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Title page

Title: Internet delivered transdiagnostic treatment with telephone support for pain patients with emotional comorbidity: a replicated single case study

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Internet delivered transdiagnostic treatment with telephone support for pain patients with emotional comorbidity: a replicated single case study

Abstract

In pain patients, comorbid emotional problems have been linked to negative outcomes, including suboptimal treatment gains. Developing parsimonious and accessible treatment options is therefore important. The overarching aim of this study was to test an internet delivered therapist guided transdiagnostic treatment with telephone support. An adapted version of the Unified Protocol for Transdiagnostic Treatments of Emotional Disorders was used as an intervention for pain patients with residual pain problems and comorbid emotional problems after having received a multimodal pain rehabilitation. The study used a replicated AB single case experimental design (N=5; 3 females). Outcome measures were depressive and general anxiety symptoms, pain intensity, pain coping problems, and diagnostic status. Feasibility measures (completion and compliance) and patient satisfaction were also assessed. Scores on Nonoverlap of All Pairs (NAP) indicate a decrease of anxiety for three participants and a decrease of depression for four participants. Decreases were small and did not always reach statistical significance. Also, Tau-U scores could only confirm a reliable trend for one participant. Two out of four patients who were diagnosed with psychiatric disorders before treatment did no longer fulfill diagnostic criteria posttreatment. No improvements could be seen on pain problems. The treatment was feasible and patient satisfaction was high. Hence, while an internet delivered transdiagnostic treatment with telephone support may be a feasible and accepted secondary intervention for pain patients with comorbid emotional problems, the effects are unclear. The gap between high patient satisfaction and small changes in symptomatology should be explored further.

1. Introduction

In pain patients, comorbid emotional problems have been linked to various negative pain-related outcomes, including suboptimal treatment gains (Wurm, Edlund, Tillfors, & Boersma, 2016). Therefore, developing parsimonious and accessible treatment options for individuals with these comorbidities is essential. This study explores the benefits of a guided internet delivered transdiagnostic treatment with telephone support for pain patients with comorbid emotional problems.

People's experience of pain inevitably includes an emotional reaction, which influences how pain is appraised and handled. Individuals with chronic pain are more likely to have emotional problems than individuals without pain, both in clinical and non-clinical samples (Castro et al., 2009; Demyttenaere et al., 2007). Emotional comorbidity has been related to negative pain-related consequences, such as higher pain intensity and functional disability (Bair et al., 2013; Lerman, Rudich, Brill, Shalev, & Shahar, 2015) as well as less pain reduction, lower return to work, and higher levels of pain-related disability following multimodal pain treatment (Michaelson, Sjölander, & Johansson, 2004; Vowles, Gross, & Sorrell, 2004; Wurm et al., 2016). Also, comorbid emotional problems in pain patients have been found to remain at clinically high levels following multimodal rehabilitation (Wurm et al., 2016). Thus, while multimodal treatment is the treatment of choice for debilitating chronic pain (SBU, 2010), it is important to explore ways of improving treatment effects for pain patients with emotional comorbidities.

One way of improving results may be to focus on underlying and maintaining factors occurring across diagnoses, that is, transdiagnostic factors. For comorbid pain and emotional problems, suggested factors are anxiety sensitivity, threat focused cognitions, and avoidance (Asmundson & Katz, 2009). Transdiagnostic treatments focus on these factors in a general rather than a diagnose-specific way and can therefore simultaneously target multiple

diagnostic areas in or across individuals (Harvey, 2004). Hence, a transdiagnostic treatment is promising for our target group, which includes pain patients with heterogeneous anxious and depressive symptomatology.

One promising emotion focused transdiagnostic intervention is the Unified Protocol for Transdiagnostic Treatments of Emotional Disorders (UP, Barlow et al., 2010). It focuses on emotional awareness and exposure to emotional experiences and has been found effective in the treatment of depression and anxiety disorders (Bullis, Fortune, Farchione, & Barlow, 2014). It has also shown promise in addressing comorbid chronic pain problems in youth (Allen, Tsao, Seidman, Ehrenreich-May, & Zeltzer, 2012). Treatment studies using the UP found decreased functional impairment, anxiety, and depressive symptoms (Farchione et al., 2012) as well as decreased anxiety sensitivity and fear of emotions, and increased emotional awareness and acceptance (Sauer-Zavala et al., 2012). However, to our knowledge, no study has investigated the effectiveness of the UP in adult chronic pain patients. Given the shared mechanisms between chronic pain and emotional disorders, combined with high levels of comorbidity, this approach is promising when attempting to address key factors and may provide a parsimonious additional treatment approach for this complex patient group.

A prerequisite for a clinically useful treatment is that it matches patients' needs. One important aspect is accessibility, which advocates internet based treatments (Andersson, 2016). A great advantage of internet based treatments is that they are accessible from the patient's home at times that suit the patient. Internet based treatments are available to those who live far from clinics and may provide additional advantages for the unique needs of pain patients who commonly have problems with function and concentration.

Indeed, studies suggest that internet-delivered CBT treatments may be effective in relieving symptoms of depression, anxiety, and persistent pain (for reviews, see: Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Buhrman, Gordh, & Andersson, 2016). Also, a few

studies that used internet delivered treatments for pain patients with comorbid emotional problems showed positive effects (Buhrman et al., 2015; Dear et al., 2015). However, while a transdiagnostic internet delivered treatment for individuals with varying mood and anxiety disorders has been investigated with positive results (Titov et al., 2011), no studies have as yet tested an internet based transdiagnostic approach for chronic pain and comorbid emotional problems.

