# A tiered multi-disciplinary approach to the psychosocial care of adult cancer patients integrated into routine care: The PROMPT study (a cluster-randomised controlled trial)

**Jane Turner[a,*], Brian Kelly[b], David Clarke[c], Patsy Yates[d], Sanchia Aranda[e], Damien Jolley[f,1], Andrew Forbes[g], Suzanne Chambers[h], Maryanne Hargraves[i,2], Lisa Mackenzie[a]**

[a] School of Medicine, University of Queensland and Royal Brisbane and Women's Hospital, Brisbane, Australia

[b] University of Newcastle and John Hunter Hospital, Newcastle, Australia

[c] Monash Medical Centre, Melbourne, Australia

[d] Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Australia

[e] Cancer Institute New South Wales, Sydney Australia, and Peter MacCallum Cancer Centre, Melbourne, Australia

[f] School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia

[g] Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Australia

[h] Menzies Health Institute Queensland, Griffith University, Brisbane, Australia;

[i] ICON Cancer Services, Brisbane, Australia

[1] Died prior to completion of the trial

[2] School of Nursing and Midwifery, Queensland University of Technology, Brisbane, Australia

* *Corresponding author*: Professor Jane Turner, Level K, Mental Health Centre, Royal Brisbane and Women's Hospital, Herston, QLD 4029. Australia. Ph: +61 7 3365 5154, Fax: +61 7 3365 5488. E-mail: jane.turner@uq.edu.au

This trial is registered with the Australian and New Zealand Clinical Trials Registry. ANZCTR 1260000448044.

**Acknowledgements**

We thank participating health professionals and patients at Monash Medical Centre, Melbourne; John Hunter Hospital, Newcastle; Royal Brisbane and Women's Hospital, Brisbane; Haematology and Oncology Clinics of Australasia, Brisbane. We thank BaCT at Peter MacCallum Cancer Centre for data management and research personnel including Amy Finlay, Nathalie Darlison, Jane Campbell, Sally Licence, and Kerry Fleming. We especially acknowledge Damien Jolley who developed the methodology for the study. Damien died from melanoma on 15.2.2013 and his colleague Andrew Forbes generously undertook statistical analysis.

**Abstract**

**Purpose:** A stepped-wedge cluster-randomised controlled trial was conducted to evaluate the feasibility and effectiveness of a brief psychosocial intervention for depressed cancer patients, delivered by trained front-line health professionals in routine clinical care.

**Methods:** 902 patients were assessed across four treatment centres which were allocated in random order from control epoch to intervention epoch. Eligible patients had Hospital Anxiety and Depression Scale (HADS) scores of 8 or greater. Of eligible patients, 222 were recruited in control epoch and 247 in intervention epoch. 27 health professionals (HPs) were trained to deliver the psychosocial intervention consisting of up to four sessions, tailored to patient symptoms and distress. HPs participated in group supervision with a psychiatrist. The primary outcome, analysed by intention to treat, was depression measured with the HADS at 10 weeks after receiving the intervention.

**Results:** At 10-week follow-up, there were no significant differences in HADS score for the 181 patients in control epoch and 177 in intervention epoch (adjusted difference -1.23, 95% CI -3.81- 1.35, p=0.35). Patients with disease progression who received the intervention experienced significant benefits in unmet practical support needs including care and support, information, and physical and daily living.

**Conclusion:** A brief psychosocial intervention delivered by front-line oncology health professionals is feasible to deliver but is insufficient as a stand-alone treatment for depression in cancer patients. Psychosocial interventions should be targeted to populations most likely to experience benefit.

**Keywords**: Cancer, depression, distress, psychosocial, treatment, training

## Introduction

The International Psycho-Oncology Society advocates integration of psychosocial care into routine clinical practice [1]. However there is little consensus on the optimal method and timing of patient screening, nor the type of treatment which should be offered to those who are distressed. Specialist-based interventions have been used to treat depression in cancer patients [2-5] however these intensive therapies are unlikely to be available outside of large treatment centres because of a shortage of trained health professionals [6]. Up-take of such interventions when offered is low reflecting barriers in the acceptability of treatment because of stigma or the belief that it would not help [7] and reticence about taking antidepressant medication [8]. There is little research examining the broad range of therapeutic strategies typically applied by clinicians, such as dignity-enhancing and supportive-expressive therapies [9] nor attention to sustainable models of psychosocial care which could be integrated into routine clinical practice. We evaluated a stepped model of care [10] in which patients were systematically screened for psychosocial risk factors and depressive symptoms then allocated via a pre-defined algorithm-based pathway to receive a brief psychosocial intervention tailored to their level of distress delivered by "front-line" oncology health professionals (i.e. clinicians in routine cancer care roles without specialist mental health training). Patients with low-level distress received written resources. Patients with moderate distress were allocated to receive the psychosocial intervention delivered by the trained and supervised health professionals. Patients with very high distress were referred for specialist assessment and treatment.

The study aimed to evaluate whether a brief intervention delivered by front-line health professionals who received training and clinical supervision could improve depression in cancer patients who were not already receiving treatment for depression (e.g. antidepressant medication), and to evaluate the feasibility of delivering this model of care in routine clinical practice.

## Methods

### Study design and participants

The study was conducted between 2011 and 2013 at four cancer treatment centres in Australia. Another treatment centre in a non-metropolitan area agreed to participate in the study but withdrew early due to operational difficulties. No data from this site were included in the study.

The design was a stepped-wedge cluster randomised trial, a cross-over design in which different clusters (the clinical sites) are randomly assigned to a time to cross over in one direction only from control to intervention epoch [11]. The trial protocol has been published elsewhere [12].

Adults aged 18 years or over were eligible regardless of disease or cancer treatment status. Patients receiving treatment for depression and those who could not participate because of disease burden, cognitive impairment, inability to read and speak English or predicted life expectancy of less than six months were excluded.

Expressions of interest were sought from front-line health professionals without core psychosocial training, at least 12 month's clinical experience, and current clinical contact of at least six hours per week.

