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COVID Feel Good - an easy self-help virtual reality protocol to overcome the psychological burden of coronavirus

Submission date
02/07/2021

Recruitment status
No longer recruiting

Registration date
06/08/2021

Overall study status
Completed

Last Edited
18/09/2024

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
Living during the COVID-19 pandemic means experiencing not only a global health emergency but also extreme psychological stress which could cause potential emotional side effects such as sadness, grief, irritability, and mood swings. Crucially, lockdown and related social restrictive measures isolate people who become the first and the only ones in charge of their own mental health: people are left alone facing a novel and potentially lethal situation, and, at the same time, they need to develop adaptive strategies to face it, at home. Because of this, easy-to-use, inexpensive, and scientifically validated self-help solutions aiming to reduce the psychological burden of coronavirus are extremely necessary.

This study aims to test the efficacy of “COVID Feel Good” a self-help Virtual Reality (VR)-based program to help individuals to cope with the psychological burden related to the COVID-19 pandemic and restrictive social distancing measures.

Who can participate?
Adults who have experienced at least two months of social distancing measures (e.g. staying at least 6 feet from other people who are not from your household, wearing masks) who are able to access the internet using a smartphone with Internet access and have normal, or corrected-to-normal, vision.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin), to receive treatment with the “COVID Feel Good” a self-help Virtual Reality (VR)-based program or no treatment and to be put on a waiting list for the VR program. The program involves watching a 10 min three hundred sixty–degree (360°) video, titled “The Secret Garden” at least once a day for a week. Each day, after the VR protocol, participants are invited to perform a series of social exercises with targeted goals for each day of the week. Participant levels of depressive and anxiety symptoms, general distress, perceived levels of stress,

hopelessness, perceived interpersonal closeness with the social world, and fear of COVID-19 will be assessed at the beginning of the study, at the end of the VR program (after 7 days), and at a 2-week follow-up (21 days).

What are the possible benefits and risks of participating?
it is hoped that the weekly VR-based self-help program will be associated with a reduction of depressive and anxiety symptoms, general distress, perceived levels of stress, hopelessness, and fear of COVID-19, with an increase in perceived interpersonal closeness with the social world at the end of treatment compared with both responses from participants in the waiting list condition and baseline responses at the start of the study. It is also predicted that treatment benefits will be maintained at 2-weeks follow-up.

There are no significant risks associated with participating in the study. Participants will be adequately informed about the fact that VR can cause fatigue or slight symptoms of cybersickness (e.g. dizziness), and if these occur, participants are invited to stop the session. Symptoms of cybersickness should subside within a few minutes after terminating exposure to VR.

Where is the study run from?
Istituto Auxologico Italiano (Italy) and centers in Australia, Germany, Italy, Japan, Romania, Spain, and the United States of America

When is the study starting and how long is it expected to run for?
From April 2020 to December 2021

Who is funding the study?
Istituto Auxologico Italiano (Italy)

Who is the main contact?
Prof Giuseppe Riva
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2020_06_16_09

Study information

Scientific Title
An easy self-help virtual reality protocol to overcome the psychological burden of coronavirus (COVID Feel Good)

Acronym
COVID Feel Good

Study objectives
1. The use of the weekly VR self-help protocol will decrease depressive and anxiety symptoms, general distress, perceived levels of stress, hopelessness (primary outcome measures)
2. The use of the weekly VR self-help protocol will increase the perceived interpersonal closeness with the social world and will decrease the fear of COVID-19 (secondary outcome measures)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/06/2020, Istituto Auxologico Italiano Comitato Etico (Via L. Ariosto 13, 20145 Milano, Italy; +39 (02) 619112237; comitato.etico@auxologico.it), ref: 2020_06_16_09

Study design
Multi-center interventional randomized wait list-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychological burden related to the COVID-19 pandemic and restrictive social distancing measures

Interventions
COVID Feel Good is a self-help Virtual Reality (VR)-based protocol aimed at helping individuals to overcome the psychological burden related to the COVID-19 pandemic and restrictive social distancing measures.

Participants will be randomly allocated (1:1) to either the "COVID Feel Good" a self-help Virtual Reality (VR)-based program group or waiting list control group. Randomization will be done using a computer-generated, block randomization sequence (R psych library, block.random function).

Participants are invited to use the VR program at least once a day for 7 days. Participants will receive six modules consisting of two integrated parts: the first part consists of a 10 min 360° VR video entitled "Secret Garden" and the second part includes a series of social exercises, with a specific goal for each day of the week. The immersive experience is accompanied by a relaxation induction narrative structured following the principles of Compassion Focused Therapy. At the end of the VR exposure, participants were invited to perform a series of social tasks related to personal identity and interpersonal relationships. The tasks have the following general aims:
1. Helping participants to pay attention and recognize their emotional discomfort
2. Supporting participants to reinforce their coping skills
3. Helping participants to monitor themselves and protect self-esteem
4. Support participants in finding a personal meaning even in difficult times

Intervention Type
Behavioural

Primary outcome(s)
1. Depression, anxiety, and stress symptoms measured using the Depression Anxiety Stress Scale (DASS-21) at baseline, 7, and 21 days
2. Perceived stress measured using the 10-item Perceived Stress Scale (PSS) at baseline, 7, and 21 days
3. Pessimistic thoughts or negative attitude towards the future measured using the Beck Hopelessness Scale (BHS) self-report questionnaire at baseline, 7, and 21 days

Key secondary outcome(s))
1. Social connectedness measured using the Social Connectedness Scale (SCS) self-report questionnaire at baseline, 7, and 21 days
2. Fear experienced during the COVID-19 pandemic measured using the Fear of Coronavirus (FCOR) scale at baseline, 7, and 21 days

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Fluent in the language of the country where they are enrolled
3. Has experienced at ≥2 months of the social distancing measures (such as wearing masks and staying ≥6 feet from other people who are not from their household) implemented by the country where they reside

4. Has a partner who is available and agrees to participate in the relational component of the treatment
5. Has a smartphone with internet access
6. 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
40

Key exclusion criteria
1. Diagnosis of major mental disorder
2. Lack of stereoscopic vision or a balance/vestibular problem that would disrupt the VR experience

Date of first enrolment
30/06/2020

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
Australia

Germany

Italy

Japan

Romania

Spain

United States of America

Study participating centre
Istituto Auxologico Italiano
Applied Technology for Neuropsychology Lab
Via Magnasco 2
Milan
Italy
20146

Study participating centre
Private University Göttingen
Weender Landstraße 3-7
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Study participating centre
Clemson University, Virtual Reality and Nature Lab
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Study participating centre
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Study participating centre
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3122

Sponsor information

Organisation
Istituto Auxologico Italiano

ROR
https://ror.org/033qpss18

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Istituto Auxologico Italiano

Alternative Name(s)
Auxologico

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/08/2021	20/12/2021	Yes	No
Results article	Results for German sites	07/04/2022	12/08/2022	Yes	No
Results article	Results for other European sites	06/04/2023	14/04/2023	Yes	No
Results article		02/03/2023	18/09/2024	Yes	No
Protocol article		23/09/2020	12/08/2022	Yes	No
Preprint results		14/09/2021	20/12/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes