Effectiveness of briefer coping-focused psychotherapy for common mental complaints on work-participation and mental health. A pragmatic randomized trial with 2-year follow-up.

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Abstract

Purpose

The aim of this study was to assess short and long-term effectiveness of brief coping-focused psychotherapy (Brief-PsT) compared with short-term psychotherapy (Short-PsT) on work-participation (WP) and mental health. Both treatments were preceded by group education.

Methods

All participants were on, or at risk of, sick leave due to common mental complaints. Patients were selected for inclusion in this study based on levels of self-reported symptoms ('some' or 'seriously affected') of anxiety and depression. They were randomized to Brief-PsT (n=141) or Short-PsT with a more extended focus (n=143). Primary outcome was the transition of WP-state from baseline to 3 month follow-up. In addition, WP at 12 and 24 months follow-up were assessed. The secondary outcome, clinical recovery rate (CR-rate) was obtained from the Beck Depression and Beck Anxiety Inventories, at 2-year follow-up. In addition, self-reported mental health symptom severity, self-efficacy, subjective health complaints and life satisfaction were assessed.

Results

At 3 months follow-up, WP was significantly more increased in Brief-PsT compared with Short-PsT ($p=.039$). At 3 months, 60% in Brief-PsT and 51% in Short-PsT was at work, partial or full. Thereafter, these differences diminished, 84% and 80% were at work at 2-year follow up.

The 2-year follow-up of the secondary outcome measurements was completed by 53% in Brief-PsT and 57% in Short PsT. CR-rate was significantly greater in Brief-PsT compared with the Short-PsT (69% vs. 51%, $p=.024$). Furthermore, there was a greater reduction in the number of subjective health complaints in Brief-PsT (4.0 vs. 1.9 $p=.012$). All other measurements favoured Brief-PsT as well, but did not reach statistical significance.

Conclusions

Brief coping-focused psychotherapy added to group education for persons with depression or anxiety complaints seemed more effective in enhancing early work participation compared with additional short-term psychotherapy of standard duration with more extended focus. Clinical recovery rate and decline of comorbid subjective health complaints at 2-year follow-up were also in favour of the brief coping-focused program.

Introduction

Mental health complaints are common in the general population and frequently affect working ability [1, 2]. As work participation (WP) generally is regarded as beneficial for mental health [3-5], it may be of great importance to prevent long-term sick-leave. Early action and easy access to effective treatment is regarded as essential, but is usually challenging with regard to availability, capacity and resources [6]. A delay in the start of treatment may reduce effectiveness and the probability of maintaining or returning to work significantly [7-9].

Brief interventions (BI) has shown to be effective with regard to clinical outcome, with both mental health problems [10-14] and other common health complaints as low back pain and neck pain [15]. However, in particular for depression, clinical effect size (ES) measures for brief psychotherapy (5-8 sessions) appear to be smaller than that which is achieved with standard-duration short-term psychotherapies (12 to 20 sessions)[11, 12]. It is suggested that clinical effects of BI might not be long-lasting and might be insufficient in persons with relatively severe depression or with somatic comorbidity [11, 12, 16-20].

In common mental health problems, evidence for WP effectivity is still uncertain. In several low back pain (LBP) studies, however, BI has shown to be superior in facilitating WP compared with more comprehensive interventions [21-24]. Common for these BI approaches was a non-injury approach with focus on normalization of LBP symptoms by providing insight and understanding of the natural occurrence and harmlessness of non-specific LBP and hereby adequate coping of symptoms [25].

The outpatient clinic of the current study was part of a governmental initiated and financed "Rapid Return to Work program". The ambition was to contribute to enhanced WP by accomplishing more rapid clarification, treatment, and to shorten the waiting lists to treatment for persons on sick leave, or persons who are in danger of becoming sick listed. The outpatient clinic was transdiagnostic, including patients with common mental and/or musculoskeletal complaints. In addition to preceding group education, participants with mental health complaints were offered brief psychotherapy.

As with LBP symptoms, the experience of depressive and anxiety symptoms can usually be perceived as normal responses to life's challenges which sometimes may become disproportionately strong and inhibitory. In line with the experiences in the BIs for LBP, when facing patients with common mental health complaints, a 'normalization-approach' was applied. This implicated narrow problem emphasis and reframing the current problems as facts of life that one need to cope with, rather than focus on detection of underlying causes and psychopathology that has to be cured [26]. This obliged the therapists to have focus on normalization of symptoms, redirecting patients' concerns, restoring confidence, focus on resources, acceptance and consequently coping of their health problems and working life.

Running evaluation of this outpatient clinic preceding to this study had given us the impression that the patients obtained a more active coping style towards their health problems with consequential enhanced WP. These evaluations, in addition to our experiences in BI for LBP has generated the current hypothesis of this study towards WP. Yet, the sustainability of WP and long-term effects on mental health remained questionable. In this pragmatic RCT the objective was to compare brief psychotherapy with focus on normalization and coping (Brief-PsT) with short-term psychotherapy of standard duration with more extended focus (Short-PsT), as otherwise used in our Mental Health services. The primary aim of this study was to assess differences in effect on WP and the secondary aim was to assess differences in clinical response. We hypothesized that in the short term, Brief-PsT could facilitate or sustain WP in a superior fashion to Short-PsT in persons who are on, or at risk of sick leave due to mental health problems. Although we expected a substantial long-term rate of clinical recovery and reduction in mental health-related symptoms in both groups, we had no specific hypothesis regarding the extent and direction of possible group differences in these clinical measurements.

Methods

Design

This study is a pragmatic randomized controlled trial (RCT), with a 2-year follow-up period, nested in the clinical routine of the transdiagnostic program of our outpatient-clinic. Patients were stratified into two parallel trials according to self-rated symptom severity (mild vs substantial). In this study, only data from the participants with substantial mental complaints were applied.

Participants

Participants were invited to participate if 'mental complaints' was the main reason for referral to the outpatient clinic. All referrals were assessed by the clinic's psychologist coordinator. In cases of acute or severe pathology that required greater input than the clinic could offer, the patient was referred to the ordinary Mental Health service. To be included, the patients had to be employed and on or at risk of sick leave. Sick-leave had to be less than 9 months during the preceding 2 years.

Shortly following acceptance, the patients were invited to an individual introductive consultation to obtain information about the treatment modalities offered by the clinic. If the patient was at least 18 years of age, and had adequate ability to communicate in Norwegian they were also informed about the trial and invited to participate. If an informed consent was signed, the baseline questionnaire was completed.

Based on the scores on the anxiety (#28) and depression (#29) items of the Subjective Health Complaint inventory (SHC)[27] the participants were categorized as having 'substantial mental complaints' (73% of all participants) if they classified their complaints as 'some' (score 2) or 'seriously affected' (score 3) on at least one of the anxiety or depression item of the SHC. The

remaining 27% who responded either 'not at all' (score 0) or 'a little' (score 1) on both items were categorized as having 'minor mental complaints' and randomized to a parallel trial which is not discussed here. The anxiety and depression-question with the mentioned cut-off point has earlier shown overall accuracy of 90% and 89% respectively in identifying patients diagnosed according to Mini-International Neuropsychiatric Interview (MINI) results [28].

Randomization

Randomization procedure was carried out at Uni Research, Bergen, Norway. It was concealed and based on computer-generated randomization lists but stratified by gender. If the participant had completed the baseline questionnaire, the research assistant, not involved in the treatment, called the randomization unit to be informed about allocation.

The participants were randomized to either brief psychotherapy (Brief-PsT) or short-term psychotherapy with more extended focus (Short-PsT).

Intervention

A part of the "Rapid Return to Work program", the outpatient clinic operated with a low-threshold for admission and without a waiting list for individuals with mental health- or musculoskeletal complaints. The clinic was a collaborative initiative of the psychiatric and physical medicine department and located in a non-hospital setting. It embraced an interdisciplinary team of psychologists, physicians, physiotherapists and health educators. The intervention had a narrow focus on normalisation of common health complaints, redirecting patients' concerns and restoring confidence, acceptance and adaptive coping strategies with their health problems and working life. Although the implicit aim was to enhance work participation, this was not an explicit objective. Work-site contacts and visits were not incorporated.

Following a short individual orientation consultation, a 5-hours transdiagnostic group-education over two days was offered, guided by a health care professional. The education was aimed at providing insight and understanding and coping with common health complaints. Participants were supplied with updated evidence-based knowledge concerning anxiety, depression, natural responses to stress, musculoskeletal pain and various approaches to manage common health problems. Fundamental to the approach was the assumption that subjective health complaints are inevitable features of human life. In addition, all participants had the opportunity to participate in a five-day coping-course and individual coaching sessions with another health care professional. Valued areas of life such as meaningful work, personal growth and relationships despite health problems, were emphasized. Both courses applied a non-directive approach. Following the group-education, participants started psychotherapy.

Psychotherapy

Ten psychotherapists were involved in the study. Client-therapist allocation was done on a random basis

according to capacity. Two therapists were full-time employed with the clinic and eight therapists worked part-time during the project period. In both groups, the first session was a 90-minute intake session and, subsequently, 50-minute psychotherapy sessions. The sessions were individual, tailored and not manualized. In both interventions a standard treatment duration was set and communicated to the participants at the start of treatment, but therapists were allowed to adapt this number according to the dynamics of the therapy.

In the Brief-PsT psychotherapy, the focus was on normalizing, accepting and coping with their present mental health complaints and their hindrance for work participation. Primarily, there was no intention to process previous pathogenic experiences. The standard duration was set on 6 sessions.

In the Short-PsT, with more extended focus, there was besides coping of mental health and challenges concerning WP, an emphasis on both an extensive anamnesis and possibility to establish a so-called central theme based on previous or current challenging issues such as trauma, difficult childhood conditions, and personality-related issues. Additional aims of the intervention could include reducing symptoms and problematic behaviour and an improvement of home situation, with deeper focus on cognitive maladaptive coping strategies or dynamic repetitions. The number of sessions was aimed to be 20 on average.

Outcome

Following the first individual information consultation but prior to any intervention, a questionnaire package containing various standardised validated Norwegian versions of questionnaires, was completed at the clinic. A questionnaire was either provided at the clinic or sent by mail with reply-envelop three month's post baseline and by mail at two-year follow-up.

Changes at 3 months were defined as short-term effects and at 24 months as long-term effects.

Primary outcome measure

The primary outcome, short-term WP, was based on registry data from the Norwegian Labour and Welfare Administration (NAV). Sick leave data were obtained at 3, 12 and 24 months following inclusion. Sick leave less than 30% of ordinary working time were considered as being full-WP, 30-70% as partial-WP, and a sick leave gradient exceeding 70% as no-WP. Any-WP was defined as having partial- or full-WP.

The principal outcome of interest was the transition of WP-state from baseline to 3-months follow-up. As there were recorded three different WP-states, a new variable was created to make it possible to take baseline differences in account and to analyse both positive, negative and absence of transitions between baseline and the different follow-up states. In addition, this measure could value stable partial- or full-WP as well. Based on the three WP-states (no/partial/full), nine possible transitions from baseline to the follow-up time-points could be defined. These were ranked from 1 - the most unsuccessful change in WP, to 9 - the most successful change in WP (1. full to no-WP, 2. Partial to no-WP, 3. Unchanged no-WP, 4. Full to partial-WP, 5.

Unchanged partial-WP, 6. No to partial-WP, 7. Unchanged full-WP, 8. Partial to full-WP, 9. No to full-WP).

Secondary outcome measure

Clinical effect was determined by questionnaire-based changes in mental health. Severity of symptoms of anxiety and depression and mental distress were evaluated with the Beck Depression Inventory-II[29] (BDI), Beck Anxiety Inventory[30] (BAI) and Hopkins Symptoms Checklist-10[31] (HSCL) respectively. Higher scores reflect higher levels of symptoms or distress. Since a considerable proportion of the study group had minimal scores on either BDI or BAI at baseline already, a clinical recovery (CR) measure was composed from both Beck Inventories in order to improve the statistical capacity to detect clinical intervention effects. This measure was regarded as the main secondary outcome measure. A participant was considered as clinically recovered and achieved a non-clinical status if a minimal score on both Beck Inventories ($BDI \leq 13$ and $BAI \leq 9$) was obtained [32, 33]. HSCL-10-scores ≥ 1.85 was applied as the cut-off for indication of symptoms of mental distress. Self-graded severity of depression and anxiety symptoms during the past 30 days were evaluated with #28 and #29 item of the 29-item scale of the SHC on a four-point scale (0=no complaints, 1=minor, 2=some, 3=seriously affected).

The 30-day prevalence of 29 comorbid subjective somatic and psychological symptoms, was assessed using the SHC[27] as well. Perceptions relating to coping were assessed using the General Self-Efficacy Scale (GSE)[34], which determines optimistic self-beliefs about coping with a variety of difficult demands in life. A lower GSE-score reflects a lower generalized sense of self-efficacy. Quality of life was measured with the Life Satisfaction Questionnaire [35] (Lisat-11) targeting various areas of life. Higher scores indicate a greater degree of satisfaction.

At follow-up, the participants' self-assessed appraisal of Global Perceived Effect (GPE) was measured on a 7-point Likert scale ranging from -3 ('worse than ever') through 0 ('unchanged') to 3 ('completely recovered'). Impact on several health and life aspects was assessed on a 4-point Likert scale ranging from 'high degree' to 'absolutely not'. Treatment satisfaction was evaluated on a 5-point Likert scale ranging from 'very dissatisfied' to 'very satisfied'.

Statistical analysis

This study was designed as an Intention-to-treat (ITT) design, attempting to follow up all randomised individuals, including those who withdraw from treatment. All analysis were performed by original assigned groups. Categorical and ordinal data are presented as proportions (%), normally distributed numeric data as means with a standard deviation (SD), and not-normally distributed data as medians with an interquartile range (IQR). Shapiro-Wilk test was applied to determine normality of data.

Baseline group comparisons of demographic data were performed, using Pearson's Chi square tests for categorical variables and Mann-Whitney U tests for non-normally distributed continuous variables. Kruskal-Wallis H test was applied to assess median differences among therapists.

Time effects on WP for all follow-up moments were tested with Friedman's Test₍₃₎ per intervention group, followed by post hoc paired-samples Wilcoxon sign rank tests with Bonferroni correction for 3 pairwise comparisons within each group. Between-group differences at baseline and at each moment of follow-up was tested with Mantel-Hanzel Linear by Linear association. The main primary outcome was the transition of WP-state from baseline to 3-months follow-up. Results are presented as proportions for WP-states at all time-point and as proportions of the ranked possible transitions between WP-state at baseline to follow-up. Between-group differences in changes in WP-state between the consecutive time-points were measured with Mann-Whitney U test.

To test within-group intervention effects of categorical data with two categories McNemar's test was applied. For between-group difference in CR-rate and other dichotomous variables at 2-year follow-up, a Chi square test, with Yates' correction for continuity, was performed. To assess the impact of the two interventions on the other continuous secondary outcome measurements, mixed between-within subject analyses of variance between baseline and 2-year follow-up were conducted. The effect of time and the interaction effects (Time x Group) are reported. Effect sizes for comparisons within the groups are reported as Cohen's d and for between group comparison, effect sizes estimates are reported as generalized eta squared (η_G^2) and partial eta squared (η_p^2)[36]. For assessing between group differences in variables with ordinal categories, Mantel-Haenszel Test of Linear Association was applied. In the results, the proportions of only one or a combined category is mentioned, but the corresponding statistics for group-differences are applied for all categories. The significance threshold of all tests was set at .05.

For WP evaluations, both Full-ITT and Partial-ITT analyses were applied. In case of Full-ITT analysis, the last-observation-carried-forward rule (LOCF) for missing data was used. In the Partial-ITT analyses treatment group membership was retained as per random allocation, but at each assessment moment excluding participants with no follow-up data [37]. For the secondary outcome variables Full-ITT analyses were planned as well, but considering the high proportion of non-responders (47% and 43%) complete-case (CC) analyses were applied for those who completed the secondary outcome measurement according to original group allocation.

Data analyses were performed using IBM SPSS Statistics version 23.0. The study was approved by the Regional Committee for Ethics in Medical Research in South-Norway (Ref. 2013/1034/REK Sør-ØstB).

Figure 1. Consort diagram of participant flow.

Results

Loss to follow-up

Of 287 included in this trial, 143 participants were allocated to Brief-PsT and 144 to Short-PsT. Respectively 128 and 134 participants actually received psychotherapy. There were no significant differences in response rate at any time point between the randomization groups. See Figure 1 for details about drop-out and loss to follow-up.

Due to a serious administrative error, the three months follow-up of the secondary outcome measures was unsuccessful, so reporting on this is omitted.

Response rates of the questionnaire embracing the secondary outcome measures at 2-year follow-up was 53% in Brief-PsT and 57% in Short PsT ($p=.48$). Female participants of Short-PsT showed a higher

return rate of the questionnaire than the male participants (Brief-PsT: 58% vs. 44%, $p=.12$; Short-PsT: 68% vs. 42%, $p=.003$). In addition, the responders were significantly older than the non-responders (Brief-PsT: 43.4 vs. 36.5, $p=.001$; Short-PsT: 44.7 vs. 40.2, $p=.009$). There were no significant differences in WP at any time, nor in other demographic or clinical baseline characteristics. In both groups, responders had received more psychotherapy sessions (Brief-PsT median 5 vs. 3, $p<.001$; Short-PsT median 8 vs. 5, $p=.042$), more often counselling (Brief-PsT: 36% vs 6%, $p>.001$, Short-PsT 29% vs 10%, $p=.008$) and participation in coping course (Brief-PsT: 64% vs 23%, $p<.001$; Short-PsT 56% vs 39%, $p=.046$). Differences in participation in group education were only significant in Brief-PsT, (Brief-PsT: 97% vs. 85%, $p=.007$; Short-PsT: 95% vs. 88%, $p=.12$).

Table 1. Baseline characteristics of participants

	Brief-PsT (n= 141)		Short-PsT (n= 143)		
	mean	(sd)	mean	(sd)	P value
Age, years** (n=141,143)	40.3	(10.9)	42.9	(10.4)	.037
Gender, women* (n=141,143)	n	(%)	n	(%)	
Education* (n=137,139)					.51
Primary school	1	(0.7)	1	(0.7)	.91
Secondary school	37	(27.0)	37	(26.6)	
Vocational education	34	(24.8)	34	(24.5)	
University/college	60	(43.8)	62	(44.6)	
Other	5	(3.6)	5	(3.6)	
Employment status* (n=141,143)					.69
Full WP (<30% sick leave or disablement)	36	(25.5)	28	(19.6)	
Work & sick leave	29	(20.6)	28	(19.6)	
Work & partially disablement	1	(0.7)	1	(0.7)	
Fully on sick leave (> 70%)	73	(51.8)	85	(59.4)	
Sick leave & partially disablement	2	(1.4)	1	(0.7)	
Sick leave because of current complaints last 12 months** (n=131, 127)					.48
< 10 days	37	28.2	25	19.7	
10-24 days	17	13.0	23	18.1	
25-99 days	56	42.7	60	47.2	
≥ 100 days	21	16.0	19	15.0	
Health complaints* (n=136,135)					.24
Mainly mental health complaints	52	(38.2)	44	(32.6)	
Both mental and physical health complaints	83	(61.0)	87	(64.4)	
Mainly physical health complaints	1	(0.7)	4	(3.0)	
Duration mental health problem, present episode* (n=134,134)					.57
< 3 months	24	(17.9)	24	(17.9)	
3-6 months	33	(24.6)	40	(29.9)	
6-12 months	30	(22.4)	31	(23.1)	
1-3 year	26	(19.4)	14	(10.4)	
> 3 year	21	(15.7)	25	(18.7)	
Secondary outcome measures**	mean	(sd)	mean	(sd)	P value
Depression (BDI) (n=137,135)	25.8	9.4	24.9	9.2	.76
Minimal depression (0-13)	8.0 %		12.6 %		
Mild depression (14-19)	18.2 %		17.0 %		
Moderate depression (20-28)	38.7 %		34.8 %		
Severe depression (29-63)	35.0 %		35.6 %		
Anxiety (BAI) (n=137,136)	16.2	10.6	15.4	9.8	.68
Minimal anxiety (0-9)	32.1 %		30.9 %		
Mild anxiety (10-16)	27.0 %		27.9 %		
Moderate anxiety (17-29)	27.0 %		30.9 %		
Severe anxiety (30-63)	13.9 %		10.3 %		
Mental health (HSCL average) (n=139,139)	2.7	0.6	2.6	0.5	.95
High mental distress (>1.85)	91.4 %		92.8 %		
Self-efficacy (GSES) (n=138/138)	2.6	0.5	2.6	0.6	.98
Life satisfaction (LISAT average) (n=139,139)	3.6	0.7	3.7	0.6	.58
Subjective health complaints, number (SHC-nr) (n=136,137)	13.9	4.8	13.7	5.2	.62

