Acceptance and commitment therapy for adults with advanced cancer (CanACT): A feasibility randomised controlled trial

Marc Serfaty[1], Megan Armstrong[1,2], Victoria Vickerstaff[1,3], Sarah Davis[1], Anna Gola[1], Philip McNamee[1,2], Rumana Z. Omar[4], Michael King[1], Adrian Tookman[5], Louise Jones[1], and Joseph T S Low[1]

1. Marie Curie Palliative Care Research Department, Division of Psychiatry, University College London, Maple house, 149 Tottenham Court Road, London, W1T 7NF
2. Camden and Islington NHS Foundation Trust, St. Pancras Hospital, London, UK
3. Department of Primary Care and Population Health, University College London, London, UK
4. Department of Statistical Science, University College London, London, UK
5. Marie Curie Hospice Hampstead, 11 Lyndhurst Gardens, London, UK.

Corresponding Author:
Dr Megan Armstrong
Marie Curie Palliative Care Research Department,
Division of Psychiatry, University College London,
Maple house,
149 Tottenham Court Road,
London, W1T 7NF
Megan.armstrong@ucl.ac.uk

Key words: cancer, oncology, palliative, feasibility, randomised controlled trial, acceptance and commitment therapy

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002/pon.4960

Objective: To understand the feasibility of recruiting people with advanced cancer into a randomised controlled trial of Acceptance and Commitment therapy (ACT) vs a standardised Talking Control (TC) and delivering ACT to this population; to explore the acceptability of outcome measures and generate normative data.

Methods: This was a feasibility two-arm randomised controlled trial. Participants were attendees with advanced cancer at one of three hospice-based day- therapy units in London, UK, who demonstrated low scores on the Functional Assessment of Cancer Therapies – General (FACT-G). The primary end point was three months.

Results: The recruitment target was 54 participants; 42 people were recruited and randomised to up to eight individual sessions of ACT (n=20) or TC (n=22). 18/42 (43%) of participants completed the primary outcome at three months, and at least one follow-up was available in 30/42 (71%) participants. An exploratory analysis revealed a non-significant adjusted mean difference after three months in the main outcome FACT-G of -3.41 (CI= -18.61, 11.79) with TC having better functioning. Over six months the adjusted mean difference between trial arms was 2.25 (CI= -6.03, 10.52) in favour of ACT.

Conclusions: It is feasible to recruit people with advanced cancer in a trial of ACT versus TC. Future research should test the effectiveness of ACT in a fully powered trial.

Trial Registration: ISRCTN13841211 (registered 22 July 2015)

In the UK, the National Institute for Clinical and Care Excellence recommends that people with advanced illnesses should have their psychological needs met[1]. Acceptance and Commitment Therapy (ACT) has shown promise in a range of populations[2]. ACT involves key processes that include helping people to work towards doing what is important to them (values) through building up resilience to uncomfortable experiences such as thoughts and feelings (acceptance)[2]. Increased acceptance is associated with decreased psychological suffering[3] and facilitates engagement with life despite limitations imposed by illness[4].

Whilst ACT may be beneficial for a range of psychological disorders, studies in life threatening illnesses are limited[5]; only one trial has been identified for people with advanced (ovarian) cancer[6], which suggested that ACT, compared to cognitive behavioural therapy type intervention, was associated with improved quality of life and decreased psychological distress[6].

Our study is based on previous work, which found an association between acceptance, psychological and physical function in hospice day-therapy attendees (i.e., those receiving palliative care);this work supported the rationale for an ACT based intervention for improving outcomes for those with palliative care needs[7]. As non-specific effects of therapy, such as therapist warmth, may contribute to improvement, a 'Talking Control' (TC) was used as a comparison[8]. A TC also facilitates engagement, by minimising attrition through offering an intervention[9].

This paper presents a feasibility randomised controlled trial comparing ACT with a TC (CanACT) for hospice attendees with impaired function. The aims were to test: (i) the feasibility and acceptability of delivering ACT in people with advanced cancer; (ii) the feasibility of conducting an RCT of ACT versus TC in this population; (iii) the acceptability of a range of outcome measures; and (iv) whether outcomes on the FACT-G were consistent with potential change with treatment.

METHOD

Design

A feasibility, parallel group, two-armed, randomised controlled trial of ACT versus TC.

Study population

We aimed to recruit 54 participants based on pragmatic grounds to demonstrate feasibility in terms of recruitment, acceptance of randomisation, and likely attrition without the need for a power calculation.[10] People with advanced cancer attending day-therapy services, as in or out-patients, at three hospices in London, UK were considered for participation if they were aged 18 years or more with a diagnosis of advanced cancer not amenable to cure (i.e., metastases at first diagnosis, subsequent recurrence, or lung cancer with or without metastases). People were excluded if they had a clinician-estimated survival of less than four months, an insufficient command of English to engage in a talking therapy, cognitive impairment, or were currently receiving CBT or ACT: please see protocol[11]. Potential participants were screened using the FACT-G (lower scores indicating lower functioning)[7]. The mean FACT-G score in a cancer population is 80.9 (SD 17.0)[12]. Therefore, a threshold of below 81 for entry into the trial was selected.