The study was approved by institutional ethics committees of the participating clinical sites. All participants received written information about the study and provided written informed consent.

### Randomisation and blinding

Sites were randomised to the time of introduction of the intervention epoch using a computer-generated list of numbers. Between the final control epoch and first intervention epoch at each site there was a 10-week training epoch during which health professionals were trained to deliver the intervention and no patients were recruited. All patients enrolled during the intervention epochs were assigned to a level of intervention based on their symptom severity. It was not possible to blind HPs or patients to the treatment condition. Outcomes were self-reported and HPs who delivered the intervention were not involved in their collection.

**Procedures**

After each site was allocated to the training epoch the recruited HPs received a purpose-designed self-directed training manual and participated in a one-day skill development program. Skill development was conducted in small groups at each site by a psychiatrist, adhering to a pre-defined format, focusing on core therapeutic approaches: i) supportive-expressive ii) cognitive-behavioural and iii) dignity-conserving strategies [9].

All patients in control and intervention epochs completed baseline measures. Once a site was in intervention epoch research personnel used baseline data to determine the level of intervention appropriate for each patient based on risk factors for distress [13] and Distress Thermometer (DT) Scores [14] using a cut-off of four [15] as per the algorithm.

Insert Figure 1 about here

Patients with low distress received a resource comprising a relaxation CD, links to cancer-specific internet sites, and evidence-based information about common concerns. Pilot testing with 14 patients confirmed the resources were acceptable in style and content.

Patients allocated to the intervention were assigned in sequence to trained HPs at the site. That is, the first patient allocated to the intervention was assigned to the first HP recruited at that site and so on. HPs contacted patients offering up to four individual sessions, each up to 30 minutes' duration, either face-to-face or by telephone. HPs received a copy of the patient's completed DT form listing concerns prior to delivery of the first session. HPs received site-specific information about accessing urgent psychiatric advice if necessary, and a referral pathway for patients requiring services such as physiotherapy or social work.

The focus of the intervention was mutually agreed by the patient and HP, tailored to the patient's concerns. HPs completed a logbook detailing the mode of therapy, duration and referrals made. A psychiatrist provided weekly supervision in group format, giving HPs the opportunity to discuss cases and seek guidance. Supervision sessions were conducted according to a purpose-designed manual, audio-recorded, and a subset analysed to assess change in clinical practice, reported elsewhere [16].

**Outcome measures**

The primary outcome measure was the difference in HADS scores ten weeks after recruitment compared to baseline. The HADS [17] is a 14-item scale used extensively in studies of cancer patients, with good reliability and validity. Scores of 22 and above represent severe disorder and less than eight no disorder.

Secondary outcomes were: Quality of Life (FACT-G, with Physical, Social/Family, Emotional and Functional sub-scales [18], and EQ-5D-5L, a brief self-report measure [19]); Demoralisation (Demoralisation Scale, a 24-item self-report scale measuring demoralisation in the medically ill [20]), and Unmet Needs (Supportive Care Needs Survey Short Form [21] with Psychological, Health Systems and Information, Patient Care and Support, and Physical and

Daily Living Needs subscales). Patients completed self-report questionnaires in the clinic at baseline. Follow-up measures were posted with a reply-paid envelope with subsequent telephone reminder by research personnel if necessary.

**Sample size calculations**

The primary outcome measure was change in HADS score over ten weeks from enrolment to follow-up. Estimates of HADS in similar populations [22] are a mean of 17.8 with SD=9.0, with a 10%-15% difference in mean change-scores assumed to be clinically significant. To detect this difference, with power=80%, in a before-after design assuming a baseline to follow-up correlation 0.5, approximately 200 patients in each group are needed (Stata IC, version 10). In the absence of information regarding clustering by site a design effect of 1.5 was employed, requiring 600 patients in total across five sites, so we sought to enrol 120 patients per clinic. This design effect corresponds to an intra-class correlation of approximately 0.03 for this stepped wedge design. Since one site withdrew early from the study, the remaining four sites with an average of 20 patients per site per epoch had 80% power to detect a difference of 4.2 HADS units under the same assumptions as above.

**Statistical analysis**

Summary statistics describing demographic and baseline characteristics of intervention and control patients are presented as mean+/- SD or proportions. Due to the inherent imbalance in the proportion of patients receiving the intervention across sites, the average difference of each baseline characteristic between intervention and control patients within each site was estimated using a linear mixed model with random centre effects or generalised linear mixed risk difference model as appropriate. Differences in demographic and baseline characteristics across the four sites were assessed by null linear mixed models with p-values determined from

the variance component for site using a chi-squared test with a mixture of zero and one degree of freedom.

Analyses of the continuous primary outcome variables were performed using change from baseline to 10 weeks (i.e. 10-week value – baseline value) as the dependent variable employing linear mixed models adjusting for study epoch, the baseline of the outcome variable and demographic characteristics exhibiting evidence of being differentially distributed across the intervention and control arms, namely age, gender, education level, chemotherapy, radiotherapy and surgery in past 2 months. For outcome variables with a scale on a limited range, these analyses were repeated using ordinal logistic random effects regression models with the 10-week outcome as the dependent variable and adjusting for the baseline of the outcome, and results presented as adjusted odds ratios with confidence intervals.

Analyses of the effect of the different allocations (i.e. usual care; written resources; intervention; specialist treatment) were obtained by classifying patients in the control epochs into the allocation they would have received had they been enrolled in intervention epochs. Then, for each type of allocation, intervention patients were compared with their counterpart control patients. These allocation effects were assessed jointly in multivariable models for each outcome using an "allocation type" by binary "actual allocation" interaction term, and adjusting for the same factors as in the combined allocation model for the outcome. Evidence for differing effects of the different types of allocations was assessed by the statistical significance of the interaction term using a Wald test with 3 degrees of freedom.

