Title
get.calm and move.on - tackling worries and finding strength for the crisis (COVID-19) in 10 steps

Trial Acronym
get.calm_move.on

URL of the trial
https://geton-training.de/get-calm-and-move-on

Brief Summary in Lay Language
The Corona crisis is characterized by the concern about getting infected with the virus, the concern about the health of the people close to us and many unanswered questions about how everything will develop in the near future. Perhaps the job and the financial situation have become uncertain. All this can cause worry and anxiety. Worries can sometimes become so intense that people feel paralyzed and lose courage to take the next step. If the worries are getting too strong, then it is important to calm down a bit. If the problems seem too big, then it can be important to gain confidence for the next step.

With this in mind, an online training programme has been developed to help you cope with worries: get.calm and move.on - tackle worries in 10 steps and gain strength for the corona crisis.

Every day a training unit is available in which one aspect of worries is taken into account. The training can be completed in 10 days. The contents of the training refer to reflecting on what is really important to you, to consciously address some worries and to be able to distance yourself from others, to tackle some problems step by step and to learn from others to accept and endure them. It is also explained that it is important to be able to perceive and appreciate even small pleasant experiences, to use relaxation exercises, to ensure a good night's sleep and to structure the day well.

The study serves to check the effectiveness of the training.

Brief Summary in Scientific Language
The physical consequences of an infection with the corona virus (COVID-19) are known. In addition to the direct biological consequences, fears of infection and social distancing, including an ordered quarantine, represent a considerable psychological burden. The available studies show that virus epidemics and the resulting isolation or quarantine are associated with fear of infection, depression, low spirits, post-traumatic and general stress symptoms, irritability and anger (Brooks, Webster, Smith, Woodland, Wessely, Greenberg & Rubin, 2020). Adverse effects on mental health were found up to 3 years after the crisis. During this period, longer periods of quarantine, frustration, boredom, inadequate health care, insufficient information, financial losses and fear of stigmatization had a reinforcing effect on the unfavorable effects.

The aim of the present study is to evaluate an intervention for people from the
general population (universal preventive approach) to provide support for coping with worries in the corona crisis.

In a 2-arm randomized controlled trial, (P) people from the general population who participate in the (I) self-help online training "get.calm and move.on" will be compared to (C) a waiting control group with access to the recommendations of the German Association for Psychiatry, Psychotherapy and Psychosomatics on coping with the corona crisis (O) with regard to the reduction of worries.


Recommendations of the German Association for Psychiatry, Psychotherapy and Psychosomatics on coping with the corona crisis: https://www.dgppn.de/schwerpunkte/corona-psyche.html

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: DRKS00021153
- Date of Registration in DRKS: 2020/04/06
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
- (leading) Ethics Committee Nr.: EB-Antrag_202003_12_Lehrgetcalm , Leuphana Universität, Ethikbeirat der Leuphana Universität Lüneburg, Geschäftsstelle Ethikbeirat Universitätsallee 1, C10.205 21335 Lüneburg Fon 04131.677-1692 Fax 04131.677-1575 ethikbeirat@leuphana.de
DRKS-ID: **DRKS00021153**
Date of Registration in DRKS: **2020/04/06**
Date of Registration in Partner Registry or other Primary Registry: *[---]*
Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
Ethics Approval/Approval of the Ethics Committee: **Approved**


### Secondary IDs

### Health condition or Problem studied

- Free text: **Worry**

### Interventions/Observational Groups

- Arm 1: **Intervention group, direct access to the internet intervention**
- Arm 2: **Waitlist control group, delayed access to the internet intervention**

### Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: *[---]*
- Allocation: **Randomized controlled trial**
- Blinding: *[---]*
- Who is blinded: *[---]*
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

Secondary Outcome


• Worry / Generalized anxiety (GAD-7); Löwe B, Decker O, Müller S, Brähler E, Schellberg D, Herzog W, Herzberg PY. Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. Med Care. 2008 Mar;46(3):266-74. 163-173. (t1, t2, t3, t4)


Additional variables:

• Demografics (t1)
• Status of infection (t1, t2, t3, t4)
• Duration and reasons for self isolation or quarantine (t1, t2, t3, t4)
• Reasons for dropout (t2).
Locations of Recruitment

- other Leuphana Universität Lüneburg, Deutschland

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2020/04/07
- Target Sample Size: 352
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

internet access

Exclusion criteria

- diagnosed psychosis or dissociative symptoms in the past
- Increased risk of suicide (BDI-II value for question 9>1)

Addresses

- Primary Sponsor

  Leuphana Universität Professur für Gesundheitspsychologie und Angewandte Biologische Psychologie
  Institut für Psychologie
  Mr. Prof. Dr. Dirk Lehr
  Universitätsallee 1
  21335 Lüneburg
  Germany

  Telephone: +49.4131.677-2720
  Fax: [---]*
  E-mail: lehr at leuphana.de
  URL: https://www.leuphana.de/institute/ifp/personen/dirk-lehr.html

- Contact for Scientific Queries
Contact for Scientific Queries

Leuphana Universität Professur für Gesundheitspsychologie und Angewandte Biologische Psychologie
Institut für Psychologie
Mr. Prof. Dr. Dirk Lehr
Universitätsallee 1
21335 Lüneburg
Germany

Telephone: +49.4131.677-2720
Fax: [--]*
E-mail: lehr at leuphana.de
URL: https://www.leuphana.de/institute/ifp/personen/dirk-lehr.html

Contact for Public Queries

Leuphana Universität Lüneburg
Ms. Hanna Heckendorf
Universitätsallee 1
21335 Lüneburg
Germany

Telephone: +49 4131.677-2378
Fax: [--]*
E-mail: getcalm.moveon at leuphana.de
URL: https://www.leuphana.de/institute/ifp/gesundheitspsychologie-und-angewandte-biologische-psychologie.html

Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

Leuphana Universität Professur für Gesundheitspsychologie und Angewandte Biologische Psychologie
Institut für Psychologie
Universitätsallee 1
21335 Lüneburg
Germany

Telephone: [--]*
Fax: [--]*
E-mail: [--]*
URL: [--]*

Status

■ Recruitment Status: Recruiting ongoing
■ Study Closing (LPLV): [--]*
**Trial Publications, Results and other documents**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.