Interventions, training and supervision

Participants were offered eight, weekly sessions of either ACT or TC that lasted up to an hour, and were adapted for use in advanced cancer. The sessions were delivered by one of six therapists over a period of up to three months, face-to-face in the hospice day-therapy unit, the participant's home or the therapist's clinic. Participants were given three months to complete their eight therapy session to allow for missed sessions due to reasons such as illness.

Therapists who delivered ACT also delivered TC to control for non-specific therapy factors. All therapists had at least two years' experience of using ACT and received two full days' training on ACT and TC in a palliative care population from the chief investigator (MS) and an experienced ACT therapist (MW); both were extensively trained in ACT. The training was supplemented with two half-day booster sessions during the study. There was fortnightly supervision from MS and MW, which was

also attended by a research nurse (SD) who provided support about working with a palliative care population.

The six therapists in this study were paid at sessional rates. Three out of six therapists already worked in cancer clinics and used ACT. All therapists took part in this study to improve their skills in ACT and to apply it to an advanced cancer population. We ensured at least one experienced therapist was based at each of the three hospices.

ACT sessions and manual

The first four sessions of therapy aimed at helping the participant understand the concept of ACT and the psychopathological elements (e.g., experiential avoidance, cognitive fusion) and ACT interventions (e.g. increasing acceptance, defusion techniques). Once these components had been covered, the last sessions aimed at helping the participant practice these in order to become more psychologically flexible. Further details of the therapy sessions can be found in supplementary material 1.

The ACT manual, available on request, was a bespoke piece of work prepared by MS and MW targeting therapists with existing knowledge of ACT. It was informed by previous experts in ACT[2,4] and adapted so ACT may be applied to people with advanced cancer. This manual was a guide for the therapists to use. It was stressed that strict adherence to the manual would be rigid and inconsistent with the need to model a psychologically flexible approach. The manual comprised three sections: (1) background of ACT and use in advanced cancer; (2) the content of ACT and (3) materials for use in ACT.

Talking Control sessions and manual

The TC involves a conversation led by the participant. The therapist gains the participants' interest and trust by being empathic and allowing them to feel heard, without commenting on the content of the material presented. It purposefully does not encourage exposure or avoidance of feared situations, it does not seek to problem solve, challenge beliefs, use mindfulness techniques or explore different

ways of behaving. Although there are some similarities to befriending, the TC is undertaken by the same therapist who also delivers the specified intervention, in this case ACT, but no lay equivalent of lay advice is given.

The TC manual was developed specifically for the project and is broadly based on the non-specific side effects of psychotherapy. The manual was based on previous research using a TC.[8] The TC manual provided examples and case studies of how to be empathic whilst remaining neutral and not offering advice.

Procedure

During November 2015 to 2016, day-therapy staff identified potential participants using the inclusion/exclusion criteria and sought verbal consent for researchers (MA/PM) to approach them about the study. Researchers then explained the CanACT study and asked them to complete the FACT-G. Researchers invited those with a FACT-G score below 81 to participate, and gave them written information about the study. Those who agreed to participate gave written informed consent to the researchers and completed baseline assessments. A researcher (MA/PM) allocated each participant to the next available therapist. Randomisation then took place and a senior researcher (JL) gave the allocated therapist information about the participant's group allocation and their contact details. Researchers (MA/PM), who were blinded, undertook follow-up assessments over the phone or face-to-face in a location of the participant's choice.

Randomisation

Participants were randomised by a senior researcher (JL) to either ACT or TC using an independent web-based randomisation system (Sealed Envelope)

Ethics approval

Riverside Research Ethics Committee (ref 14/LO/0813) approved the study on 4th July 2014.

Outcomes

I. Feasibility of recruitment and retention:

- The recruitment target was 54 participants over 12-months.

- Retention of at least 60% of participants (i.e., until the main follow-up time point of three months).[13]
- Rates of and reasons for attrition.
- The capacity to collect data from participants and hospice records.

II. Attitudes to and engagement with therapy, and acceptability of outcome measures

- Acceptable feasibility criterion, adapted from previous research[13], whereby 60% of participants were expected to engage at least "mostly with therapy", according to the following criteria:
    - Non-engagement: attended 0/8 sessions
    - Somewhat engaged: attended 1-4/8 sessions
    - Mostly engaged: attended 5-6/8 sessions
    - Fully engaged: attended 7-8/8 sessions
- Treatment preference was assessed at baseline using two questions: "how much would you hope to receive ACT?" and "how much would you hope to receive TC?" [14]. Scores ranged from 0 (Not at all) to 3 (Completely) for each item with higher scores indicting a preference for ACT or TC.
- Participants were asked to rate their expectation of ACT at baseline by recording on a scale of 1 (Not at all) to 10 (Completely) for how much they expected to change [15].
- Satisfaction with therapy after three months was measured using a shortened version of the Counselling Questionnaire [16].
- The amount of missing data was used as one indication of the acceptability of the outcome measures.

III. Quantitative measures

Demographics

At baseline, age, gender, ethnicity, marital status, education level, previous psychiatric history, type of cancer, date of diagnosis, and the employment status of the main salaried person in the household were recorded.