One important aspect of internet delivered treatment is the role of therapist support. Generally, therapist support is beneficial for outcome (Baumeister, Reichler, Munzinger, & Lin, 2014). Also, internet-delivered research with pain patients including telephone support have shown comparably good results (Dear et al., 2015). Telephone support may have several important benefits, such as providing additional positive reinforcement, and ascertaining that participants read materials and understand treatment content. Given the complex and debilitating nature of chronic pain and comorbid anxiety and depression, it is likely that telephone support is of particular importance in this patient group. Taken together, research indicates a potential for internet delivered, transdiagnostic CBT based treatments with telephone support for pain patients with comorbid emotional problems.

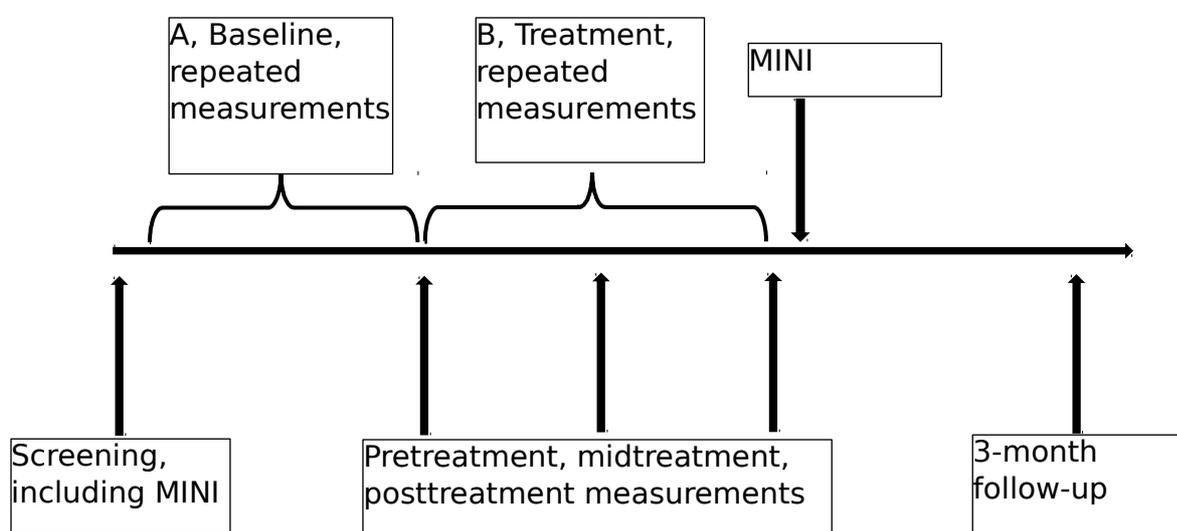
The purpose of the current study was therefore to investigate the effect of an internet-delivered adapted version of the UP with systematic telephone support. Since multimodal rehabilitation is the treatment of choice for debilitating pain we chose to focus on testing this treatment option as a secondary intervention for pain rehabilitation patients with residual pain problems and comorbid emotional problems after rehabilitation. Since this is a new target group and mode of delivery for the UP, we used a single case experimental design and focused on changes in general anxiety, depressive symptoms, and pain problems as well as treatment feasibility and patient satisfaction. Effects on diagnostic status were also assessed.

2. Method

2.1. Design

Figure 1 shows a flow chart of the design of this study. A single case experimental design (SCED), replicated across 5 participants was used. Repeated measurements were taken during baseline (phase A) when no treatment was provided and continued during the treatment phase (phase B). To establish the internal validity of a SCED, scores during treatment are compared to scores during baseline, which serve as a control (Kazdin, 2011). The baseline needs to contain at least three, but preferably more, measurements to detect a trend and to reach stability. Since pain patients are a heterogeneous group, a SCED is especially useful as it enables visualizing variability in individual participants (Barlow, Nock, & Hersen, 2009). Replicating a single case design across more than one participant is done to strengthen the external validity of effects (Barlow et al., 2009).

Figure 1 Flowchart of measurements



2.2. Procedure and participants

2.2.1. Procedure.

Three pain clinics and five primary care centers in central Sweden sent letters containing an ad for the study to former rehabilitation patients (N=600). The ad was also published online on the universities' homepage. No reward was offered for taking part in the study. Potential participants who declared interest via e-mail or mail (N=53) were given access to a secure internet platform to provide demographic information and fill in screening measurements. Of these, 12 withdrew interest or did not fill in screening measurements. The others (N= 41) received a telephone call after screening to follow up on inclusion and exclusion criteria and to provide further information about the study. Inclusion criteria were: a) chronic pain problems (≥ 3 months duration and an average of ≥ 5 on the Örebro Musculoskeletal Pain Screening Questionnaire (ÖMSPQ-sv, Linton, Nicholas, & MacDonald, 2011), b) depressive symptoms (≥ 15 on the Montgomery Åsberg Depression Rating Scale (MADRS-S, Svanborg & Åsberg, 2001) and/or anxiety symptoms (≥ 7 on the Overall Anxiety Symptoms and Impairment Scale (OASIS, Norman, Hami Cissell, Means-Christensen, & Stein, 2006), c) having received multimodal rehabilitation within the last three years, d) age ≥ 18 years, e) fluency in reading and writing Swedish, and f) internet access. Exclusion criteria were: a) ongoing or planned psychological treatment delivered by a psychologist or a psychotherapist, b) planned surgery, c) severe depression (> 36 on the MADRS-S), and d) suicidal ideations, ongoing alcohol or substance abuse, and/or ongoing psychosis (assessed using Mini International Neuropsychiatric Interview (MINI), Sheehan et al., 1998). Individuals not fulfilling criteria (N=17) were informed about the reason for non-inclusion and given recommendations regarding alternative treatment options when indicated. A random twelve individuals were asked to participate in a pilot trial testing the protocol. The other random twelve individuals were scheduled to participate in this study. Due to therapists' technical

