Evaluation of Managing Cancer and Living Meaningfully (CALM) in people with advanced non-small cell lung cancer treated with immunotherapies or targeted therapies: protocol for a single-arm, mixed-methods pilot study

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ABSTRACT

Introduction People with advanced non-small cell lung cancer (NSCLC) treated with immunotherapies (IT) or targeted therapies (TT) may have improved outcomes in a subset of people who respond, raising unique psychological concerns requiring specific attention. These include the need for people with prolonged survival to reframe their life plans and tolerate uncertainty related to treatment duration and prognosis. A brief intervention for people with advanced cancer, Managing Cancer and Living Meaningfully (CALM), could help people treated with IT or TT address these concerns. However, CALM has not been specifically evaluated in this population. This study aims to evaluate the acceptability and feasibility of CALM in people with advanced NSCLC treated with IT or TT and obtain preliminary evidence regarding its effectiveness in this population.

Methods and analysis Twenty people with advanced NSCLC treated with IT or TT will be recruited from Peter MacCallum Cancer Centre, Melbourne, Australia. Participants will complete three to six sessions of CALM delivered over 3–6 months. A prospective, single-arm, mixed-methods pilot study will be conducted. Participants will complete outcome measures at baseline, post-intervention, 3 months and 6 months, including Patient Health Questionnaire, Death and Dying Distress Scale, Functional Assessment of Cancer Therapy General and Clinician Evaluation Questionnaire. The acceptability of CALM will be assessed using patient experiences surveys and qualitative interviews. Feasibility will be assessed by analysis of recruitment rates, treatment adherence and intervention delivery time.

Ethics and dissemination Ethics approval has been granted by the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC/182047/PMCC). Participants with cancer will complete a signed consent form prior to participation, and carers and therapists will complete verbal consent. Results will be made available to funders, broader clinicians and researchers through conference presentations and publications. If CALM is found to be acceptable in this cohort, this will inform a potential phase 3 trial.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The use of mixed methods will capture detailed qualitative and quantitative information on the acceptability of Managing Cancer and Living Meaningfully in this cohort.
⇒ The inclusion of outcome measures at multiple time points allows for full evaluation of the feasibility of this study design to inform a larger trial.
⇒ The primary limitation of this study is the small sample size limiting interpretations on efficacy.
⇒ A second limitation is that people who did not speak, read or write fluently in English were excluded.

INTRODUCTION

Advanced non-small cell lung cancer (NSCLC) has historically had a poor prognosis, with 5-year overall survival approximately 6%.1 In recent years, however, improved understanding of molecular subtypes of metastatic NSCLC and the introduction of immunotherapies (IT) and targeted therapies (TT), (subsequently referred to as ‘novel therapies’), has improved the prognosis for a subset of people with metastatic NSCLC. For example, 5-year overall survival rate is now 62.5% for people with advanced NSCLC with anaplastic lymphoma kinase translocations who received first-line alectinib,2 and 31.9% for people with cancers that have a programmed death ligand-1 with Tumour Proportion Score ≥50% who received first-line pembrolizumab.3 This growing number of people living with advanced NSCLC who experience durable tumour responses to modern treatment approaches may have unique psychological needs.4–7
A recent qualitative study of people with NSCLC treated with immunotherapy or targeted therapy found significant unmet needs, including: difficulty managing treatment side effects and toxicities; uncertainty regarding prognosis and treatment duration; not fitting into the ‘sick’ role; and the emotional strain of seeking tailored health information. Similar concerns have been identified in this cohort in the USA, the UK and Denmark. These concerns can have a significant impact on quality of life, decision-making and health information-seeking behaviours. There is therefore an urgent need to address the unique psychological concerns of people with advanced NSCLC treated with these novel therapies.