Functioning

The primary outcome was the Functional Assessment of Cancer Therapies – General (FACT-G) (Version 4). It was selected as it has widely been used in people with advanced cancer and focuses on more than one aspect of pathology[17]. It comprises 27 items in four domains: physical well-being; social/family well-being; emotional well-being; and functional well-being. Each item is rated 0-4. The total score ranges from 0 to 108. A lower score indicates poorer functioning.

Psychological distress

The Kessler Psychological Distress Scale (K10) [18], a validated 10 item scale;[7], rating each item 1-5, total score 10 to 50, with ≥ 20 indicating psychological distress.

Physical functioning

Two tests of physical functioning were used [19]:

- A two minute walking test – the distance in metres that participants were able to walk in two minutes.
- A one minute sit-to-stand test – the numbers of times participants were able to stand up from a chair without using their arms in a minute.

Acceptance Commitment Therapy process

(i) Acceptance

The Acceptance and Action Questionnaire II (AAQII):[20] A validated 10 item measure, used in the preliminary study [7] to assess experiential avoidance and psychological inflexibility. Each item is scored from 1 to 7, total range of 10-70, where higher scores indicate greater psychological inflexibility.

(ii) Living according to one's values

The Valued Living Questionnaire (VLQ)[21], a validated 20 item scale evaluating the consistency of people's actions with their values. Each item is rated 1-10. Higher scores indicate living consistently with one's values.

Economic

(i) The EQ-5D-5L [22]: a validated quality of life (QoL) measure. A visual analogue scale (0-100) rates current health status. Higher scores indicate a better QoL.

(ii) The short modified version of the Client Services Receipt Inventory (CSRI) [23] collects participants' use of health services in the preceding three months.

Sources of bias

Assessment of blindness

Neither participants nor therapists were blind to treatment allocation. To assess the blindness of the researchers (MA/PM), each attempted to guess the participant's treatment group at the three and six months' assessment.

Other treatments used

From medical notes and participants' self-report we recorded:

(i) Prescribed medications.
(ii) Other psychological therapies offered as part of treatment as usual.
(iii) Use of gym and physical therapies.

Timing of measures

All measures were collected at three time-points: at baseline, three months (post-intervention), and six months. Additionally, the FACT-G was collected at six weeks and 18 weeks post baseline. Responses were accepted that were within +/- 3.25 weeks (23 days) of the due date 3.25 weeks was chosen as this was the mid-point between the follow-ups.

Data analysis

Our main analysis focused on recruitment, engagement with therapies and attrition from the research process. Summary measures are presented for the baseline characteristics of each trial arm as mean and standard deviation for continuous variables, and frequencies and percentages for categorical variables. We based these summaries on observed observations only.

In an exploratory analysis, we estimated differences (with confidence intervals) in the main outcomes between the trial arms at three months. A linear regression adjusted for baseline values of the outcome and the stratification factor (centre) was used. The normality assumptions of the residuals were investigated using residual plots. We also used a mixed effect model, using all patient data over the 6-months, to investigate the effect over time. Such models allow analysis of repeated outcome measurement data whilst taking into account the correlation between measurements from the same patient. All analyses were carried out as allocated and based on complete cases using the statistical software STATA Version 14.

RESULTS

Characteristics of the participants

Over 12-months, 42 out of a target of 54 participants (78%) were recruited into the study (Figure 1). Forty-two people were randomised; 22 to TC and 20 to ACT. Due to an administration error, one participant allocated to TC received ACT. Data from this participant was analysed as part of the TC group according to the protocol. The sample was predominately female (31/42; 74%), white (34/42; 81%), educated to a diploma level or higher (28/42; 67%) with a mean age of 62 years (SD=11.5) and the most common diagnosis was breast cancer (20/42; 48%) (Table 1). The characteristics of participants in both arms were similar except in the ACT arm where there were fewer people educated to diploma level (i.e., completed two or more years at degree level or similar) and above.

Feasibility

Recruitment

We recruited 78% (42/54) of the target. The main barriers to achieving the recruitment target were limited availability of therapists, all eligible participants already taking part in the study and restriction of the sample to those with advanced cancer..

Follow up

Data from 18/42 (43%) were available at three months (the primary end point), which missed our aim of 60% retention. Data from at least one follow-up were available in

30 out of 42 (71%) participants. Reasons for attrition included death, deteriorating health, and loss to follow-up (see Figure 1). One person felt the therapy was unsuitable. At the primary time point (three months) there was no statistical difference in attrition between the arms.

Collecting participants' data

Collecting data on medication was limited as hospice notes were not easily accessible and omitted medication prescribed by general practitioners.

Acceptability

Uptake of therapy sessions

26/42 (62%) mostly or fully engaged with therapy by attending 7 or more therapy sessions: (11/21 (52%) ACT participants and 15/21 (71%) TC participants), which met our aim of at least 60% engaged in therapy Six (14%) participants received no therapy (five in ACT and one in TC). Reasons for non-attendance included: sudden deterioration in health (one death, two hospital admissions), two felt therapy "involved too much commitment" and one gave no reason. Of those 36 participants who attended at least one therapy session, 69% (11/16) mostly or fully engaged with therapy in ACT and 75% (15/20) in TC.

