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A Feasibility Study of a Novel Work-focused Relational Group CBT Treatment Programme for Moderate to Severe Recurrent Depression.

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1 **A Feasibility Study of a Novel Work-focused Relational Group CBT Treatment**
2 **Programme for Moderate to Severe Recurrent Depression**

Mental Health Review Journal

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3 **Abstract**
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5 **Purpose:** No current psychotherapeutic intervention is designed to enhance job retention in
6 employees with moderate-severe recurrent depression. The aim of this study was to test the
7 feasibility of a new, interdisciplinary Work-focused Relational Group CBT Treatment
8 Programme for moderate-severe depression.
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12 **Design:** The programme was based on a theoretical integration of occupational stress,
13 psychological, social/interpersonal, and bio-medical theories. It consisted of (i) up to four 1:1
14 psychotherapy sessions; (ii) twelve work-focused, full-day, weekly CBT sessions facilitated
15 by a cognitive behavioural therapist and occupational therapist; and (iii) up to four optional
16 1:1 sessions with an occupational therapist. Depression severity (primary outcome) and a
17 range of secondary outcomes were assessed before (first CBT session) and after (twelfth
18 CBT session) therapy using validated instruments.
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23 **Findings:** Eight women (26-49 years) with moderate-severe depression participated. Five
24 were on antidepressant medication. While there was no statistically significant change in
25 HAM-D depression scores after therapy (n=5; p=0.313), BDI-II depression scores
26 significantly decreased after therapy (n=8; -20.0 median change, p=0.016; 6/8 responses,
27 7/8 minimal clinically important differences, two remissions). There were significant
28 improvements in the secondary outcomes of overall psychological distress, coping self-
29 efficacy, HRQoL, and interpersonal difficulties after therapy. All clients in work at the start of
30 therapy remained in work at the end of therapy. The intervention was safe and had 100%
31 retention.
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38 **Originality:** While limited by a recruitment shortfall, missing data, and client heterogeneity,
39 this study showed promising immediate positive outcomes for the new programme in terms
40 of depressive symptoms, interpersonal difficulties, and job retention that warrant exploration
41 in a definitive study.
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45 **Keywords:** Cognitive behavioural therapy; depression; interpersonal difficulties; job
46 retention
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49 **Article classification:** Research Paper
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52 Introduction

53 Depression is associated with limitations in work functioning and work participation that may
54 result in exit from permanent employment on health grounds (Lagerveld *et al.*, 2010, van
55 Rijn *et al.*, 2014). The National Institute of Health and Care Excellence recommends
56 combining antidepressant medication concurrently or sequentially with psychological therapy
57 such as cognitive behavioural therapy (CBT) or interpersonal psychotherapy (IPT) to treat
58 severe depression, as well as providing active support and advice on self-management
59 (National Institute for Clinical Excellence, 2009). Vocational rehabilitation is also
60 recommended for people who have lost their job due to chronic moderate-severe
61 depression.

62 However, there is currently only one specific clinical guideline for chronic depression (Jobst
63 *et al.*, 2016), which recommends combining pharmacological treatment with an
64 interpersonally focused psychotherapy. Cognitive behavioural analysis system of
65 psychotherapy (CBASP) should be offered as a first-line treatment and IPT as a second-line
66 treatment based on the conceptualisation of recurrent depression as causally and
67 dynamically related to interpersonal excesses and deficits, which might make establishing a
68 therapeutic alliance problematic (Weck *et al.*, 2013).

69 This study focuses on employed service users of UK Community Mental Health Teams
70 (CMHTs) with moderate-severe recurrent depression or with long-standing depression plus a
71 high degree of chronicity, complexity, and comorbidity causing work dysfunction. For CMHT
72 service users, Care Programme Approach guidance recommends that employment
73 problems should be addressed as part of the care plan (Agnew, 2004). However, only 27%
74 of service users reported that NHS mental healthcare services 'definitely' gave them any
75 support with finding work or maintaining employment in the previous twelve months (Care
76 Quality Commission, 2020), suggesting that gaps exist in the care delivered to these
77 individuals.

78 **In terms of the prevalence, quality, and effectiveness of work-focused interventions for**
79 **depression, several studies have evaluated face-to-face psychotherapeutic interventions and**
80 **reported both clinical and work outcomes. Indeed, several meta-analyses evaluating**
81 **interventions to support people with or at risk of developing mental health problems found**
82 **that they are effective at reducing sickness absence and reducing levels of anxiety and**
83 **depression compared to doing nothing at all (Doki *et al.*, 2015, Mikkelsen and Rosholm,**
84 **2018, Nieuwenhuijsen *et al.*, 2020, Nigatu *et al.*, 2016, Tan *et al.*, 2014), including a**
85 **Cochrane review describing specific components in detail (Nieuwenhuijsen *et al.*, 2020).**
86 **Another recent systematic review of work-based depression programmes found that a**

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3 87 primary preventative CBT-informed psychotherapeutic intervention, 'Be Well At Work', was
4 88 'promising' for American organisations, but no study focused on employees with moderate-
5 89 severe recurrent depression (Bond *et al.*, 2019). Universal and targeted CBT-based
6 90 interventions that promote adaptive coping, delivered in the workplace and mostly in a group
7 91 format, also appear to be effective in reducing depressive symptoms in employees (Yunus *et*
8 92 *al.*, 2018).

93 In terms of the types of interventions that might help to prevent work disability in employees
94 with depression, Cullen *et al.* (2018), in their systematic review, found that 'multi-domain
95 interventions' integrating 'healthcare provision, service coordination, and work
96 accommodation components' were beneficial because CBT alone was ineffective in
97 improving return-to-work outcomes for employees with mental health problems. Two other
98 systematic reviews found evidence that CBT-based interventions with a work focus and that
99 included problem-solving return-to-work strategies (Joyce *et al.*, 2016) improved work (i.e.,
100 duration of sickness absence) and clinical outcomes at the tertiary (indicated) prevention
101 level. Psychological treatments were found to be more effective than care as usual with a
102 small effect size in reducing the length of sickness absence and in reducing symptoms of
103 common mental health disorders (Finnes *et al.*, 2019, Salomonsson *et al.*, 2018). However,
104 psychological treatments were found to be no more effective than other clinical interventions
105 (Finnes *et al.*, 2019).

