Brief Metacognitive Therapy for Emotional Distress in Adult Cancer Survivors

Peter L. Fisher^{1,2*}, Angela Byrne^{1,2}, Louise Fairburn^{1,2}, Helen Ullmer^{1,2} Gareth Abbey¹ and

Peter Salmon^{1,2}

¹ Psychological Sciences, University of Liverpool, Liverpool United Kingdom

² Liverpool Psychology Cancer Service, Royal Liverpool and Broadgreen NHS Trust

Running title: Brief MCT for cancer survivors

*Correspondence

Peter L. Fisher
Department of Psychological Sciences
University of Liverpool
Whelan Building, Brownlow Hill
Liverpool L69 3GB
United Kingdom

Phone: +44 (0)151 794 4160; fax: +44 (0)151 794 5537

Email: peter.fisher@liverpool.ac.uk

ABSTRACT

Background: Adult cancer survivors often experience substantial psychological morbidity following the completion of acute cancer treatment. Unfortunately, current psychological interventions are of limited efficacy. This study explored if metacognitive therapy (MCT); a brief transdiagnostic psychological intervention was potentially efficacious and could be delivered effectively to adult cancer survivors with psychological morbidity.

Method: An open trial with 3- and 6-months follow-up evaluated the treatment effects of MCT in 27 consecutively referred individuals to a clinical psychology health service specialising in psycho-oncology. Each participant received a maximum of six 1-hour sessions of MCT. Levels of anxiety, depression, fear of cancer recurrence, post-traumatic stress symptoms, health related quality of life, and metacognitive beliefs and processes were assessed using self-report questionnaires.

Results: MCT was associated with statistically significant reductions across all outcome measures which were maintained through to 6 months follow-up. In the ITT sample on the primary treatment outcome measure, the Hospital Anxiety and Depression Scale-Total, 59% of participants met recovery criteria at post treatment and 52% at 6 months follow-up, respectively No participants significantly deteriorated. In the completer sample (N=20), 80% recovered at post-treatment and 70% at 6 months follow-up. MCT was acceptable to patients with approximately 75% of patients completing all treatment sessions.

Conclusion: MCT, a brief transdiagnostic psychological intervention can be delivered effectively to a heterogenous group of cancer survivors with promising treatment effects. Examining the efficacy of brief MCT against the current gold standard psychological intervention would be a valuable advance towards improving the quality of life of cancer survivors.

Keywords: Cancer survivors, Emotional distress, Metacognitive therapy, Open trial

INTRODUCTION

The incidence of cancer in the UK is projected to increase by 2% over the next 15 years with survival rates also increasing. It is estimated that survival rates have doubled over the past 40 years with a ten-year survival rate of approximately 50% (Cancer Research UK, 2017). in 2016, there were an estimated 15.5 million cancer survivors which is expected to increase to 20.3 million by 2026 (National Cancer Institute, 2018). Psychological morbidity is common in cancer survivors. Approximately 25% of cancer survivors have clinically significant levels of anxiety and depression that could benefit from treatment (Hoffman, 2009). Posttraumatic stress disorder symptoms are common in cancer survivors with estimates ranging from 6% to 45% (Swartzman et al., 2016). Fear of cancer recurrence (FCR) is highly prevalent, a systematic review concluded that almost 60% of cancer survivors experience debilitating FCR (Simard & Savard, 2015). Psychological morbidity adversely impacts ongoing cancer care by reducing attendance at follow up screening appointments (DiMatteo, Lepper & Croghan, 2000; Thewes et al., 2014), health related quality of life (Lemasters et al., 2013) and increases healthcare costs (Carlson & Butz, 2004; Jansen, et al., 2016) and use of healthcare services (Elliot et al., 2011).

1 2

The substantial prevalence and associated problems with psychological morbidity in cancer survivors requires effective interventions. Unfortunately, highly efficacious psychological interventions are unavailable (Demoncada & Feurstein, 2006; Rehse & Pukrop, 2003; Faller et al., 2013). The most widely evaluated and recommended psychological intervention is cognitive behavioural therapy (CBT) but it may be that core components of CBT; labelling cognitive distortions and reality testing negative automatic thoughts (NATs) are clinically limited where NATs will frequently reflect accurate thoughts about cancer recurrence and morbidity (Greer et al., 2010, Cook et al., 2015a). An intervention which does not need to focus on the content of cognition i.e. NATs, but instead focuses on core psychological processes underpinning psychological morbidity may be more efficacious for cancer survivors.

Metacognitive therapy (MCT; Wells, 2009) offers an alternative psychological approach to the treatment of psychological morbidity in cancer survivors. MCT is derived from a transdiagnostic theory of psychopathology, the Self-Regulatory Executive Function (S-REF) model (Wells & Matthews, 1994, 1996). The model states that psychological morbidity becomes persistent when people use the cognitive-attentional syndrome (CAS) in response to unwanted thoughts. The CAS has three broad main components; (i) perseveration (worry, rumination, over-analysing, repeatedly questioning one's thoughts); (ii) attentional strategies (a heightened focus on possible signs of threat which can be internal e.g. signs of anxiety or external e.g. reminders of cancer); and (iii) unhelpful coping strategies (e.g. searching the internet for positive outcomes by cancer survivors, avoidance of reminders of cancer).