Satisfaction with therapy

Of those followed up at three months, 5/6 (83%) ACT participants and 5/10 (50%) TC participants found the therapy useful and 6/6 (100%) ACT and 6/10 (60%) TC participants found talking to the therapists easy. (See Supplementary material 2).

Treatment preference

The treatment preference was a mean of 1.6 (SD=1.2) for ACT and 1.3 (SD=1.2) for TC, indicating no strong preference for receiving either ACT or TC at baseline.

Expectation of ACT

Participants' expectancy of improving was a mean of 5.9 (SD=2.5) for ACT and 5.6 (SD=2.5) for TC.

Acceptability of measures

For the participants who provided follow-up data at three months, there were no missing items for the Kessler 10, EQ-5D-5L and CSRI. On the FACT-G, two participants (11%) had missing items (2 and 6 items respectively), one person (6%) had one missing item on the AAQ-II and six (38%) participants had at least one missing item on the VLQ (range 1-8 missing items). At three months, 12 out of 18 participants did not complete the physical function test, the main reasons being physical limitations, lack of time, or recent activity in the hospice gym.

Participant reported outcomes

Functioning (Table 2 and Figure 2)

At three months, there was an adjusted mean difference of -3.41 (95% CI= -18.61, 11.79) in FACT-G scores between the TC and ACT groups, with TC having higher scores. The FACT-G subscales at three months showed mean differences in favour of TC for physical, emotional and functional wellbeing and in favour of ACT for social/family wellbeing. Over six months, the adjusted mean difference in total FACT-G scores was 2.25 (95% CI= -6.03, 10.52) in favour of ACT.

Psychological distress

Psychological distress, measured using the Kessler 10, showed that at baseline, there was mild distress in both the ACT (mean=26.3; SD=7) and TC (mean=23.2; SD=7.9) groups. At three months, psychological distress was mild for those in the ACT (mean=22.1; SD=7.9) group and absent for those in the TC (mean=18.3; SD=4.9) group. The adjusted mean difference at three months was 0.6 (CI= -7.25, 8.53). (See Table 2 for all secondary outcomes).

Physical functioning

Walking test: the mean at baseline was 78.6 metres (SD=15.5, N=7) and 67.5 (SD=23.3, N=2) at three months for those receiving ACT and 79.8 (SD=24.9, N=9) at baseline and 107 (SD=65.5, N=5) at three months for TC.

Sit-to-stand test: the mean at baseline was 11.7 (SD=3.1, N=7) and at three months was 20.5 (SD=3.5, N=2) for ACT. In TC, the mean was 17.4 (SD=8.7, N=9) at

baseline and 10.6 (SD=6.4, N=5) at three months. Due to the level of attrition for both physical functioning tests, mean differences at three months were not calculated.

Process of ACT

In the ACT arm, the mean score on the AAQ-II was 34.1 (SD 10.2) at baseline and 31.1 (SD 8.0) at three months. In the TC arm, the score was 31.5 (SD 9.8) at baseline and at three months was also 30.0 (SD 5.6).

For the Valued Living Questionnaire, the adjusted mean difference between ACT and TC was 0.22 (95% CI= -19.42, 19.87) at three months.

Economic

For the EQ-5D-5L, the adjusted mean difference at three months between ACT and TC was -0.01 (95% CI= -0.14, 0.13); for EQ-VAS it was -5.45 (95% CI= -18.61, 11.79). The modified CSRI showed a mean difference of 3.28 (95% CI= -14.76, 18.61) between ACT and TC at three months.

The total cost of the intervention, which included provision of both therapies, mentoring and training over the study duration, was £22,970.

For patients who received ACT, total costs associated with therapy provision were £7,820 while costs associated with training and mentoring were £2,180 and £765respectively. The cost per participant was £538.25.

For TC, the total cost of providing therapy was £10,030, while training and mentoring costs were £1,920 and £255 respectively. The cost per participant was £554.77, which is slightly higher than ACT due to the higher session uptake (26 sessions more than ACT). This cost is hypothetical, however, as were a talking treatment of this nature scaled up, it would not be delivered by such a skilled or costly therapist.

Sources of bias

Assessment of blindness

The researchers correctly guessed the participants' group allocation on 65% (11/17) of occasions at three months and 73% (11/15) of the time at six months. This suggests some degree of un-blinding at three months.

Other treatments used

At three months in the ACT group, 4/7 (57%) participants had received psychological therapy, 4/7 (57%) complementary therapy, and 4/7 (57%) attended the gym. In TC, 1/11 (10%) received psychological therapies, 7/11 (70%) received complementary therapies, and 6/11 (60%) attended the gym.

CONCLUSIONS

It is feasible to recruit people with advanced cancer into a trial of ACT versus TC. Participants engaged well with therapy; of those who attended at least one session, 10/16 (63%) went on to be fully engaged in ACT (i.e., attend 7-8 sessions). Moreover, participants reported satisfaction with the intervention they received. However, completion of the main outcome at the primary endpoint (3 months) was low. This finding suggests that participants from a palliative care population found ACT highly acceptable, but researchers should focus on reducing the burden of research and therefore increasing the feasibility of this research.