106 However, most studies have concentrated on interventions designed to improve return-to-
107 work or reduce absenteeism rather than preventing exit from work in people with mild-
108 moderate depression, common mental health conditions, and work-related stress or burnout.
109 Most excluded people with more severe and enduring mental health problems. Only five
110 studies met inclusion criteria for this study (Vlasveld *et al.*, 2012, Wang *et al.*, 2007,
111 Schoenbaum *et al.*, 2002, Burnand *et al.*, 2002, Knekt *et al.*, 2008). Therefore, while the
112 impact of psychotherapeutic interventions on work-related outcomes has been examined,
113 there is still a gap in terms of work-focused psychotherapeutic interventions specifically
114 designed to enhance job retention in employees with more severe mental health problems.
115 To our best knowledge, there is currently no psychotherapeutic intervention specifically
116 designed to enhance job retention in employees with moderate-severe recurrent depression.

117 We therefore hypothesized that interdisciplinary, work-focused psychotherapy would have
118 the triple benefits of alleviating the symptoms of depression, improving interpersonal
119 difficulties, and enhancing job retention. Using Medical Research Council (MRC) guidance
120 for developing, evaluating, implementing and reporting on complex health and social care
121 interventions (Campbell *et al.*, 2000, Craig *et al.*, 2008, Moore *et al.*, 2015), we tested the
122 feasibility of implementing and evaluating a new Work-focused Relational CBT Treatment

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3 123 Programme for moderate to severe depression. The new programme was based on a
4 124 theoretical integration of occupational stress, psychological, social/interpersonal, and bio-
5 125 medical theories and consisted of (i) 1:1 sessions with a psychotherapist; (ii) a work-focused,
6 126 twelve-week group CBT programme; and (iii) optional 1:1 sessions with an occupational
7 127 therapist. **The balance of content, process and job retention components, and the high**
8 128 **intensity and high dose of therapy differentiated this intervention from other interventions**
9 129 **such as Work-Related Interpersonal Group Psychotherapy (W-IPT) (Niedermoser *et al.*,**
10 130 **2020), which targets employees depressed due to work-related stress and excludes those**
11 131 **on medication or with personality disorder traits, i.e., common CMHT service users with**
12 132 **longstanding and/or treatment-resistant mental health problems.** Using a series of validated
13 133 instruments to assess the severity of depression, coping and self-efficacy, health-related
14 134 quality of life, interpersonal difficulties, and work and social functioning, we show that the
15 135 new intervention had a positive impact on most of these domains by the end of group
16 136 therapy, paving the way for a definitive clinical trial.

137

138 **Method**

139 *Ethical statement*

140 The University [redacted] Research Ethics Committee, the NHS Local Research Ethics
141 Committee (LREC) via IRAS, and the NHS Trust's Research and Innovation department
142 approved the study protocol. The study conformed to the Declaration of Helsinki (World
143 Medical Association, 1996) and Good Clinical Practice (Medicines and Healthcare products
144 Regulatory Agency, 2012). The study was indemnified by the University of [redacted]. All
145 participants provided written informed consent.

146 *Study setting, design, participant recruitment, and inclusion and exclusion criteria*

147 This feasibility study was a single-centre, quasi-experimental study with a pre-post design
148 and non-blinded outcome assessment conducted in an NHS secondary mental healthcare
149 service in the UK using an established conceptual framework and recommended format for
150 carrying out feasibility studies (Eldridge *et al.*, 2016). **The study is reported using the**
151 **Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement**
152 **checklist (Des Jarlais *et al.*, 2004).**

153 Potential participants were adult service users of several inner-city and rural CMHTs.
154 Inclusion criteria were: adults aged between 18-64 years; met the service threshold for
155 moderate to severe recurrent depression (BDI-II >20); able to communicate in English;
156 employed either full-time/part-time or on short-term sickness absence due to recurrent

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3 157 depression; intended to maintain or resume employment; and were willing to participate in
4 group therapy and abide by group ground rules. Following screening with the BDI-II,
5 158 potential participants were assessed by [redacted], a qualified psychotherapist, using a
6 159 structured clinical interview to confirm a diagnosis of moderate-severe recurrent depression
7 160 (ICD-10 F33.1 or F33.2). Axes II disorders were not assessed. Exclusion criteria were: an
8 161 intellectual disability (IQ <70); severe medical illness or physical disability that would
9 162 significantly interfere with participation in group therapy; a recent history of interpersonal
10 163 violence, which is contraindicated for group therapy; symptoms of an acute psychotic illness,
11 164 organic brain disorder, an anxiety or eating disorder as the main presenting problem;
12 165 substance misuse as the main presenting problem; current, frequent and serious self-harm
13 166 (requiring medical intervention \geq once a week); and/or had not worked in the previous 12
14 167 months. Clients on psychotropic medication and showing mild-moderate Axes II personality
15 168 disorder traits were not excluded, as these features are common in UK CMHT service users.
16 169
17 170 Different strategies were used to elicit referrals and self-referrals, with the most successful
18 171 strategy being a direct referral from the CMHT at intake and the least successful strategy
19 172 being writing to clients on psychotherapy waiting lists offering information about the study.

173 *The intervention*

174 The programme theory of the new intervention was further refined through consultation with
175 key stakeholders in eight focus groups. The treatment programme had triple foci: (i)
176 presenting problems (such as symptoms of depression), (ii) work issues (such as
177 occupational stress), and (iii) underlying issues (such as trauma, core beliefs and
178 maladaptive coping). There were three main components (individual sessions, group
179 sessions, and optional occupational therapy sessions), as well as a discharge-planning
180 session. No incentives were provided to increase compliance or adherence, although a
181 range of strategies were used to engage and motivate clients to attend sessions and persist
182 with treatment such as case tracking and between-session outreach (see **Table 1** and
183 **Supplementary** for complete details of the intervention).

