •

Thank you!

CONDITION 3: NON-HUMOROUS SCENARIO

(female version)

Creativity Task: Transform Your Stressful Issue into a Scenario

Transform your fears related to the chosen stressful issue into a rational, plausible story by following these seven steps:

1) Start by admitting again what you fear could happen:
2) If your worry does come true, what is most likely to happen?
3) Next ask, "And then what?"
4) Continue this process, writing down further negative outcomes that are as realistic as possible.
"And then what?":
"And then what?":
Continue for as long as you wish.
"And then what?":
"And then what?":
"And then what?":
5) When you determine realistically what is the worst that could happen, write down a final positive outcome.
"And then what?"

For example, you could write something similar to this:

I'm afraid that my company might downsize and I could lose my job.

"And then what?" ...

I would receive unemployment benefits while I look for another job.

"And then what?" ...

I won't find a good job.

"And then what?" ...

I will get some inferior job, for little pay.

"And then what?" ...

I will not be happy with this job. I will keep looking for a new one but to no avail.

"And then what?" ...

I will have to complete additional training to get a better job.

"And then what?" ...

I will spend a lot of time and money on this training.

"And then what?" ...

Finally, I got an interesting and well-paying job!

6) Now, resume the question-and-answer session starting where you left off.

"And then what?"

.....

7) This time, respond with positive outcomes, each one slightly more optimistic than the previous one, but still rational and plausible. Continue until you feel safe or happy.

For example: Finally, I got an interesting and well-paying job! "And then what?" ... I started the job. I'm happy with it and doing well. "And then what?" ... My supervisor is impressed by my work and offers me a promotion. "And then what?" ... This job is the best one I have had so far. "And then what?" "And then what?" "And then what?"

Continue for as long as you wish.

Let your scenario be about positive, yet not exaggerated, events.

"And then what?":
"And then what?":

Thank you!

16. APPENDIX 2

Participant Information Sheet (translated from Polish).

Title of Research Project:

Cognitive Functioning and Creativity in the Face of Personal Stress in Previously-Depressed People.

We would like to invite you to take part in a research study. Before you decide you need to understand why the study is being done and what it would involve for you. Please take time to read the following information carefully. Please, ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part in this research.

What is the purpose of this research?

This study is aimed to examine the importance of cognitive functioning in previously-depressed people for creative writing of short scenarios after remembering a personally stressful event. The study also targets to determine how writing different scenarios affects emotions, experienced distress, recalling memory content, and negative thinking.

What will taking part involve?

After signing the Consent Statement, you will meet with a clinician to complete questionnaires assessing your psychological and cognitive functioning. Next, within a week, you will participate in an individual meeting in the lab, where you will be handed a printed packet containing all necessary materials. The researcher will be present in the room throughout the meeting. According to the instructions included in the printed materials you will be asked to recall any of your currently stressful issues to be addressed in more detail later in the study, and reflect on it. In the next step, participants will be randomly allocated to one of three groups. Then, you will be asked to write a scenario in the form of a sequence of future events. All the tasks will be accompanied by examples. Next, you will view a nature video (15 min.) and answer 9 short questions. Also, you will be rating your emotions and experienced distress several times during the study. The entire lab meeting will last 45-60 minutes.

Why have you been invited to take part?

Your doctor has found that you are in remission after depression. People with remitted depression are particularly vulnerable to the detrimental effects of stress, which is why studies, such as this one, attempt to determine effective ways of dealing with stress and resulting emotions. In this research, we also take into account the importance of individual's creativity and cognitive functioning. Research in this area contributes to the development of effective therapeutic interventions for people with remitted depression.

Do you have to take part?

No, participation is completely voluntary. You have the right to refuse participation, refuse any question and withdraw at any time without any consequence whatsoever.

What are the possible risks and benefits of taking part?

Recalling a personally stressful event can cause negative emotions.

However, by participating in this study, you will be contributing to the new scientific knowledge, which in the future can help to develop effective therapeutic methods for improving dealing with distress and increasing resilience to depression in previously-depressed people. Participating in this study may also provide you with 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 research. As a thank you for taking part in the study, each participant will receive 12 euros in the form of a gift card or a guide on depression prevention.

Will taking part be confidential?

Yes, all the information about the participants will be anonymous and confidential. Once you have been initially recruited into the study and completed the Consent Statement, you will be assigned an individual code that will be used in the later stages of the study instead of your personal information. The data obtained will not allow any individuals to be identified or identifiable. Database may be shared in an anonymised form to allow reuse for scientific purposes. Non-anonymised data in the form of signed consent will be collected and retained as part of the research process, however they will be stored separately from the rest of the data.

How will information you provide be stored and protected?

We will follow ethical and legal practice and all the data that we collect about you during the course of the research will be kept strictly confidential. Any data collected about the participants will be stored in our lab at the SWPS University of Social Sciences and Humanities in Warsaw, where it will be locked in a secure location.

What will happen to the results of the study?

Results of this study will be published. You will not be identified in any report or publication. If you wish to be given a copy of reports resulting from the research, please ask us to put you on our circulation list.

Who has ethically reviewed the project?

The study has been ethically approved by The USSH Ethics Committee on Ethics of Empirical Research Involving People as Research Subjects (No 1/2015).

Who should you contact for further information?

Dr Anna Braniecka, University of Social Sciences and Humanities, Institute of Psychology - Warsaw, Tel: +48 696232981; Email: <u>abraniecka@swps.edu.pl</u>

Thank you for your interest in this study.

If you wish to participate, please complete the Consent Statement at the end of this document.