THE UNIVERSITY of EDINBURGH

PROTOCOL

Marie Curie Care and support through terminal illness

Development of an online self-directed Acceptance and Commitment Therapy (ACT) intervention to improve ability to cope and quality of life after bereavement

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List of Abbreviations

AAG	-	Adult Attitude to Grief Scale
ACT	-	Acceptance and Commitment Therapy
CBT	-	Cognitive Behavioural Therapy
COVID	-	Coronavirus
Cruse (Scotland)	-	Bereavement support service, Scotland **(Key stakeholder Organisation)**
WEMWBS	-	Warwick-Edinburgh mental wellbeing scale
ICECAP	-	Measure of capability for the general adult population
IDWL-M	-	Inventory of daily widowed life (modified)
LO	-	Loss-orientated coping
RO	-	Restoration-orientated coping
Marie Curie	-	Bereavement support service, UK **(Key stakeholder organisation)**
MGMW	-	My Grief My Way
MRC	-	Medical Research Council
NICE	-	National Institute for Health and Care Excellence
PC	-	Personal Computer
PPI	-	Patient and Public Involvement
RCT	-	Randomised Controlled Trial

Introduction

1.1 Background

Grieving is a natural process; typically, 60% of people who are bereaved are at low risk of complex grief issues and learn to adjust with support from family and friends. For three in ten people, additional support provided by volunteers or peer support groups is helpful; and for one in ten people specialist support provided by mental health professionals is needed.[1, 2] Despite this need, access to support is inconsistent.[3]

Since the COVID-19 pandemic, the demand for bereavement support has increased. There was a 17.6% increase in the number of deaths in the UK during first 12 months of the pandemic compared to the average over the previous 5-years, resulting in sharp increases in the numbers of bereaved people. [4] This has been described as a 'silent epidemic of grief'. [5] Evidence from a national online survey of people bereaved during the COVID pandemic indicated high levels of emotional support needs, with over half of those responding to a questionnaire reporting severe problems with grief.[6] Less than one third felt that the support provided to them by friends and family was enough, yet most were not accessing support services. This was due to long waiting lists, lack of availability of services and feeling uncomfortable seeking support.[6]

The increased unmet need requires greater availability of, and access to evidence-based bereavement services. We propose that an Acceptance and Commitment Therapy (ACT, said as one word rather than three letters) psychological intervention has strong potential to improve coping and quality of life following bereavement and can be scaled-up to meet growing demand for bereavement support across the UK. ACT is an empirically supported form of Cognitive Behavioural Therapy (CBT), which uses behavioural psychology, values, acceptance, and mindfulness techniques to improve mental health and wellbeing. (Figure 1)[7, 8] The Acceptance and Commitment Therapy model consists of six interdependent and overlapping processes; (1) **Acceptance** – making space for challenging thoughts and emotions versus suppression or avoidance; (2) **Defusion** – stepping back from unhelpful thoughts and emotions to reduce their influence versus being entangled in and dominated by thinking; (3) **Contact with the present moment** – maintaining flexible awareness of the present versus being overly influenced by concerns about the past or future; (4) **Self as context** – flexible perspective taking on our own self narratives versus being dominated by a rigidly held set of beliefs about who we are; (5) **Values** – identification of personal qualities and behaviours for a meaningful life versus dominance by expectations; (6) **Committed Action** – effective actions guided by values versus inaction or

impulsivity.[9] These six processes can also be described more simply by three broad response styles or skill sets: becoming more OPEN, more AWARE and more ENGAGED.

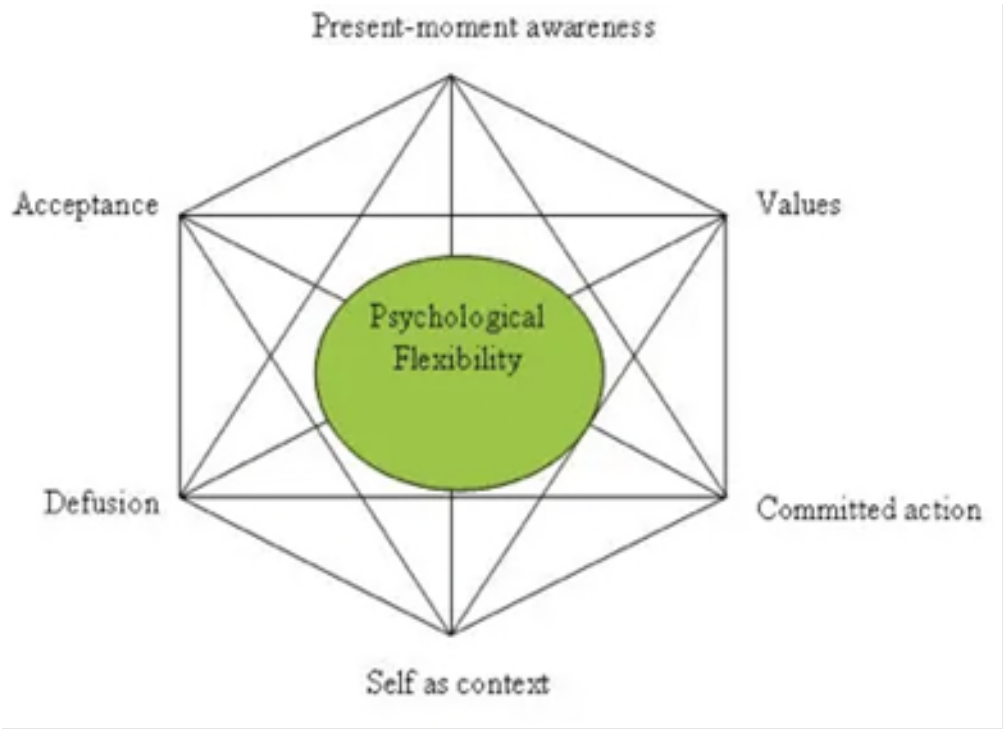

Figure 1: Acceptance and Commitment Therapy (ACT).

Systematic review evidence and meta-analyses suggests that ACT is efficacious in treating depression, anxiety and improving wellbeing in a broad range of settings.[7, 10, 11, 12] However, although ACT is commonly used in palliative care settings,[13] research evidence on ACT for bereavement is sparse. [14, 15] Recent literature reviews have identified only three peer-reviewed research studies and two doctoral theses[16] on ACT and bereavement. Of these, only one was an intervention study examining the feasibility of a self-help ACT intervention for grief and distress in bereaved carers of people with a terminal illness. The results indicated that an ACT based skilled development booklet and telephone support was generally feasible, though as this was a feasibility study, with a small sample size, evidence on effectiveness could not be ascertained.