184 [insert Table 1 here]

185 Clients received up to four 1:1 sessions with a psychotherapist for assessment and
186 formulation prior to the group sessions so that each client's problems could be personalised
187 and contextualised taking into consideration intrapersonal, interpersonal, and work factors. A
188 work-focused care plan was developed in collaboration with the participant based on the
189 person-environment-occupation (PEO) model (Law *et al.*, 1996) with the bio-psychosocial-
190 ecological (BPE) model of mental health (Lehman *et al.*, 2017) such that the care plan was
191 compliant with the Trust's Care Programme Approach (CPA) policy. **1:1 assessment**

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3 192 sessions took place either in a CBT clinic based at a mental health hospital or at an
4 193 outpatient psychotherapy service.

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6 194 The group CBT sessions were co-facilitated by a group psychotherapist [redacted]
7 195 accredited in CBT and by an OT [redacted] with a postgraduate qualification in Vocational
8 196 Rehabilitation. This component consisted of twelve weekly sessions (10 am to 3 pm). The
9 197 intervention incorporated job retention goals prescribed for each client every week during
10 198 group sessions and the opportunity to discuss an 'interpersonal situation' at work (or at
11 199 home) which had triggered distress using the 'double donut' exercise. The psychoeducation
12 200 content included basic CBT concepts and skills, whilst the interpersonal process of the group
13 201 sessions included the skilful facilitation of peer interaction for the purposes of behavioural
14 202 activation, cognitive restructuring, problem-solving, and emotional co-regulation.

15 203 In addition, clients were offered up to four 1:1 sessions with an OT to undertake an
16 204 occupational analysis in terms of 'the worker, their work, and the workplace' (Cameron *et al.*,
17 205 2012) and to intervene in helping the client maintain, gain, or change employment, including
18 206 low-key liaison with the workplace for some clients as necessary.

19 207 Fidelity to the model was promoted by setting aside time before, during, and after each
20 208 group session for briefing and de-briefing, whereby both facilitators provided feedback to the
21 209 other after each session using a group CBT competencies checklist. Quality assurance was
22 210 similarly provided by a Consultant Psychologist, a specialist in CBT, who provided live
23 211 supervision through close observation of one group session and scored fidelity using the
24 212 same checklist.

25 213 *Hypotheses*

26 214 The primary hypothesis was that participation in a new Work-focused Relational Group CBT
27 215 Treatment Programme would result in statistically and clinically significant changes in
28 216 symptoms of depression and in interpersonal functioning and that these changes would help
29 217 participants maintain their employment.

30 218 The secondary hypothesis was that participation would also result in statistically and
31 219 clinically significant changes in: 1) overall psychological distress, 2) workplace stress, 3)
32 220 quality of life, 4) coping self-efficacy, and 5) interpersonal skills compared to baseline.

33 221 The null hypothesis was that participation would not result in statistically or clinically
34 222 significant changes in any of the above measures and that participants would lose their jobs.

35 223 *Outcome measures*

36 224 The primary outcome depression measured using the Hamilton Rating Scale for Depression
37 225 (HAM-D 21-item: clinician-rated) (Moberg *et al.*, 2001, Hamilton, 1986). **Independent**

226 **outcome assessors (OAs) were trained to administer the HAM-D over the telephone.**

227 Secondary outcomes measures were: the Beck Depression Inventory-II (BDI-II 21-item: self-rated) (Beck *et al.*, 1996); the Work and Social Adjustment Scale (WSAS 5-item: self-rated) (Mundt *et al.*, 2002); the Coping Self-Efficacy Scale (CSES 26-item: self-rated) (Chesney *et al.*, 2006); the Inventory of Interpersonal Problems (IIP-32-item: self-rated) (Horowitz *et al.*, 1988); the Health and Safety Executive Management Standards Indicator Tool (35-item: self-rated) (Edwards *et al.*, 2008); Clinical Outcomes in Routine Evaluation (CORE 34-item: self-rated) (Evans, 2000); Agnew Relationship Measure-5 (ARM 5-item: self-rated) (Agnew-Davies *et al.*, 1998); quality of life (EQ-5D 5-item: self-rated) (Herdman *et al.*, 2011); Client Satisfaction Questionnaire (CSQ 8-item: self-rated) (Attkisson and Zwick, 1982). Job retention was assessed using a dichotomous two-point scale (Yes/No) on a bespoke weekly questionnaire which also determined the proportion (expressed as %) of agreed hours at work in the last week and intention-to-quit (expressed as %). The CORE-OM was used weekly as a case tracking tool.

240 *Economic evaluation*

241 An economic evaluation was undertaken to estimate the total direct and indirect costs of providing the intervention using Healthcare Financial Management Association (HFMA, 2014) guidance. The total direct cost was calculated by working out how much each practitioner was paid by the hour (plus 22% uplift for on-costs) multiplied by how much time they spent on direct clinical contact, and the total indirect cost was calculated by working out how much time each practitioner spent on non-clinical activity such as clinical supervision, preparation, brief/debrief, and administration, multiplied by each practitioner's hourly rate.

248 *Sample size, data collection, and statistical analysis*

249 **The sample size was pragmatically determined by the number of participants recruited in the time available. Nevertheless, some assumptions were made about the power calculation based on detecting a difference of 4.0 units on the HAM-D total score, a standard deviation (SD) of 8, an alpha level of 5%, and a power of 80%. This indicated that the required number of subjects based on these figures would be 45 per treatment group or 90 subjects in total in a future definitive trial.**

255 Quantitative data were collected at the first CBT group session (pre-treatment) and after the twelfth CBT group session (post-treatment) for all instruments except CORE and BDI-II, which were collected at enrolment (pre-treatment) and after the twelfth CBT group session (post-treatment). Quantitative data were managed in SPSS v14 (IBM Statistics, Armonk, NY). Group scores for the primary and secondary outcomes (mean scores, confidence

intervals, and effect sizes) were compared before and after treatment using the Wilcoxon matched-pairs signed rank test. A p-value <0.05 was considered statistically significant.

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263 **Results**

264 *Participant demographics and baseline clinical characteristics*

265 Several different recruitment strategies were used: writing to clients on psychotherapy
266 waiting lists, eliciting referrals from clinicians, encouraging self-referrals, and canvassing
267 third sector organisations. Of 79 potential participants invited in two sites, fifteen asked for
268 more information, eleven gave consent, and eight finally entered treatment. Baseline
269 demographics are summarised in **Table 2**. All participants were female and aged between
270 36-49 years; seven were White-British and one was African-British. Seven women were
271 married or co-habiting, one was single, and four had children.