Missing data were assessed by development of a prediction model for individual's 10-week outcome being missing, followed by inverse probability-of-missingness weighting of the above

regression models. Since these resulted in only minimal differences from the unweighted complete case results, only the unweighted results are presented.

Insert Figure 2 about here

**Results**

Of 902 patients screened, 224 declined participation because they felt too unwell or that participation would pose a burden. We excluded 187 who were already receiving treatment for depression or were otherwise not eligible. We recruited 222 patients during control epochs and 247 during intervention epochs. Most participants were female, married, not currently employed, and were receiving chemotherapy. At baseline the intervention group had more women than the control group (p=0.01), and more who had undergone surgery within the previous two months (p=0.002) (Table 1). One-third of all patients had disease progression.

Insert Table 1 about here

Insert Table 2 about here

Thirty-seven HPs completed training. Ten withdrew before completion of the study, the majority because of change in work or personal circumstances. The remainder were all female, comprising oncology nurses (19), physiotherapists (3), radiation therapists (2), cancer care coordinators (2) and one occupational therapist. HPs had worked an average of 11.83 years in oncology (range 1-34, SD 8.62).

Insert Table 3 about here

Table 2 presents baseline patient scores. Of patients recruited in the intervention epochs, 112 were allocated to written resources, 115 to the intervention and 18 to specialist treatment.

Complete HP logbooks were obtained for 275 intervention sessions provided for 84 patients. The average duration of each session was 26 minutes (SD 12.9) and the average number of sessions per patient was 3.2 (SD 0.95). Logbooks recorded that 120 sessions (43.6%) were conducted face-to-face, the remainder by telephone. Thirty-three patients received a total of 53 referrals (e.g. to physiotherapy).

Outcomes for 177 patients recruited in intervention epochs were compared with 181 patients recruited during control epochs. There were no statistically significant differences between groups for any of the outcome measures (Table 4, $p>0.20$ for all measures). Adjustment for missing data due to loss to follow-up using inverse probability weighting of baseline factors predictive of loss to follow-up did not alter the conclusions ($p>0.16$ for all measures).

Insert Table 4 about here

In exploratory post-hoc analyses we examined whether the effect of the intervention differed according to selected factors unique to this study, namely: i) we included patients with HADS scores of 8 and over, other studies using HADS scores of 15 or over, and ii) we included a large proportion of patients currently receiving cancer treatments and a high proportion of patients with advanced disease, and iii) we offered a range of sessions up to four in total. Among patients with a baseline HADS total score of 15 or greater, there was an increase in the Anxiety/Depression subscale of the EuroQol of 0.42 in intervention patients but not in control patients (-0.26, $p=0.02$). This difference was not apparent in patients with baseline HADS <15 ($p=0.60$, interaction $p=0.001$). The intervention displayed a significantly greater benefit over control for patients with disease progression compared to its effect for those without disease progression for Supportive Care Needs in the following domains: Health Systems and Information (interaction $p=0.032$), Patient Care and Support ($p=0.012$) and Physical and Daily

Living (p=0.016). Among control epoch patients, those with higher HADS scores at baseline were more likely to demonstrate a reduction of 1 point or more in HADS anxiety, depression or total scores over the 10-week period ($p<0.04$ for all HADS measures). Patients who received 1 or 2 therapy sessions experienced a greater reduction in HADS depression score than those who received 3 or more sessions (mean +/- SD of change was -1.7+/- 4.1 with 1 or 2 sessions , and 0.24+/- 3.6 with 3 or more sessions, p=0.009).

The feasibility of delivering this model of brief psychosocial care was maximal for HPs with greater autonomy and flexibility in their clinical roles such as care coordinators and physiotherapists. Oncology nurses working in inpatient units or day units administering chemotherapy reported greater difficulty accommodating the therapy within the demands of their clinical roles.

**Discussion**

Identification and treatment of depression in patients with cancer is a major imperative as it is common [23] undermines adherence to treatment [24], compounds distress, and increases health care costs [2]. The clinical challenge is in ascertaining which patients are depressed, and providing timely treatment despite the paucity of health professionals with psychosocial expertise in many treatment settings. Our study was designed to assess a model of psychosocial care which was brief, delivered by "front-line" cancer care professionals, as this has implications for clinical generalisability. The brief intervention in this trial was not effective as a stand-alone intervention in reducing depression in patients with cancer. The result may relate to the nature of the intervention, patient selection, the training of health professionals who delivered the intervention or a combination of these, discussed below.

Effective studies of treatment for depressed cancer patients have been intensive, typically at least 10 sessions [3], drawing on a cognitive-behaviour therapy framework, in patients treated with antidepressant medication [25], in many instance with a specific focus on enhancing compliance with antidepressant therapy [26,27] including use of a stepped pharmacotherapy algorithm and an emphasis on enhancing compliance with antidepressant therapy [4]. However emerging evidence suggests that brief interventions may be as effective as complex longer-term interventions [28,29]. This has intuitive appeal in a patient population coping with the demands of treatment and disease burden, and represents an efficient use of scarce therapist resources. We wanted to assess the minimum requirement for therapy to be of benefit both in number of sessions and duration of sessions, as these have clear cost implications and may also influence patient acceptability. Hence we offered patients up to four sessions, each of up to 30 minutes in duration. Our finding that patients who received fewer sessions had a greater reduction in HADS scores is not consistent with reports that intensive longer-term therapies are needed to achieve benefit [30,31]. However it should be noted that in this study the decision regarding the number of sessions was based on patient need. Hence fewer sessions reflects lower levels of patient distress, meaning that these patients were more likely to improve because their perceived needs were lower.

Another critical point of difference in this study was the exclusion of patients taking antidepressant medication. This was based on evidence that patients may be reluctant to consider use of antidepressant medication [7], and evidence of variability of effectiveness and tolerability in cancer patients [32]. We aimed to provide an intervention which was brief and acceptable and which did not include treatment with antidepressant medication. Hence it is not clear if a brief intervention might improve depression in patients who are taking antidepressant medication.

