Participant Information Sheet – informal carer

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

We would like to invite you to take part in our research study, which will involve taking 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 and 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 a 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 in the UK 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 family carers to include in their approach to caring for the person using LIO. That is why we are inviting family carers of people testing LIO to take part in an interview with the research team.

In the interview, we will talk about the design of LIO with you, and ask you to think about the practicality of including LIO in the care of the person you are looking after. You will be asked to consider the features of its design and if and how they may need to be adapted to suit you and the person you care for. You will also be asked to think about what resources or support you may need with including LIO in your approach to care. We would also like to discuss with you any risks or benefit you may have observed for the person testing LIO, or for yourself. We want to use your insights, together with those of the people with terminal illness trialling LIO, to inform and refine its design to make sure it suits the specific needs of people receiving hospice care, as well as their family carers.

We will also separately be exploring the views of health and social care professionals who may be involved in delivery of LIO to explore their views and experience with the intervention.

Why have I been chosen?

You have been invited to participate in this study because you are a family/friend caring for someone who is living with a terminal illness, who is receiving care from a hospice in the UK and who is testing the LIO intervention as part of this research study.

Do I have to take part?

No, your participation in this study is completely voluntary. If you do not want to answer the questions, please make the researcher aware. If you do not wish to participate, it will not affect the treatment or care provided to you or your friend/family member in any way. You can 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 three months after your participation in the study is complete. After this point all data will be anonymised and we will no longer be able to withdraw your data.

Taking part in the study

If you decide to take part, please download a copy of this information sheet to keep and fill out the online consent form by following the link at the end of this sheet. Directly after the informed consent form, there will be a short demographics questionnaire asking for basic details about your background and relationship with the person who is testing the LIO intervention. 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, you will be invited to take part in an interview with a researcher from UCL. The interview will take over a video call (using the platform Microsoft Teams) or, if face-to-face meetings are viable, at a time and place that suits you. If this place is not your home, you will be paid for the cost of your travel. We expect the interview to last up to 40 minutes. The interview will be voice-recorded, and we will also take notes by hand, to help us check the recordings.

During the interview, you will be asked to think about the practicality of LIO for your friend/family member using LIO. You will be asked to consider the features of its design and if and how they may need to be adapted to suit both you and your family member. You will also be asked to think about where LIO might fit into your current approach to caring for your friend/family member and what additional resources or support you may need when using it. We would also like to discuss with you any risks or benefit you may have observed your friend/family member experiencing when trying the intervention, as well as any impact their use of LIO may have had on you.

We want to use your insights, together with those of the people testing LIO, and staff members involved in delivering it, to inform and refine its design. In this way we can make sure it suits the specific needs of people receiving hospice care, as well as those who deliver it.

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 will combine the insights from the interview, with our insights from our research with people with terminal illnesses who have tested the intervention, and hospice staff members, to inform the tailoring and refinement of the LIO intervention. We hope by incorporating these views into the design of the intervention, we can help make the tool as beneficial and practical to implement in the hospice environment as possible. We will also use your insights to inform the design of any future research studies that we may run to test the effectiveness of the intervention developed as a result of this research project.

How long will I be in the study?

You will be asked to participate in an interview lasting up to 40 minutes.

Benefits of taking part

There will be no direct benefit to you for taking part in this study. However, by taking part you will help to inform the design of the LIO intervention and any future research evaluating its feasibility and efficacy. This is important because people living with terminal illness often experience significant psychological and emotional distress, and we hope that in the future, hospice teams may be able to use LIO to help alleviate some of this distress for some of their patients.

Risks/harm of taking part

We do not anticipate any risks or harm to you as a result of taking part in this study, although it is possible that these discussions may touch on some difficult subjects. If you should wish further advice or support we will signpost you to relevant resources.

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. 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 (x09724).

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

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 notes from the interview. 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). Voice recordings will be downloaded from the portable recorder onto a secure computer server, and the original recording 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 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 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 terminal illnesses, 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 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 informed consent form. It is vital that you complete this form before taking part in the focus group or interview.