272 All clients were either currently or recently in employment. The inclusion criteria were relaxed
273 so that two clients who had lost their jobs while on the waiting list for CBT were included. Of
274 those working at the start of CBT, three worked part-time, three worked full-time, one was in
275 voluntary work, and one was unemployed. Two women were in skilled jobs and were
276 professionally qualified, while three women were in low paid unskilled jobs. One woman was
277 in a semi-skilled job and was also a self-employed shopkeeper. One woman recently lost an
278 unskilled job, and one woman was volunteering but previously in a skilled job that required
279 specific training. Three women were off sick at enrolment and one was claiming welfare
280 benefits.

281 Clients had a high degree of complexity, comorbidity, chronicity, and complicating risks; all
282 clients reported childhood trauma, adversity and/or abuse (data not shown). However, all
283 except one also reported a high level of occupational stress.

284 [insert Table 2 here]

285 *Outcome evaluation*

286 Prior to the intervention, the median scores were in the severe range for self-rated
287 depression, psychological global distress, interpersonal problems, and work-related stress.
288 For health-related quality of life, work and social adjustment, and coping self-efficacy, mean
289 scores were in the moderately poor, lower, or unhealthy range (**Table 3**).

290 With respect to the primary outcome of depression severity, while there was no statistically
291 significant change in HAM-D scores after therapy (n=5; p=0.313), most likely due to missing
292 data, BDI-II scores significantly decreased after therapy (n=8; -20.0 median change,

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3 293 p=0.016). There were significant reductions in overall psychological distress and
4 294 interpersonal difficulties, and significant improvements in coping self-efficacy and HRQoL
5 295 after therapy measured using the CORE, IIP-32, CSES, and EQ-VAS instruments,
6 296 respectively.

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10 297 [insert Table 3 here]

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12 298 Individual changes in instrument scores are illustrated in **Figure 1**. Reflecting the group
13 299 statistics, therapy had a positive effect on the majority of clients for most metrics. With
14 300 respect to BDI-II scores, 6/8 clients showed responses (>50% reduction), 7/8 clients showed
15 301 minimal clinically important differences (>30% reduction), and two clients were deemed in
16 302 remission after group sessions (scores ≤ 9). Only one client had an increase in depression
17 303 severity (HAM-D and BDI-II) and overall psychological distress (CORE), although this client
18 304 showed stability or mild improvements in all the other instruments. At the end of the
19 305 treatment programme, five clients had significant improvements in IIP-32 scores.

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23 306 [insert Figure 1 here]

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27 307 The EQ-VAS scores were used to compare client quality of life data with the UK general
28 308 population (EuroQol Group, 2009). While there was a significant improvement in EQ-VAS
29 309 after therapy ($p = 0.031$), there was a highly significant difference between the clients' quality
30 310 of life and the general population's quality of life after treatment ($p=0.002$).

31 311 *Work status – qualitative analysis*

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36 312 The pre- and post-treatment employment statuses of the study participants are shown in
37 313 **Table 4**. Overall, all clients used their job retention goals to effect positive changes with
38 314 regards to their employment status. Of the clients in employment at enrolment, no-one lost
39 315 their job during the intervention. Of the clients on short-term sickness absence due to
40 316 physical health problems at enrolment, by the end of the group CBT programme, both clients
41 317 had returned to their part-time contracted hours. One client had returned to her full-time
42 318 contracted hours from restricted duties having negotiated reasonable adjustments. The client
43 319 in voluntary work had increased her voluntary hours

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49 320 Of the clients who were working their contracted hours at baseline, by the end of the group
50 321 CBT programme, one had maintained her contracted hours and was coping much better at
51 322 work, and one had maintained her employment but was considering other jobs that would be
52 323 better suited to her interest and skills.

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56 324 [insert Table 4 here]

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58 325 *Recruitment, utility of the outcome measures, intervention delivery, therapeutic alliance,*
59 326 *client satisfaction, and economic analysis*

327 The most effective recruitment strategy was through direct contact with CMHT practitioners
328 so that the researchers could explain the study and describe the intervention. In future, more
329 time would be required to engage potential participants, preferably at intake, bearing in mind
330 possible barriers to recruitment of men and members of minority groups.

331 The new intervention was delivered successfully and safely as planned. There were two
332 adverse events during group CBT: one client took a parasuicidal overdose (without suicidal
333 intent) that required hospital treatment; she was discharged the following day and attended
334 the next group session. The other client made use of the 24/7 crisis helpline on one
335 occasion. Both clients' mental health had improved by the end of group CBT.

336 There was a 100% client retention rate. The group programme was well attended [mean
337 number of sessions attended 10.63 (SD 1.87); mean number of clients per session 7.08 (SD
338 0.95)]. Adherence was high, with the majority of out-of-session assignments completed by
339 most clients. Whilst some clients struggled to attempt all of their goals, everyone attempted
340 at least one goal every week.

341 As assessed by the ARM-5 after each session, the mean therapeutic alliance per session
342 was 34.4 (SD 0.68) and the mean therapeutic alliance per client was 34.4 (SD 1.14),
343 suggesting a positive bond and partnership with the co-facilitators and confidence in the
344 treatment. The mean client satisfaction measured by the CSQ-8 was 27.0 (SD 2.08),
345 suggesting that clients were highly satisfied with their overall treatment.

346 The mean direct cost per client was calculated as £4,552, with mean total costs per client of
347 £6,457.

348

349 Discussion

350 Depression is associated with an increased risk of job loss and subsequent adverse
351 outcomes, and individuals with depression are less likely or able to access available
352 occupational help (Lagerveld *et al.*, 2010, van Rijn *et al.*, 2014). Current solutions tend to
353 focus on returning to work rather than preventing exit from work. While depressed clients
354 may therefore benefit from work-focused interventions to address the specific effects of
355 depression that contribute to workplace limitations, there have been few attempts to develop
356 work-focused psychotherapeutic interventions for moderate-severe recurrent depression.