We aimed to deliver an intervention tailored to the individual's unique needs, based on a number of factors. Our understanding of the development of depression in cancer patients is incomplete. It is likely that the disorder represents a final common pathway of a complex and interacting constellation of personal attributes and social factors superimposed on disease processes, symptoms and burden, treatments and their adverse effects [33]. In addition, for those with poor prognosis, the inevitable existential concerns [34] and concerns about family [35] are unlikely to be fully met with a cognitive-behavioural approach. Indeed the precise components of cognitive-behavioural therapies which are effective for depressed cancer patients are not clear [36], and emerging research suggests that the effectiveness of cognitive therapies is less substantial than reported in seminal studies [37]. Thus the nature of therapy in this study extended beyond a cognitive-behavioural approach focused solely on depressed mood, and ranged from a focus on practical issues to more challenging issues including end-of-life decision-making, incorporating aspects of dignity promotion and supportive-expressive techniques. Hence detection of differences in effectiveness may relate in part to comparison of small representative samples of the various therapy components. Of further note, given the high prevalence of depression in the community [38], it is likely that at least some of the patients in this study had pre-existing depression which may have been less amenable to change, particularly if symptoms were long-standing. The brief intervention delivered in this study focused on cancer-related concerns.

We aimed to examine a model of psychosocial care provided by novel service providers rather than one which relied solely on highly-specialised psychologists and psychiatrists. Oncology nurses have been trained to provide a focused intervention for depressed cancer patients, leading to improvements in depression [3]. We aimed to determine if other front-line health professionals without psychosocial expertise could be trained to provide psychosocial care. In addition to enhancing capacity, the embedding of psychosocial care into routine clinical

practice is likely to improve patient access and reduce stigma, hence increase acceptability. We based our training on a model previously demonstrated to improve knowledge, skills and confidence of oncology nurses [39]. Psychosocial training and clinical supervision were acceptable for participating HPs who self-reported changes in skills and attitudes which they considered enhanced their clinical practice beyond the scope of the study. However it appears that the skills developed by the HPs in our study were insufficient for them to remediate depression. This may be because the training was broad in focus with insufficient attention to alleviation of depressive symptoms. It is also likely that the HPs were more focused on practical problem identification and support, consistent with their background training. This finding is also consistent with findings that better results in therapy are noted with more experienced therapists [37].

This study examined feasibility of a stepped model of care in a clinical setting. Although not effective in improving depression we demonstrated that information and support provided by health professionals improved a number of areas of practical needs of patients with disease progression, a population whose practical needs may be overlooked in acute care settings. Further research is necessary to determine the precise components of therapy likely to be of most benefit for depressed cancer patients in routine clinical care.

**Limitations:**

The intervention was tailored to the individual's unique needs. Thus the intervention ranged from a focus on practical issues to more challenging issues including end-of-life decision-making. Hence detection of differences in effectiveness may relate in part to comparison of a range of differing therapeutic strategies. We aimed to evaluate a model of care in routine clinical practice, and included a heterogeneous patient population. One-third of patients in our study had disease progression and the majority were receiving active anti-cancer treatment.

The intervention was feasible to deliver for this population but their inclusion is likely to be an additional factor contributing to a null result.

Although the stepped-wedge design has appeal in evaluation of psychosocial interventions, it is vulnerable to significant loss of information from withdrawal of sites due to its heavy reliance on comparisons pre- and post-intervention within each site. The withdrawal of a clinical site in this study highlights the importance of having a suitably large number of participating sites to be able to accommodate such attrition. With our remaining sites the detectable difference was 4.2 HADS units, which many would consider a large difference to detect, particularly in a non-clinically-depressed population such as ours. In addition, the brief duration of follow-up means that any emergent improvement in depression was not able to be detected.

The development and evaluation of complex interventions is emerging as a key theme in clinical research, and incorporation of process measures may shed light on the outcomes [40]. Inclusion of in-depth interviews with participants in studies of this kind may assist in defining core aspects of therapy which are considered beneficial and understanding factors underpinning acceptability of this therapy.

**Conflict of interest statement:** We declare that we have no conflict of interest

**Disclosures:** None

**Funding**: *beyondblue*: the national depression initiative. (Study ID:631570)

The funding body had no role in the study design, collection, analysis or interpretation of data, or writing of report, or decision to submit for publication. The authors have no financial relationship with the funding source, The authors have full control of all primary data and agree to allow the journal to review data if requested

**Ethical approval:** All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**REFERENCES**


1. Holland J, Watson M, Dunn J (2011) The IPOS new international standard of quality cancer care: integrating the psychosocial domain into routine care. Psycho-Oncol 20: 677-680

2. Kroenke K, Theobald D, Wu J, Loza JK, Carpenter JS, Tu W (2010) The association of depression and pain with health-related quality of life, disability, and health care use in cancer patients. J Pain Symptom Manag 40:327-341

3. Strong V, Waters R, Hibberd C, Murray G, Wall L, Walker J, McHugh G, Walker A, Sharpe (2008) Management of depression for people with cancer (Smart oncology 1): a randomised trial. Lancet 372: 40-48

4. Fann JR, Fan M-Y, Unuetzer J (2009) Improving primary care for older adults with cancer and depression. J Gen Intern Med 24: 417-424

5. Ell K, Xie B, Quon B, Quinn DL, Dwight-Johnson M, Lee P-J (2008) Randomized controlled trail of collaborative care management of depression among low-income patients with cancer. J Clin Oncol 26: 4488-4496

6. Rankin N, Barron JA, Lane LG, et al (2011) Psychosocial oncology services in New South Wales. Aust Health Rev 35: 156-163

7. Dilworth S, Higgins I, Parker V, Kelly B, Turner J (2014) Patient and health professionals' perceived barriers to the delivery of psychosocial care to adults with cancer: a systematic review. Psycho-Oncol 23: 601-614