The few psychological interventions trialled in people with metastatic cancer treated with novel therapies have limited their focus to a single area, such as fear of cancer recurrence, or promoting hope, or have been limited to a single psychological consultation delivered to only two participants. While these have shown promise in addressing these specific areas, they are unlikely to address the broader range of needs identified in the qualitative studies specific to people with advanced NSCLC who have been treated with novel therapies. Managing Cancer and Living Meaningfully (CALM) is a brief evidence-based intervention for people with advanced cancer that has potential to address broader psychological concerns in this population related to four content domains. These are: (1) symptom management and communication with healthcare providers; (2) changes in identity and relationships; (3) sense of meaning and purpose; (4) sustaining hope and facing mortality. CALM is intended to help people attend to the dual tasks of preparing for progressive disease and end-of-life, while simultaneously focusing on living (a challenge identified by this cohort). CALM has been shown to reduce depressive symptoms, improve preparation for end-of-life and is associated with subjective improvements in relationships, communication, values identification and reduced concerns about the future.

Though CALM is currently being trialled in other cohorts, such as people with primary malignant brain tumours, it has not yet been specifically studied in people with advanced cancer treated with novel therapies. Unlike the cohort in the original CALM randomised controlled trial (RCT) who had a 12–18 months prognosis, people with advanced NSCLC treated with novel therapies may live longer with their disease. It is essential to examine the feasibility and acceptability of CALM in this unique population before undertaking larger-scale studies to evaluate its efficacy.

The overall aim of the present study is to assess the acceptability, feasibility and preliminary evidence of potential impact of CALM in people with advanced NSCLC treated with novel therapies. The specific objectives of this project are to:

- Assess the feasibility of the CALM intervention, outcome measures and study design to guide the development of a possible subsequent phase 3 RCT.
- Explore the acceptability of CALM for people with advanced NSCLC treated with novel therapies, their carers, as well as for therapists delivering the CALM intervention.
- Provide preliminary evaluation of the potential impact of CALM in this population.

METHODS AND ANALYSIS
Study design
This study is a prospective, single-arm pilot study. A mixed-methods design will be used. The study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials checklist (see online supplemental file 1).

Patient and public involvement
This pilot study was conceived and designed by a multidisciplinary group of clinicians, researchers and people with a lived experience of lung cancer (‘patient representatives’). Patient representative co-investigators were intimately involved in the design of this project and will continue to be involved in management oversight through membership of the steering committee. Feedback from participants with cancer and their carers will be provided through a patient experiences survey and qualitative interviews regarding their experience of the intervention and their satisfaction and level of burden with the intervention. This will inform the intervention delivery in a future RCT.

Participants
Twenty people with advanced or metastatic NSCLC treated with novel therapies will be recruited from outpatient clinics at an Australian comprehensive cancer centre. This target number is in line with numbers that have been recruited to the treatment arm in a previous pilot study for people with advanced cancer.

Inclusion criteria
- ≥18 years old.
- Diagnosis of unresectable, locally advanced NSCLC or metastatic NSCLC.
- ≥6 months post initiation of immunotherapy or targeted therapy or combination chemotherapy/immunotherapy (to avoid sampling individuals immediately after initial diagnosis or immediately on learning about IT/TT).
- Expected prognosis of ≥6 months.
- Able to read and write in English.
- Able to commit to three to six sessions.

Exclusion criteria
- Major communication difficulties that would impair ability to engage in a time-limited talking therapy such as significant speech or hearing difficulties.
- Cognitive impairment on the basis of a Short Orientation-Memory-Concentration Test (SOMCT) score ≥7 or indicated by the clinical team or medical record.
Recently receiving any ongoing formal psychological therapy according to self-report for their cancer or other concerns at the time of consent. If a patient wants to pause their current therapy to participate in the CALM project for the duration of their CALM participation, this may no longer be an exclusion criteria if deemed clinically appropriate by the research staff member.

Recruitment and consent
Participants will be recruited from outpatient lung cancer clinics, over an anticipated 6-month period at a comprehensive cancer centre in a large urban setting. Potential participants will be identified by a member of the research team via review of the relevant clinical lists. Eligibility and appropriateness for each potential participant to take part will be confirmed with a lung cancer clinical nurse consultant. The potential participant’s treating oncologist may advise the patient of the study, and seek agreement for the research team to contact the potential participant.