357 To address this gap, we performed a feasibility study of a new complex intervention, the
358 Work-focused Relational Group CBT Treatment Programme. The balance of content,
359 process and job retention components, and the high intensity and high dose of therapy
360 differentiated this intervention from other interventions such as Work-Related Interpersonal

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3 361 Group Psychotherapy (W-IPT) (Niedermoser *et al.*, 2020), which targets employees
4 362 depressed due to work-related stress and excludes those on medication or with personality
5 363 disorder traits. The programme theory for the new intervention was based on the
6 364 interpersonal theory of depression. Group processes were used deliberately and
7 365 purposefully to target patterns of aversive, rejection-eliciting, and stress-inducing relational
8 366 behaviour which are thought to perpetuate depression (Hammen, 2006, Horowitz and Vitkus,
9 367 1986, Joiner and Coyne, 1999, McCullough Jr, 2003, Starr and Davila, 2008).

14 368 Despite the small number of clients, we detected significant improvements in depression
15 369 severity (BDI-II), overall psychological distress, coping self-efficacy, HRQoL, and
16 370 interpersonal difficulties after therapy. Furthermore, all clients in work at the start of therapy
17 371 remained in work at the end of therapy, with two having returned from sick leave and one
18 372 having progressed from restricted to full duties. Although relatively expensive, the
19 373 intervention was safe, had 100% retention, and clients were confident and satisfied with their
20 374 treatment. These findings provide a promising platform for the initiation of a larger-scale
21 375 clinical trial to assess the full effects of this intervention over the longer term.

27 376 A few RCTs have evaluated work-focused CBT interventions in different client populations.
28 377 Most concentrated on return-to-work rather than job retention and involved clients off sick
29 378 with mild-moderate common mental disorders, work-related stress, or burnout (Dalgaard *et al.*
30 379 *et al.*, 2017b, de Weerd *et al.*, 2016, Lagerveld, 2017, Noordik *et al.*, 2013, Reme *et al.*, 2015).
31 380 One RCT evaluated individual placement and support enhanced with work-focused CBT for
32 381 CMHT service-users in the UK, but the clients were unemployed and 77% were diagnosed
33 382 with psychosis (Schneider *et al.*, 2016). Only two studies included some employees at work
34 383 (Lagerveld, 2017, Reme *et al.*, 2015), and whilst a return-to-work plan was usually
35 384 formulated, only three liaised directly with the workplace (Dalgaard *et al.*, 2017b, de Weerd
36 385 *et al.*, 2016, Reme *et al.*, 2015). Overall, results were disappointing, with five studies
37 386 reporting unexpected or negative results and the intervention being associated with a similar
38 387 or longer time to the full resumption of normal duties than waiting list or care-as-usual
39 388 (Dalgaard *et al.*, 2017a, de Weerd *et al.*, 2016, Lagerveld, 2017, Noordik *et al.*, 2013) or
40 389 number of hours worked (Schneider *et al.*, 2016). Non-randomised studies of work-focused
41 390 CBT have included clients off sick with mild-moderate depression (Brenninkmeijer *et al.*,
42 391 2019, Gjengedal *et al.*, 2020) and clients off sick with moderate-severe depression (Ito *et al.*,
43 392 2019). The interventions were in the 1:1 format except for one that used a group-based
44 393 intervention (Ito *et al.*, 2019). Only one study was based in the UK, and none of the
45 394 interventions was designed specifically for employed service-users accessing CMHTs for
46 395 moderate-severe recurrent depression.

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3 396 Our intervention appeared to have a positive impact on clinical status. While there was no
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5 397 significant difference in median HAM-D scores pre- and post-treatment, there were
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7 398 significant changes in median BDI-II values. These discrepancies may have been due to
8
9 399 statistical and/or methodological reasons. Pre- and post-treatment HAM-D data were only
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11 400 available for five of the eight participants, reducing the statistical power of the analysis;
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13 401 regardless, four clients showed post-treatment improvements in symptoms. Furthermore
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15 402 HAM-D is designed to detect changes in somatic symptoms (Hamilton, 1960), whereas the
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17 403 BDI-II is designed to detect changes in affective and cognitive symptoms (Beck *et al.*, 1961);
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19 404 therefore, physical health problems may have had a disproportionate impact on HAM-D
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21 405 scores.

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23 406 However, not every client benefitted, which may have been related to their individual
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25 407 contexts. The two women who achieved remission on the BDI-II were in stable, committed
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27 408 relationships, which may have been beneficial to both their mental health and their capacity
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29 409 to work. For women, being married or cohabiting is associated with a better therapeutic
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31 410 outcome (Meyers *et al.*, 2002, Thase *et al.*, 1992) and improved job satisfaction and
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33 411 engagement at work (Burnett *et al.*, 2012). These women were also in skilled or semi-skilled
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35 412 jobs, and this occupational context may have had a beneficial effect both on their mental
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37 413 health and their capacity to work. Conversely, the woman who had a limited or negative
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39 414 response to the new intervention was in an unstable relationship. This context may have had
40
41 415 a deleterious effect both on mental health (Whisman, 2001) and work performance (Burnett
42
43 416 *et al.*, 2012); dissatisfaction and discord in marital relationships are associated with worse
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45 417 depression (Whisman *et al.*, 2002) and vice versa (Najman *et al.*, 2014, Whisman and
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47 418 Uebelacker, 2009), and being single is also a risk factor for a limited or negative response to
48
49 419 group CBT (Gelhart and King, 2002). Of the clients in unskilled low paid jobs, one
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51 420 deteriorated and scored worse than baseline. Lower socio-economic status is associated
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53 421 with less improvement in psychotherapy for depression (Falconnier, 2009) and lower
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55 422 educational achievement predicts partial or non-response to CBT (Stiles-Shields *et al.*,
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57 423 2015). Some employment may be worse for mental health than unemployment (Chandola
58
59 424 and Zhang, 2018), and, in one small study, employed clients were more symptomatic at the
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61 425 end of a group CBT skills-building programme for depression than unemployed clients
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63 426 (Gelhart and King, 2002). The relationships between these potential confounders and
64
65 427 treatment effect need examining in a larger cohort of clients.