The S-REF model states that perseveration is guided by positive metacognitive beliefs about the helpfulness of worry and rumination: e.g. "worry will help me be better prepared", worry will ensure that I complete my daily tasks". Unfortunately, worry and rumination achieve the opposite, because the person experiences more negative thoughts and views more situations as potentially dangerous. The individual repeatedly acts as if unwanted negative thoughts are meaningful which leads to the development of an inflexible way of responding to thoughts. A more flexible response style can help to alleviate perseveration. Similarly, the S-REF model specifies that threat monitoring (e.g. scanning for symptoms or for negative thoughts) is determined by positive metacognitive beliefs. More specifically, a person comes to believe that scanning the environment or one's mind and/or body for symptoms will reduce distress

whereas it leads to the persistence of threat and distress. Furthermore, negative metacognitive beliefs about the uncontrollability and danger of worry sustain and increase worry. Modifying negative metacognitive beliefs is fundamentally important in the S-REF model because, if patients believe that worry is uncontrollable, they will not attempt to control it. Therefore, it is possible that through targeting metacognitive beliefs and processes rather than cognitive content, MCT offers a particularly close 'fit' with the needs of cancer survivors indicating potential for greater efficacy (McNicol et al., 2013).

> The development of MCT for psychological morbidity in cancer is evolving with encouraging evidence for the explanatory and therapeutic utility of MCT. There is increasing evidence for the role of metacognitive beliefs and processes in emotional distress in cancer survivors from cross-sectional and prospective studies (Butow, et al., 2015; Thewes, Bell, & Butow, 2013; Cook et al., 2014, Cook et al., 2015a; Cook et al., 2015b; Fisher et al., 2018 and in adult cancer patients undergoing chemotherapy (Quantropani et al., 2016; Quatropnai, Lenzo, & Filastro, 2017). There have been two tests of the potential efficacy of MCT in cancer survivor. First, an open trial of MCT for emotional distress in adolescent and young adult cancer survivors found clinically significant reductions in anxiety, depression and posttraumatic stress symptoms (Fisher et al., 2015). Second, a multiple baseline study of MCT in four adult cancer survivors (Fisher, Byrne, & Salmon, 2017) reported substantial reduction in anxiety, depression and fear of cancer recurrence over six one-hour sessions These studies illustrate that MCT can rapidly alleviate psychological morbidity in cancer patients but before progressing to a randomised controlled trial, further evidence of the potential efficacy and feasibility of delivering MCT is required. The present study therefore examined if MCT delivered over six one-hour individual treatment sessions would result in clinically significant improvements in anxiety, depression, posttraumatic stress symptoms, fear and cancer recurrence and overall quality of life immediately following treatment and over a six-month follow-up period. The study also examined if MCT would be associated with reductions in the metacognitive beliefs and processes.

Materials and Method

Design

An open trial with follow-up at 3 and 6 months evaluated the potential efficacy of brief MCT for adult survivors of cancer experiencing emotional distress. Data was also gathered on recruitment and retention rates. Ethical approval was provided by the National Health Service North West Research Ethics Committee (reference 15/NW/0820).

Participants and procedure

Potentially suitable participants were identified from consecutive referrals to an adult clinical heath psychology service which specialises in psychological interventions for cancer patients. Those patients with elevated scores on the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) and indicated a willingness to be approached for possible participation in an intervention were provided with an information sheet about the study. Those patients were contacted and invited to attend an assessment appointment to determine their suitability for inclusion. Following the informed consent procedure, clinical and demographic data was obtained by interview and participants completed a range of questionnaires assessing the severity of psychological morbidity (see section on measures). Participants also completed all questionnaires at posttreatment, and again at 3- and 6-months follow-up. All questionnaires were returned to an independent assessor who scored and entered the data.

Twenty seven cancer survivors participated in the study and met the following inclusion criteria: i) a score of >15 on the Hospital Anxiety and Depression Scale-Total (HADS-T); ii) had been diagnosed with cancer ≥6 months previously; iii) were aged 18 years or over; iv) had completed acute medical treatment for cancer (i.e. chemotherapy, radiotherapy, surgery); v) were not receiving concurrent psychological treatment; vi) were not actively suicidal; vii) reported no current substance use; vii) were not experiencing a psychotic or organic illness; viii) were free from psychotropic medication or has been on a stable dose for at least 8 weeks; and (viiii) were able to speak and understand English.

