Participant Information Sheet – Patient

LIO (Let it out): developing and evaluating an online emotional disclosure-based intervention in UK hospices

We would like to invite you to take part in our research study, which will involve testing a new tool we are developing called LIO. As part of the study, you may also be invited to take part in an interview with a researcher from UCL. 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?

People living with advanced disease can often find they are experiencing psychological or emotional distress. Research suggests that writing or talking about your feelings can have both physical and psychological benefits. Our research team are evaluating an online tool (or 'intervention') called LIO (Let It Out) that is based on this principle. LIO is tailored specifically for people receiving palliative care from hospices. It provides self-guided instructions to help people to express their feelings in a way that may help to bring them comfort.

We are asking people who are receiving care from hospices to try out LIO and tell us about their experience with it. We are going to use their views and experiences to further refine its design so it is as easy to use and as beneficial as possible, and to help us understand more about if and how it might work.

It is also important that LIO can fit into a person's overall care programme, and that includes ensuring it is easy, practical and acceptable for hospice staff, volunteers and family carers to include in their approach to caring for the person using LIO. That is why we are also inviting hospice staff, volunteers and friend and family carers of people testing LIO to take part in interviews or focus groups with the research team to share their views and experiences with it.

Why have I been chosen?

You have been invited to participate in this study because a member of your clinical team has recommended that you are suitable to take part in this study. We are asking patients over the age of 18 who are living with an advanced illness and receiving care from a hospice 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 the standard of your treatment or care in any way.

Taking part in the study

Once you have read the information in this sheet, follow the link at the bottom of this page to go to the online LIO study platform. The first page will be a form where you can indicate to the research team how you feel about taking part in the study:

- If after reading this information sheet you are sure you would like to take part, you should tick the appropriate box on the form. You will be asked to electronically sign an online consent form. Once you have signed the consent form, you will officially be enrolled in the study. We will also ask you to sign an advanced consent form that you can use to tell us what you would like us to do if at any point during the study you become too unwell to give your informed consent to take part in this study. As part of the consent process we will also ask for your name, contact details and the name of the hospice where you provide care, so that we can let your hospice care team know that you are taking part, and to allow us to keep in touch with you throughout the study. If you do decide to take part you are free to withdraw from the study at any time and without giving a reason. If you decide to take part, you should download a copy of this information sheet to keep.
- If you are not sure, have some questions or would like more information before making a decision, you should go the online study platform. There you can provide your contact details and ask for the research team to contact you to discuss the study
- If you decide you do not want to take part, it would be helpful for us to understand why. We would appreciate it if you could let us know these reasons via the online response form. However, this is completely voluntary and you do not have to do this if you'd rather not.

What do I have to do?

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

Week 1 – download the guide and complete the questionnaires

Immediately after providing consent you will be directed to a page with instructions about how to work through the LIO intervention – first you will have to set up a password and unique ID generator to help track your responses through the study. Next, you will be prompted to fill out some online questionnaires asking for 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. These questionnaires will take approximately 20 to 30 minutes to complete. Once you have completed these questionnaires, you will be able to download a PDF guide to LIO, which you can save or print. We would encourage you to read this guide fully before going any further with the study. The guide provides a full set of instructions for 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.

The 2 week intervention period officially begins when you have completed the first set of questionnaires and downloaded the LIO PDF guide.

Week 1 – 2: completing LIO

Following the instructions in the guide, LIO asks you to either write down (with pen or paper, or typing) or talk about and record your feelings about certain aspects of your illness in three, 20-30 minute 'expression sessions' across two weeks. You can choose if you would prefer to write down, type or talk about your feelings:

- **If you type:** you can type your responses directly into the online LIO study platform. When you finish each session you can submit your response and complete some short questions asking about your mood and how you found the session. The next day, you will then be sent a new link where you can complete the next session.
- **If you handwrite:** you can follow the online instructions or the instructions in your guide on what topics to write about. Once you have finished writing, you should log on to the online LIO study platform to indicate that you have completed the session, and to complete the short questions asking about your mood and how you found the session. You also have the option to send a photo of your

handwritten response to the research team via WhatsApp if you would like it to be included in our analysis.

- **If you audio-record**: you can follow the online instructions or the instructions in your guide on what topics to talk about. Once you have finished recording, you should log on to the online LIO study platform to indicate that you have completed the session, and to complete the short questions asking about your mood and how you found the session. You also have the option to send your recording to the research team via WhatsApp, or uploading it to the LIO platform, if you would like it to be included in our analysis.

The LIO guide provides you with more detailed instructions on the different ways you can do this, and which topics you should write or talk about. You are free to complete the three sessions at any time within two weeks, and in any location of your choosing where you feel comfortable. If you would like help writing, recording or sharing your responses, you are free to ask somebody you trust to help you (for example, they can type or write for you, or help to set up the audio-recording software for your phone). Ideally you can complete each session somewhere that is private where you will not be disturbed, although we do understand this may not always be possible.

After the third and final expression session, you will be prompted to complete a longer set of online questionnaires about your health. One of these questionnaires 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 build this into your schedule. 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 submit your responses.*

A researcher will contact you by phone or email (depending on your preference) 1 week and 2 weeks after your complete the first set of questionnaires to check how you are getting on, to ask if you are experiencing any issues or require any help.

Weeks 3 – 10: Follow-up questionnaires

One week, 4 weeks and 8 weeks after you have completed the final expression session, we will send you a link to fill out the same set of online questionnaires asking about your health. This should take around 20 minutes and will help us to understand if LIO has any longer term effects on wellbeing. After you have submitted the final set of questionnaires, your involvement in the study will be finished, unless you are invited to a follow-up interview.