* Chi-Square test, ** Mann-Whitney test

Participant characteristics

Baseline demographic and clinical characteristics of the participants are presented in Table 1. The participants in the Brief-PsT group were slightly younger. Apart from this, there was no difference in any other demographic or clinical characteristic. According to the Beck inventories 36% in Brief-PsT and 37% in Short-PsT were classified with moderate or severe degrees of both depression and anxiety symptoms. Prevalence of moderate or severe symptoms of depression only was 38% and 34% respectively. In both groups 6% had only anxiety in moderate or severe degree.

At baseline 74% of Brief-PsT and 80% of Short-PsT were on sick leave, (see table 1 and 3). Comorbid

musculoskeletal symptoms for at least three months were reported by 37% (Brief-PsT) and 47% (Short-PsT) (p=.08). The prevalence of SHC in the past 30 days was high, with 85% and 84%, respectively reporting back or neck pain (p=.76).

Intervention

Intervention participation is presented in table 2, according to ITT principle. The median number of psychotherapy session among the participants who actually had received psychotherapy was 5.0 in Brief-PsT (n=128) and 7.5 in Short-PsT (n=134) (p<.001). The participants in the Short-PsT group had received significantly more sessions of psychotherapy over a longer time-span, but there were no significant differences in participation

degree in the other, optional treatment modalities. Number of psychotherapy sessions varied widely within both groups from 0 to 31 sessions. The

one participant had problems beyond the scope of the project, three just stopped attending and the others stated that one psychotherapy session was sufficient.

[Table 2. Intervention (ITT)

	Brief-PsT		Short-PsT		Group differences p-value
Psychotherapy sessions [median, (IQR)]**	4.0	(4.0)	7.0	(10.0)	<.001
Other treatment: [n, (%)]*					
Group education	129	(91.5%)	132	(92.3%)	.80
Group coping-program	63	(44.7%)	70	(49.0%)	.47
Individual examination physiotherapist	11	(7.8%)	11	(7.7%)	.97
Individual coaching (with health worker)	31	(22.0%)	30	(21.0%)	.83
Total intervention, timespan (weeks) **					
[median, (IQR)]	15.1	(20.0)	27.4	(37.8)	<.001
categories [%]					<.001
0, no intervention	3	(2.1%)	2	(1.4%)	
1-13 weeks	60	(42.6%)	32	(22.4%)	
13-26 weeks	40	(28.4%)	36	(25.2%)	
26-52 weeks	26	(18.4%)	39	(27.3%)	
1-2 years	7	(5.0%)	26	(18.2%)	
>2 years	5	(3.5%)	8	(5.6%)	

* Chi-Square test, ** Mann-Whitney test

psychotherapy sessions after possible re-admission (1 in Brief-PsT, 2 in Short PsT) during the 2-year follow-up were included. Seventeen participants (10 Brief-PsT, 7 Short-PsT) never participated in a psychotherapy session; they either felt no need for it after group-education or just did not attend.

Twenty-one participants (14 Brief-PsT, 7 Short-PsT) terminated their psychotherapy after one session; Within the two-year follow-up period 15 (11%) Brief-PsT and 14 (10%) Short-PsT participants were referred again to outpatient treatment in secondary mental healthcare ($\chi^2=.06$, $p=.81$). From two until five years following inclusion, 21 (15%) and 20 (14%) participants respectively, received at least one psychotherapy session in secondary mental health care ($\chi^2=.05$, $p=.83$).

Two psychotherapists were involved in 61% of the study group, with 88 and 85 participants respectively. The other 90 participants who had received psychotherapy were treated by eight therapists with three to 28 patients each. For the two main therapists, proportion of Brief-PsT was 55% and 42%. For the other therapists the proportion was varying from 25% to 67%. Therapist allocation across the two interventions was non-significant ($\chi^2=8.25$, $p=.51$), indicating that the proportion of participants randomized to the two interventions was equally divided among the therapists.

Among all therapists, the median number of psychotherapy sessions by intervention did vary across the therapists in Short-PsT, ($H_{(9)}=18.58$, $p=.029$), but not in Brief-PsT ($\chi^2_{(9)}=15.30$, $p=.08$). There were no significant differences among the six therapists who had treated more than 10 participants

Group-differences in termination frequency before the second psychotherapy session did not reach statistical significance ($\chi^2=2.83$, $p=.092$).

Number of psychotherapy sessions received showed low correlation with age ($r=.23$, $p<.001$) and duration of their current health complaints ($r=.22$, $p<.001$), but were not related to any of the other demographic or clinical variables at baseline.

each (=92% of the participants that had received psychotherapy) (Brief-PsT: $H_{(5)}=5.69$, $p=.34$, Short-PsT: $H_{(5)}=9.90$, $p=.08$).

Primary Outcome Measure

Within both groups Full-ITT analyses showed statistically significant improved WP during follow-up (Brief-PsT: $\chi^2_{(3)}=128.71$, $p<.001$, Short-PsT: $\chi^2_{(3)}=137.15$, $p<.001$). Post hoc analyses are presented in table 3. At 3-months follow-up, in Brief-PsT, 47% was at work (any-WP) and 26% had full-WP. In Short-PsT, this was 40% and 20% respectively (any-WP: $\chi^2=2.45$, $p=.12$, full-WP $\chi^2=6.52$, $p=.011$). At 1-year follow-up, between group-differences were significant superior for Brief-PsT, both for any-WP and full-WP (any-WP: $\chi^2=4.68$, $p=.031$, full-WP $\chi^2=5.12$, $p=.024$). At 2-year follow-up differences were not significant.

Analyses of the transitions from baseline to follow-up showed that WP increased significantly faster following Brief-PsT compared with Short-PsT. Between-group differences in WP between baseline and the follow-up time-points were significant from baseline to 3 months follow-up. Partial-ITT analyses showed the same as Full-ITT analyses.

Table 3. Differences in proportions of no, partial or full WP of Brief- and Short-PsT at baseline and at each moment of follow-up and the differences of proportions in the 9 different ranked possible transitions between WP-state at baseline to follow-up.