Eligible individuals will be called and invited to take part in the study following their lung outpatient appointment unless the treating team advises that the individual does not wish to be contacted. The research team member will describe the study to eligible individuals, conduct the verbal informed consent process and complete cognitive screening. If the person is eligible and interested in taking part in the study, informed consent will be obtained in accordance with Good Clinical Practice guidelines. Signed consent will either be provided in person (if the patient provides consent at time of introduction of the study in person), via mail using a reply-paid envelope to return, or online via email link to a Research Electronic Data Capture (REDCap) consent form (see Supplementary file 4). Recruitment commenced in July 2022 and is ongoing at the time of submission.

Intervention
CALM is a semi-structured, manualised, individual psychotherapy designed for people with advanced cancer and their loved ones. It shares features with manualised supportive-expressive,17 18 cognitive-existential19 and meaning-centred20 group psychotherapies applied to people with advanced and terminal disease. It was developed based on empirical data, clinical observations and the theoretical foundations of relational,21 attachment22 and existential23 theory. It is informed by the founding team’s funded longitudinal research aimed at identifying the antecedents and course of psychosocial morbidity in individuals with metastatic cancer.13 24−28

CALM includes three to six individual therapy sessions, each approximately 45–60 min in length, delivered over 3–6 months. Additional sessions may be offered if clinically indicated. The sessions cover four domains: (1) symptom management and communication with healthcare providers; (2) changes in self and relations with close others; (3) sense of meaning and purpose; and (4) the future and mortality.11 All modules will be addressed with each participant, but the sequencing and time devoted to each domain will vary, based on the concerns most relevant to each person. The caregiver of the patient with NSCLC (eg, spouse, adult son/daughter, family member), or other persons accompanying the participant with cancer, are encouraged to participate in one or more of the therapy sessions, as deemed appropriate by the participant with cancer and therapist. CALM can be delivered by specially trained therapists from a wide range of disciplines, including social work, nursing, psychiatry, psychology and medicine.11 CALM will be delivered in person, via telehealth (video call) or by telephone if no alternative is available. The CALM therapists will be provided with a copy of the participant’s measures completed at each time point while the therapist is still treating the participant, including Patient Health Questionnaire-9 (PHQ-9), Death and Dying Distress Scale (DADDS) and Functional Assessment of Cancer Therapy-General (FACT-G). These are provided to inform clinical treatment and for therapists to discuss with the participant as applicable.

Qualitative interviews
Qualitative interviews employing cognitive interviewing methodologies will be conducted to assess acceptability of the intervention to people with advanced NSCLC treated with novel therapies.

1. All therapists delivering CALM to study participants will be invited to participate in qualitative interviews through a phone call or email. Therapists involved in this study will be clinical psychologists or clinical nurse consultants who are part of the research team (including authors FAL, MD and MF) and who are: (i) involved in the care of people with advanced or metastatic cancer; (ii) ≥18 years of age; (iii) able to provide informed consent; (iv) fluent in English; (v) willing/able to engage with training in the CALM therapy and attend online supervision meetings (based on feasibility of attending and scheduling in conjunction with concomitant usual role responsibilities). Therapists will complete verbal consent at the start of their interview (online supplemental file 2). Interviews will be conducted following the completion of CALM training. Potential participants will be invited to take part in a semi-structured interview in person, over Microsoft Teams or over the telephone; verbal consent will be obtained from participating therapists. Consenting therapists’ interviews will include questions regarding the therapist’s experience with CALM in this cohort, any adaptations they consider needed and intervention implementation. Therapist–patient relationships and the therapist’s perspective of CALM will also be explored. Interviews will be audio-recorded and transcribed for analysis. Demographics will be collected.