The main strength of this study was the high engagement of participants in the therapy sessions. Furthermore, recruitment was acceptable, possibly because interventions were offered to all participants. To increase recruitment rates, we suggest broadening the target population to include people receiving palliative care for all diagnoses. As ACT does not aim to restore full function, but rather helps people cope with dysfunction, it may offer promise to people with chronic, life-threatening physical disease. Although participants engaged well with therapy, their completion of the FACT-G was inconsistent, largely because of ill health at the time of data collection. We have therefore been cautious not to interpret or extrapolate these findings for comparison with other studies.

Study limitations

A weakness of this study was participants often declined to complete the follow-up assessments. High attrition is a common issue in palliative care[24] and future research should focus on ways to increase retention. Twelve per cent of participants died during their first three months in the trial. Whilst theoretically retention could be enhanced by recruiting people with a better estimated prognosis, in reality clinicians are poor at predicting outcome[25]. We suggest it may be more beneficial to limit the number of outcome measures and follow-up time points in a future trial based on the participant feedback received. In particular, the physical outcome measures were unacceptable for this population and could be omitted. Whereas, a main outcome measure like the FACT-G provides an acceptable measure of functioning in several domains in this population. More flexibility around the timing of follow-ups would allow for the challenges raised by the unpredictable course of advanced illnesses.

This study used a TC to control for non-specific therapy factors. Future research should test the effectiveness of ACT against treatment as usual. Furthermore, we collected data at baseline on participants' expectation of change were they to receive ACT; in hindsight, to allow comparison of both groups, participants' expectations with TC should also have been recorded. Lastly, we aimed to rate the fidelity of the therapy sessions but due to cost constraints this was not possible.

Clinical and research implications

Our two measures of ACT processes suggested that compared to a normal population, the sample had higher levels of experiential avoidance, psychological inflexibility and were less able to act in accordance with what is important to them (values),[20,21] which is consistent with the rationale for using ACT in a palliative population. Psychotherapies can only be beneficial if participants choose to engage with them [26]. The CanACT trial has demonstrated that ACT is an acceptable psychotherapy, demonstrated by a high attendance of therapy sessions, for people with advanced cancer. Reducing the number of outcome measures and research burden on participants may limit attrition. The next stage of this research is to test the clinical and cost effectiveness of ACT in a palliative population in a larger trial.

REFERENCES

1. Part A, Gysels M, Higginson IJ. Improving supportive and palliative care for adults with cancer. 2002.
2. Hayes SC, Strosahl KD, Wilson KG. Acceptance and commitment therapy: An experiential approach to behavior change: Guilford Press; 1999.
3. Hall PS, Edlin R, Kharroubi S, Gregory W, McCabe C. Expected net present value of sample information: from burden to investment. Medical Decision Making. 2012;32(3):E11-E21.
4. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and commitment therapy: Model, processes and outcomes. Behaviour research and therapy. 2006;44(1):1-25.
5. 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.
6. Rost AD, Wilson K, Buchanan E, Hildebrandt MJ, Mutch D. Improving psychological adjustment among late-stage ovarian cancer patients: Examining the role of avoidance in treatment. Cognitive and Behavioral Practice. 2012;19(4):508-17.
7. Low J, Davis S, Drake R, King M, Tookman A, Turner K, et al. The role of acceptance in rehabilitation in life-threatening illness. Journal of Pain and Symptom Management. 2012;43(1):20-8.
8. Serfaty M, Csipke E, Haworth D, Murad S, King M. A talking control for use in evaluating the effectiveness of cognitive-behavioral therapy. Behaviour research and therapy. 2011;49(8):433-40.
9. Stevens SE, Hynan MT, Allen M. A Meta-Analysis of Common Factor and Specific Treatment Effects Across the Outcome Domains of the Phase Model of Psychotherapy. Clinical Psychology: Science and Practice. 2000;7(3):273-90.
10. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC medical research methodology. 2013;13(1):104.
11. Low J, Serfaty M, Davis S, Vickerstaff V, Gola A, Omar RZ, et al. Acceptance and commitment therapy for adults with advanced cancer (CanACT): study protocol for a feasibility randomised controlled trial. Trials. 2016;17(1):77.
12. Brucker PS, Yost K, Cashy J, Webster K, Cella D. General population and cancer patient norms for the Functional Assessment of Cancer Therapy-General (FACT-G). Evaluation & the health professions. 2005;28(2):192-211.
13. Buszewicz M, Cape J, Serfaty M, Shafran R, Kabir T, Tyrer P, et al. Pilot of a randomised controlled trial of the selective serotonin reuptake inhibitor sertraline versus cognitive behavioural therapy for anxiety symptoms in people with generalised anxiety disorder who have failed to respond to low-intensity psychological treatments as defined by the National Institute for Health and Care Excellence guidelines. Health technology assessment (Winchester, England). 2017;21(45):1.
14. Sepúlveda C, Marlin A, Yoshida T, Ullrich A. Palliative care: the World Health Organization's global perspective. Journal of pain and symptom management. 2002;24(2):91-6.
15. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. Journal of behavior therapy and experimental psychiatry. 1972;3(4):257-60.
16. Dahl J, Wilson KG, Nilsson A. Acceptance and commitment therapy and the treatment of persons at risk for long-term disability resulting from stress and pain symptoms: A preliminary randomized trial. Behavior therapy. 2004;35(4):785-801.
17. Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. Journal of clinical oncology. 1993;11(3):570-9.
18. Andrews G, Slade T. Interpreting scores on the Kessler psychological distress scale (K10). Australian and New Zealand journal of public health. 2001;25(6):494-7.