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67 428 Suboptimal treatment responses may also have been due to an inadequate dose of therapy.
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69 429 Risk factors for relapse include experiencing residual symptoms at the end of treatment and
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71 430 having prior episodes of depression (Bockting *et al.*, 2015, Buckman *et al.*, 2018). For clients
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73 431 who have completed a course of CBT for prior episodes of depression, residual symptoms

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3 432 predicted both short-term relapse and long-term recurrence (Wojnarowski *et al.*, 2019). In a
4 433 study of clients completing a 16- or 20-week course of CBT for depression, 9% of those who
5 434 fully recovered and 52% of those that partially recovered relapsed in the following twelve
6 435 months (Thase *et al.*, 1992). Keeping clients in therapy for longer so that they achieve full
7 436 remission and targeting affective reactivity, cognitive and information processing biases, and
8 437 interpersonal stress may be required for recovery (Buckman *et al.*, 2018). Any future trial of
9 438 our intervention requires long-term follow-up to examine the persistence of treatment effects.

10 439 In terms of mediator variables such as interpersonal problems (IPPs), all clients identified at
11 440 least one IPP matching the top 5-10% of an outpatient sample (Leach *et al.*, 2004),
12 441 suggesting that they had serious difficulties in relationships in at least one IIP-32 domain. By
13 442 the end of the treatment programme, five clients had significant improvements in IIP-32
14 443 scores (overall $p=0.016$). A systematic review of different types of psychotherapy for
15 444 depression that included IPPs as an outcome reported that clients showed an improvement
16 445 in IPPs after brief psychotherapy (McFarquhar *et al.*, 2018). Similarly, a study evaluating IPT
17 446 found that solving IPPs was correlated with an improvement in symptoms (Markowitz *et al.*,
18 447 2006). Other studies have shown that clients with more severe pre-treatment IIPPs had a
19 448 poorer outcome in 1:1 cognitive therapy for depression (Renner *et al.*, 2012), and specific
20 449 IPPs predicted less reduction in depression regardless of whether they received 1:1 CBT or
21 450 1:1 IPT for depression (Quilty *et al.*, 2013). Conversely, another study found that more
22 451 severe pre-treatment IPPs were unrelated to post-treatment depressive symptoms in 1:1
23 452 CBT but predicted less symptom change in group CBT for depression (McEvoy *et al.*, 2014).
24 453 Whilst our group-based therapeutic approach appeared to have a positive impact on IPPs,
25 454 non-relational group CBT may not provide adequate support for vulnerable clients to relate
26 455 effectively with each other in group sessions or might dilute the therapeutic relationship,
27 456 limiting opportunities to target IPPs and personalise treatment.

28 457 For clients who had a positive work outcome, employment support and low-key liaison
29 458 provided by an OT may have been a useful component of a work-focused psychotherapeutic
30 459 intervention. However, it seemed to have only limited impact on occupational stress. For
31 460 clients who did not access OT, it is unclear why they did not seek help. However, a possible
32 461 drawback to involving an OT for 1:1 employment support and low-key liaison with the
33 462 workplace was that clients who opted for this component had to disclose their mental health
34 463 problem to their employer, which some may have been unwilling to do. In one study, only
35 464 21% of over 400 people with depression had ever disclosed it or asked their manager for
36 465 help (Heinz *et al.*, 2018). One client was already receiving employment support through the
37 466 Work Programme as a condition of her welfare benefit claim, which may have limited the

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3 467 appeal of adjunctive OT. The exact impact of the OT component of the intervention is,
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5 468 therefore, uncertain.

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7 469 The high and concentrated dose of therapy was well tolerated. Although the sample was
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9 470 small, the finding that all clients persisted with treatment despite various barriers is
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11 471 encouraging (Barrett *et al.*, 2008). For example, pooled results from a review comparing
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13 472 outcomes for 1:1 CBT and group CBT (Hans and Hiller, 2013) found that approximately 25%
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15 473 of all participants dropped out of CBT, with the attrition rate twice as high for 1:1 CBT
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17 474 compared to group CBT, perhaps because group CBT programmes generally have fewer
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19 475 sessions. Other studies have shown that the type and format of therapy do not affect drop-
20
21 476 out rates (Swift and Greenberg, 2012). Our results also compare favourably to other
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23 477 psychotherapeutic interventions where attrition rates are high: for CBT outpatients in 1:1
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25 478 psychotherapy drop-out is approximately 40% (Bados *et al.*, 2007); 25% for chronically
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27 479 depressed clients (Arnow *et al.*, 2007); and 50% for group CBT for mood disorders (Oei and
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29 480 Kazmierczak, 1997). A range of factors might influence decisions to attend, but our positive
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31 481 results are likely to be because we aimed to identify drop-out early through various methods
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33 482 of case tracking; different strategies were used to enhance engagement; group cohesion
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35 483 was created by the skilful facilitation of peer interaction; and the therapeutic alliance was
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37 484 strengthened by incorporating 1:1 sessions before and during group sessions.

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39 485 The costs of delivering the intervention were relatively high, with the mean total per client
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41 486 estimated at £6,457, which compares to £2,895 per average course of treatment for people
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43 487 with mild-moderate symptoms in Improving Access to Psychological Therapies
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45 488 (Radhakrishnan *et al.*, 2013) and £4,418 for a complete course of 1:1 CBT (16 sessions plus
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47 489 two booster sessions) as mono-therapy for people with moderate-severe depression in
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49 490 secondary mental healthcare (Koeser *et al.*, 2015). The intervention was relatively expensive
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51 491 since it was labour-intensive, multi-modal, and delivered by a Cognitive Behavioural
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53 492 Therapist and an OT. Nevertheless, most clients remain on the caseloads of CMHTs for
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55 493 between 1-5 years (Care Quality Commission, 2020), so while reducing the dose and
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57 494 shortening the psychotherapeutic intervention may reduce immediate costs, it is possible
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59 495 that interventions are not long or focused enough to prevent re-referral, readmission, and the
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496 consequent economic burden. Clients who have responded to treatment but not fully
497 remitted may subsequently relapse and seek further psychotherapy (Buckman *et al.*, 2018),
498 and some clients frequently re-refer themselves because they need or want more help
499 (Bouras *et al.*, 2018, Lousada *et al.*, 2015) due to complex environmental, historical,
500 psychological problems (Cairns, 2014). However, according to the dose-effect model, clients
501 might not necessarily need longer treatment programmes but rather a higher dose of therapy
502 to achieve clinically meaningful change (Haase *et al.*, 2008).