Intervention

100

101

102

103

104

105

106

107 108 109

110

111112

113

114

115 116

117

118 119

120

121 122

123124

125

126

127

128

129

130

131132133

134

141

149

MCT was delivered over a maximum of 6 individual face-to face sessions that were 45-60 minutes in duration. The intervention followed a manualized protocol (Wells, 2009). As the intervention was transdiagnostic, MCT followed the same protocol for each patient in the study regardless of symptom presentation. In session 1, the formulation template used when treating depression served as the basis for the development of an idiosyncratic case formulation for each participant, thus following the approach adopted in previous evaluations of MCT for cancer survivors (McNicol et al., 2013; Fisher et al., 2015; Fisher, Byrne, Salmon, 2017). The next step in treatment is socialization which proceeds by sharing the case formulation and by Socratic Ouestioning to help the patient understand that each aspect of the CAS and several types of metacognitive beliefs are maintaining emotional distress. MCT then focuses on modifying negative beliefs about uncontrollability of rumination/worry through training in detached mindfulness (DM) and in rumination/worry postponement (Wells, 2009). Patients are helped to understand how naturally occurring thoughts (e.g. "I'm useless", "What if my cancer comes back?", "My family will not be able to cope") do not necessarily lead to perseveration.). Rumination/worry postponement is a behavioural experiment to challenge the negative metacognitive belief that perseveration is an uncontrollable process. Positive metacognitive beliefs about the helpful nature of worry/rumination and the other unhelpful coping responses are also highlighted to the patients and addressed. Final sessions address relapse prevention and involve modifying remaining use of the 'cognitive attentional syndrome', reviewing any remaining conviction in positive and negative metacognitive beliefs and consolidating and alternative ways of responding to negative thoughts. Three therapists delivered MCT (PF, AB and LF). Supervision was provided by PF on a weekly basis.

Measures

- Hospital Anxiety Depression Scale (HADS; Zigmond and Snaith, 1983)
- The HADS is a 14-item self-report questionnaire measuring anxiety and depression (seven items each) over the past week. Each item is rated on a 4-point scale (0–3). Scores for each subscale range from 0 to 21 with higher scores reflecting more sever anxiety or depression. Scores of 11 or more on each of the subscales indicate caseness. Combining the two subscales provides a measure of emotional distress. The HADS-Total is the "gold standard" outcome measure for evaluating the efficacy of interventions on emotional distress in cancer

populations, and has excellent psychometric properties (Luckett et al., 2010).

142143 Impact of Events Scale-Revised (IES-R; Weiss, 2007)

- The IES-R is a 22-item self-report questionnaire measuring trauma-related symptoms The total scale score ranges from 0 to -88 with higher scores indicative of more severe trauma symptoms.

 A total good of 22 indicates a makeble diagraphic of PTSD (Waiss 2007). The IES R is
- 146 A total score of \geq 33 indicates a probable diagnosis of PTSD (Weiss, 2007). The IES-R is 147 validated for use in cancer populations with good psychometric properties (Salsman et al., 148 2015).

150 151

- Fear of Cancer Recurrence Inventory (FCRI; Simard & Savard, 2009) 152
- The FCRI is 42-item self-report questionnaire assessing 7 aspects of FCR. Each item is rated 153
- on a 5-point scale (0-4). A total score for the FCRI is obtained by summing scores on the 7 154
- subscales, with higher scores indicating greater severity (range 0-168). The FCRI is the most 155
- validated measure of FCR across a wide range of cancer types (Simard & Savard, 2009). 156
- 157
- 158 Functional Assessment of Cancer Therapy-General (FACT-G; Cellla et al., 1993)
- The FACT-G is a 27 item self-report questionnaire that measures four domains of health-159
- related quality of life (HRQOL). Each item is rated on a 5-point scale from 0 (not at all) to 4 160
- (very much). The FACT-G total score ranges from 0-108 with higher scores indicating a better 161
- 162 HRQOL. The FACT-G has been used extensively in mixed cancer populations and has
- 163 excellent psychometric properties (Brucker et al., 2005)
- 164
- Metacognitions Questionnaire-30 (MCQ-30; Wells & Cartwright-Hatton, 2004). 165
- 166 The MCQ-30 measures 5 domains of metacognition by 30 items. Participants rate the extent to
- which they "generally agree" with statements presented on a 4-point scale from 1 (do not agree) 167
- to 4 (agree very much), providing total scores for each subscale ranging from 6 to 24. Higher 168
- 169 scores indicate greater conviction in metacognitive beliefs. The MCQ-30 assesses: (1) positive
- 170 beliefs about worry, (2) negative beliefs uncontrollability and danger of worry, (3) cognitive
- confidence, (4) beliefs about the need to control thoughts, and (5) cognitive self-consciousness. 171
- 172 The MCQ-30 has been validated for use in cancer patients (Cook et al., 2014)
- 173
- 174 Cognitive Attentional Scale-1 (CAS-1; Wells, 2009)
- 175 The CAS-1 is a 10 item self-report questionnaire that assesses metacognitive processes and
- beliefs. Items 1 to 6 assess the fundamental components of the CAS (perseverative thinking, 176
- threat monitoring and unhelpful coping strategies) Each item is rated on a 10-point scale from 177
- 0 (none of the time) to 100 (all the time). Items 7 to 10 assess metacognitive beliefs and are 178
- not reported in the present study. To provide an overall measure of the CAS, the 6 items were 179
- summed and divided by the number of items. The same method has been used previously 180
- (Heffer-Rahn & Fisher, 2018; Fisher, Reilly, & Noble, 2018). 181