2. All participants with cancer will be invited to take part in a semi-structured interview in person, over the telephone or via telehealth. If participants with cancer...
agree, their primary carer will also be invited to take part with them. When participants agree, the research team will call the carer to discuss the project in more detail and determine if they wish to participate in the joint interview with the person with cancer. Carers will complete verbal consent at the start of the qualitative interview (online supplemental file 3). Participants with cancer and carers will be asked detailed questions about their experience of the illness and the intervention. They will be asked how they experienced or evaluated: the overall CALM therapy; each of the four CALM dimensions; the therapeutic alliance; and the structure and time frame of CALM. Interviews will be conducted at completion of the CALM intervention or following study withdrawal.

Interviews will be semi-structured and the interview guide will be revised on a reflexive ongoing basis relative to feedback and responses from participants. All interviews will be audio-recorded and transcribed. Recruitment of participants in the qualitative substudy will continue until thematic saturation is reached.

**Evaluation measures and data collection**

The measures and data collection, according to the project aims, are described below. Demographic and medical data will be collected, and evaluation measures will be administered to determine the acceptability and potential impact of the intervention. Feasibility of delivering the intervention and of the study protocol will be assessed by evaluation of the uptake, adherence to the intervention and therapist fidelity in administering the intervention.

**Demographics and medical history**

Demographic and clinical characteristics of the participant with cancer will be collected from the participant’s medical record and liaison with the treating team after the patient has consented to the project. Data collected will include:

- Age of patient.
- Sex.
- Treatment received.
- Disease status including date of diagnosis with NSCLC, date of diagnosis with advanced or metastatic NSCLC (if not de novo metastatic), date of most recent restaging imaging and outcome (stable disease; partial response; complete response; progressive disease), cranial involvement.
- Demographic information such as ethnicity, marital status, education level and previous psychotherapy received will be obtained through participant verbal self-report during the assessment part of the CALM sessions or at screening.

**Measures**

**Patient Health Questionnaire-9**

The PHQ-9 is a widely used self-report measure of depression with strong reliability and validity. Scores range from 0 to 27. Higher scores represent higher levels of depression.

**Functional Assessment of Cancer Therapy-General**

The FACT-G is a 27-item self-report questionnaire that measures health-related quality of life across four domains in people with cancer: physical, social, emotional and functional well-being. The FACT-G produces scores on each of the four subscales, as well as a total score. Higher scores indicate higher quality of life. The FACT-G has previously been demonstrated as having high reliability and validity.

**Death and Dying Distress Scale**

The DADDS is a validated 15-item self-report scale measuring death anxiety in people with advanced cancer. The DADDS addresses fears about the dying process and distress about lost opportunities and self-perceived burdens placed on others as a result of the possibility of the person with cancer dying from their disease. The DADDS has shown good construct validity with two factors, one related to distress about the shortness of time and the other to distress about dying and death.

**Clinician Evaluation Questionnaire**

The Clinician Evaluation Questionnaire (CEQ) is a 7-item validated patient-reported experience measure that will be completed by participants with cancer to evaluate the extent to which they perceived benefit from the components of the CALM intervention. The CEQ has shown strong internal consistency (Cronbach’s alpha=0.94–0.95), factor structure and concurrent validity. The CEQ will be administered post-intervention.

**Patient experiences survey**

This survey has been purpose-built based on previous studies (eg, 1), in consultation with the lead Principal Investigator of CALM, Gary Rodin, to determine the experience of participants with cancer of the intervention, including which aspects they found helpful or unhelpful and any changes in their well-being following the intervention. This survey consists of nine questions and is expected to take approximately 10 min to complete. Participants will be invited to complete the survey within 2 weeks of completing the CALM intervention, or earlier if they withdraw prior to completion of the intervention.