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3 503 This study has a number of limitations. Only a few clients were recruited, some data were
4 504 missing, the client population was heterogeneous, no men were recruited, and the study was
5 505 single-centre and unblinded. The referral rate was particularly low, which may be due to a
6 506 research-resistant culture in mental health services, research being a low priority when
7 507 services are being cut (Borschmann *et al.*, 2014), negative attitudes to psychotherapy
8 508 (Denman, 2007), or unconscious biases such as referring fewer men (Talbot *et al.*, 2014).
9 509 Some clients would not even consider taking part in research; some think they are ineligible,
10 510 or that they do not need therapy; or that there are disadvantages to taking part in depression
11 511 trials (Hughes-Morley, 2017). Clients may be put off by lengthy leaflets (Locock and Smith,
12 512 2011); some may not be able to access necessary travel expenses or childcare (Woodall *et al.*
13 513 *et al.*, 2010). Some may have had previous negative experience of CBT (Barnes *et al.*, 2012)
14 514 or may have preferred a different modality (Liddon *et al.*, 2018, Seidler *et al.*, 2018). Clients
15 515 prefer 1:1 psychotherapy over group psychotherapy (Haugh *et al.*, 2019, Strauss *et al.*,
16 516 2015) due to worries about confidentiality, fear of being criticised, or of losing control in front
17 517 of others (Piper, 2008). In any future trial, the sample would need to be larger and more
18 518 representative. The high rate of missing data for the HAM-D may have been because it can
19 519 be time-consuming and may have been burdensome to clients (D'Avanzato and
20 520 Zimmerman, 2017) or due to problems in collecting data over the telephone; clients may
21 521 have found telephone calls from Outcome Assessors inconvenient or intrusive, especially if
22 522 other family members were present, although other research shows that collecting
23 523 questionnaire data over the telephone is acceptable (Aneshensel *et al.*, 1982, Simon *et al.*,
24 524 1993). Finally, our study only assessed immediate post-treatment outcomes, and further
25 525 follow-up is necessary to establish whether the positive outcomes persist over time.

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38 526 **While these limitations do not allow us to draw unambiguous structural conclusions**, this
39 527 feasibility study of a new complex intervention, the Work-focused Relational Group CBT
40 528 Treatment Programme for moderate to severe recurrent depression, showed promising
41 529 immediate post-treatment outcomes in terms of depressive, interpersonal difficulties, and job
42 530 retention that warrant further exploration in a larger-scale, longer-term, definitive study.

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31 896 **Figure Legend**

32 897 **Figure 1.** Individual changes in instrument scores before and after therapeutic intervention.
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Table 1. An overview of the Work-focused Relational Group CBT Treatment Programme.

	Content components	Process components
1	The Ability to REFLECT The three feeling systems Types of thoughts The donut model: Inner me and outer me How the brain works (Video 1)	MORNING Icebreaker Experiential exercise: <ul style="list-style-type: none"> • <i>What is a thought, feeling, behaviour experiment</i> Skills practice: <ul style="list-style-type: none"> • <i>Abdominal breathing</i> • <i>Superman pose</i> AFTERNOON Small group discussion (two groups) Goal planning in reciprocating pairs Feedback in plenary
2	The Ability to REGULATE The threat system Types of feelings The ABC model: Triggers and past-present link How the brain works (Video 2)	MORNING Icebreaker Goal review in reciprocating pairs Feedback in plenary Experiential exercise: <ul style="list-style-type: none"> • <i>Symptom provocation, panic induction</i> Skills practice: <ul style="list-style-type: none"> • <i>Worry time</i> • <i>Appraisal and reappraisal</i> AFTERNOON As above.
3	The Ability to RESOLVE The motivation system Types of behaviour The behaviour change model: Vicious and virtuous cycles How the brain works (Video 3)	MORNING As above plus: Experiential exercise: <ul style="list-style-type: none"> • <i>My journey and overcoming obstacles to progress</i> • <i>One small change</i> Skills practice: <ul style="list-style-type: none"> • <i>Goal setting</i> AFTERNOON As above.
4	The Ability to RELATE The affiliation system Types of relationships The double donut model: Stress-reducing communication How the brain works (Video 4)	MORNING As above plus: Experiential exercise: <ul style="list-style-type: none"> • <i>Animal metaphor cards</i> • <i>What does the IIP-32 say about me?</i> Skills practice: <ul style="list-style-type: none"> • <i>Sharing my thoughts and feelings safely</i> AFTERNOON As above
5-10	Ad hoc content based on subjects / issues raised by clients on the day	MORNING As above plus: Double donut exercise: interpersonal problem-solving The Hot Seat or Telling My Story AFTERNOON As above
11	As above plus relapse prevention planning as a between-session goal	MORNING As above

		AFTERNOON As above
12	As above plus ending celebration event	MORNING As above
		AFTERNOON Relapse prevention planning in reciprocating pairs. Feedback and goodbyes in plenary

