

PARTICIPATION INFORMATION SHEET

Managing CoronaStress: An internet based program based on CBT principles

INTRODUCTION

You are being offered the opportunity to participate in a research study, due to managing stress during the COVID-19 pandemic. This information sheet is designed to help you decide whether you would like to take part. Please take the time to read the information and discuss it with friends, relatives, your GP or the study team, if you wish. Our contact details are on the last page if you would like any further information or you can email us at coronastress@mail.huji.ac.il. This application has been reviewed by The Hebrew University of Jerusalem Human Research Ethics Committee.

WHAT IS THIS RESEARCH ABOUT?

We are investigating whether a self-help program of CBT via the internet is helpful for people want to manage their stress or are having difficulty doing so during the COVID-19 pandemic. The study will include people who feel stressed and may have symptoms of depression and anxiety, sleep troubles, difficulty managing emotions or distressing memories. The study involves engaging in a self-help program which is similar to a distance or e-learning program along with study team consultation available all via a website. A prerequisite for participation is that you have access to a computer, tablet or smartphone with internet connection and the possibility to send and receive e-mail.

Half of the study participants will be drawn to start the program immediately, whereas the other half will have to wait 6 weeks before starting treatment. This is done in order to be able to compare the effect of the treatment with those waiting for the treatment.

WHO IS ELIGIBLE TO TAKE PART?

Individuals who:

- want help with stress and its associated symptoms during the time of the COVID-19 pandemic
- are 18 years old or older
- can read and write in English
- do NOT suffer from any serious psychological issues such as severe anxiety or depression, suicidality, psychosis, severe dissociation, or are currently in a severely traumatic/abuse situation.
- Do NOT have any major somatic, physical or medical conditions
- Are not currently in psychotherapy or psychological counseling
- have daily access to a computer, tablet, or smartphone with internet
- have the opportunity to participate for 6 weeks and agree to complete all assessments (weekly, post treatment and at 6 and one-year follow-up)

Your participation is voluntary and it is your decision whether you want to participate.

You are also entitled to withdraw from the study at any time. Your anonymized data collected prior to this point will still be used during statistical analysis unless you ask for all your data to be removed from the analysis.

WHAT WILL HAPPEN IF I TAKE PART?

If you are interested in participating, you need to register for the study online, by logging onto www.iterapi.se/sites/coronastress and provide consent to partake. After you register, you will be asked to complete a brief screening questionnaire. If you are determined to be eligible, then you will be asked to complete pretreatment questionnaires that will take around 15-20 minutes. When these are completed, the first module (chapter) will be opened for you. Once you do the first chapter, the rest of the chapters will be available to you. You will be asked to focus on those that you think apply to you best. Each chapter includes reading text and doing some brief exercises over a few days to a week. After you have completed the chapters you are interested in, there is a final summary chapter to help you put it all together and work on maintaining your gains. Once you complete the final chapter, or have decided to discontinue the program, we will ask you complete another set of questionnaires and to have a brief chat online via the system with one of the study team. We will also ask you to complete these questionnaires 6 months and one year after you have completed the program. If you are randomized to the waitlist condition, we will ask you to report your symptoms immediately, after six weeks, and then upon completion, six months, and one year later.

HOW WILL MY PROGRESS BE MONITORED?

- While partaking you will be asked to keep a record of your activities and reflect on your experiences
- You will be sent 22 questions on a weekly basis, which should take less than ten minutes to complete
- After completing the program, your progress will be evaluated by an online questionnaire, which should take less than 20 minutes to complete
- To determine the longer-term effects, there will be another online questionnaire six months and one year after completing the treatment. This should take no longer than 20 minutes to complete.

WHAT ARE THE POSSIBLE BENEFITS OF PARTAKING?

This program will provide you with up to date information about managing stress using evidence-based principles derived from cognitive behavioral therapy. This program is likely to help you manage your stress and associated symptoms.

WHAT ARE THE POSSIBLE RISKS INVOLVED IN TAKING PART?

Some of the modules ask you to do things that are challenging. People often feel anxiety when facing their fears. In all of the modules, people sometimes feel frustrated with themselves that they do not do what they planned. We will encourage you to continue in these situations, as most of the time, people feel better by completing such programs.

What if I run into unforeseen difficulties?

You are able to contact the research team through a messaging system at any time or emailing coronastress@mail.huji.ac.il. Professor Jonathan Huppert is the principle investigator at The Hebrew University of Jerusalem (jonathan.huppert@mail.huji.ac.il).

If you have any enquiries or concerns, please feel free to contact any of the researchers on the team, so that these concerns can be addressed.

Are there risks to my confidentiality?

No, as all the information collected for the research will be kept confidential. Your personal information will only be available to a few members of the research team. All data analysis will also be done using study codes and not using any identifiable information.

Will my data be safely stored?

All information provided by participants will be saved safely at Linköping University, Sweden at the address <https://www.iterapi.se/sites/coronastress>. The reason that the web portal holding the data is in Sweden is due to Linköping University being world leaders in internet interventions. The servers are located in a locked room and all data will be stored encrypted and require passwords to access.

HOW WILL THE INFORMATION I PROVIDE BE USED?

All data collected during the study may be published in a report, journal or presented at a conference but only in the group or anonymized format.

WHO IS INVOLVED IN THE RESEARCH?

The research is being carried out by The Hebrew University of Jerusalem and Bar Ilan University in Israel and Linköping University in Sweden. You can see more details on the website at www.iterapi.se/sites/coronastress/public/7