8. Wu SM, Brothers BM, Farrar W, et al (2014) Individual counseling is the preferred treatment for depression in breast cancer survivors. J Psychosoc Oncol 32:637-646

9. Griffith JL, Gaby L. (2005) Brief psychotherapy at the bedside: Countering demoralisation from medical illness. Psychosomatics 46: 109-116

10. Butow P, Price M, Shaw JM, Turner J, Clayton J, Grimison P, Rankin N, Kirsten L (2015) Clinical pathway for the screening, assessment and management of anxiety and depression in adult cancer patients: Australian guidelines. Psycho-Oncol 24: 987-1001

11. Hussey MA, Hughes JP (2007) Design and analysis of stepped wedge cluster randomised trials. Contemp Clin Trials 28: 182-191

12. Turner J, Kelly B, Clarke D, Yates P, Aranda S, Jolley D, Chambers S, Hargraves, McFadyen L (2011) A randomized trial of a psychosocial intervention for cancer patients integrated into routine care: the PROMPT study (promoting optimal outcomes in mood through tailored psychosocial therapies). BMC Cancer 11: 48

13. National Breast Cancer Centre and National Cancer Control Initiative. Clinical practice guidelines for the psychosocial care of adults with cancer. National Breast Cancer Centre, Camperdown, NSW. 2003.

14. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™) for Distress Management V.1.2011. © 2010 National Comprehensive Cancer Network, Inc.

15. Donovan KA, Grassi L, McGinty HL, Jacobsen PB (2014) Validation of the distress thermometer worldwide: state of the science. Psycho-Oncol 23: 241-250

16. Dilworth S, Higgins I, Parker V, Kelly B, Turner J (2014) Examining clinical supervision as a mechanism for changes in practice: a research protocol. J Adv Nurs 70: 421-430

17. Zigmond AS, Snaith RP (1983) The Hospital Anxiety and Depression Scale. Acta Psychiatr Scand 67:362-370

18. Cella DF, Tulsky DS, Gray G. Sarafian B, Linn E, Bonomi A, Silberman M, Yellen SB, Winicour P, Brannon J (1993) Functional Assessment of Cancer Therapy (FACT) scale: Development and validation of the general measure. J Clin Oncol 11:570-579

19. EuroQol Group: EuroQol – a new facility for the measurement of health-related quality of life. The EuroQol Group (1990) Health Policy 16: 199-208

20. Kissane DW, Wein S, Love A, Lee XQ, Kee PL, Clarke DM (2004) The Demoralization Scale: a report of its development and preliminary validation. J Palliat Care 20: 269-276

21. Bonevski B, Sanson-Fisher RW, Girgis A, Burton L, Cook P, Boyes A and the Supportive Care Review Group (2000) Evaluation of an instrument to assess the needs of patients with cancer. Cancer 88: 217-225

22. Cameron IM, Crawford JR, Lawton K, Reid IC (2008) Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. Brit J Gen Pract 58: 32-36

23. Zabora J, Brintzenmhofeszoc K, Curbow B, Hooker C, Piantadosi S (2001) The prevalence of psychological distress by cancer site. Psycho-Oncol 10:19-28

24. DiMatteo MR, Lepper HS, Croghan TW (2000) Depression is a risk factor for noncompliance with medical treatment. Meta-analysis of the effects of anxiety and depression on patient adherence. Arch Intern Med 160:2101-2107

25. Hopko DR, Aremento MEA, Robertson SMC, Ryba MM, Carvalho JP, Colman LK, Mullane C, Gawrysiakl Bell J, McNulty JK, Lejuez CW (2011) Brief behavioural activiation and problem-solving therapy for depressed breast cancer patients: Randomized trial. Journal of Consulting and Clinical Psychology 79:834-849

26. Sharpe M, Walker J, Hansen CH, Martin P, Symeonides S, Gourley C, Wall L, Weller D, Murray G for the SMaRT (Symptom Management Research Trials) Oncology-2 Team (2014) Integrated collaborative care for comorbid major depression in patients with cancer (SMaRT Oncology-2): a multicentre randomised controlled effectiveness trial. Lancet 384: 1099-1108

27. Walker J, Hansen CH, Martin P, Symeonides S, Gourley C, Wall L, Weller D, Murray G, Sharpe M for the SMaRT (Symptom Management Research Trials) Oncology-3 Team (2014) Integrated collaborative care for major depression comorbid with a poor prognosis cancer (SMaRT Oncology-3): a multicentre randomised controlled trial in patients with lung cancer. Lancet Oncol 15: 1168-1176

28. Lovell K, Richards D (2000) Multiple access points and levels of entry (MAPLE): ensuring choice, accessibility and equity for CBT services. Behav Cogn Psychoth 28: 379-391

29. Willemse GR, Smit F, Cuijpers P, Tiemens BG (2004) Minimal-contact psychotherapy for sub-threshold depression in primary care. Brit J Psychiat 185: 416-421

30. Faller H, Schuler M, Richard M, Heckl U, Weis J, Kuffner R (2013) Effects of Psycho-Oncologic Interventions on Emotional Distress and Quality of Life in Adult Patients with Cancer: Systematic Review and Meta-analysis. J Clin Oncol 31: 782-793

31. Walker J, Sawhney A, Hansen CH, Ahmed S, Martin P, Symeonides S, Murray G, Sharpe M (2014) Treatment of depression in adults with cancer: a systematic review of randomized controlled trials. Psychol Med 44: 897-907

32. Riblet N, Larson R, Watts BV, Hotlzheimer P (2014) Reevaluating the role of antidepressants in cancer-related depression: a systematic review and meta-analysis. Gen Hosp Psychiat 36:466-473

33. Peveler R, Carson A, Rodin G (2002) Depression in medical patients BMJ 325:149-152

34. Chochinov HM, Hack T, Hassard T, Kristjanson LJ, McClement S, Harlos (2005) Dignity therapy: a novel psychotherapeutic intervention for patients near the end of life. Journal of Clinical Oncology 23:5520-5525