difficulties and miscommunication on how to deliver the treatment, the protocol was not followed for three of the eight participants who finished the whole treatment (including follow-up), and these were therefore excluded from the analyses. In addition, one participant greatly improved during the waiting time prior to study start, one had accepted treatment elsewhere, and two participants dropped out directly after receiving the first module. Therefore, the final number of participants included in the current study was N=5. The N=7 participants not included are described in a section on drop-outs at the end of the result section. Participants were randomly assigned to one of five therapists. Therapists were two clinical psychology students in their last year of training, one graduated clinical psychologist, one postgraduate clinical psychology fellow and one certified clinical psychologist. Participants gave written informed consent. The Regional Ethical Review Board in Uppsala approved the study (No. 2013: 349).

2.2.2. Participant characteristics.

Three of five participants were female. Age ranged from 34 to 57. Participants lived up to 194 km from the study location (M= 61 km). Further details are found in Table 1.

2.3. Measures

Repeated measures of anxiety, depressive symptoms, and pain intensity were filled in during baseline (A) and treatment (B), at posttreatment, and 3 month follow-up. Repeated measures were filled in once a module, that is, approximately once a week, but separated by at least five days. Four participants started their baseline 10 weeks and one participant five weeks before treatment start. In addition, pain coping problems were assessed pre-, mid-, posttreatment and at 3 month follow up. Diagnostic status was assessed at screening and posttreatment. Treatment satisfaction and self-rated improvement were assessed posttreatment.

Table 1*Individualized description of participants at screening*

Participant	Age	Gender	Diagnoses	Pain- localization	Pain, years	ÖMPSQ (0-10)	OASIS (0-20)	MADRS (0-57)	Education	Employment status
1	45	F	GAD	Generalized ¹	4	8.0	5	23	University	Working
2	57	M	-	Neck, arms, hands, head	17	6.2	11	24	University	80% sick leave
3	34	F	SAD, GAD, Dysthymia	Neck, shoulders, head, other	7	8.0	8	21	University	100% sick leave
4	54	M	Agoraphobia, GAD	Neck, shoulders, hands, lower abdomen	7	7.8	10	21	High school	100% sick leave
5	42	F	GAD	Generalized ¹	11	7.5	5	18	University	50% sick leave

Note. ¹ Generalized pain= pain in more than 6 areas. ÖMPSQ = pain functioning. OASIS= general anxiety. MADRS= depressive symptoms.

GAD= Generalized Anxiety Disorder. SAD= Social Anxiety Disorder.

2.3.1. Screening measures.

2.3.1.1. Pain coping problems were assessed using pain duration, pain intensity, pain-related functioning, emotional functioning, and pain-related fear avoidance belief items (6/10) of the Örebro Musculoskeletal Pain Screening Questionnaire, short version (ÖMPSQ-sv, Linton, Nicholas, & MacDonald, 2011). For the purpose of screening we left out one avoidance item and questions about sleep and expectations for the future. Items are rated on a scale between 0-10 with higher scores indicating more difficulties in coping with pain. An average score of ≥ 5 was defined as indicating risk for persistent pain problems, which mirrors the cut-off score of 50 for the 10-item scale (Linton et al., 2011).

2.3.1.2. Depressive symptoms were assessed with the Montgomery Åsberg Depression Rating Scale (MADRS-S, Svanborg & Åsberg, 2001). The MADRS-S contains nine items listing areas affected by depressive symptoms, rated on a scale from 0 (normal functioning) to 6 (maximal disturbance) with total scores between 0-54. Following Carlbring, 2015; Leentjens, Verhey, Lousberg, Spitsbergen, & Wilink, 2000, participants with depression scores in the range 15 (in the upper mild depression range) - 35points (severe depression) were deemed eligible for study inclusion.

2.3.1.3. Anxiety symptoms were assessed with the Overall Anxiety Symptoms and Impairment Scale (OASIS, Norman, Hami Cissell, Means-Christensen, & Stein, 2006). It contains five items rated on a scale between 0-4, with total scores between 0-20. Higher scores indicate more problems. In a study using both clinical and non-clinical populations, a cut-off score of 8 for clinical anxiety correctly classified 67% of the sample (Moore et al., 2015). A total score of 7 (just under the clinical cutoff) was required for inclusion in the current study. The OASIS has demonstrated adequate psychometric properties when administered online (Ito, Oe, et al., 2015).

2.3.1.4. Psychopathology (suicidality, alcohol and drug use, psychotic symptoms) was assessed using parts of the Mini International Neuropsychiatric Interview, version 6 (MINI, Sheehan et al., 1998). The MINI is a widely used, brief, clinician rated structured interview designed to facilitate psychiatric diagnosis according to the Diagnostic and Statistical Manual of Mental Disorders (DSM). The version used in the current study was based on the DSM-IV, but adapted to match the DSM-V (American Psychiatric Association, 2013). In addition to exclusion purposes, the MINI was also used to describe patients' specific emotional problems at screening and posttreatment, assessing criteria for depression, mania, panic disorder, agoraphobia, social phobia, obsessive compulsive disorder, posttraumatic stress disorder, and generalized anxiety disorder.