Status	No-WP		Partial-WP		Full-WP		Test statistics											
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)	<i>p</i> -value											
Baseline (between-group differences)							$\chi^2_{(1)}=1.74$	.19										
Brief PsT	75	(53.2)	30	(21.3)	36	(25.5)												
Short PsT	86	(60.1)	29	(20.3)	28	(19.6)												
3 months follow-up (between-group differences)							$\chi^2_{(1)}=5.00$	.025										
Brief PsT	56	(39.7)	23	(16.3)	62	(44.0)	Z=4.52	<.001										
Short PsT	70	(49.0)	31	(21.7)	42	(29.4)	Z=2.85	<.001										
12 months follow-up (between-group differences)							$\chi^2_{(1)}=5.52$	.019										
Brief PsT	21	(14.9)	12	(8.5)	108	(76.6)	Z=5.81	<.001										
Short PsT	36	(25.2)	15	(10.5)	92	(64.3)	Z=5.84	<.001										
24 months follow-up (between-group differences)							$\chi^2_{(1)}=0.87$	.35										
Brief PsT	22	(15.6)	7	(5.0)	112	(79.4)	Z=0.43	.67										
Short PsT	29	(20.3)	6	(4.2)	108	(75.5)	Z=2.50	.012										
Transitions from baseline to follow-up																		
Status at Baseline:	Full-WP	Partial-WP	No-WP	Full-WP	Partial-WP	No-WP	Full-WP	Partial-WP	No-WP									
Status at Follow-up:	No-WP	No-WP	No-WP	Full-WP	Partial-WP	Partial-WP	Full-WP	Full-WP	No-WP									
	(substantial decrease)	(decrease)	(unchanged)	(decrease)	(unchanged)	(increase)	(unchanged)	(increase)	(substantial increase)									
Transition ranks:	1	2	3	4	5	6	7	8	9									
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)									
Baseline to 3 months follow-up (between-group differences)									U=8700.0	.039								
Brief PsT	0	0.0	8	5.7	48	34.0	2	1.4	14	9.9	7	5.0	34	24.1	8	5.7	20	14.2
Short PsT	5	3.5	6	4.2	59	41.3	1	0.7	16	11.2	14	9.8	22	15.4	7	4.9	13	9.1
Baseline to 12 months follow-up (between-group differences)									U=9068.0	.13								
Brief PsT	1	0.7	5	3.5	15	10.6	1	0.7	6	4.3	5	3.5	34	24.1	19	13.5	55	39.0
Short PsT	2	1.4	7	4.9	27	18.9	1	0.7	6	4.2	8	5.6	25	17.5	16	11.2	51	35.7
Baseline to 24 months follow-up (between-group differences)									U=9974.0	.87								
Brief PsT	2	1.4	6	4.3	14	9.9	1	0.7	5	3.5	1	0.7	33	23.4	19	13.5	60	42.6
Short PsT	0	0.0	6	4.2	23	16.1	0	0.0	5	3.5	1	0.7	28	19.6	18	12.6	62	43.4

The bold values are used to indicate statistical significant differences, according to Bonferroni corrections for the post-hoc paired samples.

Analyses: Within-group time-changes: Friedman Test, Brief PsT: $\chi^2(3)=129.71$, $p<.001$, Short PsT: $\chi^2(3)=137.15$, $p<.001$. Post hoc paired-samples Wilcoxon sign rank tests (Z) at each follow-up moment with comparison to the former time-point.

Between-group differences at baseline and at each moment of follow-up: Mantel-Haenszel Linear by Linear association (χ^2).

Between-group differences of transitions from baseline at each moment of follow-up: Mann-Whitney test (U).

During follow-up, 16% of the Brief-PsT group and 18% of the Short-PsT group showed a decline in the degree of WP (from full-WP to partial-/no-WP, or from partial- to no-WP) compared with a previous follow-up time-point ($\chi^2=.06$, $p=.80$). It is noteworthy that at 3 months, significantly more participants of the Short-PsT group who had full-WP at baseline had changed to no-WP (0 of 36 participants vs. 5 of 28 participants, $\chi^2=6.97$, $p=.008$).

At 2-year follow-up, in both intervention groups, the participants with no-WP had received a significantly greater number of psychotherapy sessions (Brief-PsT: 7.2 vs 4.6, $p=.018$; Short-PsT 11.6 vs. 8.1, $p=.040$). WP was not related to participation degree in any of the additional modalities.

Secondary Outcome Measures at 2-year follow-up

CC analyses of the CR-rate (minimal symptoms on both BDI and BAI) at 2-year follow-up showed significantly higher rates in the Brief-PsT group compared with the Short-PsT group: 69% vs 51% ($\chi^2=4.36$, $p=.037$).

Table 4 presents time-effects within and between the groups of the clinical measures. Within both groups, time effects were significant for all measures, with mostly large effect sizes. At 2 year follow-up, 76% in Brief-PsT had minimal symptoms on BDI and 78% on BAI. For Short-PsT this was 57% and 67% respectively. Improvements showed p-values <.001 for both measures, in both groups. Between group-differences of the proportions of minimal BDI and BAI scores were only significant for BDI (BDI: $\chi^2=6.01$, $p=.014$, BAI: $\chi^2=2.34$, $p=.13$). In addition,

in the Brief-PsT group, significantly more participants could be regarded as not being mentally distressed (HSCL) compared with the Short-PsT group (76% vs. 57%, $\chi^2=5.47$ $p=.019$). The proportion of participants with a self-rated absence of depression or anxiety complaints during the last 30 days, assessed with the SHC, was highest in the Brief-PsT group compared with the Short-PsT group (depression: 43% vs. 25%, $\chi^2=6.06$ $p=.014$; anxiety: 57% vs. 42%, $\chi^2=3.89$ $p=.049$). There were no significant interaction effect (time by group) for reduction in severity of mental complaints, self-efficacy or life satisfaction. There was an interaction effect in comorbid #SHC indicating a greater reduction in the Brief-PsT (28%) group compared with the Short-PsT group (13%), but effect size was small. The proportion of participants that showed an increased number of SHC at follow-up was higher in the Short-PsT group as well (17% vs. 32%, $\chi^2=4.34$ $p=.037$).

Two years post-baseline, no group-differences in GPE could be observed ($U=2799.5$, $p=.19$). In the Brief-PsT-group (median 2, IQR 0), 21% considered themselves as 'completely recovered' and 55% as 'much improved'. In the Short-PsT-group, (2, IQR 1), this was 19% and 45% respectively. However, significantly more participants in the Brief-PsT group than in the Short-PsT group ($\chi^2=4.30$, 70% vs. 54%, $p=.038$) rated their health as (very) good.

The participants of both groups, reported that they had substantial changes since baseline on: symptom reduction (high degree: 42% vs. 30%, ($\chi^2_{(1)}=0.48$ $p=.49$), coping with health complaints (high degree: 50% vs. 41%, $\chi^2_{(1)}=1.25$ $p=.26$) and understanding

the cause of the complaints (high degree: 54% vs. 55%, $\chi^2_{(1)}=.01$ $p=.98$). Impact on reducing the use of medication was greater in the Brief-PsT compared with the Short-PsT group (high degree: 44% vs. 32%, $\chi^2_{(1)}=4.79$ $p=.029$).