Despite the lack of direct evidence to date, we believe that ACT has strong potential to improve outcomes for people who have been bereaved. ACT is a good fit with the Dual Process Model of coping with bereavement. The Dual Process Model posits that bereaved people oscillate between

dealing with the loss of the deceased person (loss-orientated coping [LO] e.g. grief work) and negotiating the practical and psycho-social changes to their lives that occur as a result of the bereavement (restoration-orientated coping [RO] e.g. forming new roles and relationships).[17] ACT can support this process by providing empirically supported intervention techniques that help people to engage with painful loss related emotions (loss-oriented coping), to take perspective, recreate meaning and engagement in life after bereavement (restoration-oriented coping).

2 Study Aims

The overall aim of our study is to develop an online Acceptance and Commitment Therapy (ACT) intervention to improve coping, quality of life and wellbeing for people seeking bereavement support. The intervention will be primarily oriented to the needs of people with low and moderate level of bereavement support needs, as described by the NICE bereavement support needs components (Table 1).

Table1. NICE three-tiered model of bereavement support components.

Level of Public Health Interventions	NICE Components	Type of Support	Support provided by	Target Population and Level of Support Needed	Proportions Bereaved (Sobell House Hospice in UK, 1989-2002)
Universal	1	Information about bereavement and relevant supports	Family and friends (information supplied by health and social care professionals)	All bereaved (normal grief) Low level of need	54%
Selective or Targeted	2	Non-specialist support	Trained volunteers, mutual-help groups, community supports	Those at-risk of developing complex needs Medium level of need	33%
Indicated	3	Professional specialist interventions	Mental health services, bereavement services, or psychotherapy	Those with complex needs High level of need	9%

Source: From Aoun et al. 2012, p.15.[17] (totals to 96% due to missing data)

In-person interventions, delivered by bereavement and psychological support specialists are costly, resource intensive and difficult to offer to large numbers of people. Such support needs to be available for those with complex bereavement support needs (NICE Component 3). Alternative cost effective, accessible models are required for people with low and moderate level needs. Online interventions can increase bereavement service accessibility and availability, and there is systematic review evidence for their effectiveness.[18] We will develop an online self-directed ACT intervention to improve coping and wellbeing for people with low and moderate level bereavement support needs.

2.1 Objectives and research questions

1. To develop a programme theory to illustrate how an online ACT based bereavement support intervention could lead to improved coping, quality of life and wellbeing following bereavement. (Phase 1).

    a. What works in bereavement support and what are the theorised causal pathways between ACT and improved coping, quality of life and wellbeing for people who have been bereaved?
    b. What components of ACT are useful in supporting wellbeing of people with bereavement support needs?
    c. What format and mode of delivery should an online ACT intervention for people bereavement support needs take?

2. To design, test and refine an online ACT-based psychological intervention to improve ability to cope and quality of life after bereavement (Phase 2)
    a. What is the acceptability and user experience of an online ACT intervention for people with low and moderate level bereavement support needs, and are there any differences in acceptability depending on level of need?
    b. What are the views of bereavement support volunteers regarding ACT-based bereavement support training?
    c. What types of health care and non-health care related resource use, costs and benefits are associated with the delivery of an online ACT intervention, from the perspective of the bereaved person, the service provider, and the wider health and social care system?
    d. What outcome measures are indicated for use in future feasibility and evaluation studies of an online ACT intervention to improve coping, quality of life and wellbeing for people with bereavement support needs?

3 Methods

3.1 Study design overview

This 24-month study will follow recent guidance on intervention development,[19] informed by the person-centred approach to intervention development, and set within the MRC framework.[20] Person centred approaches are particularly relevant to the development of online interventions as people typically use these independently, so the intervention needs to be designed in a format that maximises

engagement and accessibility. Central to the person-centred approach is the idea that behaviour change interventions should promote autonomy, competence, and a positive experience - these design objectives will guide our intervention development process.[21]

In Phase 1, we will develop a programme theory to illustrate how an online ACT based bereavement support intervention could lead to improved coping, quality of life and wellbeing following bereavement. This will be informed by : (i) relevant theory and evidence from existing literature reviews; (ii) a rapid review of the literature regarding the feasibility and effectiveness of online bereavement support (iii) views of therapists on how ACT is used for bereavement support; (and iv) feedback from stakeholders and people with lived experience of bereavement. We have recently completed Phase 1.

In Phase 2, we will design the intervention prototype. The intervention will be delivered in one of two ways: **(i) Self-directed:** Whereby people seeking bereavement support can access the materials free of charge in a flexible manner. Or **(ii) Volunteer facilitated:** Whereby people seeking bereavement support will access the online bereavement support materials and also have access to a bereavement support volunteer, who will provide ACT congruent bereavement support. We will train current bereavement support volunteers in ACT so they can provide ACT-congruent support. The intervention (both self-directed and facilitated) will then be delivered to bereaved participants and refined iteratively using rapid qualitative[22, 23] and mixed method designs.[24]

3.1.1 Patient and Public Involvement (PPI)

Guided by UK standards for public involvement in research, we have established **a bereaved persons PPI group** to guide this research.[25] This group consists of nine people with experiences of bereavement. These were identified through Marie Curie, Cruse Scotland and the Ubele Initiative. This group is advising the research team on intervention development and research design (e.g. participant information sheets, interview schedules and outcome measures being assessed). The PPI group is also providing feedback on the intervention development and content, including helping us to name the intervention. It will be called 'My Grief, My Way' (MGMW, in recognition of the flexibility that online self-directed work has and that fact that there are many ways through grieving. The group will meet together on approximately six occasions over the course of the project. Our team is also linking in with the Marie Curie Voices Group – a group of bereaved carers co-ordinated by Marie Curie, who offer advice and support to researchers conducting Marie Curie funded studies. PPI input will be

documented using the Public Involvement in Research impact Tool (PIRIT).[26] Members of our project specific bereaved persons group will be compensated for their time in line with NIHR PPI guidance. [27]

3.1.2 Literature reviews

Members of our team have recently published reviews on bereavement support interventions,[28] core outcomes for evaluating bereavement support,[29] digital interventions in palliative care[30] and ACT interventions for palliative care including bereavement.[14] We are currently completing a rapid review of the literature pertaining to identify any new evidence on online bereavement support interventions since the COVID pandemic (PROSPERO: crd.york.ac.uk/prospero/display_record.php?RecordID=397982). Evidence from these reviews has informed the development of the intervention programme theory.