2.3.2. Outcome measures

2.3.2.1. General anxiety and depressive symptoms were assessed weekly with the OASIS (described above, Norman et al., 2006) and the Overall Depressive Symptoms and Impairment Scale (ODSIS, Bentley, Gallagher, Carl, & Barlow, 2014). These scales each contain five items rated on a scale between 0-4. Item 1 and 2 reflect symptom intensity and frequency, item 3 reflects avoidance, and item 4 and 5 reflect interference in daily life due to symptoms. The ODSIS has also demonstrated adequate psychometric properties when administered online, and in a study using both clinical and non-clinical populations, a cut-off score of 8 for clinical depression correctly classified 82% of the sample (Ito, Bentley, et al., 2015).

2.3.2.2. Pain problems

Pain intensity was assessed weekly using one item: "How much pain have you had during the last week". The item was rated on a scale between 0-10, with higher scores indicating more problems. In addition, the ÖMSPQ (complete short version see above) was

used to assess pain coping problems pretreatment, mid-treatment, posttreatment and at 3 month follow up.

2.3.3. Feasibility measures.

2.3.3.1. Completion and compliance were assessed by examining 1) the number of participants who completed the treatment within the time frame and 2) the number of homework exercises registered on the platform.

2.3.3.2. Patient satisfaction was assessed following the recommendations from the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (Turk et al., 2003). Participants rated 1) their overall satisfaction with the treatment (very satisfied, mainly satisfied, indifferent or slightly dissatisfied, very dissatisfied), and 2) whether they would recommend the treatment to a friend (yes/no). Questions were administered as a paper and pen questionnaire via mail.

2.3.3.3. Self-reported improvement on UP treatment targets was assessed by asking participants whether they experienced considerable improvement (yes/no) regarding a) emotional avoidance, b) unhelpful emotion-driven behaviors, c) the ability to observe emotional experiences without judgement, d) the overestimation of probabilities and catastrophizing, and e) emotional discomfort caused by bodily sensations. Questions were administered as a paper and pen questionnaire via mail.

2.4. The treatment

Appendix A gives an overview of the treatment which consisted of an adapted telephone and e-mail guided internet-delivered version of the patient workbook of the UP (Barlow et al., 2010). Modules consisted of texts and homework exercises. The treatment is transdiagnostic and targets underlying mechanisms relevant in both pain and emotional problems, such as avoidance and catastrophizing. All participants got access to the same modules and exercises, but filled them with individual content. For example, the exposure

exercises contained individualized tasks relevant to the participant's goals and needs. To adapt the workbook to the internet delivery and the target group we shortened the psychoeducational texts, reduced the number of exercises, and added pain related psychoeducation and examples. The final text contained 11622 words, divided into 10 modules. More details about the adaptations are available from the correspondent author. The treatment was administered via a secure platform, which included an e-mail function for participants' questions. Therapists gave feedback within 24 hours (during workdays). Telephone support was provided contingent on starting a new module, including reading the new week's material. The calls were manualized, but therapists generally gave supportive feedback, clarified treatment content, and helped to plan exercises for the next week. Some weeks, specific topics were raised (see appendix A). This support is in line with the requirement of adapting the treatment to the patient's individual needs (Barlow et al., 2010). Total time spent on phone-calls and written feedback on the platform for each participant varied between 15 minutes to an hour a week, mostly due to variation in the length of the phone conversation.

3. Analyses

Repeated ratings of pain intensity, anxiety and depressive symptoms were displayed as graphs and analyzed by visual inspection, as is standard practice when conducting a SCED (Kazdin, 2011). The graphs were evaluated in terms of trend, i.e. the general direction in which the data is changing. Inspection of graphs was done independently by two raters with prior experience in single case design (MT and KB), and the main author (MW), followed by discussion for convergence. No formal inter-rater reliability was calculated. Since variability was high and trend was sometimes hard to establish visually, trendlines were employed during inspection to better detect potential downward trends during baseline. Also, co-authors were asked to inspect the graphs and raise potential concerns about the raters' assessment. Graphs

with complete data are included in the result section to enable readers to inspect and judge the data. In addition, change from baseline to treatment was quantified in three ways. First, the percentage of scores above the clinical cut off (≥ 8) on the OASIS and ODSIS during baseline and treatment phase were compared. Second, participants' change in mean levels on OASIS, ODSIS, and pain intensity from baseline to treatment phase was calculated. Third, Nonoverlap of All Pairs (NAP) and Tau-U were calculated. NAP is a nonparametric quantitative approach comparing every measurement in phase A with every measurement in phase B to determine overlap, non-overlap or tie (Parker, 2009). Scores between 0-0.65 are defined as small effects, 0.66-0.92 as medium, and >0.92 as large (Parker, 2009). Tau-U is calculated by dividing the net improvement sum, S, by the number of pairs in the data and expresses the trend in data as the percentage of data points that improved over phases (Parker, 2011). Scores of below 75% are considered questionable, between 75-90% effective, and $>90\%$ highly effective (Parker, 2011).

