



## Participant Information Sheet

### **Let It Out (LIO-C) and COVID19: testing an online writing intervention during the COVID19 pandemic**

*We would like to invite you to take part in our research study. The aim of the study is to find out whether a tool we have developed, called LIO-C, can help improve the wellbeing of people experiencing the current coronavirus (COVID19) pandemic. This information sheet explains the aim of the study, and what it would involve for you. Before you make a decision, it is important for you to understand why the study is being carried out, and what it will involve. Please take your time to read the following information carefully and discuss it with your family or friends if you wish. Please feel free to email us if there is anything that is not clear or if you would like more information.*

#### **Why is the study being done?**

The world is currently experiencing unprecedented and challenging times as result of the COVID-19 pandemic. Many countries are enforcing measures such as lockdowns, social distancing and self-isolation to slow down the spread of the disease. Although these measures are necessary and important, it is likely they might have negative effects on the psychological and emotional wellbeing of the general population, and cause feelings such as worry, confusion, anger or loneliness.

Evidence suggests that writing for short periods of time on a regular basis can have positive effects on wellbeing for many people. Our research team are evaluating an online tool called LIO-C, which has been developed based on this evidence. LIO-C stands for 'Let It Out – COVID19 response'. LIO-C provides instructions for people to write in response to certain prompts. LIO-C asks you to complete three 20-minute online writing sessions over the course of a week on an online LIO-C hub.

The aim of this study is to find out if LIO-C is effective at improving people's wellbeing during this pandemic. This will help us to know if more people around the world should have access to LIO-C to help them cope with the challenges of living during this time.

#### **LIO-C or writing task**

Sometimes we do not know which way of helping people is best. To find out, we need to compare different approaches. In this study, we will put people into groups and give each group a different writing exercise. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). As the study is 'blinded', this means that you will not know which treatment group you are in. At the end of your involvement in the study, you will be told what group you were in. All participants will be given the option to try the other writing task in their own time once they have completed the study.

#### **Why have I been chosen?**

You have been invited to participate in this study because you have responded to an advert about this study that was posted on an online forum, network, mailing list or social media platform. We are asking people over the age of 18 who are able to read and write clearly in English to participate in this research.



## ***Do I have to take part?***

No, your participation in this study is completely voluntary. You can also withdraw from the study at any time without giving a reason. If you withdraw from the study all the data that has been collected as part of the interview can be destroyed if you wish for up to 3 months after you finish the study. After 3 months, all data will be anonymised and you will no longer be able to withdraw your data. If you do not wish to participate, or if you withdraw from the study at any time without giving a reason; it will not affect your rights in any way.

## ***Taking part in the study***

If you decide to take part, you should download a copy of this information sheet to keep. Then follow the link at the bottom of this document to go to the online LIO-hub, where you will be asked to electronically sign a consent form. Once you have signed the consent form, you will be asked some questions that will be used to generate your unique ID code. Once you have generated the code, you will officially be enrolled in the study. Remember though, even if you do decide to take part, you are free to withdraw from the study at any time and without giving a reason.

## ***What do I have to do?***

If you agree to participate in the study and electronically sign the consent form, you will be asked to proceed through the study in the following steps:

### **Week 1 – Step 1:**

Immediately after providing consent you will be asked to fill out some questionnaires online asking you to provide some details about yourself and your background (such as your age group, ethnicity and religious beliefs). We will also ask some questions about your health (for example, we will ask about your current stress levels, feelings of loneliness and quality of your sleep). These questionnaires will take approximately 20 minutes to complete. When you have completed the questionnaires, you will be prompted to submit your responses.

### **Week 1 – Step 2:**

After submitting your questionnaire responses, you will be sent a new link by email to the main phase of the study. Here you will be given the option to download the LIO-C toolkit, which is a PDF guide that you can download and keep with instructions on how to work through the study, as well as a list of organisations who are available to offer you additional emotional support should you feel you need it.

You will be asked to follow the instructions in the LIO-C toolkit as closely as possible. This will involve typing online in the spaces provided in three, 20-30 minute writing sessions across one week. You are free to complete these three sessions at any time within that week, and in any location of your choosing where you feel comfortable. Ideally you can complete them somewhere that is private and you will not be disturbed, although we do understand this may not always be possible. There are instructions to follow on screen as well as in the toolkit that tell you what to write about, where to write it and for how long.