182 183

Statistical Analyses

- 184 Intention to treat (ITT) analyses were used to determine the potential efficacy of brief MCT for
- 185 emotional distress in cancer survivors. Missing data for the non-completers in the study were
- replaced by using the last observation carried forward (LOCF) method. The LOCF has been 186
- 187 considered a conservative approach when evaluating treatment outcomes in open trials.
- 188 Treatment effects across time (pretreatment, posttreatment, and 3-and 6-month
- follow-up) were assessed with repeated-measures analysis of variance (ANOVA); the 189
- 190 Greenhouse–Geisser correction was applied when the assumption of sphericity was violated.
- 191 Main effects were followed by Bonferroni-adjusted pairwise comparisons for each outcome
- 192 measure. Within group effect sizes were calculated using Cohen's d to assess the magnitude of
- 193 treatment effects from pretreatment to post-treatment and from pre-treatment to both 3 month
- 194 and 6-month follow-ups. To determine the clinical significance of treatment effects the
- 195 methodology developed by Jacobson and colleagues (Jacobson, Follette, & Revenstorf, 1984,
- Jacobson & Truax, 1991) was applied to the HADS-Total. Each patient can be allocated to one 196
- 197 of four treatment outcomes: reliable deterioration, no change, reliable improvement, or
- 198 recovered. The first three outcomes are calculated using from the Reliable Change Index (RCI),
- 199 which determines whether the magnitude of change is statistically significant. Data to calculate

the RCI was drawn from a large non-clinical sample (Crawford et al., 2001). The cut-off score for the HADS-Total was ≤ 13 determined using "criterion a" To be classified as recovered, patients must demonstrate reliable change and their posttreatment or follow-up scores must be below the cut off score. The data were analysed using SPSS version 24.

Results

Participant characteristics

Forty-three consecutive referrals were identified as potentially eligible. There were 16 patients who did not enter the study; 10 did not wish to participate, 3 did not attend the assessment interview 1 patient did not have a have a cancer diagnosis, 1 patient did not meet the threshold for severity of distress with a HADS-T score of less than 16 and 1 patient had a recurrence of cancer.

Twenty-seven patients began the trial of whom 20 completed treatment; a completion rate of 74%. Of the seven patients who did not complete the six sessions of MCT; three patients attended only one session, two patients 2 sessions, one patient 3 sessions and the final patient attended 4 sessions but sporadically and decided that it was not feasible to continue therapy. Reasons for non-completion were; one patient was hospitalised for cancer recurrence, one participant stopped therapy to be able to provide full time care for a relative, 2 participants did not wish to undertake psychological therapy and 3 patients dropped out without providing a reason. The demographic and clinical characteristics of the sample shown in **Table 1**. It is notable that 96% of the sample met casesness for anxiety with 93% also scoring above the clinical cut-off for PTSD. Additionally, 8 of the 27 patients had experienced a cancer recurrence, none of these patients discontinued MCT.

Treatment effects

There were significant main effects of time on all outcome measures (**Table 2**). Follow-up Bonferroni pairwise comparisons demonstrated significant differences from pre-treatment to post-treatment, and from pre-treatment to 3-and 6-month follow up on all outcome measures indicating that treatment effects were maintained. Overall, there was significant improvement across all symptom and quality of life measures and significant reductions in metacognitive beliefs (MCQ-30) and processes (CAS-1).

Effect size estimates

Within group effect sizes for the ITT sample are shown in **Table 3**. There are large pre to post treatment effect sizes across all outcome measures (0.83 -1.66). There are comparable effect sizes across all measures at both follow-up timepoints illustrating that the magnitude of treatment effects is maintained from post-treatment to 6-months follow-up.

Clinically significance of treatment

In the ITT sample, most participants were recovered on the HADS-Total at post-treatment and across the follow-up period. In terms of the proportion of patients that responded to treatment, 81% were improved at post-treatment and 74% at 6-months follow-up. Examination of the recovery rates for those patients that completed treatment shows recovery rates of 80% at post-treatment and 70% at 6-months follow-up. A summary of the clinical significance of treatment outcomes is shown in **Table 4**.

Discussion

This study provides further support for the potential of brief MCT to alleviate psychological morbidity in cancer survivors. Following six 1-hour sessions of MCT, there were significant reductions in anxiety depression, post-traumatic stress symptoms, fear of cancer recurrence and improvements in quality of life. There were also significant reductions in metacognitive beliefs and the cognitive attentional syndrome as predicted by the metacognitive model (Wells & Matthews, 1994, 1996). Treatment gains were sustained across all measures of psychological morbidity and metacognitive beliefs and processes through to six-months follow-up. The practical significance as opposed to the statistical significance of the results was assessed using the Jacobson approach to clinical significance. In those patients who completed brief MCT, there were very high recovery rates on the primary outcome variable assessing the severity of general distress; 80% of patients were recovered following six onehour sessions of individually delivered MCT. The recovery rate of 70% at six months followup suggests that the effects of the intervention persist beyond treatment completion. Brief MCT appeared acceptable to cancer survivors with approximately 75% of participants starting treatment completed treatment. It is possible that the treatment completion rate can be improved and early drop-outs from treatment prevented by ensuring patients are more effectively socialised to the aims of MCT.