**CALM Treatment Integrity Measure**

The CALM Treatment Integrity Measure (CTIM) is a 32-item questionnaire that assesses treatment integrity of the CALM intervention using 8 subscales: 13 items on the therapeutic process subscales: (1) Therapeutic Relationship; (2) Modulating Affect; (3) Shifting Frame; (4) Interpretations; and 19 items on the therapeutic content subscales: (5) Symptom Management and Communication with Healthcare Providers; (6) Changes in Self and Relations with Close Others; (7) Spirituality, Sense of Meaning and Purpose; (8) Preparing for the Future, Sustaining Hope and Facing Mortality. The CTIM will
be completed by the CALM supervisor at each supervision session for each therapist who has presented and will be used to assess fidelity to the intervention and therefore the appropriateness of the CALM intervention for this population. Adherence to the item is estimated on a 3-point Likert scale with ‘1=needs improvement’, ‘2=satisfactory’, ‘3=excellent’ implementation of the CALM therapy technique. Items that were not observed in the supervision presentation are left blank indicating that they were not applied. Adherence to the protocol is defined as administering 10/19 items on the therapeutic content subscales in at least 50% of the CTIMs, and 4/19 of these to a satisfactory or excellent extent in at least 50% of the CTIMs, consistent with previous research analysing the treatment integrity according to the first and last CALM sessions.34

Appropriateness and acceptability
The appropriateness and acceptability of the intervention will be assessed by evaluation of the (1) patient experiences survey, (2) CEQ, (3) transcribed qualitative interview data.

Feasibility
Feasibility of the intervention will be assessed by (1) a review of supervisor-rated treatment fidelity using the CTIM completed after each supervisory session, (2) audio recording all sessions and then reviewing sections of therapy sessions during supervision to check compliance with protocols using the CTIM.

Referral rates/uptake and adherence
A case report form (CRF) will be used by the researcher and/or therapist to assess referral rates into the study, uptake of the intervention and participant adherence to the intervention. Reasons for declining to participate will also be noted. The project team, using the CRF will collect variables listed in online supplemental table 1.

Feasibility outcome criteria are presented in online supplemental table 2.

Therapist time
Time and cost of delivering the intervention will be determined based on the number of minutes or hours spent per task costed according to the role of the staff member. An outline of the variables to be collected is presented in online supplemental table 3, and this data will be collected on the screening log and CRF.

Impact
The PHQ-9, FACT-G and DADDS will be used for preliminary evaluation of the impact of the intervention and to assess the feasibility of the trial methodology. As illustrated in online supplemental table 4, participants will be asked to complete PHQ-9, FACT-G and DADDS at baseline (T1), immediately post-intervention (T2), 3 months (T3) and 6 months (T4).

Data analysis
Data will be managed through REDCap35 36 and quantitative data analysed using SPSS (V.24) or Excel.

Quantitative analysis
Descriptive statistics
Descriptive statistics (eg, count/percentage, mean/SD, median/IQR as appropriate) will be used to summarise demographic, clinical, feasibility data (including time measures), treatment details (modality; if carers were present) and responses to outcome measure questionnaires.

Feasibility
Feasibility data (including time measures) will be analysed using count/percentage. Feasibility outcome criteria are presented in online supplemental table 2 and these figures are based on previous CALM studies.12 37–40

Impact
Change scores will be calculated for participants who complete at least three sessions of CALM as well as for the full sample. Participants who reported a reduction of ≥5 points on the PHQ-9 at T2, T3 and T4 compared with baseline will be summarised with a proportion of the sample and 95% CI for the full sample and separately for participants with a baseline PHQ-9 ≥8. The proportion and CI will be reported for participants experiencing a 10% or more reduction on the DADDS, or 10% or more increase on the FACT-G. This is consistent with accepted guidelines for interpreting clinically significant changes in patient-reported outcomes.41 The number and proportion of the sample who have a remission in depressive symptoms of at least threshold severity (indicated by PHQ-9 ≥8 points) in those participants with PHQ-9 ≥8 at baseline will be reported (as per12). Continuous variables will be compared using a paired samples t-test or Wilcoxon signed-rank test as appropriate before and after the intervention, and a Kazis effect size will be reported.