19. Lemieux J, Topp A, Chappell H, Ennis M, Goodwin PJ. Economic analysis of psychosocial group therapy in women with metastatic breast cancer. Breast cancer research and treatment. 2006;100(2):183-90.
20. Bond FW, Hayes SC, Baer RA, Carpenter KM, Guenole N, Orcutt HK, et al. Preliminary psychometric properties of the Acceptance and Action Questionnaire–II: A revised measure of psychological inflexibility and experiential avoidance. Behavior therapy. 2011;42(4):676-88.
21. Wilson KG, Sandoz EK, Kitchens J, Roberts M. The Valued Living Questionnaire: Defining and measuring valued action within a behavioral framework. The Psychological Record. 2010;60(2):249.
22. Group TE. EuroQol-a new facility for the measurement of health-related quality of life. Health policy. 1990;16(3):199-208.
23. Chisholm D, Knapp MRJ, Knudsen HC, Amaddeo F, Gaite L, Van Wijngaarden B. Client Socio-Demographic and Service Receipt Inventory-European Version: development of an instrument for international research. The British Journal of Psychiatry. 2000;177(39):s28-s33.
24. Addington-Hall J. Research sensitivities to palliative care patients. European journal of cancer care. 2002;11(3):220-4.
25. Glare P, Virik K, Jones M, Hudson M, Eychmuller S, Simes J, et al. A systematic review of physicians' survival predictions in terminally ill cancer patients. Bmj. 2003;327(7408):195.
26. Cuijpers P, van Straten A, Andersson G, van Oppen P. Psychotherapy for depression in adults: a meta-analysis of comparative outcome studies. Journal of consulting and clinical psychology. 2008;76(6):909.

Acknowledgements

The authors would like to thank all the clinicians, nurses and physiotherapists who helped with recruitment and the patients who participated in the study. We would like to thank Karen Turner in helping develop the idea for the study and the principal investigators at each hospice site for their support and involvement with the study. We would also like Mark Webster for his help developing the ACT manual and supervising the therapists.

Declaration of conflicting interests

The authors declare no potential conflicts of interest with respect to the research, authorship or publication of this article.

Funding

We acknowledge funding from the National Institute for Health Research (NIHR): Research for Patient Benefit (ref: PB-PG-1111-26043).

Table 1: Participant Characteristics (n=42)

Characteristic	N (%)	ACT, n= 20	TC, n=22
Age, mean (SD)	62.0 (11.5)	63.3 (10.6)	60.9 (12.5)
Gender, Female	31 (74)	14 (70)	17 (77)
Ethnicity, White	34 (81)	17 (85)	17 (77)
Marital Status			
Married/cohabiting	19 (46)	8 (40)	11 (50)
Divorced	5 (12)	3 (15)	2 (9)
Widowed	3 (7)	3 (15)	0 (0)
Single	15 (36)	6 (30)	9 (41)
Highest level of education			
Degree or above	19 (45)	8 (40)	11 (52)
Diploma or equivalent	9 (21)	3 (15)	6 (29)
Secondary school	13 (31)	8 (40)	5 (23)
Other	1 (2)	1 (5)	0 (0)
Employment status of main salaried person in household			
Employed	39 (93)	18 (90)	19 (95)
Unemployed	3 (7)	2 (10)	1 (5)
Cancer diagnosis (primary)			
Breast	20 (48)	8 (40)	12 (55)
Colon	4 (10)	2 (10)	2 (9)
Myeloma	4 (10)	3 (15)	1 (5)
Prostate	3 (7)	1 (5)	2 (9)
Bowel	2 (5)	2 (10)	0 (0)
Non-Hodgkin Lymphoma	2 (5)	2 (10)	0 (0)
Other	7 (17)	2 (10)	5 (23)