3.1.3 Qualitative evidence on practitioner experiences of using ACT for bereavement support

We have undertaken a qualitative study exploring the experiences of practitioners (e.g., therapists and counsellors) regarding how they use ACT for bereavement support. This study, conducted by a group of University of Edinburgh postgraduate students, identified three themes in relation to how ACT is used for bereavement support: (i) creating psychological space around grief, (ii) using psychological space for value-directed action in the midst of grieving, and (iii) adapting ACT for bereavement support. The findings have been submitted for publication [31] and have been used to inform the programme theory. Ethical approval was provided by the University of Edinburgh Clinical Psychology Research Ethics Committee (9.04.22).

3.1.4 Stakeholder meetings and workshops

We have held regular meetings and four intervention development workshops with our research team, collaborators and stakeholder organisations, Marie Curie and Cruse Scotland. These meetings and workshops have allowed us to specify the proposed links between an online ACT-based bereavement support intervention, short and longer-term outcomes, modes of delivery, change mechanisms, and potential costs and benefits set within the wider health and social care context and the support currently available by key providers.

3.1.5 Programme theory articulation

We have drawn on each stage outlined briefly above to develop a draft programme theory (Appendix 1). This will inform decisions regarding the prototype, which we will design and test in Phase 2.

3.2 Phase 2 – My Grief, My Way Intervention prototype design, testing and refinement

3.2.1 Design

We will use rapid qualitative and mixed methods design to test and refine the prototype over a series of three rapid iterations. Each cycle will involve bereaved participants working through the intervention individually or with the support of a bereavement support volunteer, and providing feedback on content, format, and usefulness. We will also gather feedback from bereavement support volunteers involved in intervention delivery.

3.2.2 Participant recruitment

Bereavement support volunteers:

We aim to recruit approximately 20 bereavement support volunteers and professional staff currently providing bereavement support through our collaborator organisations, Marie Curie and Cruse Scotland. A target sample size of approximately 20 was chosen based primarily on pragmatic considerations in consultation with our key stakeholder organisations. We will train two groups of volunteers. In our experience, group sizes of about ten participants tend to work well in allowing opportunities for participants to get to know each other and contribute to the discussion.

Bereavement support service managers at Marie Curie and Cruse Scotland will share study information and the participant information sheet (bereavement support volunteer version) (Appendix 2) with their current bereavement support volunteers via team meetings, regular bulletins disseminated via email and their usual organisation communication platform(s). Volunteers will be eligible to participate if they meet the following criteria: (i) have completed Marie Curie or Cruse Scotland bereavement support training; (ii) have been actively supporting bereaved clients at Cruse or Marie Curie for at least one year; and (iii) speak English fluently. We will exclude student volunteers who are on placement with key stakeholder organisations for continuity purposes. If a volunteer is interested in taking part, they can either contact the research team directly for further information, or they can give their manager permission to send their contact details to the research team. A member of the research team will then contact them via email, Microsoft Teams or telephone if they prefer, to answer any questions they may have. If they want to sign up, a member of the research team will email the volunteer a link to the online consent form. Having completed the online consent from, (Appendix 3) the participant will then be directed to complete a short background questionnaire

(e.g., gender; age range; years' experience as a volunteer; ethnicity) so the sample can be described. (Appendix 4).

Once consented, bereavement support volunteers (our participants) will be scheduled to take part in four half-day training sessions in the principles of ACT over a period of a month (see section on ACT training below). On completion of this training, they will inform the research team and their line manager (at Cruse or Marie Curie) whether they wish to provide ACT based support to research participants as part of this intervention development study. If they do, they will form part of a group of volunteers who will be available to provide ACT-congruent bereavement support to participants recruited.

Bereaved participants:

We will recruit 30-45 bereaved participants in total (N=10-15 participants per cycle). Participants will be recruited from Marie Curie bereavement support services, and Cruse Scotland. Eligible participants will include: (i) bereaved adults who have contacted Marie Curie or Cruse Scotland for bereavement support; (ii) age 18 or over; (iii) English speakers. We will exclude: (i) individuals who are judged to have complex bereavement support needs (Nice Level 3), and who are currently or may require specialist mental health input.

The approach to recruitment will differ slightly given that the bereavement support provided by both stakeholder organisations differs slightly:

- **Cruse Scotland** will offer the opportunity to access the My Grief My Way resource (**self-directed**) to anyone who does not meet the current Cruse criteria for individual help. After triage, if Cruse are not intending to offer a one-to-one appointment, the client will be informed about the study and given a participant information sheet by Cruse. (Appendix 5). If they are interested in hearing more, their details will be passed to the study team, who will contact them and go through the participant information sheet, consent (Appendix 6) and baseline assessments. Once they consent and provide background and baseline information, they will be given a link to the MGMW materials, and will be contacted for follow-up data collection (questionnaires and focus group or interview) after approximately eight weeks.

- Where **Cruse Scotland** decides that a client would benefit from one-to-one bereavement support (in line with their usual assessment in-house protocols), the assessing practitioner will inform the client of the My Grief My Way study (**facilitated option**) and give the participant

information sheet. (Appendix 5) This process will be coordinated by Nicola Reed, Director of Client Services at Cruse Scotland. Interested participants will be directed to the research team to find out more and consent to take part should they wish (or with their permission, their name and contact details will be passed to the research team). If they do not wish to find out about the study, they will be allocated a to a Cruse bereavement support volunteer as normal. If they do decide to take part in the study, they will complete an online consent form and baseline assessments. (Appendix 6 and Appendices 7-13 respectively) The research team will then inform Cruse that the client has been recruited. Cruse will allocate an ACT-trained volunteer to the research participant, who will contact them and arrange weekly or fortnightly meetings by telephone or other preferred means for up to six sessions (in line with usual practice).