4. Results

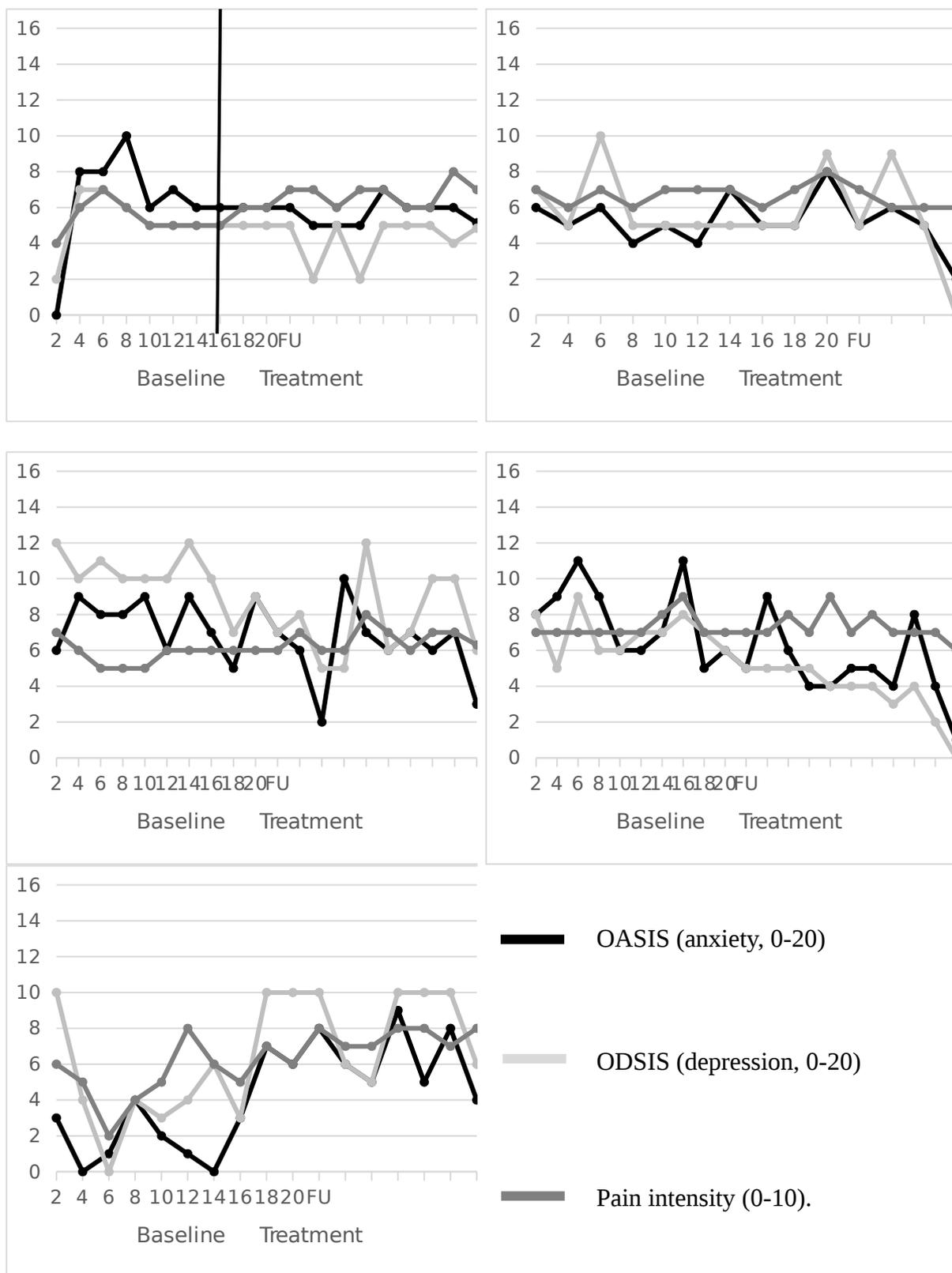
All 5 participants (labelled with 1-5 in texts, tables, and figures) worked through all 10 treatment modules and filled in follow-up measurements.

4.1. Anxiety, depression, and pain intensity

In Figure 2, repeated ratings of OASIS (anxiety), ODSIS (depression), and pain intensity during baseline and treatment are visualized in individual graphs. As can be seen, participants had more (1, 5) or less (2, 3, 4) variable baselines, usually without any clear downward trend in slope, indicating no significant change during baseline. There are exceptions: a downward slope can be seen before treatment start for participant 4 on anxiety, and for participant 5 on depression. Visual inspection shows no clear downward trend on the measures during the

treatment phase, except for depression and anxiety for participant 4. Scores at 3 month follow-up were stable (1, 3, 5) or decreased (2, 4), compared to the treatment phase.

Figure 2 Individual graphs visualizing repeated measurements



Note. FU= 3-month follow-up. Numbers on x-axis indicate weeks; the vertical line indicates treatment start.

Table 2 shows participants' results on anxiety (OASIS). Specifically, the table shows the proportion of scores above the clinical cut-off (≥ 8) during baseline and treatment phase, mean baseline and treatment phase scores, changes in mean across phases, NAP scores and Tau-U scores. Participant 1 and 4 started with a relatively high proportion of scores above the clinical cut-off and both showed large decreases. The other participants had none or a relatively low proportion of scores on clinical levels during baseline. Participant 3 and 5 showed an increase in the proportion of scores above the clinical cutoff. Participant 1, 2, 3, and 4 showed slight decreases in mean scores across phases. Participant 5 showed an increase. Regarding NAP-scores, participants 1, 3, and 4 showed changes in the medium range, but these were only significant for participant 4. Regarding Tau-U, the effects were questionable for all participants.