249

250

251252

253

254255

256

257258

259

260

261

262

263

264265

266

267268

269

270271

272273

274

275

276277

278279

280

281

282 283 284

285

286287

288

289

290

291292

293294

295296

297

298

The within group effect sizes on FCR provide the opportunity to benchmark the effects of brief MCT with those reported in recent randomized controlled trial (Butow et al., 2017) evaluating an integrative approach for FCR. The psychological treatment in the trials conducted by Butow and colleagues evaluated an intervention (ConquerFear) based on the treatment components drawn from three theoretical frameworks; common sense model (Levanthal, Diefenbach, & Levanthal, 1993) the self-regulatory model (Wells & Matthews, 1994) and relational frame theory (Hayes et al., 2006). Although the ConquerFear intervention was more efficacious than an attention control condition, the within group effect size for FCR from pre to post treatment was 0.77. This compares to a within group effect size of 1.66 in the present study. Although, the present study had a much smaller sample size thereby limiting the generalizability of this finding. However, unlike the ConquerFear study, our open trial included participants with depression and severe trauma symptoms indicative of PTSD. Developing specific interventions for each aspect of psychological morbidity for cancer survivors may be unnecessary and integrating treatment components from theoretically inconsistent models could "dilute" treatment efficacy and compromise therapist training (Wells & Fisher, 2015; Byrne, Salmon, & Fisher, 2018).

The present open trial is a valuable step in the translation of MCT from adult mental health populations to cancer survivors and is following the recommended framework for translating psychological interventions to a new population (Medical Research Council UK, 2008). The limitations of open trials are well known but should not undermine their place in treatment development research (Medical Research Council UK, 2008). No data was collected on either treatment adherence or therapist competency beyond that achievable through weekly supervisory sessions. Subsequent studies should include independent assessment of both treatment adherence and therapist competency to increase confidence in the conclusions drawn and that any treatment effects were attributable to MCT.

A comparatively small sample was used, but the sample appeared representative of cancer survivors referred to the clinical health psychology service. Other limitations include the lack of ethnic diversity and that most of the sample were female, thereby compromising external validity. Treatment outcome was assessed exclusively by self-report questionnaires in the present study. Although exclusive reliance on self-report questionnaires could be

considered a methodological weakness, the study was not focused on changes psychiatric diagnosis, rather the study was designed to measure general distress for which the "gold standard" outcome measure for evaluating the efficacy of interventions on emotional distress in cancer was used (Luckett et al., 2010).

Overcoming other limitations of open trials can be achieved through conducting randomised controlled evaluation. It would be valuable to assess the hypothesised mechanisms of change in the context of an RCT against the current recommended treatment approaches, it may be that the treated patients who recover change to most on metacognitive variables regardless of the treatment received. There were statistically significant reductions in all metacognitive beliefs and the CAS over treatment, which were maintained through to the six months follow up assessment. This study adds to the extant literature that MCT has the potential to be an efficacious psychological intervention for adult cancer survivors. Given the limited outcomes of currently available interventions, there is an obvious need to conduct a controlled evaluation of the potential of brief MCT to alleviate psychological morbidity in cancer survivors.

Ethics Statement

All subjects gave written informed consent in accordance with the Declaration of Helsinki. Ethical approval was provided by the National Health Service North West Research Ethics Committee (reference 15/NW/0820).

Author Contributions

PF and PS were responsible for designing the study. AB, LF and PF were the therapists. PF drafted the manuscript. GA and HU recruited and assessed participants at intake and following treatment. All authors have contributed to drafting and revising the manuscript and approved its submission.

Conflict of Interest Statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Funding

This study was supported by funds from the by the UK Medical Research Council Confidence in Concept Scheme, awarded to the University of Liverpool

$\boldsymbol{\neg}$	$^{\circ}$	
4	٠.	

	Mean (SD)	Range337
Age	51.15 (11.67)	29-67
Age at time of cancer diagnosis	46.71 (10.99)	28-64338
Months since completion of acute medical treatment	25.81 (27.93)	3-142
Tronds since completion of acute medical treatment	23.01 (27.53)	339
	N	337
Gender		
Female	23	
Male	4	
Ethnicity		
White Caucasian	26	
Asian	1	
Cancer Diagnosis		
Breast	13	
Haematological	6	
Ovarian	3	
Sarcoma	2	
Colorectal	1	
Ocular	1	
Lung	1	
Cancer Treatment		
Chemotherapy, radiotherapy, and surgery	8	
Chemotherapy plus surgery	5	
Chemotherapy alone	4	
Surgery alone	3	
Chemotherapy, plus radiotherapy	2	
Radiotherapy plus surgery	1	
Radiotherapy alone	1	
Other/not reported	3	
Employment Status	12	
Employed	13	
Unemployed	14	
Education Level	26	
School level or higher	26 1	
No qualifications	1	
Relationship Status	11	
Married/cohabiting Live alone	16	
Psychotropic Medication	10	
Current taking	11	
Previously taken	5	
Never taken	11	
Previous Psychological Treatment	11	
Yes	17	
No	10	
Distress Outcomes	10	
Anxiety (HADS-A >11)	26 (96	5%)
Depression (HADS-D>11)	12 (44	
PTSD symptoms (IES-R >33)	25 (93	
1 15D symptoms (ILB-IV /55)	23 (93	, , , ,

Table 2. Means, standard deviations (in parentheses) and repeated measures analysis of variance for outcome measures: Intention-to-Treat Sample (n = 27).