Qualitative analysis
Free text items from the patient experiences surveys and transcribed interviews will be analysed using summarising content analysis. A deductive content analysis approach will be used for coding data. Predefined categories will be formulated based on the research questions informing the study. Additional inductive codes will be identified from the survey responses.

ETHICS AND DISSEMINATION
Ethics approval and consent to participate
This study, protocol (V7 as of writing), and all instruments including the informed consent document, have been approved by the Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC) in Melbourne, Australia, HREC reference number: HREC/82047/PMCC. Protocol modifications will be communicated to

the reviewing HREC, steering committee and principal investigators.

All participants with cancer will complete a signed consent form prior to participation, and carers and therapists will complete verbal consent with a written explanatory statement provided (see online supplemental files 2–4).

Data storage and privacy issues
A unique study identification number system will be used for data collected for this project. This system involves keeping a ‘key’ that specifies and links the patient’s personal identifying information (eg, names, unique record numbers) with the patient’s corresponding study identification number (eg, PT01/PR01). The key will be kept electronically (in a password-protected Excel spreadsheet) on a Peter MacCallum Cancer Centre server separate from all hardcopy and softcopy data collected. Electronic data will be stored in password-protected folders on Peter MacCallum Cancer Centre’s secure servers. Identifying information of the patient’s name and contact details will be obtained from the medical record and/or consent form only to maintain contact with the patient. This information will not be used in data analysis, and will be deleted from the database at the conclusion of the project.

Only members of the project team and therapists will have access to this data, in accordance with the National Statement on Ethical Conduct in Human Research 2007 and the Australian Code for Responsible Conduct of Research 2018. Hardcopy data will be stored in locked filing cabinets within the Peter MacCallum Cancer Centre Department of Psychosocial Oncology. Five years after publication or dissemination of project outcomes, hardcopy and electronic data will be destroyed.

CALM therapists will complete a short documentation on the patient’s medical file of each therapy session. This medical file documentation will provide a brief summary of the session as relevant to the treating team. A more detailed therapy note will be completed by the CALM therapist and kept in a password-protected file in the research folder accessible only by the research team members. This more detailed note will be sent to Associate Investigator Professor Gary Rodin before the patient is presented at group supervision to evaluate fidelity of CALM. Research team members will document on the medical file any attempted contact with the patient or research status change (eg, completed, withdrawn).

Withdrawal criteria
It is not expected that patients will be withdrawn by the research team or therapist involved in delivering the intervention as the intervention and/or assessment schedule can be modified depending on patient needs. If patients require referral to other practitioners for complementary care (eg, medication), or care for unrelated morbidity, this will be recorded on the database.

Should a participant withdraw from the study, it will be confirmed if they wish to withdraw from: (1) all components of the study; (2) completing questionnaires and interview, but wish to continue therapy sessions; (3) therapy sessions, but willing to complete questionnaires or interviews; or (4) the qualitative substudy. Patients who opt to withdraw from the study will be asked if they would consent to continue completing follow-up measures, evaluation and for any of their existing data to be included in analyses. If consent is not given for the latter, their data will be deleted from the database except reasons for withdrawing and demographic details including treatment, sex, age, marital status, highest level of education completed and previous psychotherapy received. Any electronic or paper records pertaining to their involvement will be destroyed at the completion of the study, except medical notes that have been committed to the electronic system. A record of patients who have withdrawn from the study will be maintained in a secure database until the completion of the study, to ensure that these patients are not approached again by the project team. Patients will be unable to withdraw their data after the completion of the study as their data may have already been used in analyses.

Confidentiality
It is not expected that participating in this project will pose any risks of harm to participants. If any disclosures of risks to safety (eg, suicidal ideation) occur during any stages of the project, standard clinical processes will be followed including safety planning with the participant and, when needed, advising an appropriate support person such as a member of the participant’s treating team and/or a family member. This limit to confidentiality is included in the participant information and consent form.