Table 2: Results from the analysis of the FACT-G outcome and secondary outcomes

	Descriptive: Mean (SD)							
	Baseline	**1.5 months**	**3 Months**	**4.5 months**	**6 Months**	**N**	**Mean diff. at 3 months***	**95% CI**
Physical Well-Being (PWB, 7 questions)								
ACT	15.1 (5.6)	18.8 (5.6)	17.4 (7.7)	19.4 (6.6)	16.4 (7.2)	18	-3.085	(-10.17, 4.00)
TC	15 (3.6)	13.8 (5.4)	18.7 (4.4)	15.6 (4.9)	16.1 (4.3)			
Social/Family Well-Being (SWB, 7 questions)								
ACT	16.4 (6.1)	18.7 (7.1)	18.7 (5.3)	21.2 (4.3)	19.5 (7.2)	18	1.746	(-1.46, 5.67)
TC	18.1 (7.8)	18.8 (6.1)	19.4 (6.2)	19.7 (6.7)	16 (7.6)			
Emotional Well-Being (EWB, 6 questions)								
ACT	12.3 (5.2)	12.9 (6.0)	15.4 (4.5)	16.6 (5.5)	15.6 (4.2)	18	-1.77	(-6.53, 2.99)
TC	13.6 (4.9)	15.0 (5.5)	16.6 (4.9)	17.1 (4.4)	16.5 (3.7)			
Functional Well-being (FWB, 7 questions)								
ACT	12.6 (4.8)	11.9 (8.3)	12.2 (8)	15.7 (7.3)	16.3 (8.8)	18	-1.77	(-8.47, 4.92)
TC	14.7 (6.4)	13.8 (6.1)	17.5 (4.5)	15.5 (4.9)	14.6 (5.6)			
Total FACT-G (27 Questions)								
n	42	24	18	14	15			
ACT	56.4 (15.5)	62.3 (20.8)	63.8 (19.8)	72.9 (19.1)	67.7 (23.8)	18	-3.41	(-18.61, 11.79)
TC	61.4 (14.4)	61.4 (15.6)	72.2 (16.6)	67.9 (16.7)	63.2 (16.6)			
Kessler 10, n	41		17		15			
ACT	26.3 (7)	N/A	22.1 (7.9)	N/A	22.3 (11)	17	0.639	(-7.25, 8.53)
TC	23.2 (7.9)	N/A	18.3 (4.9)	N/A	19.5 (5.2)			
Physical function – walk (metres)								
n	16		7		6	Due to small numbers at 3 months follow up only summary statistics are provided.		
ACT	78.6 (15.5)	N/A	67.5 (23.3)	N/A	164.5 (159.4)			
TC	79.8 (24.9)	N/A	107 (65.5)	N/A	65 (14.1)			
Physical function – stand (times)								
n	16		7		7	Due to small numbers at 3 months follow up only summary statistics are provided.		
ACT	11.7 (3.1)	N/A	20.5 (3.5)	N/A	17 (6.5)			
TC	17.4 (8.7)	N/A	10.6 (6.4)	N/A	12.3 (4.9)			
AAQ-10								
n	40		17		15	The regression model assumptions are violated and therefore only summary statistics are provided.		
ACT	34.1 (10.2)	N/A	31.1 (8.0)	N/A	31 (7.7)			
TC	31.5	N/A	30.0	N/A	31			

	(9.8)		(5.6)		(10.3)			
Valued living questionnaire								
n						16	0.224	(19.42,
	39		16		13			19.87)
ACT	54.2		55.8	N/A	53.9			
	(17.7)	N/A	(17.3)		(22)			
TC			49.1	N/A	45.3			
	52.1 (16)	N/A	(19.6)		(11.9)			
EQ-5D-VAS								
n	41		18		15			
ACT	49.3		46.5	N/A	70	18	-5.26	(-14.42,
	(17.1)	N/A	(12.7)		(12.7)			10.95)
TC	57.4		63.1	N/A	49.2			
	(16.9)	N/A	(16.2)		(25.8)			
5Q-5D-5L								
n	41		18		15			
ACT	0.53		0.57	N/A	0.72	18	0.01	(-
	(0.31)	N/A	(0.14)		(0.18)			0.12,0.13)
TC	0.62			N/A	0.57			
	(0.27)	N/A	0.7 (0.3)		(0.14)			
Modified CSRI								
n	41		18		15			
ACT, £	1974.7		2139.4	N/A	1887.6	18	3.36	(-13.61,
	(2861.3)	N/A	(3328.3)		(3227.4)			18.29)
TC, £	2431.3		2044	N/A	1332.2			
	(4135.1)	N/A	(3651.9)		(2462.2)			

*****Mean difference was adjusted for centre and baseline value of the corresponding outcome.

FACT-G: A higher score indicates a better health state. Kessler 10: higher scores indicate a higher level of psychological distress; Acceptance and Action Questionnaire (AAQ): Higher scores equal greater levels of psychological inflexibility. Valued living questionnaire: . EQ-5D: higher score has better health status.