Most participants rated their perceived benefit of the psychotherapy sessions as (very) high (77% in Brief-PsT and 86% in Short-PsT group, $\chi^2_{(1)}=p=.18$). In both groups, overall satisfaction for the majority of participants was (very) high (79% vs. 77%, ($\chi^2=3.91$ $p=.4281$) as well.

In both groups, CR was not related to gender, age or to the number of psychotherapy sessions received. CR was associated with 2-years WP only in the Brief-PsT group: WP-rate among CR+ vs. CR- : 94% vs. 74% ($\chi^2=6.06$, $p=.014$) and in the Short-PsT group 88% vs. 75% ($\chi^2=2.35$, $p=.13$).

the Brief-PsT group; seven out of ten were recovered in the Brief-PsT group compared with half of the subjects in the Short-PsT group.

The results concerning WP were in accordance with our hypothesis and to what have been seen in common LBP; shifting from a curative approach to a normalization approach may be effective. However, the superior CR- rates favouring the briefest intervention were more surprising. In reality, the similarities of these two interventions were greater than the differences. Low-threshold, flexibility, preceding group-education, were prominent in both interventions. On the other hand, Brief-PsT had a normalising approach, while the more problem-oriented Short-PsT had some more sessions and a longer time-span on average.

Short- and long-term work participation

Table 4 Baseline and two-year follow-up comparisons of the secondary outcome measures (CC): depression (BDI), anxiety (BAI), mental health (HSCL), self-efficacy (GSES), life satisfaction (LISAT) and number of subjective health complaints (SHC). Effect sizes of time effects within- and between-groups generalized eta squared and partial eta squared.

	Brief-PsT		Short-PsT		Time			Time x group		
	Mean	95% CI	Mean	95% CI	F-value,	η^2	η_p^2	F-value,	η^2	η_p^2
					p-value			p-value		
BDI (total)*	<i>n</i> =71		<i>n</i> =80							
Baseline	25.6	(23.4-27.8)	25.1	(22.9 -27.3)	$F_{1,149}=236.0$,	.36	.61	$F_{1,149}=2.3$,	.01	.02
2-years	9.9	(8-12.2)	12.2	(10.1-14.4)	$p<.001$			$p=.14$		
d	-1.69		-1.31							
BAI (total)*	<i>n</i> =71		<i>n</i> =80							
Baseline	16.5	(13.7-19.2)	16.6	(14.2-18.9)	$F_{1,149}=98.79$,	.15	.40	$F_{1,149}=2.0$,	<.01	.01
2-years	6.8	(4.9-8.8)	9.3	(7.0-11.7)	$p<.001$			$p=.16$		
d	-0.94		-0.69							
HSCL (average)*	<i>n</i> =74		<i>n</i> =82							
Baseline	2.7	(2.5-2.8)	2.7	(2.6-2.8)	$F_{1,154}=257.6$,	.35	.63	$F_{1,154}=3.1$,	.01	.02
2-years	1.7	(1.5-1.8)	1.9	(1.7-2.0)	$p<.001$			$p=.08$		
d	-1.62		-1.28							
GSES (average)*	<i>n</i> =73		<i>n</i> =82							
Baseline	2.6	(2.5-2.7)	2.6	(2.5-2.7)	$F_{1,153}=100.1$,	.17	.40	$F_{1,153}=1.5$,	<.01	.01
2-years	3.1	(3.0-3.2)	3.0	(9-3.1)	$p<.001$			$p=.23$		
d	1.13		0.73							
LISAT (average)*	<i>n</i> =74		<i>n</i> =82							
Baseline	3.7	(3.5-3.9)	3.7	(3.6-3.9)	$F_{1,154}=129.7$,	.21	.46	$F_{1,154}=1.7$,	<.01	.01
2-years	4.6	(8.8-11.4)	4.4	(4.2-4.6)	$p<.001$			$p=.19$		
d	1.12		0.92							
SHC (total nr.)*	<i>n</i> =75		<i>n</i> =82							
Baseline	14.0	(12.9-15.1)	14.1	(13.0-15.4)	$F_{1,155}=53.9$,	.07	.26	$F_{1,155}=6.4$,	.01	.04
2-years	10.1	(8.8-11.4)	12.3	(10.9-13.7)	$p<.001$			$p=.012$		
d	-0.73		-0.32							

The bold values indicate statistical significant differences. *Mixed between-within subject analyses of variance.

d = Cohen's d within groups, η^2 = generalized eta squared, η_p^2 = Partial eta squared

Discussion

The main result of this pragmatic RCT indicated that brief psychotherapy focused on normalizing common mental health concerns and coping was superior in facilitating early WP compared with short-term psychotherapy with a more extended focus. Group-differences in WP were vanished by the 2-year follow-up, with the Short-PsT group having almost caught up with the Brief-PsT group. Still, the proportion that was regarded as clinically recovered at the 2-year follow-up was in favour of

It is difficult to compare results of WP with the available literature in mental health research. Time to first time WP is often applied as outcome and do herewith not consider partial or recurrent sick listing, which is quite common in this population [38, 39]. Relating to these studies may underrate intervention success of our study. Measuring 'lasting-WP', defined as a minimum fixed period of work assumption, or assessing number of days without sickness leave during follow-up might be a more reliable measure for WP [40]. Unfortunately, in this

study the obtained data did only allow us to evaluate the proportion of participants at sick leave at set single points of time from baseline. Comparing to studies evaluating lasting-return to work (RTW) will overestimate our results. Besides the lack of consistency in defining and measuring WP, WP is only occasionally an outcome measure and the follow-up duration is usually no more than 12 months [11, 12, 41]. Unlike our study, most other intervention studies with WP as outcome are specifically targeting workplace processes. Yet, it is rather uncertain whether specific work-focused psychological interventions are effective on work-participation [42-44]

A Norwegian governmental initiated low threshold clinical mental health care project with a comparable number of treatment sessions (median 5), showed only minor improvements in full-WP from pre- to post-treatment (from 40% to 46%)[45]. The few previous clinical studies comparing shorter interventions with more extensive programs in mental health have not found any differences in WP effectiveness of the shortest one either [41, 46, 47]. This lack of differences was found even though the contrasts between programs were usually much greater than in our RCT. LBP research, however, have found a similar superiority of BI in facilitating early RTW as in our study [22, 23].

It has been postulated that (too) early RTW may involve recurrent sickness absence [48, 49]. This was not observed in our study; both the number of WP-relapses, quantified as a decline in the degree of WP, and the number of re-admissions were not greater in Brief-PsT at any moment during follow-up. Within both groups, many participants started working again whilst still receiving treatment.

