Participant Information Sheet

Research Evaluating Staff Training Online for Resilience (RESTORE): A cluster randomised controlled trial of online Acceptance and Commitment Training (ACT) to improve mental wellbeing in staff caring for terminally ill people and their caregivers.

You are invited to consider whether you wish to take part in a research study examining the usefulness of online Acceptance and Commitment Training (ACT) for staff working in palliative care settings. It is important you understand why the research is being done and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. You can speak with the research champion at your hospice or a member of the research team if you would like more information or have any questions. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Palliative care work is generally viewed as rewarding, bringing meaning, and purpose to professional care staff. However, alongside positive experiences, stress, distress and burnout are common. Balancing the rewards associated with palliative care work with the emotional challenges is an ongoing task.

The RESTORE trial involves a psychological skills training course based on Acceptance and Commitment Training (ACT), to promote mental wellbeing in palliative care staff, and to support staff to manage work-related stress and distress. Acceptance and Commitment Training uses values, acceptance, and mindfulness techniques to improve mental health and wellbeing by increasing psychological flexibility. ACT emphasizes how we respond to thoughts and feelings, rather than trying to alter the meaning of the situation as in traditional cognitive therapy. Two trained therapists have been hired to provide ACT to hospice staff in this study.

As this is a randomised controlled study, there are two groups your hospice could be randomly assigned to. The intervention group will receive ACT plus the usual wellbeing supports available to staff at your hospice, and the control group will receive reminder emails directing participants to available wellbeing support. Those in the control group will be offered the ACT based training at a later stage.

The purpose of the study is to find out whether Acceptance and Commitment Training (ACT) plus usual staff wellbeing supports (the Intervention group) results in lasting changes in work-related quality of life and wellbeing compared to usual wellbeing supports alone (the control group).

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Why have I been invited to take part?

You are being invited to take part as you are a member of staff who provides care for people with terminal illnesses and their families.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you are interested, please discuss this with your line manager. If you do decide to take part, you can stop participating in this study at any time without giving a reason. Deciding not to take part or withdrawing from the study will not affect your employment.

If you withdraw from taking part, we will retain any research data gathered up to the point of withdrawal for analysis.

What will happen if I take part?

Once you have finished reading this Participant Information Sheet, you will be directed to a consent form. If you wish to take part, you will need to complete the consent form online. Having completed the online consent form, you will then be invited to complete an online baseline questionnaire which will allow the collection of participants' characteristics.

Once interested staff at your hospice have consented to take part, your hospice will be randomly assigned to either the intervention group (i.e., you will receive ACT training in conjunction with access to usual wellbeing support) or the control group (i.e., access usual wellbeing supports). All participants at the same hospice be in the same group. You will only find out what group your hospice has been randomised to after enough participants have consented at your hospice and completed the baseline questionnaires. All participants at hospices assigned to the control group will be offered ACT training at a later stage.

Intervention Group: If your hospice has been randomised to the intervention group you will be asked to attend four live online workshops (90 mins each) and commit approximately eight to ten hours of self-directed learning and skills practice using video, audio, and workbook exercises over a 12-week period. This can be done at a time convenient to you, and in any location.

Control Group: If your hospice has been randomised to the control group, you will receive email reminders reminding you of the wellbeing supports available to you over a 12-week period.

Participants in both the intervention and control arm will be required to complete an online questionnaire that will take approximately 20 minutes. You will complete questionnaires at the following points:

- Following providing consent
- At around 8 weeks

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- At around 12 weeks
- At around 24 weeks

(The term 'around' is used to reflect some flexibility with regards to your personal/professional time commitment and completion of questionnaires).

The questionnaires measure wellbeing, burnout, thinking style and flexibility. These questionnaires will assess if the intervention is effective and allow us to determine how the intervention works.

You may also be invited to take part in an optional interview on completion of the intervention.. You will be asked if you are agreeable to being interviewed at the consenting stage. We intend to randomly select a proportion of study participants for interview, and if selected, you will be contacted by a member of the research team via email to discuss your preferred format for the interview (Microsoft Teams or telephone) and to make arrangements for this to happen, i.e., a convenient date and time. We will send you an email containing an electronic link to the online platform Jisc where we will ask you to complete another Informed Consent Form to show that you understand your rights in relation to the research, and that you are happy to participate. Interviews are expected to last between 30–40 minutes and will be audio/video recorded, although you may switch off your camera if wished. The Jisc link will also facilitate the collection of brief demographic details so that we can describe the participant sample. (i.e., gender, age, ethnicity, role, number of years' experience in palliative care). Once you consent to an interview, you will be provided a unique 5-digit Participant ID, and this will be used in place of any identifiable information. Audio recordings will be stored securely and will be deleted once transcribed. Data will be collected via Microsoft Teams, and we will use the automatic transcription function in Teams to transcribe interviews. All electronic data will be stored on a password-protected computer file. Your consent information will be kept separately from your responses in order to minimise risk of identification.