35. Wentlandt K, Burman D, Swami N, Hales S, Rydall A, Rodin G, Lo C, Zimmerman C (2012) Preparation for the end of life in patients with advanced cancer and association with communication with professional caregivers. Psycho-Oncol 21:868-876

36. Johnsen TJ, Friborg O (2015) The effects of cognitive behaviour therapy as an anti-depressive is falling: A meta-analysis. Psychological Bulletin 141;747-768

37. Rodin G (2014) Effective treatment for depression in patients with cancer. Lancet 384:1076-1078

38. Patel V, Chisholm D, Parikh R et al (2016) Addressing the burden of mental, neurological, and substance use disorders: key messages from *Disease Control Priorities*, 3rd edition. Lancet 387: 1672-1685

39. Turner J, Clavarino A, Butow P, Yates P, Hargraves M, Connors V, Hausmann S (2009) Enhancing the capacity of oncology nurses to provide supportive care for parents with advanced cancer: Evaluation of an educational intervention. Eur J Cancer 45: 1798-1806

40. Craig P, Dieppe P, Macintyre S, et al (2008) Developing and evaluating complex interventions: the new Medical Research Council guidance. Brit Med J 337: 979-983

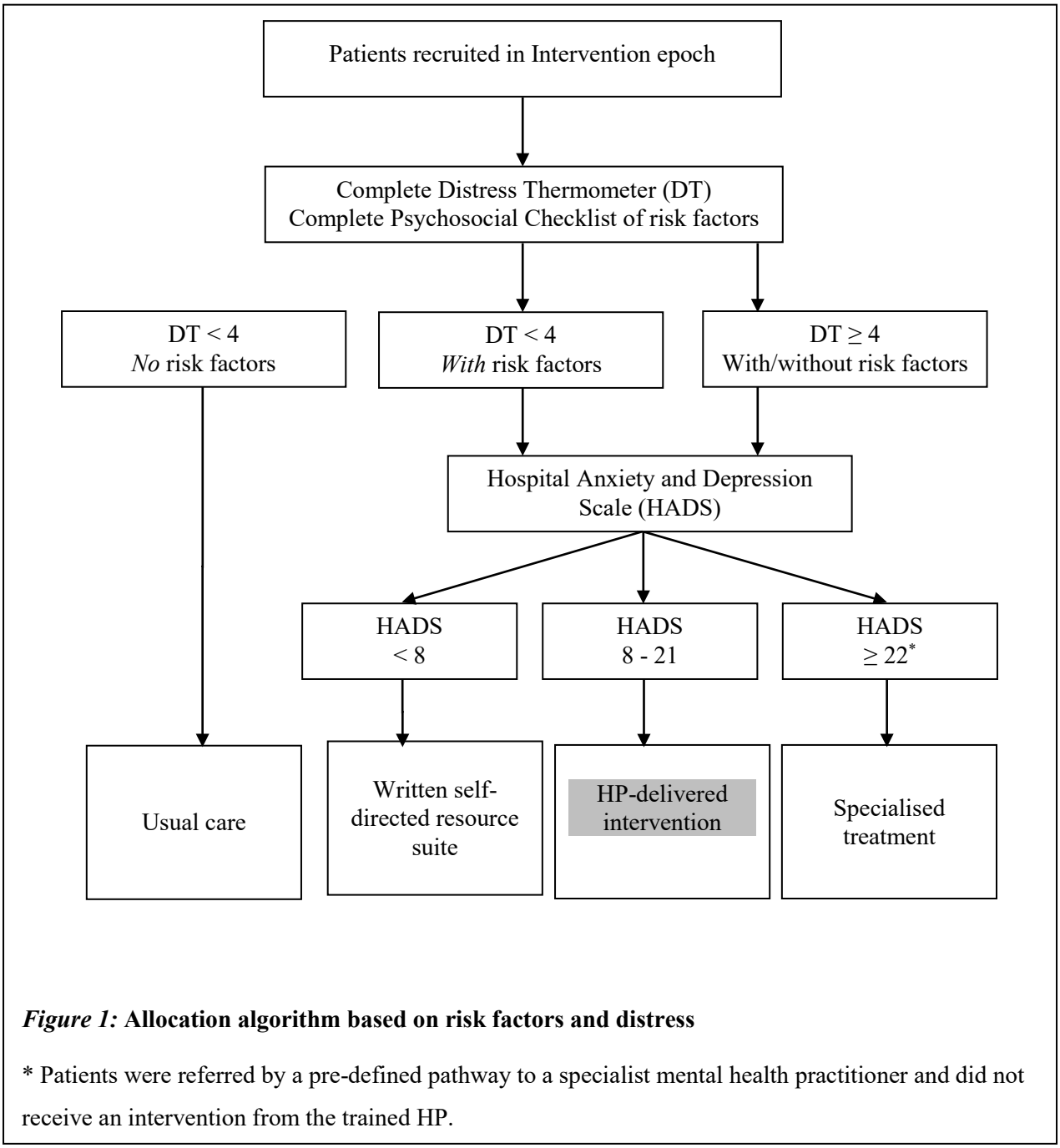


***Figure 1:*** **Allocation algorithm based on risk factors and distress**

* Patients were referred by a pre-defined pathway to a specialist mental health practitioner and did not receive an intervention from the trained HP.