Measure	Pre- treatment	Post-treatment	3-months follow-up	6-months follow-up	F(df)	
HADS -Total	25.04 (5.65)	12.70 (9.61)	13.00 (9.99)	12.67 (10.12)	39.76 (2.15, 56.05)	<i>p</i> <.0001
HADS - Anxiety	14.44 (3.51)	7.85 (5.14)	7.96 (5.49)	7.52 (5.44)	32.85 (2.21, 57.30)	<i>p</i> <.0001
HADS - Depression	10.74 (3.77)	4.81 (4.79)	5.04 (4.89)	5.15 (5.23)	31.60 (2.03, 52.71)	<i>p</i> <.0001
IES-R -Total	53.15 (16.43)	26.04 (26.93)	27.92 (26.64)	27.81 (25.35)	26.56 (2.32, 60.28)	<i>p</i> <.0001
FCRI- Total	108.29 (22.18)	59.59 (38.84)	63.37 (36.63)	63.81 (36.73)	34.42 (1.49, 38.48)	<i>p</i> <.0001
FACT-G-Total	54.33 (14.94)	76.87 (20.16)	74.55 (21.63)	74.94 (22.73)	31.09 (2.21, 57.43)	<i>p</i> <.0001
MCQ-30 Positive beliefs	11.74 (4.66)	8.22 (3.73)	8.29 (3.61)	8.33 (3.89)	9.47 (1.48, 38.53)	p<.001
MCQ-30 Negative beliefs	18.59 (3.27)	11.85 (5.23)	12.03(5.21)	11.70 (5.04)	28.87 (1.78, 46.28)	<i>p</i> <.0001
MCQ-30 Cognitive confidence	15.74 (5.28)	11.41 (4.98)	12.48 (5.61)	11.77 (5.58)	13.35 (2.18, 55.06)	<i>p</i> <.0001
MCQ-30 Need for control	14.41 (4.38)	10.07 (4.73)	9.33 (4.72)	9.26 (4.77)	23.30 (1.40, 36.40)	<i>p</i> <.0001
MCQ-30 Cognitive self-consciousness	17.93 (3.98)	12.66 (6.09)	12.52 (4.87)	12.59 (5.15)	23.85 (2.27, 59.05)	<i>p</i> <.0001
CAS-1	55.25 (19.19)	20.06 (25.85)	20.86 (26.19)	24.32 (28.61	44.67 (2.18, 56.69)	<i>p</i> <.0001

Note. df, degrees of freedom; HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale-Revised; FCRI, Fear of Cancer Recurrence Inventory; FACT-G, Functional Assessment of Cancer Therapy-General; MCQ-30, Metacognitions Questionnaire-30; CAS-1, Cognitive Attentional Scale.

Table 3. Within group effect sizes (Cohen's d) for outcome measures at post-treatment and 3- and 6-months follow-up

	Post-treatment	3-months follow-up	6-months follow-up
HADS-Total	1.56	1.48	1.51
HADS-Anxiety	1.49	1.41	1.51
HADS-Depression	1.37	1.31	1.23
IES-R Total	1.21	1.14	1.18
FCRI-Total	1.66	1.48	1.46
FACT-G-Total	-1.27	-1.09	-1.07
MCQ-30 Positive beliefs	0.83	0.83	0.79
MCQ-30 Negative beliefs	1.51	1.50	1.62
MCQ-30 Cognitive confidence	0.84	0.59	0.75
MCQ-30-Need for control	0.95	1.12	1.12
MCQ-30-Congnitive self-consciousness	1.02	1.22	1.16
CAS-1	1.55	1.49	1.27

Note: HADS, Hospital Anxiety and Depression Scale; IES-R, Impact of Event Scale-Revised; FCRI, Fear of Cancer Recurrence Inventory; FACT-G, Functional Assessment of Cancer Therapy-General; MCQ-30, Metacognitions Questionnaire-30; CAS-1, Cognitive Attentional Scale.

Table 4. Clinical significance outcomes on HADS-Total

355

358

359

	Post treatment			3-months follow-up				6-months follow-up		
	No change	Improved	Recovered	Deteriorated	No change	Improved	Recovered	No change	Improved	Recovered
ITT	5	5	17	1	4	8	14	7	5	15
(n=27)	19%	19%	62%	5%	25%	17%	58%	26%	19%	56%
Completers	1	3	16	1	0	6	13	3	3	14
(n=20)	20%	0%	80%	5%	0%	30%	65%	15%	15%	70%

Note: ITT: intention to treat sample; Completers: treatment completers sample

References

Brucker, P. S., Yost, K., Cashy, J., Webster, K., & Cella, D. (2005). General Population and Cancer Patient Norms for the Functional Assessment of Cancer Therapy-General (FACT-G). Evaluation & the Health Professions, 28(2) 192211.doi.org/10.1177/0163278705275341

Butow, P., Kelly, S., Thewes, B., Hruby, G., Sharpe, L., & Beith, J. (2015). Attentional bias and metacognitions in cancer survivors with high fear of cancer recurrence. Psycho-Oncology, 24(4), 416-423. doi:10.1002/pon.3659.

Butow, P., Turner, J., Gilchrist, J., Sharpe, L., Smith, A., Fardell, J., Tesson, S., O'Connell,
 R., Girgis, A., Gebski, V., Asher, R., Mihalopoulos, C., Bell, M., Grunewald Zola,
 K., Beith, J., & Thewes, B. (2017) Randomized Trial of ConquerFear: A Novel,
 Theoretically Based Psychosocial Intervention for Fear of Cancer Recurrence. Journal
 of Clinical Oncology, 35:36, 4066-4077.