Table 2*Results from repeated measurements on anxiety (OASIS)*

Participant	% of scores ≥ 8 ¹ during baseline	% of scores ≥ 8 ¹ during treatment	Baseline Mean (sd)	Treatment Mean (sd)	Change in mean	NAP	NAP CI 90%	Tau-U
1	57	0	6.4 (3.2)	5.8 (0.6)	- 0.6	0.73 ^a	0.00<>0.94	0.47
2	0	10	5.7 (0.6)	5.4 (1.3)	- 0.3	0.65	-0.35<>0.95	0.3
3	0	27	7.8 (1.3)	7.2 (1.5)	- 0.6	0.69 ^a	-0.08<>0.83	0.36
4	56	18	8.0 (2.2)	5.5 (1.7)	- 2.5	0.84 ^{**a}	0.24<>1	0.68
5	20	55	2.0 (1.6)	5.3 (2.9)	+ 3.3	0.17 [*]	0.13<>1	-0.65

Note. ¹scores ≥ 8 indicate clinical levels of anxiety. ^{*}significant at .05-level. ^{**}significant at .01-level. ^a moderate effect.

NAP= Nonoverlap of All Pairs. Tau-U= percent of data showing improvement between phases.

Table 3 shows participants' results on depression (ODSIS). Participant 3 started with a high proportion of scores above the clinical cutoff and showed a large decrease. The other participants had none or a relatively low proportion of scores on a clinical level during baseline. Of these, participant 4 showed a decrease in the proportion of clinical scores, with no scores on clinical levels during treatment. Participant 5 showed an increase. Participant 1, 2, 3, and 4 showed slight decreases in mean scores across phases. Participant 5 showed an increase. Regarding NAP-scores, participants 1, 2, 3, and 4 showed changes in the medium to large range. These changes were significant for participants 3 and 4. Regarding Tau-U, the effects were questionable for all participants except participant 4 whose Tau-U scores indicate a highly effective treatment.

Table 3*Results from repeated measurements on depression (ODSIS)*

Participant	% of scores ≥ 8 ¹ during baseline	% of scores ≥ 8 ¹ during treatment	Baseline mean (sd)	Treatment mean (sd)	Change in mean	NAP	NAP CI 90%	Tau-U
1	0	0	5.3 (1.7)	4.4 (1.2)	- 0.9	0.71 ^a	-0.04<>0.90	0.43
2	34	27	7.3 (2.5)	5.8 (1.7)	- 1.5	0.73 ^a	-0.18<>1	0.47
3	100	45	10.6 (0.9)	7.8 (2.2)	- 1.8	0.86 ^{***a}	0.28<>1	0.73
4	34	0	6.9 (1.1)	4.3 (1.1)	- 2.6	0.96 ^{***b}	0.48<>1	0.92 ^b
5	20	55	4.2 (3.6)	7.6 (2.8)	+ 3.4	0.21	0.05<>1	-0.58

Note. ¹ scores ≥8= indicate clinical levels of depression. **significant at .01-level. ***significant at .001-level. ^a moderate effect, ^b large effect.

NAP= Nonoverlap of All Pairs. Tau-U= percent of data showing improvement between phases

Table 4 shows results for repeated measures on pain intensity, as well as pain coping problems (ÖMSPQ) pretreatment, posttreatment and at 3 month follow up. Mean changes across phases on pain intensity show either no change or increases. NAP and Tau-U scores do not indicate an

effect, except for participant 5 where a significant increase in pain intensity is detected. Scores on pain coping show no marked changes and posttreatment mean scores remain on levels high enough to indicate problems (≥ 5).

Table 4

Results from repeated measurements of pain intensity and pain coping problems (ÖMPSQ)

Participant	Baseline	Treatment	Mean change	NAP	NAP CI 90%	Tau-U	ÖMPSQ			
	M (sd)	M (sd)					Pre	Mid	Post	FU
1	5.4 (1.0)	6.5 (0.8)	+ 1.1	0.21*	0.1<>1	-0.57	4.9	5.4	5.0	4.8
2	6.7 (0.6)	6.7 (0.7)	0.0	0.50	-0.65<>0.65	0	6.3	5.3	4.9	5.2
3	5.8 (0.7)	6.5 (0.7)	+ 0.7	0.23*	0.09<>1	0.59	6.3	5.1	7.1	4.9
4	7.3 (0.7)	7.4 (0.7)	+ 0.1	0.48	-0.40<>0.48	-0.04	7.8	7.9	7.2	6.8
5	4.4 (1.5)	7.0 (1.0)	+ 2.6	0.05**	0.36<>1	-0.89	5.7	5.4	6.1	7.4

Note. ÖMPSQ= pain functioning. *significant at .05-level. **significant at .01-level. NAP= Nonoverlap of All Pairs. Tau-U= percent of data

showing improvement between phases. FU= follow-up.

4.2. Diagnostic status

Table 1 describes whether participants were found to fulfill diagnostic criteria for specific emotional disorders, and if so, which ones. Four out five participants (1, 3, 4, and 5) fulfilled criteria for at least one emotional disorder, most commonly generalized anxiety disorder.

Posttreatment assessment of criteria showed that participants 3 and 5 still reached the same diagnostic criteria posttreatment, while participants 1 and 4 were no longer diagnosed with any specific emotional disorder.

4.3. Feasibility and patient satisfaction

Table 5 shows an overview of measures of feasibility and patient satisfaction.

Participants filled in baseline measurements between three and nine times (mean= 6.4). All five participants completed the full program, including the 3-month follow-up. Four within approximately the aimed for time-frame of ten weeks, while one needed 14 weeks and three days due to a three week vacation.

Table 5
Compliance, completion, and patient satisfaction

Participant	Baseline, weeks	Time needed (weeks, days) to finish treatment	Numbers of exercises reported on platform	Satisfied with treatment	Would recommend treatment
1	7	11	44	very	yes
2	3	11,5	54	very	yes
3	8	14,3	49	mainly	yes
4	9	10,3	52	mainly	yes
5	5	11,6	44	mainly	yes

The modules included 21 homework exercises described in the Appendix. Participants were encouraged to repeat exercises, which resulted in 44-54 exercise occasions reported on the platform. Participants reported satisfaction with the treatment and would recommend it to a friend.