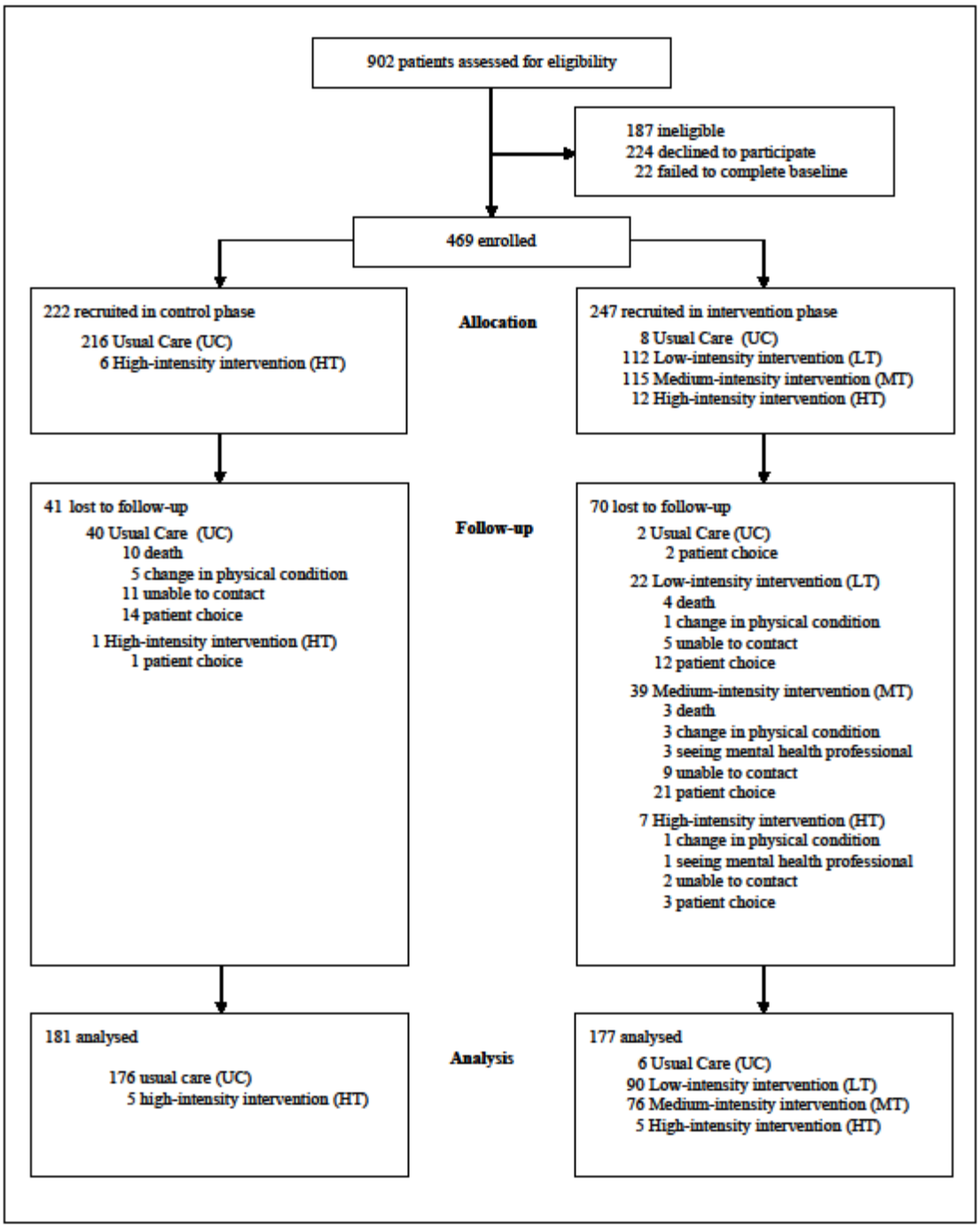


***Figure 2:*** **Trial profile**

| | Intervention Group (n=247) | | Control Group (n=222) | |
|---|---|---|---|---|
| **Sex** | | | | |
| Male | 64 | (26%) | 76 | (34%) |
| **Age** | | | | |
| Mean (SD) | 56.5 | (12.77) | 61.2 | (12.73) |
| ≤ 50 years | 79 | (32%) | 47 | (21%) |
| 51–65 years | 104 | (42%) | 84 | (38%) |
| ≥ 66 years | 64 | (26%) | 91 | (41%) |
| **Marital status** | | | | |
| Single | 52 | (21%) | 34 | (15%) |
| Married/de Facto | 162 | (66%) | 161 | (73%) |
| Separated/Divorced | 31 | (13%) | 24 | (11%) |
| Not stated | 2 | (<1%) | 3 | (1%) |
| **Employment** | | | | |
| Full time | 62 | (25%) | 39 | (18%) |
| Part time | 25 | (10%) | 34 | (15%) |
| Not working | 154 | (63%) | 146 | (66%) |
| Not stated | 6 | (2%) | 3 | (1%) |
| **Education** | | | | |
| Less than high school | 47 | (19%) | 49 | (22%) |
| High school | 71 | (29%) | 63 | (28%) |
| Trade/College | 64 | (26%) | 72 | (33%) |
| University | 61 | (25%) | 36 | (16%) |
| Not stated | 4 | (2%) | 2 | (1%) |
| **Treatment within past 2 months *** | | | | |
| Radiotherapy | 47 | (19%) | 13 | (6%) |
| Surgery | 78 | (31%) | 50 | (23%) |
| Adjuvant Chemotherapy | 153 | (63%) | 115 | (52%) |
| Palliative Chemotherapy | 52 | (21%) | 42 | (19%) |
| **Disease stage** | | | | |
| Progression | 80 | (32%) | 74 | (33%) |

Data are n (%) or mean (SD). *As some patients have received a combination of treatments totals can exceed 100%.

**Table 1: Baseline characteristics of the intention-to-treat population**

| Primary Cancer | Baseline group (n=469) | | Disease progression (n=156) | |
|---|---|---|---|---|
| Gynaecological | 123 | (26%) | 36 | (29%) |
| Breast | 100 | (21%) | 26 | (26%) |
| Blood | 73 | (16%) | 18 | (25%) |
| Gastrointestinal | 67 | (14%) | 29 | (43%) |
| Head and Neck | 25 | (5%) | 7 | (28%) |
| Lung | 22 | (5%) | 12 | (55%) |
| Renal/Bladder/Prostate | 23 | (5%) | 11 | (48%) |
| Pancreatic | 8 | (2%) | 3 | (38%) |
| Liver | 5 | (1%) | 2 | (40%) |
| Other* | 23 | (5%) | 12 | (52%) |

Data are n or n (%). * Primary cancers with < 5 per group.

