No Fun No Glory: lifestyle and loss of pleasure

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Main objectives: This exploratory intervention study is set out to examine effects of tailor-made lifestyle advice, based on observed individual temporal patterns of lifestyle factors and experienced pleasure, as a non-pharmacological means to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON42043

Source
ToetsingOnline

Brief title
No Fun No Glory: lifestyle and loss of pleasure

Condition

- Mood disorders and disturbances NEC

Synonym
anhedonia, loss of pleasure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NWO VICI subsidie

Intervention

Keyword: Anhedonia, Free Fall Experience, Personalized Lifestyle Advice, Young adults

Outcome measures

Primary outcome

The main study endpoint of the intervention study is the level of pleasure, as measured in the daily questionnaires. We will follow two approaches to evaluate the effectiveness of the intervention. First, we will examine each individual series of observations to assess individual response patterns in pleasure scores. Second, to explore group-level patterns of change, we will evaluate possible differences between intervention groups in daily-reported pleasure.

Secondary outcome

Intervention study:

As a secondary endpoint we will explore possible differences between intervention groups in monthly-reported pleasure in different dimensions (i.e., motivational, anticipatory, and consummatory dimensions) and different domains (i.e., physical, sexual, social, aesthetic, and intellectual domains).In addition to the level of pleasure endpoints, the effects of the intervention will also be examined with regard to changes in blood and saliva levels of potential biomarkers. Blood samples are taken at six different time points and saliva samples are taken four times on the day of the skydive intervention. Other secondary parameters that could affect the effectiveness of the intervention are (epi)genetic factors, perceived physical and mental health, and positive and negative affect. Furthermore, the extent to which the lifestyle advice will lead to actual lifestyle change will be investigated by

comparing the level and slope of the lifestyle variables in the pre- and post-intervention period. Furthermore, the dairy study will provide ample opportunity to examine the relations between mental and physical health, substance intake (i.e. food, alcohol, coffee, drugs) and sleep quality.

Survey:

Apart from as a screening tool, data from the survey will also be used to elucidate the various faces of pleasure loss, how often and in which combinations they occur in the general population, and how they relate to other variables such as lifestyle factors, (mental) health problems, personality, self-efficacy, emotion recognition skills and social position.

Study description

Background summary

This project focuses on anhedonia, generally defined as the inability to feel pleasure in response to experiences that are usually enjoyable. Anhedonia is one of the two core symptoms of depression. The concept of depression has been heavily debated recently, because it is plagued by a heterogeneous symptom profile. The US National Institute of Mental Health (NIMH) has recommended to investigate psychopathology according to core processes that organize emotions and behaviors rather than the existing diagnostic categories. One of the key dimensions in this new framework for studying mental disorders is positive emotionality. Anhedonia reflects a lack of positive emotionality and its study is therefore a promising avenue towards a better understanding of affective dysregulation.
Anhedonia is a major public health concern. It has particularly far-reaching negative consequences in adolescence and young adulthood, when life course decisions are made on the basis of what is satisfying. Anhedonia has proven particularly difficult to counteract and predicts poor treatment response generally. It has often been hypothesized that anhedonia can be deterred by a healthy lifestyle and engagement in stimulating social and physical events. However, it is quite unlikely that a one-size-fits-all approach will be

effective for everyone. In this study the effects of personalized lifestyle advice based on observed individual patterns of lifestyle factors and experienced pleasure will be tested. Regardless of whether the advice is tailor-made or not, lifestyle changes are in general hard to achieve or maintain for anhedonic persons, because a lack of drive to pursue rewarding activities belongs to the core of their symptoms. As mild interventions are often ineffective for this group, it is worth investigating whether a noninvasive *rebooting* of the reward system can be accomplished. It is already known that free fall provides strong boosts of dopamine, which is also involved in reward related motivation. In our study it will be investigated whether a tandem skydive preceding personalized lifestyle advice, positively influences anhedonic young adults* abilities to carry out the recommended lifestyle changes and whether this ultimately improves their self-reported pleasure.

Study objective

Main objectives:
This exploratory intervention study is set out to examine effects of tailor-made lifestyle advice, based on observed individual temporal patterns of lifestyle factors and experienced pleasure, as a non-pharmacological means to restore the pleasure of everyday activities and accomplishments. In addition, we will test whether exposure to tandem skydiving, an experience known to activate the dopamine system and to elicit strong emotions, can help to reboot the reward system and hence foster the recommended lifestyle changes. The effects of the interventions will primarily be examined with regard to experienced pleasure, but changes in blood levels of potential biomarkers are also taken into account.

Secondary objectives:
We will conduct a survey as a screening instrument to select eligible participants for the intervention study. Besides being used for screening purposes, the survey data provide the opportunity to elucidate the various faces of pleasure loss, how often and in which combinations they occur in young adults, and how they relate to, among other things, other mental health problems and lifestyle factors. Little is known about the interrelations and associated factors of these dimensions of anhedonia.

Study design

Our study design is an exploratory intervention study, preceded by a cross-sectional survey as a screening instrument. Personalized lifestyle advice will be based on a diary study, for which a replicated single-subject time-series design will be used.