Safety reporting
The potential for adverse events is deemed to be low in this study. Should participants report suicidal ideation while completing the questionnaires (specifically by answering ‘yes’ to question #9 in the PHQ-9), a member of the research or clinical team will follow distress protocols as per usual clinical practice. Specifically, research staff or psychologist will: (i) immediately inform the principal investigator and/or most responsible clinician; (ii) contact patient to assess risks and offer a referral to acute services if needed. Any additional action(s) suggested by the principal investigator(s) or most responsible clinician will be implemented and documented in the participant’s medical file. If a patient scores ≥1 on item 9 of the PHQ-9 completed online via REDCap, an automatic alert will be sent to three members of the clinical research team or clinical psychology CALM project therapists if initial contacts are on leave. The REDCap questionnaires will be turned offline when the project team or clinicians are unable to review the PHQ-9 (eg, shared leave). Patients will also receive an automated email on completion of questionnaires thanking them for completing and with crisis numbers should they need them. Should suicidal ideation be reported...
directly to CALM therapists by a patient, clinicians will follow regulations from their respective regulating bodies or as otherwise mandated by the law.

Where patients score ≥7 on the SOMCT, the research team will advise their treating team of these results for the treating team to consider and communicate to the patient if appropriate or if further testing is required. Patients will not be advised of their result as the cognitive screening is not a diagnostic tool.

The sponsor and ethics department will be notified immediately of any safety issues, and the management of these.

**Dissemination**

This study will be registered with the Australia New Zealand Clinical Trials Registry. Results from this study will be published in peer-reviewed journals and disseminated at national and/or international conferences. Study findings will also be disseminated to clients involved in the care of people with advanced NSCLC.

**DISCUSSION**

People with advanced NSCLC who are treated with novel therapies face unique psychological concerns that are often unmet in the course of routine care, such as managing uncertainty, dealing with fear of cancer progression and difficulty obtaining tailored health information.4–6 These concerns greatly impact quality of life and therefore establishing evidence for a psychological intervention, that is, suitable and effective for this cohort is a recommended high priority.6

CALM has theoretical applicability to this cohort by addressing the dual tasks of focusing on living in the present while preparing for the possibility of disease progression and end-of-life. It is also one of the few interventions developed specifically for people with advanced disease that has been shown to reduce depressive symptoms, ‘death anxiety’, and improve communication with healthcare providers and preparation for end-of-life.12 However, CALM has not yet been evaluated specifically in people treated with novel therapies who may face unique challenges of high levels of uncertainty regarding prognosis, potential extended treatment duration and lifespan and limited healthcare information available. Establishing whether CALM is suitable for people with advanced cancer treated with novel therapies is therefore necessary.

The use of a mixed-methods design in this study ensures detailed qualitative exploration of the potential acceptability of CALM to people with cancer, their carers, and therapists. The primary limitation of this study is the small sample size of 20 participants, which will limit any interpretations on efficacy of CALM for this population. However, the primary aim of this study is to examine the acceptability and feasibility of CALM and the trial design, and this sample size will allow adequate analyses of these aspects.

The exclusion criteria of this study also limits the generalisability of findings to broader populations. In particular, people who could not speak, read or write fluently in English were excluded. To date, there were no known studies published on the delivery of CALM with interpreters. Pilot studies to assess the acceptability of CALM with interpreters is a priority area for future work. A further limitation of the study design is the exclusion of people currently receiving formal psychotherapy. This may limit access to cancer-specific psychological support to potential participants who may be already receiving non-cancer-related psychological support. This exclusion criterion is needed due to the potential overlap of CALM content domains with other psychological therapies such as the focus on relationships, identity and sense of meaning. However, future work could consider offering participants the opportunity to pause their current therapy if they would like to participate in the CALM study.

Our study is an initial step towards understanding if CALM is acceptable to people with advanced NSCLC treated with novel therapies. The results of our evaluation will inform whether CALM requires any adaptations for administration in this cohort. If CALM is shown to be acceptable, and study procedures are feasible, this will inform future studies to assess the efficacy of CALM in people with advanced NSCLC treated with novel therapies.

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