**Table 2: Site of primary cancer and disease progression at baseline**

| | Intervention (n=247) | | Control (n=222) | |
|---|---|---|---|---|
| **HADS** | | | | |
| Total score | 8.80 | (6.30) | 8.58 | (5.90) |
| Anxiety | 4.77 | (3.82) | 4.82 | (3.76) |
| Depression | 4.03 | (3.29) | 3.76 | (3.18) |
| **EQ-5D** | | | | |
| Mobility | 1.50 | (0.86) | 1.60 | (0.85) |
| Personal care | 1.17 | (0.45) | 1.14 | (0.47) |
| Usual activities | 1.94 | (1.02) | 1.91 | (1.04) |
| Pain/discomfort | 1.85 | (0.89) | 1.81 | (0.89) |
| Anxiety/depression | 1.49 | (0.67) | 1.48 | (0.78) |
| Visual analogue scale | 71.88 | (17.90) | 71.90 | (20.39) |
| **SCNS-S34** | | | | |
| Psychological | 23.32 | (9.87) | 22.43 | (8.88) |
| Health systems and information | 22.94 | (7.56) | 22.49 | (6.49) |
| Patient care and support | 9.53 | (2.63) | 9.24 | (2.49) |
| Physical and daily living | 12.68 | (4.87) | 12.17 | (5.19) |
| Sexuality | 5.14 | (2.49) | 5.04 | (2.35) |
| **FACT-G** | | | | |
| Physical well-being | 21.44 | (4.89) | 21.61 | (5.46) |
| Social/family well-being | 22.53 | (5.38) | 22.55 | (5.37) |
| Emotional well-being | 19.11 | (4.15) | 19.61 | (3.97) |
| Functional well-being | 18.45 | (5.90) | 19.19 | (6.23) |
| **Demoralisation Scale** | | | | |
| Score | 18.11 | (14.15) | 17.14 | (14.11) |

Data are mean (SD). HADS = Hospital Anxiety and Depression Scale. EQ-5D = EuroQol-5 dimensions. SCNS-S34 = Supportive Care Needs Survey – Short Form. FACT-G = Functional Assessment of Cancer Scale - General.

**Table 3: Scores for patient–reported outcomes at baseline**

| | Mean change from baseline | | Adjusted Difference (CI) | p value |
|---|---|---|---|---|
| | Intervention (n = 177) | Control (n = 181) | | |
| **HADs** | | | | |
| Total score | 0.36 (5.38) | 0.71 (4.80) | -1.23 (-3.81 to 1.35) | 0.35 |
| Anxiety | -0.01 (2.99) | 0.07 (2.91) | -0.86 (-2.35 to 0.63) | 0.26 |
| Depression | 0.37 (3.22) | 0.65 (3.01) | -0.17 (-1.61 to 1.26) | 0.82 |
| **EQ-5D** | | | | |
| Mobility | 0.14 (0.88) | 0.02 (0.82) | -0.15 (-0.50 to 0.20) | 0.41 |
| Personal care | 0.08 (0.51) | 0.04 (0.59) | 0.17 (-0.09 to 0.42) | 0.21 |
| Usual activities | 0.09 (1.13) | 0.07 (1.02) | -0.25 (-0.68 to 0.17) | 0.24 |
| Pain/discomfort | 0.14 (0.82) | 0.06 (0.88) | -0.20 (-0.55 to 0.16) | 0.29 |
| Anxiety/depression | 0.06 (0.72) | 0.07 (0.69) | 0.07 (-0.28 to 0.42) | 0.68 |
| Visual Analogue Scale (VAS) | -1.66 (18.95) | 0.75 (17.94) | 1.55 (-5.70 to 8.80) | 0.68 |
| **SCNS-S34** | | | | |
| Psychological | -1.19 (7.86) | 0.16 (7.34) | -0.24 (-3.89 to 3.41) | 0.90 |
| Health systems and information | -0.20 (7.76) | 0.67 (8.67) | 0.13 (-3.08 to 3.35) | 0.93 |
| Patient care and support | 0.05 (3.18) | 0.18 (3.15) | 0.76 (-0.53 to 2.05) | 0.25 |
| Physical and daily living | 0.06 (4.19) | 0.72 (4.54) | 0.69 (-1.84 to 3.22) | 0.59 |
| Sexuality | 0.32 (2.47) | -0.03 (2.28) | 0.22 (-0.84 to 1.28) | 0.68 |
| **FACT-G** | | | | |
| Physical well-being | 0.60 (4.76) | 0.64 (4.73) | -0.89 (-2.88 to 1.10) | 0.38 |
| Social/family well-being | 0.18 (3.75) | 0.31 (4.04) | -0.28 (-2.03 to 1.47) | 0.76 |
| Emotional well-being | -0.23 (3.42) | 0.29 (3.14) | -0.94 (-2.47 to 0.58) | 0.22 |
| Functional well-being | 0.20 (5.04) | 0.05 (5.17) | -0.04 (-2.19 to 2.11) | 0.97 |
| **Demoralisation Scale** | | | | |
| Score | 1.11 (9.61) | 1.69 (8.59) | -1.02 (-5.39 to 3.36) | 0.65 |
| **Distress Thermometer** | | | | |
| Score | -0.15 (2.76) | -0.16 (2.98) | -0.25 (-1.40 to 0.91) | 0.67 |

Data are mean change from baseline (SD) or adjusted difference (CI). For each measure a positive change in mean score from baseline represents; HADS, an increase in anxiety and depression; EQ-5D (excluding VAS), lower quality of life; EQ-5D (VAS), better health; SCNS-S34, higher perceived need for help; FACT-G, higher quality of life; DS, higher levels of demoralisation and DT, more distress.

**Table 4: Changes from baseline between Intervention and control groups**