Follow-up interviews:

We may also approach you to ask for your availability to schedule a 30 to 45 minute interview with a member of the UCL research team. Ideally this interview will take place within 1 month of the last expression session. At this interview, we will ask you about your experience testing LIO, including how practical it was to use, how clear the instructions were, and whether you experienced any benefits, or negative events, as a result of using it. The interview will take place at a time and place that suits you if it is possible to meet face-to-face. If this place is not your home or the hospice where you are staying as an inpatient, you will be paid for the cost of your travel. The interview will be audio-recorded, and we will also take notes by hand, to help us check against the recordings. If it is not possible to meet face-to-face, the interview may also take place via a video call (using a programme called Microsoft Teams).

At the end of this interview, your involvement in the study will be finished.

Expenses and payments

We will pay up to £20 towards your travel to and from the interview location if you have to travel. Please keep your receipts.

What will happen to the information that I give?

We want to combine the insights from your experiences with the LIO, along with insights from our research with people with hospice staff members and family carers, to inform its tailoring and refinement. We hope that by incorporating your views into the design of the intervention, we can help make the tool as beneficial and practical to implement for people receiving hospice care as possible. We will also use your insights to help us to understand more about how the intervention might work, and to inform the design of any future research studies that we may run to test the effectiveness of the intervention. Finally, we may also use your information to understand more about the key concerns and worries that people living with a terminal disease experience. The responses that you provide to the expression sessions may be quoted from in publications. Your responses to the questionnaires and expression sessions 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 expression session responses 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 expression session responses.

How long will I be in the study?

Once you have signed the online informed consent form and completed the first set of questionnaires, you will have two weeks to try out LIO. We will send you links to online questionnaires 1 week, 4 weeks and 8 weeks after you have completed the final expression session. You may also be invited to take part in an interview lasting approximately 30 to 45 minutes that will take place within a month of completing the intervention. Your involvement in the study should last no longer than 10 weeks in total.

What happens when the research study stops?

Once you have completed the final set of questionnaires, and if invited to an interview, completed the interview, your involvement in the study will be finished. At that point you will be treated and monitored in exactly the same way as if you had not been on the study. The LIO guide does provide some signposts to further helpful resources. However, taking part or following up on these elements would not be considered part of the study.

Possible benefits of taking part

If LIO is effective, you may feel some benefit in terms of psychological or physical 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 improve psychological care for other people receiving hospice care.

Possible disadvantages of taking part

Like all psychological therapies, there may be some side-effects to trying LIO. 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 stay in contact with the research team over the course of the study through email and/or phone calls, and take the time to read the LIO guide and complete the expression sessions and questionnaires about your health.

Does LIO have any side effects?

As LIO 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 is based on the principle of self-compassionate emotional disclosure. Other similar therapies have been tested before in people with advanced disease. These

therapies tend to be safe, with minimal negative consequences being reported. However, some people who have taken part in these studies have reported feeling more distressed or emotional immediately after taking part in the expression session. Some people have also reported disruptions to their sleep.

If you feel distressed during the study, we have provided a list of organisations at the end of your LIO intervention guide who will be able to help provide you with help and support. You will also be given a telephone number and email address to contact the research team if you are concerned about any negative effect you experience when testing LIO. A member of the research team will also be in contact with you every week (either by telephone or email) and will ask if you are experiencing any negative effects. If you do report any negative effects, this information will be communicated to the clinical and research team and appropriate actions will be taken. This may include stopping the intervention, or starting other interventions to address specific problems. If at any point during the study you become concerned about your physical or mental health, please do immediately contact your clinical care team.

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 McInnerney at liostudy@ucl.ac.uk or +44(0) 7810 590441 in the first instance. If you remain unhappy, or wish to make a complaint about the conduct of the study, you can contact the supervisor of this project: Dr Nuriye Kupeli, Marie Curie Palliative Care Research Department, Division of Psychiatry, University College London, 6th Floor, Maple House, 149 Tottenham Court Road, London W1T 7NF, email: n.Kupeli@ucl.ac.uk; 020 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

If this clinical study is being carried out in a hospital or hospice, the hospital or hospice continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital or hospice's duty of care, or any negligence on the part of hospice or hospital employees. This applies whether the hospital or hospice is an NHS Trust or otherwise.

Confidentiality

All information that is collected about you during the course of the research will be kept strictly confidential. The only exception to this will be if you disclose any information which suggests possible risk to the safety of patients or staff. If this arises, you will be informed that confidentiality cannot be maintained in that particular regard, and the appropriate personnel will be informed. In all other cases, 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. An additional external transcriber may listen to the voice recordings and type these up as written scripts, but this person will have signed a confidentiality agreement with UCL. 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). Photographs and voice recordings received via WhatsApp will be downloaded from the research study phone and uploaded to a secure UCL server, and the original recording or photograph deleted.

Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at 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 (including your name and the answers you provide to generate your unique identifier) will be processed for no longer than 3 months following data collection (i.e. from the date you finish the study). Your email address will also be stored for no longer than 3 months from the date you finish the study, 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 expression sessions, 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. 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 people living with advanced disease, their family carers, health and social care professionals and researchers. We will produce accessible and informative updates through social media and by writing 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 15281/002, 19 May 2020].

Contact for further information

For further information please contact Ms Daisy McInnerney via email: liostudy@ucl.ac.uk or phone +44(0) 7810 590441.

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

Follow this link to go to the online LIO platform and let us know if you'd like to take part in the study.