- **Marie Curie** will identify potential participants from two communication sources. (i) Via the Marie Curie support Helpline, (open for calls from people anywhere in the UK who have a terminal illness or have experienced bereavement). (ii) And through their Bereavement Support Service, (a free telephone bereavement support line) for people seeking ongoing support from the same bereavement support volunteer over the phone for up to six sessions. Potential participants will be informed of the research when they call either service. Those who call the Marie Curie Support Helpline will be informed of the research, and invited to contact the research team for further information. Or, the call handler will offer to send their name and contact details (email or telephone number) to the research team, for the team to contact them directly. Participants recruited via the general Marie Curie Support Helpline will be allocated to using the online My Grief My Way resource without bereavement support volunteer input. In contrast, people that specifically call the Bereavement Support service will be informed about the volunteer facilitated version of the intervention. If they are potentially interested, their details will be passed to the research team via email who will contact them to discuss the research process. If they agree to participate, they will complete the online consent form, background information questionnaire, and baseline measurements (Appendices 6, 14 and 7-13 respectively). The research team then will inform Kelly Maton (Marie Curie Bereavement Support Coordinator) via email who will then allocate the participant to a bereavement support volunteer. Once allocated to an ACT trained Marie Curie bereavement support volunteer, the participant will receive up to six ACT congruent bereavement support sessions. The research team will contact the participant after

approximately eight weeks to collect follow up data (via questionnaire and interview or focus group).

- For both volunteer supported participants and for participants who engage with MGMW in a self-directed way (without volunteer support) the follow up evaluation will be in the form of a second online questionnaire, and an invite to take part in a focus group or interview about their experience of using the MGMW resource.

3.2.3 ACT training for bereavement support volunteers

As the intervention can be self-directed or volunteer-facilitated, we will train support volunteers in the principles of ACT and how to deliver ACT-congruent bereavement support. Training will also be offered to staff involved in co-ordinating volunteers and allocating volunteers to clients seeking bereavement support from our stakeholder organisations. During the training, the bereavement support volunteers will learn the basic of the ACT model, typical implementation strategies and specific tools for using ACT with people who are grieving.

Training will consist of four half-day sessions delivered over a period of approximately 4 weeks. Sessions will be delivered by one of the project leads (DG) who has extensive training and experience in Acceptance and Commitment Therapy. DG is also a Peer Reviewed Acceptance and Commitment Therapy Trainer and Fellow of the Association for Contextual Behavioural Science (a mark of quality and fidelity of Acceptance and Commitment Therapy knowledge and skill). These sessions will also be facilitated by AF.

The training will broadly consist of experiential exercises and practices as well as discussion of volunteer experiences and skills that will explore the following material:

- Session 1: What is ACT and why ACT for grief?
    - The six processes of the ACT model, the three broad skill sets, how do problems in these skills lead people to be stuck.
    - Common sticking points in responding to loss – seeing problems with grief through an ACT lens. Seeing grief as natural healing, examples of ways that ACT techniques can unblock the natural grieving process.
- Session 2: Developing Awareness and Openness Skills

- Language around acceptance, tracking patterns, what is influencing you? Where will that lead? Learning to let go and allow the grieving, how to develop self-compassion and patience, learning to trust the process.
- When your own mind is not your friend, how to change your relationship with your own thinking, catching the old story and beginning to write a new chapter.

- Session 3: Developing Engaged Skills and Reconnecting with
  - Continuing bonds with the deceased and bring them with you into a new chapter, courage to try new things, willingness to try and fail, being open to the new and unfamiliar.
- Session 4: Supporting people with My Grief My Way
  - Starting from where you are at – ensuring a good fit between ACT and existing skills and frameworks.
  - Supporting choices, trusting process, troubleshooting frequent problems

- Supervision during intervention delivery: Bereavement support volunteers will be invited to group supervision meetings, led by DG, once they have started providing ACT-based bereavement support. We will aim to hold two such meeting per cycle (see below).

3.2.4 Intervention content and delivery

We have chosen to name our intervention My Grief My Way following consultation with collaborators, stakeholders, our bereaved persons and Marie Curie Voices PPI groups. Based on the programme theory logic model and data gathered in Phase 1, the research team will determine specific techniques and materials to use in the intervention, and the format this will take (e.g. style, format, timing, order, emphasis, exercises used, type of materials, accessibility, opportunities for user discussion etc.). Materials will include videos, interviews with people about their experience of grieving, readings, poetry, artwork, animation, and audio exercises created and curated for the project such as:

- Stories relating to grief experiences that illustrate common sticking points in grieving.
- Stories that illustrate how the ACT skills of 'be present', 'open up' and 'do what matters', can support grieving, shared via video, audio files and images.
- Metaphors relating to the experience of grief presented via audio and video files
- Exercises which can be completed online or downloaded by the bereaved person
- Mindfulness and similar exercises, delivered via audio files
- Links to psychoeducational resources linked with coping with grief, and other therapeutic approaches including compassion focused therapy and trauma therapy.

- Signposting for bereaved people who feel they need additional support to that offered via the online resources.

We are working with Morrow Communications, a media production company, to develop these resources and make them available online. Our prototype will be user tested by members of our key stakeholder organisations and bereaved persons PPI group. Usability will be assessed by a heuristic evaluation guided by Nielsen's 10 general principles for user interface design (Appendix 15). Bereaved participants will be able to access the resource in a self-directed manner, or with the support of a bereavement support volunteer who has been trained in ACT.

3.2.5 Online access to the intervention materials

Our ACT based bereavement support resource will be hosted on the My Grief My Way website (not yet live). Study participants will be provided with the website link. The site will be live so that site usage data can be collected using Google Analytics and will inform intervention development. The landing page will include a disclaimer so in the unlikely event that the site is found by a member of the public, it will be clear to them that it is part of a research study, and who to contact for further information. The disclaimer will describe the nature of the site, will advise people that the tools and techniques are based on evidence based psychological therapy principles, but that use of a self-help website is not a substitute for professional mental health care. The page will signpost people to their primary care physician for further information and support.

3.2.6 Working through the intervention

Self-directed: Participants who are allocated to work through the intervention themselves will be given a link to the My Grief, My Way website and invited to work through the materials at their own pace for a maximum period of eight weeks.

Bereavement support volunteer facilitated: Participants who are allocated to work through the intervention with additional support from a bereavement support volunteer will be given a link to the My Grief My Way website and invited to work through the materials at their own pace for a maximum period of eight weeks. They will also have access to an ACT-trained bereavement support volunteer, who will provide them with regular ACT-congruent bereavement support for a period of up to six sessions. Six sessions is aligned with the current telephone-based bereavement support offered by our key stakeholder organisations. There is no obligation for the participant to complete all sessions, but they will have this option. The sessions will be provided by bereavement support volunteers within each key stakeholder organisation and will be delivered via the usual platforms used by the key stakeholder organisations.