Byrne, A., Salmon, P., & Fisher, P.L. (2018). The experience of learning a new psychological therapy: challenges for the integrative model of psychotherapy. Counselling and Psychotherapy Research, 18(4), 369-376. DOI: 10.1002/capr.12185

Cancer Research UK(2017) http://www.cancerresearchuk.org/health-professional/cancer-statistics. Accessed September 2018.

Cella, D. F., Tulsky, D. S., Gray, G., Sarafian, B., Linn, E., Bonomi, A., & Eckberg, K. (1993). The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. Journal of Clinical Oncology, 11(3), 570-579.

Cook, S.A., Salmon, P., Dunn, G., & Fisher, P. (2014). Measuring metacognition in cancer: validation of the metacognitions questionnaire 30 (MCQ-30). Plos One, 9 (9), e107302. doi: 10.1371/journal.pone.0107302.

Cook, S.A., Salmon, P., Dunn, G., Holcombe, C., Cornford, P., & Fisher, P. (2015a). The association of metacognitive beliefs with emotional distress after diagnosis of cancer. Health Psychology, 34 (3), 207-215.

Cook, S.A., Salmon, P., Dunn, G., Holcombe, C., Cornford, P., & Fisher, P. (2015b). A prospective study of the association of metacognitive beliefs and processes with persistent emotional distress after diagnosis of cancer. Cognitive Therapy Research, 39, 51-60. doi:10.1007/s10608-014-9640-x.

Demoncada, A., Feuerstein, M. (2006) Psychosocial interventions for depression, anxiety and quality of life in cancer survivors: meta-analyses. International Journal of Psychiatry in Medicine, 2006. 36(1): p. 13-34.

Carlson, L. and B. Bultz, Efficacy and medical cost offset of psychosocial interventions in cancer care: Making the case for economic analyses. Psychooncology, 2004. 13(12): 837-849.

411

Crawford, J.R., Henry, J.D., Crombie, C., & Taylor, E.P. (2001). Normative data for the HADS from a large non-clinical sample. British Journal of Clinical Psychology, 40, 429-434.

415

DiMatteo, M., H. Lepper, and T. Croghan, Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. Archives of Internal Medicine, 2000. 160(14): p. 2101-2107.

419

Elliott, J., Fallows, A., Staetsky, L., Smith, P. W., Foster, C. L., Maher, E. J., & Corner, J. (2011). The health and well-being of cancer survivors in the UK: findings from a population-based survey. British journal of cancer, 105 (Suppl 1), S11-20.

423

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. Journal of Clinical Oncology, 31(6), 782–793. doi:10.1200/JCO.2011.40.8922.

428

Fisher, P.L., Byrne, A., & Salmon, P. (2017). Metacognitive Therapy in Adult Survivors of Cancer: A Case Series. Cognitive Therapy and Research. 41(6), 891-901. doi 10.1007/s10608-017-9862-9

432

Fisher, P. L., Cook, S. A., & Noble, A. (2016). Clinical utility of the Metacognitions
Questionnaire 30 in people with epilepsy. Epilepsy & Behavior, 57, 185-191. doi:
10.1016/j.yebeh.2016.02.004

436

Fisher, P.L., McNicol, K., Young, B, Smith, E, & Salmon P. (2015). An open trial of metacognitive therapy for emotional distress in young adult survivors of cancer.

Journal of Adolescent and Young Adult Oncology, 4, (2), 64-69.

440

Fisher, P.L., McNicol, K., Cherry, M.G., Young, B., Smith, E., Abbey, G., & Salmon P.

(2018). The association of metacognitive beliefs with emotional distress and trauma symptoms in adolescent and young adult survivors of cancer. Journal of Psychosocial Oncology doi: 10.1080/07347332.2018.1440276

445

Greer, J. A., Park, E. R., Prigerson, H. G., & Safren, S. A. (2010). Tailoring Cognitive Behavioral Therapy to Treat Anxiety Comorbid with Advanced Cancer. Journal
 Cognitive Psychotherapy, 24(4), 294-313. doi:10.1891/0889-8391.24.4.294

449

Hayes, S. C., Luoma, J. B., Bond, F. W., Masuda, A., & Lillis, J. (2006). Acceptance and Commitment Therapy: Model, processes and outcomes. Behaviour Research and Therapy, 44, 1-25. http://dx.doi.org/10.1016/j.brat.2005.06.006

453

Hoffman, K. E., McCarthy, E. P., Recklitis, C. J., & Ng, A. K. (2009). Psychological distress in long-term survivors of adult-onset cancer: results from a national survey. Archives Internal Medicine, 169(14), 1274-1281. doi:10.1001/archinternmed.2009.179.

Jacobson, N. S., Follette, W. C., & Revenstorf, D. (1984). Psychotherapy outcome research: methods for reporting variability and evaluating clinical significance. Behaviour Therapy, 15, 336–352.

460

Jacobson, N. S., & Truax, P. (1991). Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. Journal of Consulting and Clinical Psychology, 59(1), 12–19.