Long-term clinical response

There are few studies comparing such a low number of psychotherapy sessions in both groups. The available reviews and meta-analyses indicated mostly inferior or, at best, similar clinical effects of the briefest psychotherapy programs at post-treatment [11, 12, 50]. In general, as in the current study, the number of sessions received was not associated with clinical effects, neither at post-treatment nor at follow-up [50, 51]. This was also shown in some RCT's directly comparing longer and shorter therapies [17, 19, 20, 52-56]. Therapeutic change is clearly accelerated when a time-limit is imposed on psychotherapy, so equivalent outcomes could be attained in fewer sessions[55]. It is suggested that patients and psychotherapists adopt a more active attitude in such a situation, because they only have a few sessions in which to bring about an improvement [56, 57].

In general, post-treatment CR-rates appear to average 50% [51, 58, 59], but require 15-19 sessions according to Hansen (2003)[59]. Findings concerning lasting effects of psychotherapy beyond one year post-treatment are mixed. Both

sustainability and frequent occurrence of subsequent relapses or recurrences are reported [51, 58, 60-62]. The CR-rates of 69% and 51% at 2-years follow-up, as found in our study, seems therefore rather satisfying.

Despite a possible therapeutic acceleration in the briefest group, a superior clinical effect of Brief-PsT after long-term follow-up is still remarkable. Not only was the CR-rate of the Beck inventories in favor of Brief-PsT, the proportion who scored below the clinical cut-off for mental distress on HSCL and who graded their perceived depression and anxiety complaints (SHC) as absent was also greater. Although effect-sizes for between-group differences of the other improvements of mental health, coping perceptions and life satisfaction were small and non-significant, they were congruent and all in favour of Brief-PsT.

The study group was heterogeneous, consisting of subjects with mixed common mental health complaints in varying degree. As revealed from the distribution of the severity of symptoms in table 1, the study population included also subjects with either minimal depression or anxiety symptoms for whom there was no potential benefit from the intervention on BDI or BAI respectively. The relatively large variances in the diagnostic specific Beck inventories that measures depression and anxiety on continuous scales reduced the power to detect possible within- and between-group differences. Comparison of average intervention effects on the BDI and BAI scales separately may mask possible between-group differences of intervention effects in the subjects that actually were affected with either depression or anxiety at baseline. Therefore, in this study, a clinical composite for clinical recovery was applied, taking into account the heterogeneity of symptoms. The CR-rate considers clinically recovery state concurrently in both BDI and BAI. A single outcome measure eases interpreting overall clinical effect of the study. In our study, it also successfully handled the problem of clinical heterogeneity in baseline depression and anxiety severity which most likely influenced or modified the magnitude of the effects on the diagnostic specific scales.

Difference of therapy focus reason for effect differences?

The between-group difference in the number of psychotherapy sessions obtained was far less than intended. The variation within the groups however, was large and was neither related to mental health at baseline, nor to CR-rate at follow-up. The contrast between the interventions was therefore substantially reduced. In spite of this, some significant differences in outcome were found. As mentioned earlier, therapeutic change may accelerate when a time-limit is imposed. But, because of the low contrast, it is inappropriate to explain the group-differences in clinical response

based purely upon the differences of (intended) number of sessions and the subsequent differences in expectations of rate of improvement.

Even mild and short lived mental health symptoms may cause sick leave, and risk of an evil circle where the sick leave in itself may amplify symptoms and make them long-lasting. Likewise to the previously mentioned LBP trials [21-24], in the briefest group the focus was narrow and aimed mainly at normalization of symptoms, redirecting patients' concerns, restoring confidence, acceptance of and adaptive coping with the patient's most prominent problem. The beneficial aspects of normalization in low intensity therapy of subjects with common mental health disorders has been confirmed previously in a quantitative study [63]. It seems therefore timely to ask whether it might be the differences in the focus of the therapy that explain the group-differences in clinical recovery. Is it possible that in Short-PsT the additional focus on previous or current challenging issues confounded the process of acceptance of and coping with common health complaints? Even though the aim of Short-PsT was to resolve past and current psychological issues, one may ask whether the additional focus to a certain extent also led to perpetuated worrying, ruminating and focusing on symptoms. Although symptoms were clearly reduced in both groups at follow-up, the participants of Short-PsT showed a lower perceived level of health, less reduction in number of comorbid SHC and in reported use of medication compared with Brief-PsT. In the literature, it has been shown that subjective health complaints can be linked to preceding worry, maladaptive coping strategies and low expectations of a positive outcome [64-66]. Conversely, acceptance of health complaints has been shown to be prospectively related to decline in symptoms and improved WP [67].

However, from this study it is not possible to interpret the better CR-rate in Brief-PsT as an indication that Brief-PsT *as such* is more effective than Short-PsT. An alternative interpretation is that the increased early WP in itself may have mediated improved CR, regardless of the content of therapy. Although it may be necessary for some, prolonged sick-leave confirms a sick-role [5]. Being on sick leave may aggravate feelings of loss resulting in depression, or increase anxiety as life becomes more limited to the home environment. This effect may be stronger than what can be alleviated by the psychotherapy.

Methodological Issues

From the nature of the literature that demonstrates that BI in common mental health complaints may be effective in reducing symptoms but not superior to conventional therapy, we recognise that a non-inferiority analyses appeared more appropriate in this study. In that case, the conclusion of this study had been that Brief-PsT was non-inferior to Short-

PsT in improving WP and mental health. However, the primary outcome of this study was short-term WP improvement. RCT's in common mental health complaints with WP as the primary outcome measure, are scarce. Some of the authors of this present study have been scientifically involved in evidence of superior WP effects in BI towards LBP. This was confirmed in preceding non-controlled evaluations of our clinical practice with subjects with common LBP and/or mental health complaints. Hence, in this study, superiority analyses were chosen and noninferiority margins of change had not been predetermined.

The study was incorporated into the usual healthcare setting. In order to improve generalisability of findings, a pragmatic RCT design was chosen, acknowledging that even in the normalisation oriented approach, psychopathology may appear which the therapist may feel necessary to address. Vice versa, in the Short-PsT unnecessary and excessive treatment and identification of (new) problems needed to be avoided as well. Treatment manuals had not been applied in the psychotherapy. A limitation of the study was that we did not evaluate the therapists' intervention adherence concerning the aimed focus of the interventions.

An observed consequence of the offered flexibility, however, was that the difference in the number of psychotherapy sessions between the groups was less than intended. Also the variation within groups was much greater than expected. This moderated the contrast between the interventions substantially. Another consequence of the pragmatic design was that participants could choose to take part in additional treatment modalities. An advantage for the analyses and interpretation of the results was that, unexpectedly for us, participation degree in these other modalities did not differ between the intervention groups.