3.2.7 Option to move from self-directed to volunteer facilitated option

If a participant accessing the MGMW resources in a self-directed manner feels the need for 1:1 support as they work through the intervention, they can inform the research team who will in turn inform the relevant stakeholder organisation that identified them originally. The stakeholder organisation will then allocate the person a bereavement support volunteer who will arrange up to six ACT congruent support sessions with them and the research will continue as planned.

3.2.8 Data collection and analysis

Participant background data: We will collect background information on both groups of participants (i.e., bereavement support volunteers and bereaved participants) so we can describe the sample. For bereavement support volunteers this will include: the organisation for which they volunteer, age, gender, ethnicity, length of time as a bereavement support volunteer in their current organisation, length of time providing bereavement support in their current role and any previous role, whether they have any formal qualifications relevant to their current volunteer role (Appendix 4). For bereaved individuals this will include: the organisation they were referred from; age, gender, ethnicity, relationship to the deceased person, time since most recent bereavement, other types of bereavement support previously or currently accessed (if any). These data will be collected online after they complete the consent form. (Appendix 14). Participants will be given a unique identifier by the research team so that the research team can link their pre and post data (see section 4.1 below).

Qualitative research with bereavement support volunteers: We will run approximately six online focus groups (or semi-structured interviews where focus groups are infeasible) with bereavement support volunteers. We will hold two focus groups after each research cycle. The aim will be to explore volunteer perspectives on the training provided, their experience of delivering ACT-congruent bereavement support, suggestions for resource refinement, and how a facilitated version of the intervention can be delivered in practice. We will also explore their perspectives on training for new facilitators and views on sustaining the intervention in the long term. Participants can only take part in one focus group per cycle, but may take part in more than one focus group across cycles (i.e., up to three in total). See topic Guide in Appendix 16. Focus groups/interviews will be conducted at a mutually agreed time via Microsoft Teams (or by telephone if preferred). These will be audio recorded, transcribed, and anonymised by a member of the research team. Data will be analysed using rapid qualitative analysis techniques[28] informed by a framework approach and results following each cycle will feed into intervention delivery and content creation for the subsequent cycle.

Qualitative research with bereaved participants: Participants will be invited to take part in focus groups or individual semi-structured interviews if preferred. The aim of the focus groups will be to explore their experience of accessing the My Grief My Way resource, and any impacts it might have had on them, as well as giving us feedback about the materials. We will hold 2 to 3 focus groups after each cycle, depending on participant availability. Semi-structured interviews will be conducted where a participant cannot or prefers not to take part in a focus group. See topic Guide in Appendix 17. Focus groups/interviews will be conducted at a mutually agreed time via Microsoft Teams (or by telephone if preferred). These will be audio recorded, transcribed, and anonymised by a member of the research team. Data will be analysed using rapid qualitative analysis techniques[28] informed by a framework approach and results following each cycle will feed into intervention delivery for the subsequent cycle.

Intervention module usefulness: Bereaved participants' perspectives on intervention module usefulness (n = 30-45): This will be accessed by participants via a feedback icon on each module webpage. By clicking on the icon, participants will be asked an open question on the usefulness of the module they have completed. Data will be imported into NVivo and analysed thematically following each cycle, and the findings will be used to refine the intervention prior to subsequent iterations.

Intervention engagement will be assessed via routine website activity collected via Google Analytics. This will include the times each webpage was accessed, amount of time on each webpage, downloads of materials from the website etc. We will analyse this data after each research cycle to assess the relative usage of different intervention components, and estimate levels of engagement.

Intervention feasibility and effect size estimates: Data to inform future feasibility and effectiveness studies will include bereaved participant and volunteer **recruitment** and **retention rates** throughout the intervention. We will also collect data using validated measures of coping with grief, well-being and quality of life in order to determine the feasibility of data collection for future studies, and to explore effect size estimates for use in the design of future evaluations studies. (Appendices 7-13) These measures will be administered by online questionnaires, and completion can be supported by the research team via telephone or Microsoft Teams depending on participant preference. Outcome data will be collected at baseline (i.e., following consent, but prior to accessing the intervention) and at the end of the intervention (i.e., approximately eight weeks post commencement of the intervention).

Measures

Ato Grief scale (AAG).[8] This scale provides a profile of how people are responding to their grief along three dimensions: overwhelmed, overly controlled or resilient. Together these processes are thought to reflect a person's vulnerability to complicated grief and/or prolonged grief reactions.[9] The AAG is a 9-item Likert scale inviting responses from strongly agree to strongly disagree. Maximum score =36 where vulnerability is assessed as follows: Severe vulnerability >24, High vulnerability >21-23, Low vulnerability < 20. (Appendix 7)

ICECAP-A (Health Economics).[32] ICEpop CAPability measure for Adults is a measure of capability for the general adult (18+) for use in economic evaluation. ICECAP-A focuses on wellbeing defined in a broader sense, rather than just health. The measure covers attributes of wellbeing that were found to be important to adults in the UK: 1. Feeling settled and secure. 2. Love, friendship and support. 3. Being independent. 4. Achievement and progress. 5. Enjoyment and pleasure. Responses range from one to four on a Likert scale. A score of one represents poor quality of life, with four indicating good quality. (Appendix 8)

EQ-5D-5L [33] consists of 2 pages: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. (Appendix 9)

Inventory of Daily Widowed Life - Modified (IDWL-M).[10] IDWL is a 22-item questionnaire that measures oscillation between two coping processes from the Dual Process Model of Coping with Bereavement Loss-orientation (LO) and restoration-orientation (RO).[11] Questions are evenly divided between the two categories. LO and RO scores range from 11 (low) to 44 (high). Oscillation Balance = RO score minus LO score (possible range =-33 (exclusively loss-oriented) to +33 (exclusively restoration-oriented). A score equal to zero (0) indicates perfect oscillation balance. Oscillation between RO and LO activities are considered to be an indicator of healthy, effective grieving, whilst remaining predominantly in one or other orientation is considered to be potentially problematic.