464

Jansen, F., van Zwieten, V., Coupe, V. M. H., Leemans, C. R., & Leeuw, I. M. V. D. (2016).
A Review on Cost-Effectiveness and Cost-Utility of Psychosocial Care in Cancer
Patients. Asia-Pacific Journal of Oncology Nursing, 3(2), 125-136. doi:10.4103/2347-5625.182930

469

LeMasters, T., Madhavan, S., Sambamoorthi, U., & Kurian, S. (2013). A population-based study comparing HRQoL among breast, prostate, and colorectal cancer survivors to propensity score matched controls, by cancer type, and gender. Psycho-oncology, 22(10), 2270-82.

474

Leventhal, H., Diefenbach, M., & Leventhal, E. A. (1992). Illness Cognition - Using Common-Sense to Understand Treatment Adherence and Affect Cognition Interactions. Cognitive Therapy and Research, 16(2), 143-163. doi:10.1007/Bf01173486

479

Luckett, T., Butow, P.N., King, M.T., Oguchi, M., Heading, G., Hackl, N.A., Rankin, N., & Price, M.A. (2010). A review and recommendations for optimal outcome measures of anxiety, depression and general distress in studies evaluating psychosocial interventions for English-speaking adults with heterogeneous cancer diagnoses. Supportive Care in Cancer, 18, 1241–1262.

485 486

McNicol, K., Salmon, P., Young, B., & Fisher, P.L. (2013) Alleviating emotional distress in a young adult survivor of adolescent cancer: a case study illustrating a new application of metacognitive therapy. Clinical Case Studies. 12, 22-38.

488 489

487

490 National Cancer Institute (2018) https://www.cancer.gov. Accessed September 2018.

491 492

493

Quattropani, M.C., Lenzo, V., Mucciardi, M., & Toffle, M.E. (2016). Metacognition as predictor of emotional distress in cancer patients. Life Span and Disability, 19 (2), 221-239.

494 495

496 Quattropani, M.C., Lenzo, V., & Filastro, A. (2017). Predictive factors of anxiety and 497 depression symptoms in patients with breast cancer undergoing chemotherapy. An 498 explorative study based on metacognitions. Journal of Psychopathology, 23, 67-73.

499

Rehse, B., Pukrop, R. (2003). Effects of psychosocial interventions on quality of life in adult cancer patients: meta-analysis of 37 published controlled outcome studies. Patient Education and Counselling 50(2): 179-186.

503

Salsman, J. M., Schalet, B. D., Andrykowski, M. A., & Cella, D. (2015). The impact of events scale: a comparison of frequency versus severity approaches to measuring

506 507	cancer-specific distress. Psycho-oncology, 24(12), 1738-45. doi.org/10.1002/pon.3784
508 509 510 511	Simard, S., & Savard, J. (2009). Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence. Supportive Care in Cancer, 17(3), 241-251. doi:10.1007/s00520-008-0444-y
512513514515	Simard, S., & Savard, J. (2015). Screening and comorbidity of clinical levels of fear of cancer recurrence. Journal Cancer Survivorship, 9(3), 481-491. doi:10.1007/s11764-015-0424-4
516517518519520	Swartzman, S., Booth, J. N., Munro, A. and Sani, F. (2017), Posttraumatic stress disorder after cancer diagnosis in adults: A meta-analysis. Depress Anxiety, 34: 327-339. doi:10.1002/da.22542
521 522 523	Thewes, B., Bell, M. L., & Butow, P. (2013). Fear of cancer recurrence in young early-stage breast cancer survivors: the role of metacognitive style and disease-related factors. Psychooncology, 22(9), 2059-2063. doi:10.1002/pon.3252
524 525 526 527 528 529	Thewes, B., Brebach, R., Dzidowska, M., Rhodes, P., Sharpe, L. and Butow, P. (2014), Current approaches to managing fear of cancer recurrence; a descriptive survey of psychosocial and clinical health professionals. Psycho-Oncology, 23: 390-396. doi:10.1002/pon.3423
530 531 532	Weiss, D.S. (2007). The Impact of Event Scale: Revised. In J.P. Wilson & C.S. Tang (Eds.), Cross-cultural assessment of psychological trauma and PTSD (pp. 219-238). New York: Springer.
533534535	Wells, A. (2009). Metacognitive for Anxiety and Depression. New York: Guildford Press.
536 537 538 539	Wells A, Cartwright-Hatton S. (2004). A short form of the metacognitions questionnaire: Properties of the MCQ-30. Behaviour Research and Therapy, 42, 385-396. eScholarID:1d25955 DOI:10.1016/S0005-7967(03)00147-5.
540 541 542	Wells, A., & Fisher, P. (2015). Treating depression: MCT, CBT and third wave therapies. Chichester, UK: Wiley. https://doi.org/10.1002/9781119114482 .
543 544 545	Wells A. & Matthews, G. (1994). Attention and emotion: A clinical perspective. Hove, UK: Erlbaum.
546 547 548	Wells A, Matthews G. (1996). Modelling cognition in emotional disorder: The S-REF model. Behaviour Research and Therapy, 34 (11), 881–8.
549 550 551 552 553	Zigmond, A.S. & Snaith, R.P. (1983). The hospital anxiety and depression scale. Acta Psychiatrica Scandinavica, 67 (6), 361-370.