Table 2. Demographic and clinical characteristics of the study population

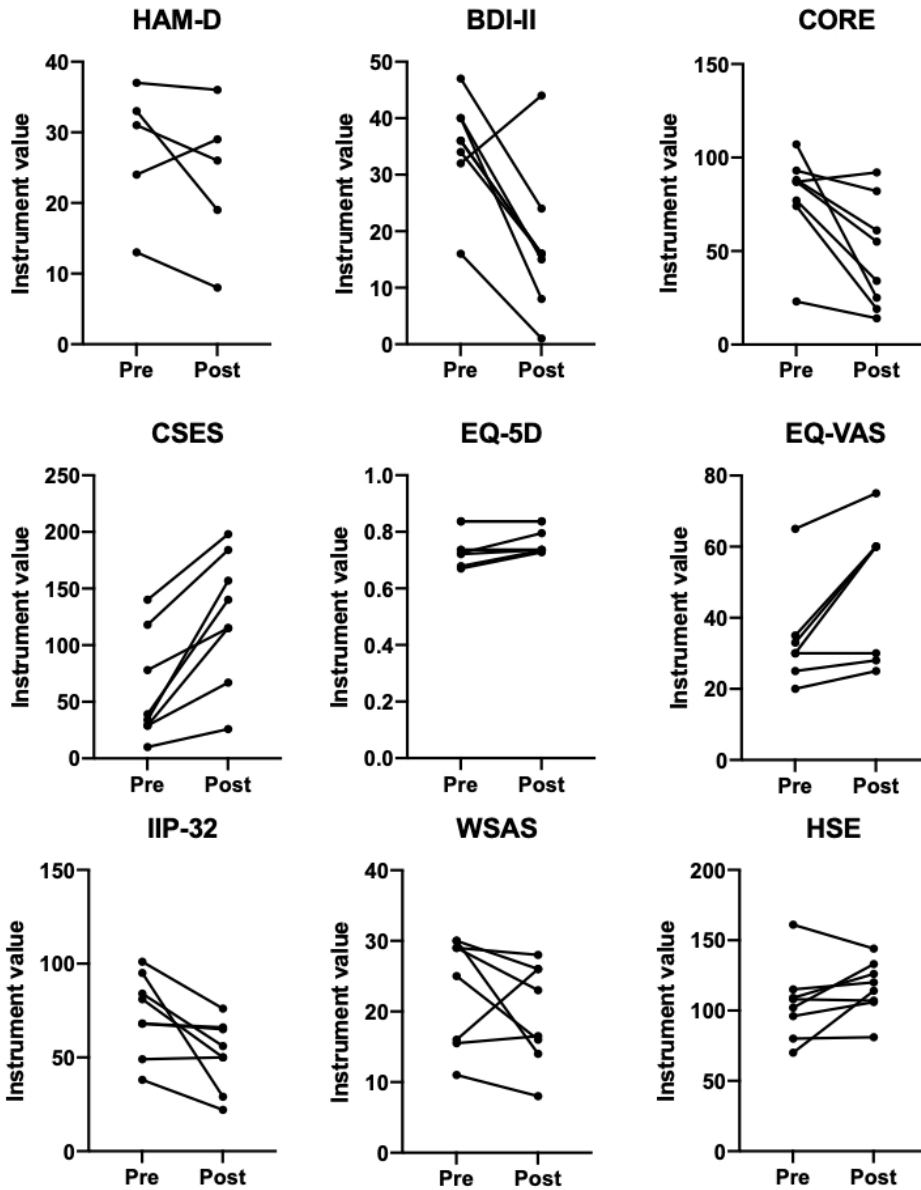
Characteristic	% (n)
Gender	
Male % (n)	0% (0)
Female % (n)	100% (8)
Age: mean (SD)	43.5 (4.42)
Number of children at home: mean (SD)	1 (1.12)
Ethnic Group	
White % (n)	87.5% (7)
Non-white % (n)	12.5% (1)
Marital Status	
Single % (n)	12.5% (1)
Married % (n)	50% (4)
Co-habiting % (n)	37.5% (3)
Divorced or separated % (n)	0% (0)
Accommodation	
Owner-occupier % (n)	75% (6)
Secure tenancy % (n)	0% (0)
Private landlord % (n)	25% (2)
Receiving state welfare benefits	
Not claiming benefits % (n)	87.5% (7)
Statutory Sick Pay % (n)	0% (0)
Employment Support Allowance % (n)	0% (0)
Disability Living Allowance % (n)	12.5% (1)
Work status	
Full-time paid % (n)	37.5 (3)
Part-time paid % (n)	37.5 (3)
Voluntary work % (n)	12.5 (1)
Unemployed % (n)	12.5 (1)

Table 31. Outcomes before and after therapeutic intervention

Outcome	Instrument	N	Before treatment Median (Range)	Clinical status	After treatment Median (Range)	Change Median (95% CI)	p-value
HAM-D	Depression	5	31 (13, 37)	Severe (>24)	26 (8, 36)	-5 (-14, 5)	0.313
BDI-II	Depression	8	36.0 (16, 47)	Severe (29-63)	16.0 (1, 44)	-20.0 (-27, -6)	0.016
CORE	Clinically-relevant psychological distress	8	87.0 (23, 107)	Severe (85-136)	44.5 (14, 92)	-29.5 (-64, -4)	0.016
CSES	Coping self-efficacy	8	36.5 (10, 40)	Unhealthy range (<150)	127.5 (26, 198)	62.0 (30, 108)	0.008
EQ-5D	Health-related quality of life	8	0.73 (0.67, 0.83)	Moderately poor (Mann, Gilbody, & Richards, 2009)	0.74 (0.73, 0.84)	0.007 (0.00, 0.07)	0.125
EQ VAS	Health-related quality of life	7	30.0 (20, 65)	Lower range	60.0 (25, 75)	10.0 (0, 28)	0.031
IIP-32	Interpersonal difficulties	8	74.5 (38, 101)	Most severe range (Horowitz et al., 1988)	53.0 (22, 76)	-20.5 (-42, -1)	0.016
WSAS	Work and social functioning	8	27.0 (11, 30)	Moderately severe (>20)	19.8 (8, 28)	-3.5 (-11, 4)	0.211
HSE	Experience of working conditions	8	105.0 (70, 161)	Low-moderate occupational stress (Cousins et al., 2004)	117.0 (81, 144)	7.5 (-6, 35)	0.156

Table 4. Changes in employment status before and after group therapy.

Client	Employment before therapy	Employment after therapy	Comments
1	Unemployed (recently dismissed)	Unemployed	Used job retention goals to tackle avoidance of seeking work through anxiety
2	Full-time, restricted duties	Full-time, full duties	Disclosed mental health problems, improved communication at work, positive changes to work behaviour
3	Part-time, off sick	Part-time	Used job retention goals to tackle avoidance of communicating with work
4	Part-time, off sick	Part-time	Used job retention goals to improve teamwork
5	Full-time	Full-time	Disclosed mental health problems, improved communication at work, but struggling to maintain employment
6	Voluntary work	Voluntary work, extra hours	Used job retention goals to write CV and reprocess trauma of previous job loss
7	Full-time	Full-time	Disclosed mental health problems, improved communication at work
8	Part-time	Part-time	Coping better at work after treatment, improved time management skills, and asked for colleague support when needed



266x323mm (72 x 72 DPI)