In order to show thanks for the amount of time participants dedicate to the study, a £25 voucher will be sent to you on completion of all data collection.

What are the possible benefits of taking part?

Participants may find taking part in the study enjoyable, informative and useful. The knowledge we gain from the study will support further development of RESTORE wellbeing resources with a view to becoming available to future palliative care staff moving forward.

What are the possible disadvantages of taking part?

There are no anticipated disadvantages aside from the time needed to take part and complete the questionnaires. However, you will need to discuss participation with your line manager and ensure that participation fits around your work patterns. You will also need to

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make time to complete the questionnaires, undertake the self-directed learning and attend the four online group meetings. Although unlikely, if you experience heightened stress or distress while undertaking the training, the trial therapist can guide you and if needed will signpost you to additional resources and support that may be helpful.

Will my taking part be kept confidential?

Your data will be processed in accordance with the Data Protection Law. All information collected about you will be kept strictly confidential. Data collected during the study will be stored securely at all times. Strict laws safeguard your privacy at every stage. We use these data to make sure the research is being done properly and to check the results after the study is finished.

How will we use information about you?
We will need to use information from you for this research project.

This information will include your:

· Name
· Email address
· Gender
· Age
· Ethnicity
· Role
· Number of years' experience in palliative care role.

The research team will use this information alongside questionnaire/interview data to explore what parts of the RESTORE intervention worked and what can be improved upon, for whom and why.

Questionnaire data and consent forms will be stored at the University of Edinburgh. Only the core research team, and the Chief Investigators, Dr David Gillanders and Dr Anne Finucane, will have access to both. With your consent, the training workshops will be audio and video recorded. The recordings will be stored securely and will be deleted after they have been checked to ensure that the training has been delivered as planned.

All electronic data will be stored on a password-protected computer file. Your consent information will be kept separately from your responses in order to minimise risk. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

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- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At https://data-protection.ed.ac.uk/privacy-notice-research
- by asking one of the research team
- by sending an email to the University of Edinburgh Data Protection Officer at dpo@ed.ac.uk

The University of Edinburgh is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Edinburgh will keep identifiable information about you until the end of the trial and your de-identified data will be retained indefinitely and may be used in future ethically approved research.

What will happen to the results of the study?

The results of the study will help us determine whether training in ACT-based psychological skills training improves mental wellbeing in staff working in palliative care settings. If we find that the training is effective, we will share information on the training more widely so that it can be further developed and delivered more widely.

We aim to publish the results of this study in a peer-reviewed journal. All data will remain de-identified and you will not be identified from any published results of this study.

The research champions at each site will be emailed copies of relevant study reports to disseminate to participants and any other interested staff following completion of the study.

Who has organised, funded and reviewed the study?

This study has been organised by researchers from the University of Edinburgh with the support of the Edinburgh Clinical Trials Unit. It is sponsored by the University of Edinburgh and funded by the National Institute for Health and Care Research – Efficacy and Mechanism Evaluation Programme. The study proposal has been looked at by an independent group of people called a Research Ethics Committee. This study was approved

by The Clinical Psychology Ethics Committee at the School of Health in Social Science, University of Edinburgh.

Research Team Contact Details

You can ask the RESTORE research champion at your hospice who sent you the link to this information sheet any questions and they will take time to discuss with you and provide more information as needed.

If you would like to speak to a member of the RESTORE trial team, please contact the Trial Manager Alix Macdonald or Assistant Trial Manager Phillip Rayson at: RESTORE.Trial@ed.ac.uk

You can also contact the study leads Dr Anne Finucane: a.finucane@ed.ac.uk or Dr David Gillanders: David.Gillanders@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact:
Dr Ingrid Obsuth
Senior Lecturer
The University of Edinburgh
Email: ingrid.obsuth@ed.ac.uk

Complaints

If you wish to make a complaint about the study, please contact:
Prof Matthias Schwannauer
Head of School of Health and Social Science
The University of Edinburgh
Email: m.schwannauer@ed.ac.uk
Tel: +44 (0)131 651 3954

If you wish to raise a complaint on how we have handled their personal data, please contact our Data Protection Officer who will investigate the matter.

Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL

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Tel: 0131 651 4114
dpo@ed.ac.uk

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Thank you for taking the time to read this information sheet.

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