Originally worded to reflect spousal loss, the modified version has had minor rewording to reflect the loss of any loved one and has ben psychometrically validated. (Appendix 10) [34]

Inventory of Social Support (ISS).[19] The 5-item instrument was developed from qualitative data obtained from bereaved adolescents who provided written responses to the questions "What helped you cope with your grief?" and "What made it harder for you to cope with your grief?" Items are scored using a 5-point Likert scale, where respondents are asked to use the prior two weeks as a time scale when rating each item. Response values are added then divided by the number of items. Response values represent the degree to which a bereaved person feels supported in the context of their world. (Appendix 11)

Psychological-Flexibility.[35] This 6-item questionnaire is a short self-report measure that covers all facets of psychological flexibility construct: The ability to be aware of and open to internal and external stimuli as they occur while choosing to act in ways that are consistent with what a person deeply cares about. Each item is scored from 1-5, one indicating low flexibility and five representing high flexibility.[18] (Appendix 12)

Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS).[12] Developed to monitor mental wellbeing in the general population; this 14-statement questionnaire has five response categories from 'none of the time' to 'all of the time'. Scores range from 14-70. Higher scores indicate good mental wellbeing. The WEMWBS responsiveness to change has been evaluated at both population and individual level, which shows that a change of three or more points can be considered significant.[13] (Appendix 13)

3.2.9 Final stakeholder workshop

We will run a final workshop involving collaborators, stakeholders, our PPI group and the research team to finalise the intervention, explore perspectives on factors that influence scalability and sustainability of the intervention, including all potential costs from multiple perspectives, and prioritise outcomes for future feasibility and evaluation research. With permission from workshop participants, the workshop will be recorded. Afterwards we will take notes on any recommendations to inform future intervention development and evaluation.

4 Data Management

4.1 Personal Data and Data Collection

Personal characteristics data will be used only to describe the population sample and will not be linked to focus group/interview data. Data will be reported at a group rather than individual level (e.g., mean age, frequency of gender, relationship to deceased, etc). To link data from pre intervention to post intervention, each participant will be given a unique study ID code. Because follow up data will be gathered with the support of the research team, participants can be prompted if they do not recall their unique study ID code.

Quantitative study data will be gathered via JISC surveys, a University of Edinburgh supported survey platform that uses secure encryption and storage of data. Survey data will be downloaded directly to University of Edinburgh managed Microsoft Office 365 Teams space (see 4.2 below). Qualitative data in the form of interview and focus group notes and auto transcripts will be generated by Microsoft Teams and downloaded to the secure Microsoft Teams space, where they will be de-identified before any further processing. There will be minimal need for transport or transfer of field notes, as all data capture will occur within Microsoft Teams. The exception is if a participant requests a telephone interview. In these circumstances, the researcher conducting the interview will take notes and then transfer these to an electronic file, for processing and storage within the secure Microsoft Teams space. Once notes are digitised in this way, any original hand written notes will be securely shredded.

4.2 Storage of Data

The research team use a secure and encrypted University of Edinburgh managed Office 365 (Microsoft Teams, SharePoint and OneDrive) space for everyday storage and processing of study materials. This has controlled access. Data will be kept within private channels within that team, and access to specific folders will be managed according to need. Personal data, used for study administration such as contacting participants for post intervention data, will be kept securely within these restricted channels and will be securely deleted at the end of the study (January 2025).

Once the study is complete, longer-term archiving of the anonymised research data will use the Edinburgh Data store, which is also password protected and encrypted. We do not plan to share data through public repositories such as Edinburgh Data Vault or any other similar data-sharing repository. The anonymised data will be retained for ten years, after which time it will be reviewed as to whether retention or secure deletion is in the public interest.

4.3 Processing of Data

Data will be processed for the purposes of study administration, and for the purposes of answering research questions. Where practical such processing will make use of Office 365 cloud-based storage and not save local copies of files. Temporary copies may be made for specific circumstances such as accessibility of reliable internet, but the files will be securely uploaded to the Microsoft Teams space as soon as practical and local copies secure deleted. All devices being used to access data are password protected.

4.4 External Transfer of Data and Data Controller

The University of Edinburgh remains the data controller, with specific responsibility for this being held by the project joint principle investigators (Anne Finucane and David Gillanders) and delegated to project Research Associate (Anne Canny). These core members of the research team have all undertaken Good Clinical Practice in Research, and University of Edinburgh Data Management training. Data will not be transferred to, shared with, supported by or otherwise available to third parties outside the research team. The UoE procedures and data capture are separate from those used by Marie Curie and Cruse Scotland. We have good relationships with our partners; they are clear about who owns the project data (University of Edinburgh) and the uses the data will be put to. We have been clear with collaborators about expectations around ownership, contribution, authorship credit and final use and ownership of the MY Grief, My Way resource and all aspects of that have been discussed and agreed.

The partner organisations (Marie Curie Bereavement Support and Cruse Scotland will pass personal data to the University of Edinburgh with the permission of the potential research participants, in the form of a name and contact details, so that they can be recruited to the study. The University of Edinburgh will inform the partner organisations if a participant consents to undertake the study, for the purpose of triage and intervention by the partner organisation.

Some of our wider project team are employed by different institutions. They may facilitate aspects of analysis of qualitative data transcripts. These will be de-identified before analysis. The project partners all have access to our secure Office 365 space and therefore they will be able to undertake their data analytic tasks within that space, except as described under section 4.3 above. These aspects of data sharing will be explicitly consented by the participant.

Anonymous usage and website feedback data will be gathered by the website itself. The web developer and production company Morrow Communications Ltd will download that data and share with the research team at the University of Edinburgh.

4.5 Data Breaches

If a potential breach is identified by the research team, the sponsor will be notified within 24 hours. The sponsor will assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

5 Risks

It is possible that some participants may be upset by thinking and talking about their grief and the impact this has on their wellbeing. However, they will have standard care support from Marie Curie and Cruse Scotland support services to address any concerns they may have during the study. Participants will be monitored carefully so that any change in their condition including deteriorating wellbeing is identified and addressed. This will include proactive checks made by Marie Curie and Cruse staff as part of routine monitoring and care.