You can choose when to complete each writing session within the week. However, we do ask that you do not complete more than one writing session on one day. You will receive up to 3 email reminders to complete each writing session.

Writing session 1: We would ask that you please try to complete the first writing session within 24 hours of completing the first set of questionnaires you filled out. Write for 20 minutes, following the writing instructions provided to you on the screen and/or in your toolkit (whichever is easier for you to follow). All writing entries need to be completed online. After you have finished the writing session, you will be asked to fill in a very short questionnaire asking how you feel and how you found the session. The questionnaire will take no more than 5 minutes. After this, you will be prompted to save your response and log-out.



**Writing session 2:** The online instructions, and the instructions in your toolkit will tell you which topic to write about. Again, after writing for 20 minutes you will be prompted to fill in the short questionnaire asking how you feel and how you found the session. After this, you will be prompted to save your response and log-out.

**Writing session 3:** The online instructions, and the instructions in your toolkit will tell you which topic to write about. Again, after writing for 20 minutes you will be prompted to fill in some more, longer questionnaires asking about your health. We will also ask for your feedback about your experience taking part in LIO-C. Please note, *the questionnaires following this writing session may take around 40 minutes, so please try to schedule around an hour for this final session. If the questionnaires are taking too long, you can complete them in more than one sitting if necessary, but please do try to complete them as soon as possible after completing the writing. Once you have completed the questionnaires, you will be prompted to save and submit your responses.*

### **Week 2:**

One week after you have completed the final writing session, we will send you a link to fill out an online questionnaire asking about your health. This will take around 20 minutes.

### **Week 8:**

7 weeks after you completed the last online questionnaire, we will send you another link to the same set of questionnaires asking about your health. Again, this will take around 20 minutes, and will help us to understand if the study has any longer term effects on wellbeing.

After you have submitted this final questionnaire, your involvement in the study will be finished.

### ***What will happen to the information that I give?***

We want to use the information you provide to help us understand if LIO-C is an effective way of improving wellbeing during the COVID-19 pandemic. By analysing the characteristics of participants who experience the greatest benefits of the intervention in the study, we will be able to use the data you provide to understand who it may be most effective for, and also to help us to understand more about how it might work. Finally, we may also use your information to understand more about the key concerns and worries that people living through the COVID-19 pandemic are experiencing. The text that you provide in the writing exercises may be quoted from in publications. Your responses to the questionnaires and writing exercises will also be made available to other researchers and the public via an open-access database (ReShare). All quotes will be completely anonymous. All data shared with other researchers and the public will be completely anonymous. Whilst your written texts will be read by researchers, this will be for research purposes only. We will not be able to respond to any concerns or queries you raise in your written texts.

### ***How long will I be in the study?***

Once you have signed the informed consent form and completed the first set of questionnaires, you will be sent a new link to your personal LIO-C hub. When you receive the link, you will have 1 week to complete the three writing sessions and questionnaires. We will send you a new link 1 week after you finish the final writing session to complete some more online questionnaires. We will then send your final link 7 weeks later to fill out the last online questionnaires. Your involvement in the study should last no longer than 9 weeks.

### ***What happens when the research study stops?***

Once you have completed the final set of questionnaires 8 weeks after your last writing session, your involvement in the study will be finished.



### ***Possible benefits of taking part***

If the writing task is effective, you may feel some positive effect on your wellbeing. It is important to remember that we cannot promise that the study will help you. However, the information we get from this study may help us to develop and/or implement LIO-C or other similar writing therapies that may help to improve the wellbeing of the wider population during the current COVID19 pandemic, or other pandemics in the future.

### ***Possible disadvantages of taking part***

Like all psychological therapies, there may be some side-effects to trying LIO-C. The possible side effects (or negative consequences) are described in the section below. Your involvement in the study may also be an added inconvenience for you. You will need to take the time to complete each writing session, and complete the questionnaires for the duration of the study. As some of the questionnaires ask you questions about some potentially sensitive topics (for example, your levels of distress, stress and loneliness) it is possible you may find filling them in upsetting. It is important you recognise if you are feeling upset and take some time for self care. In the intervention guide that you will be able to download as part of the study we provide a list of helpful organisations you can contact if you would like further support. You are also welcome to contact us using the details provided below and we can direct you towards organisations who can provide you with support.

