A pilot study to determine the feasibility of cost-effective online treatments for depression

PARTICIPANT INFORMATION SHEET

You are invited to take part in a research study. It is important for you to understand why this research is being carried out and what it will involve before you decide whether you would like to take part. This Information Sheet has been written for you and it is essential that you read through it carefully and discuss it with one of the researchers or anybody you wish. Please ask whatever questions come to mind and particularly those that this Information Sheet may not answer. Further information about the study can be provided. Take time to decide whether or not you wish to take part.

WHAT IS THIS STUDY ABOUT?

The aim of this study is to assess the feasibility of different online interventions to improve mood symptoms; cognitive abilities such as memory, attention, and planning, and daily functioning in people independently living in the community but currently experiencing depressive symptoms.

WHAT WILL I HAVE TO DO?

If you agree to participate in this study, a researcher will first ask you a few questions to determine your eligibility, namely if you are currently experiencing depressive symptoms and are not receiving psychological treatment/counselling. You will then be asked to complete a series of questionnaires about your current mood symptoms and activities in your everyday life. A researcher will also measure your cognitive abilities (memory, attention, planning) using a number of paper and pencil tests that will be completed by yourself, or by the researcher observing your performance. These assessments will be completed once consent to participate is given, repeated after 5 weeks, and again at 3-month follow-up. Assessments will happen in the Department of Psychology at the University of Limerick or the AWARE national office, Dublin, dependent on your current residence. The first assessment will take about $1^1/_2$ hours to

complete, but all subsequent assessments will take a little over 1 hour. You are under no obligation to complete questions/tests that you would prefer not to answer.

After completing the initial assessment, you will be randomly assigned to one of four conditions; you will either continue with your usual depression treatment or complete online psychological intervention(s) for 5 weeks in addition to your usual depression treatment. The four conditions include:

(1) Usual depression treatment only: participants will only partake in the three assessments. You will not have to complete any online sessions over the five weeks. However, you will be offered an online treatment following completion of the study, if you so wish.

(2) Cognitive Behavioural Therapy: this involves three, 1-hour online sessions per week targeting mood symptoms.

(3) Neurocognitive therapy: this involves four, 1-hour online sessions per week targeting attention, memory and planning ability

(4) A combination of the Cognitive Behavioural Therapy and the Neurocognitive therapy; this involves five, 1-hour online sessions per week, i.e. two Cognitive Behavioural Therapy and three of the Neurocognitive therapy sessions.

All online treatments can be completed in your own home at a time that best suits you.

WHAT WILL BE THE POSSIBLE BENEFITS OF TAKING PART?

Currently, interventions tend to treat for a recovery of mood, without specific focus on the recovery of everyday functioning. It is suggested that everyday functioning is related to our cognitive abilities such as memory, attention, and planning; however, individuals often experience difficulties with these cognitive abilities during depression. If we find that online interventions have a beneficial effect upon these difficulties, healthcare may be refined to better ensure that a full recovery from depression is achieved and sustained. By partaking in this study, you may be randomly allocated to receive an online intervention, in addition to your usual depression treatment. All of these interventions have been shown to be efficacious, at least in the short-term. At the end of the 3 months, all participants will be offered access to the online treatments that they did not receive during the pilot study. This may provide benefits in terms of mood and functional recovery, at least in the short-term.

WHAT ARE THE POSSIBLE DISADVANTAGES OF TAKING PART?

A possible disadvantage to you is the time it takes to complete the questionnaire/test assessments, as well as the online intervention sessions. Breaks and/or rescheduling of sessions are going to be offered, should these issues arise. You are also free not to answer any question you may feel uncomfortable with.

DO I HAVE TO TAKE PART?

It is your decision whether you take part of not. If you do decide to get involved with the study, you will be given this Information Sheet to keep and asked to sign a Consent Form.

WILL MY TAKING PART BE CONFIDENTIAL?

Yes. All information collected about you during the course of the research will be kept strictly confidential. Your name will be replaced with a participant number and it will not be possible for you to be identified in any published reporting of the data. All data will be kept on the Principal Investigator's computer that is password-protected.

WHO ELSE IS TAKING PART?

Individuals currently experiencing depression, but living independently in the community and not hospitalised for the depressive episode, will be invited to take part in this study.

WHAT IF SOMETHING GOES WRONG?

In the unlikely event that something goes wrong during the assessment or intervention, all sessions will be stopped by the researcher until the matter is resolved and you feel comfortable to resume the session. Alternatively, all sessions will be stopped completely.

WHAT WILL HAPPEN AT THE END OF THE STUDY?

As this is a pilot study, the results will be used to prepare a larger study to test the effectiveness of online interventions to improve mood and functioning in depression. The results will be published in scientific journals and presented at conferences, again without any breach of confidentiality. All data gathered from the research will be password-protected and stored securely and safely in the Principal Investigator's office for up to 10 years.

WHAT IF I HAVE QUESTIONS OR DO NOT UNDERSTAND SOMETHING?

If you do not understand any aspect of the research please contact any member of the research team and discuss any questions that you might have. It is our priority that you feel completely at ease during the research.

WHAT IF I CHANGE MY MIND DURING THE STUDY?

You may withdraw from the study at any time you wish and without giving a reason. Such instances will be dealt with in a sensitive and confidential manner.

ETHICS PERMISSION:

This study has been approved by the Education and Health Sciences Research Ethics committee of the University of Limerick (Approval number: **2017_03_09_EHS**). If you have any concerns about this study and wish to contact someone independent you may contact:

Chairman Education and Health Sciences Research Ethics Committee
EHS Faculty Office
University of Limerick
Tel (061) 234101
Email : ehsresearchethics@ul.ie

FURTHER INFORMATION:

If you would like to obtain further information about the nature of the study, you can do so by contacting:

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Thank you for your help with this research project.