The My Grief My Way website will also have clear contact details so that if any participant feels that the material has had a detrimental effect on them, they can contact us. If that occurs, the participant's concerns will be investigated through a phone call with Joint PI David Gillanders, who is a Chartered Clinical Psychologist, with experience of supporting people in distress. During that telephone conversation the issue will be identified, the participant offered choices to remain in the study or to exit, and help will be given to find alternative sources of support, such as a higher level of support from our partner organisations, or through NHS services such as general practitioner. Given that MGMW is aimed at people with moderate bereavement needs, it is unlikely that any such adverse events would necessitate an emergency response, but the website itself will contain clear links to UK based emergency supports, such as NHS24 and The Samaritans.

6 Oversight Arrangements

6.1 Inspection of records

Investigators and institutions involved in the study will permit study related monitoring and audits on behalf of the sponsor. In the event of audit or monitoring, the co-PIs agree to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory

inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

6.2 Study monitoring and audit

The Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

7.3 Study oversight

The study has a wider stakeholder group comprised of the research team, plus representatives of the partner organisations and PPI representatives. These are listed on Page 1 of this protocol. The stakeholder group meets on a monthly basis and the PI's report on progress and plans. Minutes are kept of these meetings and circulated. This formal meeting provides transparent oversight of study management.

7 Good Clinical Practice

7.1 Ethical conduct

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).[36] Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

8 Investigator Responsibilities

The co-PIs (AF/DG) are responsible for the overall conduct of the study and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the co-PIs. Responsibilities may be delegated to an appropriately qualified member of study staff.

8.1 Informed consent

The co-PIs (AF/DG) are responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision for a participant to participate in the research is voluntary and will be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information. Participant information sheets and informed consent forms are included in Appendices 2, 3, 5 and 6. The oral explanation to the

participant will be performed by the co-PIs or the study research associate (Anne Canny), and must cover all the elements specified in the participant information sheet and consent form.

The participant will have the opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant will be given as long as they need to consider the information provided. The participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

8.2 Study Staff

Investigators must be familiar with the protocol and study requirements. It is the responsibility of co-investigators (AF/DG) to ensure that all staff assisting with the study are adequately informed about the protocol and their study-related duties.

8.3 Good Clinical Practice (GCP) Training

Drs Anne Finucane, David Gillanders and Anne Canny (Co-PIs and a post-doctoral researcher, respectively) have completed University of Edinburgh Good Clinical Practice training in Research.

8.4 Confidentiality

All investigators and study staff must comply with the requirements of the General Data Protection Regulation (2018) with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.[37] Access to collated participant data will be restricted to individuals from the research team, representatives of the sponsor and representatives of regulatory authorities. Computers used to collate and store data will have limited access measures via user names and passwords. Published results will not contain any personal data that could allow identification of individual participants.

8.5 Data protection

Drs Anne Finucane, David Gillanders and Anne Canny (Co-PIs and a post-doctoral researcher, respectively) have completed the University of Edinburgh Data Protection training.

9 Study Conduct Responsibilities

9.1 Protocol Amendments

Any changes in research activity will be reviewed and approved by the co-PIs (AF/DG). Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in

writing to the Clinical Psychology Research Ethics Committee for approval prior to participants being enrolled into an amended protocol.

9.2 Management of Protocol Non Compliance

Joint PIs will ensure study protocol compliance as part of their responsibilities, through weekly meetings of the research team and monthly meetings of the stakeholder group. If they learn of protocol non-compliance, it will be investigated by one of the joint PI's and reported to the sponsor, who will help the PI's to determine if the non-compliance represents a serious threat to the scientific integrity of the study.

If such investigation reveals a suspected or potential issue of capability or conduct within the research team, this will be pursued using standard University of Edinburgh policies such as the Capability Policy and Disciplinary Policy.

If such investigation reveals a suspected or potential issue within one of our partner organisations, this will be reported in writing to that organisation's representative on our stakeholder group (Fiona Arnott-Barron for Cruse Scotland and Angharad Burden for Marie Curie Bereavement Services).

9.3 Serious Breach Requirements

As described above in section 4.5, section 6 and section 10.2, the study will be monitored daily by the research associate and via weekly meetings of the joint PI's and research associate and any serious breaches will be investigated as soon as they are discovered. Safety and wellbeing of participants will be the most important consideration. Any breaches will be reported to the sponsor who will help the study team to determine if the breach represents a threat to the scientific integrity of the study. Implications of any serious breach will be investigated as described in section 10.2

9.4 Study Record Retention

All study documentation such as approvals, proof of sponsorship etc. will be kept for a minimum of 3 years from the protocol-defined end of study point. Storage, retention and deletion of study data is specifically described in section four.

10 End of Study

The study will finish in January 2025. At that point, the sponsor will be informed of the study completion and a report will be prepared for the funder (Marie Curie), and stakeholder organisations.

11 Insurance and Indemnity

The study sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the co-PIs and study staff.

12 Reporting, Publications and Notification of Results

Study findings will be disseminated as follows:

- Presented to Marie Curie and Cruse Scotland bereavement support services.
- Presented at national and international conferences (e.g. Marie Curie Annual Research conference, The Palliative Care Congress, The European Association of Palliative Care conference, The International Psycho-Oncology Society World Congress, The Association for Contextual Behavioural Science World Conference)
- Published in peer reviewed, open access journals (e.g. Palliative Medicine, Bereavement, Journal of Contextual Behavioural Science)
- Once peer reviewed publications are accepted, wider dissemination via social media will be undertaken.

Participants may request a copy of study findings and this is made clear in participant information sheets.