Intervention

The group of 60 individuals without anhedonia will serve as a control group only during the observation month of the diary study, in which no intervention takes place, and will not partake in the intervention itself. After this first month (observation month), the anhedonic participants are randomly assigned to three groups. At the start of the second month (the first intervention month), one group receives personalized lifestyle advice based on patterns observed in the first month. The second group also receives personalized lifestyle advice, but their advice will be closely followed by a tandem skydive. The third anhedonic group serves as a control group and therefore receives neither lifestyle advice nor a tandem skydive.
At the start of the third month (the second and last intervention month), all participants are free to choose between: (1) no intervention, (2) (continued) lifestyle advice, and/or (3) (another) tandem skydive.

Study burden and risks

Screening phase
Participants (N = 2000) will fill out a questionnaire that will take circa 50-60 minutes to complete. They will receive an incentive of a 10 Euro gift card and, through a lottery, have a chance to win a city trip, tablet or gift card.

Intervention phase
All anhedonic participants of the intervention study (N = 72) will be requested to:
(1) fill out online questionnaires at six different time points, which will take up to 45 minutes to complete each;
(2) fill out a daily questionnaire for three and a half months (three months including intermediate periods), using a smartphone, which is estimated to take about fifteen minutes per day;
(3) provide blood samples (one 10 ml EDTA K2E tube and one or two 4 ml EDTA K2E tubes) at six different time points. Blood sampling will take place at the *prikpoli* of the UMCG.

The anhedonic participants will be randomly assigned (stratified on gender) to one of three intervention groups. Two of these groups will receive personalized lifestyle advice. In one of these two groups, the lifestyle advice is followed by a tandem skydive. After two months, all anhedonic participants can choose whatever intervention they prefer, varying from nothing to (another) lifestyle advice plus skydive. The skydive takes altogether 1,5 hours, traveling times excluded. Before and after their first skydive, participants will be asked to give a total of four saliva samples.

The non-anhedonic control group (N = 60) will fill out the online questionnaires only at the first two time points and will be asked to fill out a daily questionnaire three times a day during one month.

Depending on the specific group individuals are assigned to, different kinds of benefits are expected. In all groups, the mere process of recording pleasure and related factors will potentially improve participants* insight in their own pleasure-related patterns. Personalized lifestyle advice is expected to contribute to further insight in factors that affect pleasure, and practical advice for regaining pleasure is expected to result in higher self-reported pleasure rates. The group with a complementary skydive potentially benefits even more in terms of symptom reduction, since this type of experience may help to reboot the reward system which could positively influence the ability to carry out lifestyle changes and ultimately also self-reported pleasure. Another way in which the tandem skydive may work out positively for anhedonic individuals is that conquering one*s fear is expected to boost self-confidence and to make one feel more vibrant; altogether a promising starting point for implementing lifestyle changes. Moreover, even independent of possible subsequent changes in pleasure, performing a tandem skydive is in itself expected to be a unique and unforgettable experience.

Besides the potential benefits, participants also receive an incentive as a reimbursement for the time and effort invested, and to keep them motivated to participate in our study. Anhedonic participants receive up to 500 Euro in total and the non-anhedonic control group up to 75 Euro.

Regarding the risks: tandem skydiving is relatively safe. Data acquired from the *Koninklijke Nederlandse Vereniging voor Luchtvaart* (KNVvL: Royal Netherlands Aeronautical Association) show that tandem skydiving is the safest form of skydiving. For 2005-2012, the KNVvL reported 0.29-0.91 injuries per 1000 tandem skydives. No fatalities have occurred in the Netherlands with respect to tandem skydives, despite the fact that around 10000 tandem skydives per year take place with a total of 157284 tandem skydives between 1999 and 2013. The incidents that did occur in the Netherlands were usually caused by people not lifting their legs upon landing, resulting in ankle or leg-injuries. Our participants will receive safety-instructions before their skydive and all and standard safety guidelines will be followed by Skydive Association Eelde-Hoogeveen. Based on these numbers and safety-guidelines we do not expect our participants to get injuries or accidents, but of course we cannot exclude this possibility. Furthermore, there is no evidence of long-term adverse effects of the acute stress elicited by skydiving.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Screening;- 18-24 years old
- Fluent in Dutch;Intervention;Anhedonic group:
- persistent (> 2 months) anhedonia
- willing to perform a tandem skydive;Control group:
- no anhedonia
- willing to perform a tandem skydive

Exclusion criteria

Intervention
- Inability to keep an electronic diary three times a day
- Current professional treatment for psychiatric problems
- Current use of psychopharmaca
- Epilepsy
- Pregnancy
- Conditions that make it impossible to be attached to the tandemmaster (loose prostheses)
- Height of more than 2 meters
- Weight of more than 95 kg

- Inability to raise ones legs 90 degrees (needed for save landing after tandem skydive)
- Significant visual or hearing impairments
- Previous experience with skydiving, bungee jumping, or base jumping
- Cardiovascular complaints/problems

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2015
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO

Date:	10-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL51693.042.14