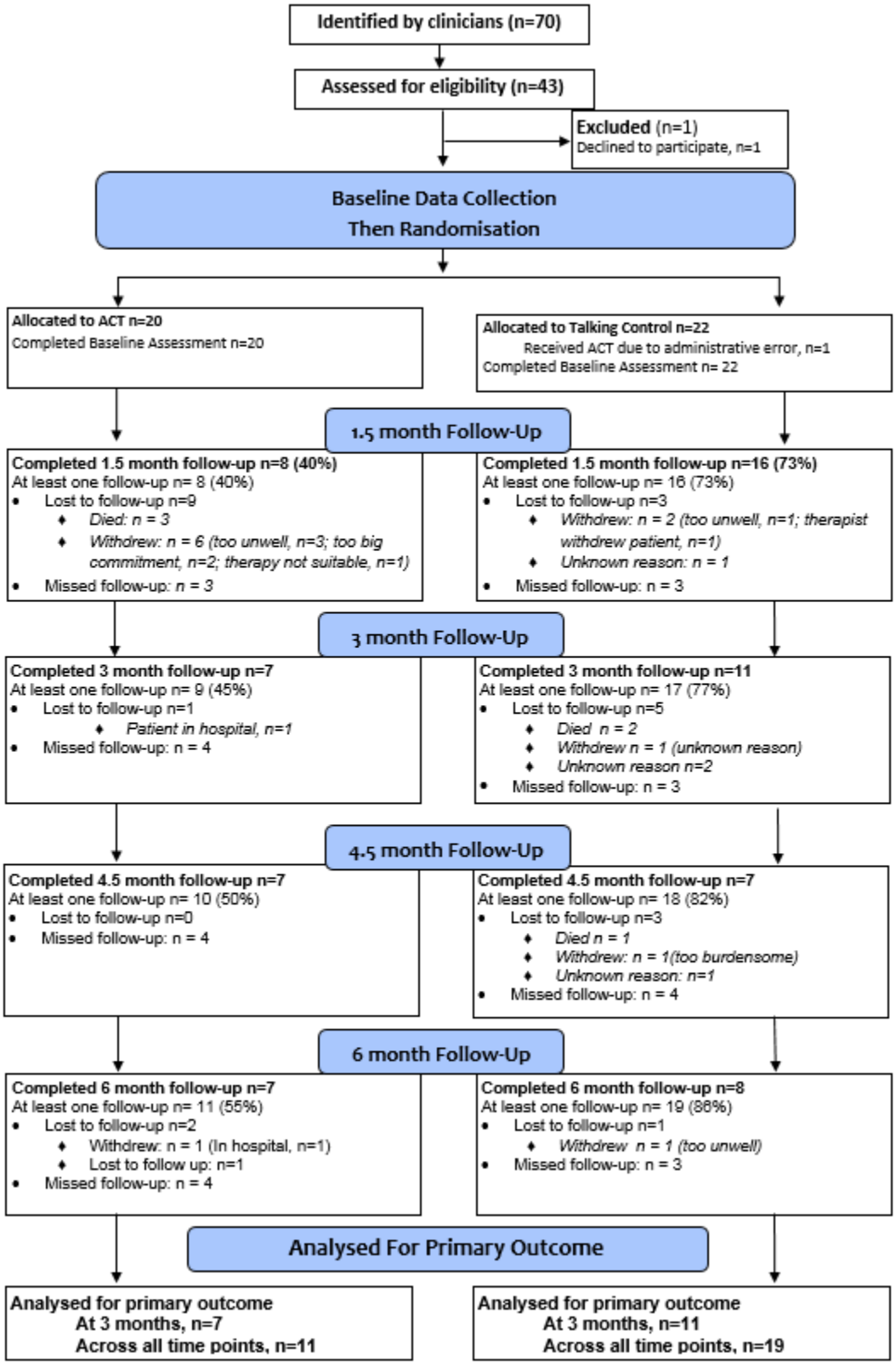

Figure 1: CONSORT flow diagram of participants

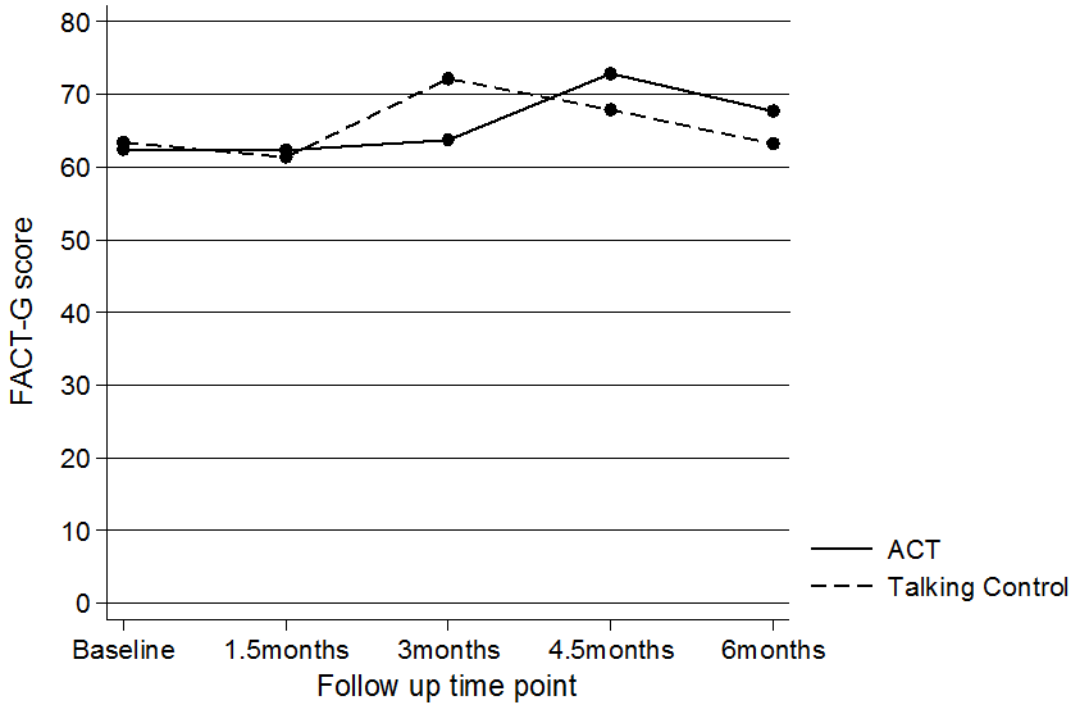

Figure 2: Mean FACT-G scores for ACT and TC at baseline and all follow ups