13 References

1. Aoun SM, Breen LJ, Howting DA, Rumbold B, McNamara B, Hegney D. Who needs bereavement support? A population based survey of bereavement risk and support need. PLoS One. 2015;10(3):e0121101.
2. National Institute for Clinical Excellence (NICE). Guidance on cancer services: improving supportive and palliative care for adults with cancer. The manual. London; 2004.
3. Wakefield D, Fleming E, Howorth K, Waterfield K, Kavanagh E, Billett HC, et al. Inequalities in awareness and availability of bereavement services in North-East England. BMJ Supportive & Palliative Care. 2020:bmjspcare-2020-002422.
4. O'Donnell SB, Bone AE, Finucane AM, McAleese J, Higginson IJ, Barclay S, et al. Changes in mortality patterns and place of death during the COVID-19 pandemic: A descriptive analysis of mortality data across four nations. Palliative Medicine. 2021:02692163211040981.
5. Pearce C, Honey JR, Lovick R, Creamer NZ, Henry C, Langford A, et al. 'A silent epidemic of grief':A survey of bereavement care provision in the UK and Ireland during the COVID-19 pandemic. BJGP Open. 2021;11:e046872.
6. Harrop E, Goss S, Farnell D, Longo M, Byrne A, Barawi K, et al. Support needs and barriers to accessing support: Baseline results of a mixed-methods national survey of people bereaved during the COVID-19 pandemic. Palliative Medicine. 2021:02692163211043372.
7. Gloster AT, Walder N, Levin ME, Twohig MP, Karekla M. The empirical status of acceptance and commitment therapy: A review of meta-analyses. Journal of contextual behavioral science. 2020;18:181-92.
8. Hayes SC. Acceptance and Commitment Therapy, Relational Frame Theory, and the Third Wave of Behavioral and Cognitive Therapies – Republished Article. Behavior Therapy. 2016;47(6):869-85.
9. Hayes SC, Pistorello J, Levin ME. Acceptance and Commitment Therapy as a Unified Model of Behavior Change. The Counseling Psychologist. 2012;40(7):976-1002.
10. Öst L-G. The efficacy of Acceptance and Commitment Therapy: An updated systematic review and meta-analysis. Behaviour Research and Therapy. 2014;61:105-21.
11. Graham CD, Gouick J, Krahé C, Gillanders D. A systematic review of the use of Acceptance and Commitment Therapy (ACT) in chronic disease and long-term conditions. Clinical psychology review. 2016;46:46-58.
12. Han A, Yuen HK, Jenkins J. Acceptance and commitment therapy for family caregivers: A systematic review and meta-analysis. Journal of health psychology. 2021;26(1):82-102.
13. McInnerney D, Candy B, Stone P, Atkin N, Johnson J, Hiskey S, et al. Access to and adequacy of psychological services for adult patients in UK hospices: a national, cross-sectional survey. BMC Palliative Care. 2021;20(1):31.
14. Gibson Watt T, Gillanders D, Spiller JA, Finucane AM. Acceptance and Commitment Therapy (ACT) for people with advanced progressive illness, their caregivers and staff involved in their care: A scoping review. Palliative Medicine. 2023:02692163231183101.
15. Jones K, Methley A, Boyle G, Garcia R, Vseteckova J. A Systematic Review of the Effectiveness of Acceptance and Commitment Therapy for Managing Grief Experienced by Bereaved Spouses or Partners of Adults Who Had Received Palliative Care. Illness, Crisis & Loss. 2022;30(4):596-613.
16. Walker KA. The experiences of therapists and bereaved clients of using an acceptance and commitment therapy approach to grief. ProQuest Dissertations Publishing; 2013.
17. Stroebe H, Schut M. The Dual Process Model of coping with bereavement: rationale and description. Death Studies. 1999;23(3):197-224.
18. Wagner B, Rosenberg N, Hofmann L, Maass U. Web-Based Bereavement Care: A Systematic Review and Meta-Analysis. Frontiers in psychiatry. 2020;11:525-.
19. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open. 2019;9(8):e029954.

20. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021;374:n2061.
21. Yardley L, Morrison L, Bradbury K, Muller I. The Person-Based Approach to Intervention Development: Application to Digital Health-Related Behavior Change Interventions. J Med Internet Res. 2015;17(1):e30.
22. Vindrola-Padros C, Chisnall G, Cooper S, Dowrick A, Djellouli N, Symmons SM, et al. Carrying out rapid qualitative research during a pandemic: emerging lessons from COVID-19. Qualitative Health Research. 2020;30(14):2192-204.
23. Vindrola-Padros C, Brage E, Johnson GA. Rapid, responsive, and relevant?: a systematic review of rapid evaluations in health care. American Journal of Evaluation. 2021;42(1):13-27.
24. Creswell J. Research design: qualitative, quantitative, and mixed methods approaches Fifth Edition ed: SAGE Inc; 2017.
25. UK Public Involvement Standards Development Partnership. Better public involvement for better health and social care research. 2019.
26. Marie Curie Research Centre. Public Involvement in Research Impact Toolkit (PIRIT) 2023 [3rd July 2023]. Available from: https://www.cardiff.ac.uk/marie-curie-research-centre/patient-and-public-involvement/public-involvement-in-research-impact-toolkit-pirit.
27. (NIHR) NIfHaCR. Payment guidance for researchers and professionals 2023 [Available from: https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392.
28. Harrop E, Morgan F, Longo M, Semedo L, Fitzgibbon J, Pickett S, et al. The impacts and effectiveness of support for people bereaved through advanced illness: A systematic review and thematic synthesis. Palliative Medicine. 2020;34(7):871-88.
29. Harrop E, Scott H, Sivell S, Seddon K, Fitzgibbon J, Morgan F, et al. Coping and wellbeing in bereavement: two core outcomes for evaluating bereavement support in palliative care. BMC palliative care. 2020;19(1):29-.
30. Finucane AM, O'Donnell H, Lugton J, Gibson-Watt T, Swenson C, Pagliari C. Digital health interventions in palliative care: a systematic meta-review. npj Digital Medicine. 2021;4(1):64.
31. Willi N, Pancoast A, Drikaki I, Gu X, Gillnaders D, Finucane AM. Practitioner perspectives on the use of acceptance and commitment therapy for bereavement support: a qualitative study Under review.
32. Al-Janabi H, N Flynn T, Coast J. Development of a self-report measure of capability wellbeing for adults: the ICECAP-A. Quality of Life Research. 2012;21(1):167-76.
33. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727-36.
34. Hefren J. An examination of the significance parents place on belongings as a predictor of complicated grief following the death of a child. (Order No: 3625868) 2014 [17 August 2023]. Available from: https://www.proquest.com/dissertations-theses/examination-significance-parents-place-on/docview/1556561329/se-2.
35. Gloster AT, Block VJ, Klotsche J, Villanueva J, Rinner MTB, Benoy C, et al. Psy-Flex: A contextually sensitive measure of psychological flexibility. Journal of contextual behavioral science. 2021;22:13-23.
36. International council for harmonisation of technical requirements for pharmaceutical for human use (ICH). ICH harmonised guideline 2016 [26 July 2023]. Available from: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf.
37. GOV.UK. Data protection act (GDPR) 2018 [26 July 2023]. Available from: https://www.gov.uk/data-protection#:~:text=The%20Data%20Protection%20Act%202018%20is%20the%20UK's%20implementation%20of,used%20fairly%2C%20lawfully%20and%20transparently.