### ***Does LIO have any side effects?***

As LIO-C is a new intervention, there are no known side effects, and therefore the risk that you may experience side-effects or complications is not known. However, LIO-C is based on the principle of the therapeutic benefits of writing. Other similar therapies have been tested before and tend to be safe, with minimal negative consequences being reported. However, in rare cases, some people who have taken part in these studies have reported feeling more distressed or emotional immediately after taking part in a writing session. It is important you recognise if you are feeling this way, and take steps to look after yourself. We have provided a list of helpful organisations who you can contact if you are experiencing distress. You can download this list from the LIO-C hub. You are also feel free to contact the research team using the contact details provided below at any time if you are feeling particularly distressed. We will be able to give you details of organisations that you can contact for additional support.

### ***What if there is a problem?***

If you are concerned about any aspect of this study, please speak to the researchers who will do their best to answer your questions. Please contact Ms Daisy McInerney at [liostudy@ucl.ac.uk](mailto:liostudy@ucl.ac.uk) or +44(0)20 3108 5683 in the first instance. If you remain unhappy, or wish to make a complaint about the conduct of the study, you can contact the Principal Investigator of this project: Dr Nuriye Kupeli at [N.Kupeli@ucl.ac.uk](mailto:N.Kupeli@ucl.ac.uk) or +44(0)20 7679 9724.

If you are not satisfied with the way your complaint is handled, please contact the UCL Research Ethics Committee (REC) Chair at: [ethics@ucl.ac.uk](mailto:ethics@ucl.ac.uk)

### ***Confidentiality***

All information that is collected about you during the course of the research will be kept strictly confidential. Any personal information will have your name and address removed so that you cannot be identified from it. Only the research team will have access to the data. All data will be handled, processed, stored and destroyed in accordance with the Data Protection Act 2018 (DPA 2018) and General Data Protection Regulations (GDPR 2018).

### **Data Protection Privacy Notice**

The controller for this project will be University College London (UCL). The UCL Data Protection Officer, Alex Potts, provides oversight of UCL activities involving the processing of personal data, and can be contacted at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

For participants in health and care research studies, click [here](#)

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

Your personal data will be processed for the purposes outlined in this notice.

The lawful basis that will be used to process your personal data are: 'Public task' for personal data and 'Research purposes' for special category data.

The personal data you provide to generate your unique identifier will be processed for no longer than 3 months following data collection. Your email address will be stored for no longer than 3 months, unless you specifically indicate on the consent form that you would like us to keep it in order to send a summary of study results to your and/or to hear about future opportunities to be involved in related research. In those instances, your email address will be stored for no longer than 18 months following data collection. We will pseudo-anonymise (key-code) the personal data you provide, and we will endeavour to minimise the processing of personal data wherever possible.

If you include any personally identifying information in your written text, this will be deleted during analysis so that your text is completely anonymised.

If you are concerned about how your personal data is being processed, please contact UCL in the first instance at [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk). If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/>

### **Results of the research study**

We will present the findings of this study to the public through accessible and informative updates on social media and blogs for relevant organisations. We will present the findings to health and social care professionals and researchers at academic meetings. We will also seek to publish papers in scientific journals. All information collected during the study will be combined to form the results, so no individual will be identified in any report or publication. If you take part in the study you will be asked if you wish to receive a written summary of the results.

### **Funding and review of the research study**

This research has been reviewed and funded by Marie Curie and by the Economic and Social Research Council, and is being conducted by researchers in the Marie Curie Palliative Care Research Department at UCL. It has been reviewed and approved by the UCL Research Ethics Committee [project ID 15281/003 , 13 May 2020].

**Contact for further information**

For further information please contact Ms Daisy McInnerney via email: [liostudy@ucl.ac.uk](mailto:liostudy@ucl.ac.uk)

***Thank you for taking the time to read this information sheet.  
Your help makes our research possible.***

**Follow this link to go to the LIO-C hub and sign up to take part in the study:**

**[Link to LIO-C study](#)**