4.4. Self-reported improvement

Table 6 summarizes self-reported improvements on UP treatment targets. Four participants reported improvement regarding the ability to observe emotional experiences without judgement, and discomfort caused by bodily sensations while three reported improvements regarding emotional avoidance, unhelpful emotion driven behaviors, as well as overestimation of probabilities and catastrophizing.

Table 6

Self-reported improvement

Participant reports considerable improvement (yes/no) regarding:					
Participant	Emotional avoidance	Unhelpful emotion-driven behavior	Ability to observe emotional experiences without judgement	Overestimation of probabilities and catastrophizing	Emotional discomfort caused by bodily sensations
1	yes	yes	yes	yes	yes
2	yes	yes	yes	yes	yes
3	no	yes	no	no	yes
4	yes	no	yes	yes	yes
5	no	no	yes	no	no

4.5. Dropouts

This section gives an overview of background data on the participants not included in the main report due to early drop out or diversions from the protocol. Table 7 shows a description of participants at screening. Participants 6, 7, and 8 finished treatment, but the treatment did not fully follow the protocol. Diversions from the protocol were related to the mode of delivery of the treatment: one participant did not get feedback online and two were called weekly instead of contingent on opening a new module. Participants 11 and 12 dropped out before the start of baseline measurement and participant 9 and 10 dropped out after receiving the first module. The reasons for drop out were getting treatment elsewhere (11), having improved considerably during the waiting period (12) and not agreeing with the main treatment conceptualization, for example regarding the need to not avoid emotions (6, 7). Background and screening characteristics show no systematic difference compared to the participants finishing the treatment. While there were diversions from the protocol for participants 6, 7, and 8, they did receive the same treatment content, and therefore their results may be of interest. We make the data on their response to treatment available in appendix B. In short, the results are in line with the results for the five participants in this report.

Table 7*Individualized description at screening of participants not included in main results*

Participant	Age	Gender	Diagnoses	Pain-localization	Pain, years	ÖMPSQ (0-10)	OASIS (0-20)	MADRS (0-57)	Education	Employment status
6¹	54	F	DEP	Lower back, legs feet, stomach	“Several years”	8	7	30	High school	75% sick leave
7¹	54	F	DEP, GAD	Generalized*	21	6.8	9	24	High school	100% sick leave
8¹	53	F	-	Generalized*	5	7.5	5	23	High school	Unclear (no work, no sick leave)
9²	45	F	DEP, PD, Agoraphobia,	Generalized*	30	6.7	11	20	University	100% sick leave
10²	61	F	SAD, GAD SAD	Neck, abdomen, lower back, legs	10	4.7	7	18	Compulsory school only	Working
11³	30	F	DEP, PD, Agoraphobia,			5.8	9	19	Information missing	Working
12³	40	M	SAD, GAD -	Shoulders,	7	6.7	6	19	University	Working

lower back

Note. ¹ Did not follow protocol. ² Declined participation at module 1. ³ Declined participation before baseline. GAD= Generalized Anxiety Disorder, DEP= major depression, SAD= Social Anxiety Disorder, PD= Panic Disorder. * Generalized pain= pain in more than 6 areas.

5. Discussion

The aim of this study was to investigate the effect of an internet delivered transdiagnostic treatment with telephone support for pain patients with residual pain coping problems and emotional comorbidity after having received multimodal pain rehabilitation.

Four out of five participants showed improvements on either anxiety or depressive symptoms or both, indicated by medium to large NAP-scores. Nevertheless, changes were small and only statistically significant for two participants of which only one participant had a Tau-U score indicating a reliable trend. Two participants improved regarding diagnostic status. Similar results could be seen for the three additional participants finishing treatment (see appendix B for details). At follow-up, decreases were maintained or, for two participants, had improved further. This is in line with earlier studies using the UP, including the small study on pain patients where participants also showed further improvement at follow-up (Allen et al., 2012). Nevertheless, both previous studies using the UP for other target groups (Farchione et al., 2012) and studies using a different treatment with a similar sample (Dear et al., 2015) showed stronger results on emotional problems. There are several possible reasons for this.

The small effects could be due to changes in treatment content and length. In an effort to adapt the treatment to the need of pain patients and to the internet format we considerably shortened the text and amount of exercises. We deemed this necessary since our pilot study showed that participants had difficulty understanding the material and translating it into concrete action, which made them get stuck and drop out (Lorenz & Klein Strandberg, 2016). Even though the essence and primary goal of each module was retained, important information and homework experiences may have gotten lost in this process. On the other

hand, the positive results on patient satisfaction, and patients' own positive judgment on their improvements on UP treatment targets, imply that the resulting texts and exercises still resonated with patients' experiences and were perceived as credible and helpful. An additional reason for small changes could be that our measures were not sensitive enough to pick up changes, especially considering that for some participants, baseline levels of anxiety and depressive symptoms were already relatively low, which leaves less room for improvement. Finally, earlier studies provided more time and training per module. Potentially, a longer treatment with more time spent on important aspects of the treatment, such as exposure, would have improved results. The two participants who still reached diagnostic criteria posttreatment (3, 5) also reported that they did not feel they had improved on catastrophizing and avoidance, two central treatment targets of the UP that are believed to be central mechanisms in both emotional disorders and pain problems.

