

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/08/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/09/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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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Study website

<https://www.covidfeelgood.com/>

Contact information

Type(s)

Scientific

Contact name

Prof Giuseppe Riva

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

54 participants for each center. 324 total participants.

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

Göttingen

Germany

37073

Study participating centre**Clemson University, Virtual Reality and Nature Lab**

Clemson Virtual Reality and Nature Lab

College of Behavioral, Social and Health Sciences

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Clemson, SC

United States of America

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Study participating centre**University of Tsukuba**

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Ibaraki

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Study participating centre**Universitat de Barcelona**

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Barcelona

Spain

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Study participating centre**West University of Timisoara**

Vasile Pârvan Blvd

Timisoara

Romania

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Study participating centre**Swinburne University of Technology**

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Sponsor information

Organisation

Istituto Auxologico Italiano

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.auxologico.it/>

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

Publication and dissemination plan

Planned publication in a high-impact journal. The study protocol can be found at www.covidfeelgood.com

Intention to publish date

31/12/2022

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?
Preprint results		14/09/2021	20/12/2021	No	No
Results article		02/08/2021	20/12/2021	Yes	No
Protocol article		23/09/2020	12/08/2022	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