The psychologists treating the participants were not involved in any of the research processes of this present study and were not directly involved in sickness certification of the participants. They were experienced in both interventions methods. To avoid bias from specific therapist relationship factors and to assure rapid treatment admission, we chose not to have different therapists for the two different treatments. Their distribution across Brief- and Short-PsT was non-significant. Most psychotherapists were only part-time involved in the project and also employed at other mental health care settings where longer treatments were standard.

The aimed average of six psychotherapy session as a standard at our outpatient clinic had rather been a management directive than an aspiration of the therapists. The substantial reduced number of sessions in the Short-PsT could suggest treatment fidelity issues. Yet, we consider a specific expertise or fidelity to BI as unlikely, rather the opposite. This is consistent with earlier findings that therapists may

perceive managed care, in which time and or focus limits on therapy may be externally imposed, as ineffective [57]. Therefore, the low number of sessions in Short-PsT was unexpected. Rather, we may have underestimated the positive impact of the involvement of other health professionals, participation in the group education, optional coping course and individual coaching sessions. This may have facilitated the participants' insight and understanding of common health complaints and adequate coping of their health problems and herewith speeded-up and enhanced the impact of the psychotherapy. Recent systematic reviews confirm the clinical and economical value of patient education interventions in general [68, 69].

The intention for most participants at baseline was to return to work or to maintain in work despite health concerns. Although not significant, WP was slightly in favour for Brief-PsT at baseline already. As this was challenging to adjust for in ordinary non-parametric analyses a new conservative measure was composed. This was not protocolized in advance. The nine possible transitions between baseline and the different follow-up states were ranked: Changes of WP degree from full at baseline to no-WP at follow-up was considered as the least successful outcome and change from no- to full-WP was considered as the most successful outcome. Full-WP at the follow-up was valued highest and obtaining more WP-degree was rewarded compared with maintaining the same WP-degree. The main focus was on the transitions from baseline to 3-months follow-up. The potential for increasing WP is inflated when a larger percentage is already in work at baseline. Thus, the finding of not only larger WP at 3 months but larger increase in WP as well for the Brief PsT-group, must be considered very robust.

In both intervention groups, completeness of the follow-up of the primary outcome measure was satisfying, and the reasons for loss to follow-up could be considered as 'missing completely at random'; independent of the intervention or measurements. Therefore, Full-ITT analyses were applied [37]. Most of the cases with missing-data had missing data at all follow-up moments. Therefore, Partial-ITT analyses showed a slightly higher WP during follow-up because in the Full-ITT analyses the baseline value was carried-forward until 2-year follow-up, LOCF may give conservative estimates of outcomes within randomized groups and in conditions which tend to improve over time, this however, did not change the group-differences. The 2-year follow-up response rates of the secondary outcome measures were disappointing, but not related to treatment allocation. The low response rate, is however, basically not due to dropping out of treatment. It merely reflects that nearly half of the participant's did not replied the questionnaire, probably because they either considered their previous mental complaints as a closed chapter as

they moved on with life, or they were unsatisfied with the treatment. An additional factor might be that after treatment termination, there had been no contact with the participants anymore.

Responders had received more intervention which could implicate that non-responders either successfully terminated treatment early or discontinued treatment for other reasons. We have to mention that in this study the number of psychotherapy sessions received was not associated with clinical recovery. Essential is that losses to follow-up were neither related to treatment assignment, nor to clinical baseline measures or the primary outcome WP any follow-up moment. Nevertheless, some attrition bias may have occurred and may affect the validity of the clinical effectiveness within the groups. We presume, though, that this has not produced substantial bias in between-group differences of the clinical outcomes. As we had a substantial proportion of missing data, expected substantial natural time changes of outcome because of the long time-span and only one follow-up time-point, imputation or replacement to handle missing 2-year follow-up data from baseline data seemed inappropriate. This most likely may have resulted in an underestimation of the measure's variance, and possibly produced an increase in type II error [70]. Considering the mentioned lack of associations with allocation and with the clinical baseline variables and WP follow-up that hypothetically are associated to clinical recovery, a missing-at-random assumption appeared reasonable. For this reasons, a complete-case estimator seemed most appropriate and consistent. CC-analyses were conducted for all allocated participants, regardless of intervention adherence.

Implications for practice and further research

We want to emphasise that we do not claim that more psychotherapy might be harmful, but it might be rather less successful for patients with common mental health complaints. The main valuable implication of the at least non-inferior findings of Brief-PsT, is that offering Brief PsT to patients with common health complaints may release more resources for patients with more severe or long-lasting symptoms. But, of course, the potential non-inferiority or superiority of Brief-PsT warrant first further evaluations and confirmations from larger multicentre RCT's. Detecting the actual mediating mechanism of the superior therapeutic effect of Brief-PsT in this population seem relevant. This refers especially to the potential beneficial effect of early return-to or remain at work. In addition, conducting subgroup analysis of the main diagnostic groups may be advisable to unmask heterogeneous treatment responses.

Group education and subsequent brief psychotherapy with focus on acceptance and adaptive coping of mental health problems seemed effective with regards to WP and mental health. It

may be that participation in the education and the concurrent coping-course, enhanced the impact of the psychotherapy. Future studies should explore its additional benefit.

Another aspect to consider is the suggestion from previous literature that participants with severe depression or somatic comorbidity tend to show poorer results in brief psychotherapy [11, 12, 16-20, 53]. Although some participants in the present study reported severe symptoms at the point of entering therapy, the referral context secured that most participants had no long-lasting or recurrent psychic disorder. This was the rationale for offering merely a normalization and coping approach. This would be the considered counter-therapeutic for subjects with long lasting and handicapping disorders. We think that the present study indicate that a normalization approach may have some merit for subjects with common health complaints with no long-lasting mental disorder, but that the limits to this approach needs to be evaluated in future research.

Although costs are not quantified, it is clear that Brief-PsT was more cost-beneficial than Short-PsT. Reduced therapist usage, earlier WP and larger long-term health gains all implicate benefits for both the individual patient and society.

Conclusion

Brief coping-focused psychotherapy may have benefits compared with short-term psychotherapy with a more extended focus in persons with depression or anxiety complaints. Both early work participation, long-term clinical recovery and decline of comorbid subjective health complaints were in favour of Brief-PsT.

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Compliance with Ethical Standards

Conflict of interest. Aage Indahl is currently employed at the outpatient clinic. Eivind Andersen and Marjon E.A. Wormgoor were previously employed at the outpatient clinic of the current study. Jens Egeland and Marjon E.A. Wormgoor are currently employed in the Divisions of Vestfold Hospital Trust that runs the outpatient clinic of the current study. None of the authors have been clinically involved in the patient population of this study.

Ethical Approval All procedures followed were in accordance with the ethical standards of the

responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all individual participants included in the study.

Data availability The data-file that the current analyses are based on, is owned by Vestfold Hospital Trust and are kept on a secure research-data-server. Application for access to the data file must be send to the Data-privacy agent at Vestfold Hospital Trust by e-mail to Forskning@siv.no.

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