Regarding pain problems, there were no changes. The lack of change on pain intensity is in line with other studies showing small to modest results on this variable (Eccleston, Williams, & Morley, 2009). However, we hypothesized stronger effects on pain coping problems, given that many of the treatment targets in the UP, such as avoidance and catastrophizing, have been successfully influenced in pain patients (Linton & Fruzzetti, 2014). Even though we adapted content to provide plenty of pain-related examples, the treatment may not have included enough pain specific content compared to earlier studies using a similar sample (Dear et al., 2015). This is potentially an area where the treatment manual could be improved.

Since the UP was a new treatment approach for this target group, feasibility, patient satisfaction, and self-reported improvement were of special interest. As described above, participants in our pilot study experienced difficulties working with the modules, leading to a high drop-out during treatment (75%). High dropout is an issue in internet based treatment

research where studies show an average drop out of 35% (range 2-85%) (Melville, Casey, & Kavanagh, 2010). Therefore, we made changes regarding the complexity and length of texts and added a supportive telephone call, contingent on starting a new module. This seemed successful in keeping participants committed to the entire program, since 8 out of the 10 participants filling in baseline measurements also finished the entire treatment. While telephone support generally has not shown to improve retention rate (Melville, Casey, & Kavanagh, 2010), the telephone support specifically contingent upon starting a new module may have stimulated participants to read materials and continue to the next module within the agreed upon time-schedule. Participants indeed showed commitment to the treatment. They read 48 A-4 pages of obligatory text (11622 words) plus up to 32 optional pages (8557 words) and reported an average of 49 homework exercises per participant. They also reported satisfaction with the treatment and improvement in areas directly targeted by exercises, such as emotional avoidance. Thus, while added telephone support is somewhat more costly and time consuming, it may lead to higher retention rates. This may be especially important for patient groups with complex problems, as was indicated by earlier studies (Dear et al., 2015). All in all, the results for feasibility and patient satisfaction were encouraging and indicate that the treatment was seen as credible.

The study had some limitations. First, choice of design was based on the potential for a detailed inspection of individual pathways, which capture information that may have gotten lost in group based analyses. However, while single case experimental designs control for threats to internal validity, the design is weaker in securing external validity. As can be seen in the procedure section, we reached out to a large population of former rehabilitation patients, but only few responded with an interest in the study. Selection procedures thereafter further reduced the patient number. While the single case study design in principle is not reliant on the number of patients included, our selection process makes it unclear how

representative our participants are for the population of pain patients. Nevertheless, the participants were all former pain rehabilitation patients with a clinically meaningful problem profile (longstanding pain duration, sick leave, comorbid emotional disorders) which raises the likelihood of external validity. Second, the measurements used limit our ability to draw conclusion about construct validity. For example, we directly asked patients whether they considered themselves improved (yes/no) on the transdiagnostic factors targeted in the UP. The reliability of these questions is unclear. Measurements that more concretely and objectively assessed treatment targets such as avoidance behavior could have improved our ability to draw valid and reliable conclusions. Also, the measurement of pain coping problems could have been more diverse. For example, including a repeated measure of pain acceptance and pain catastrophizing could have provided a better opportunity to evaluate a possible effect. Acceptance and pain catastrophizing are key pain related transdiagnostic factors that have been found sensitive to change (Vowles, McCracken & Eccleston, 2007). Hence, the recruitment process and choice of measurements can be further developed.

6. Conclusion

In summary, adapting the UP to an internet format and using it as an add-on treatment option targeting transdiagnostic problems in pain patients with emotional comorbidity has not previously been tested. There is a need for parsimonious and flexible treatment options for this complex patient group that often struggles with problems despite having received rehabilitation and other forms of advanced care. This study was an attempt to improve treatment results as well as to explore a format of internet delivery that may meet these patients' needs. By providing an internet delivered intervention and combining it with systematic phone calls, patients may have gotten the necessary combination of flexibility and support to ensure adherence. However, the effects were small and further exploration of

whether the Unified Protocol is effective for this patient group when delivered over the internet is needed.

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Appendix A

Table A 1 Overview of the treatment

Modules	Theme	Content		
		Psychoeducation	Exercises	Telephone support ¹
1	Motivation and goals	<ul style="list-style-type: none"> • Pain and emotional factors • Motivation • Goals 	<ul style="list-style-type: none"> • Problem formulation • Listing arguments and counter-arguments for and against change • Goal setting 	<ul style="list-style-type: none"> • Motivation as fluctuating
2	Under-standing emotions	<ul style="list-style-type: none"> • Nature and function of emotions • Components of emotional experiences 	<ul style="list-style-type: none"> • Identifying characteristics of different emotions • Distinguishing components of emotional experiences 	<ul style="list-style-type: none"> • Normalize the existence of negative emotions
3	Mapping emotions	<ul style="list-style-type: none"> • Antecedents of emotions • Operational learning 	<ul style="list-style-type: none"> • Mapping antecedents and consequences 	
4	Non-judgmental awareness	<ul style="list-style-type: none"> • Secondary reactions to emotional experiences • Non-judgmental awareness 	<ul style="list-style-type: none"> • Practicing non-judgmental awareness of emotional experiences • Breathing exercise 	<ul style="list-style-type: none"> • Normalize perceived difficulties with mindfulness • Acceptance ≠ to like or to give up
5	Under-standing	<ul style="list-style-type: none"> • Appraisals and meaning making • Probability over- 	<ul style="list-style-type: none"> • Counteracting overestimation of probability and catastrophizing 	<ul style="list-style-type: none"> • Check thought-content for obsessive thoughts • Remind of non-judgmental

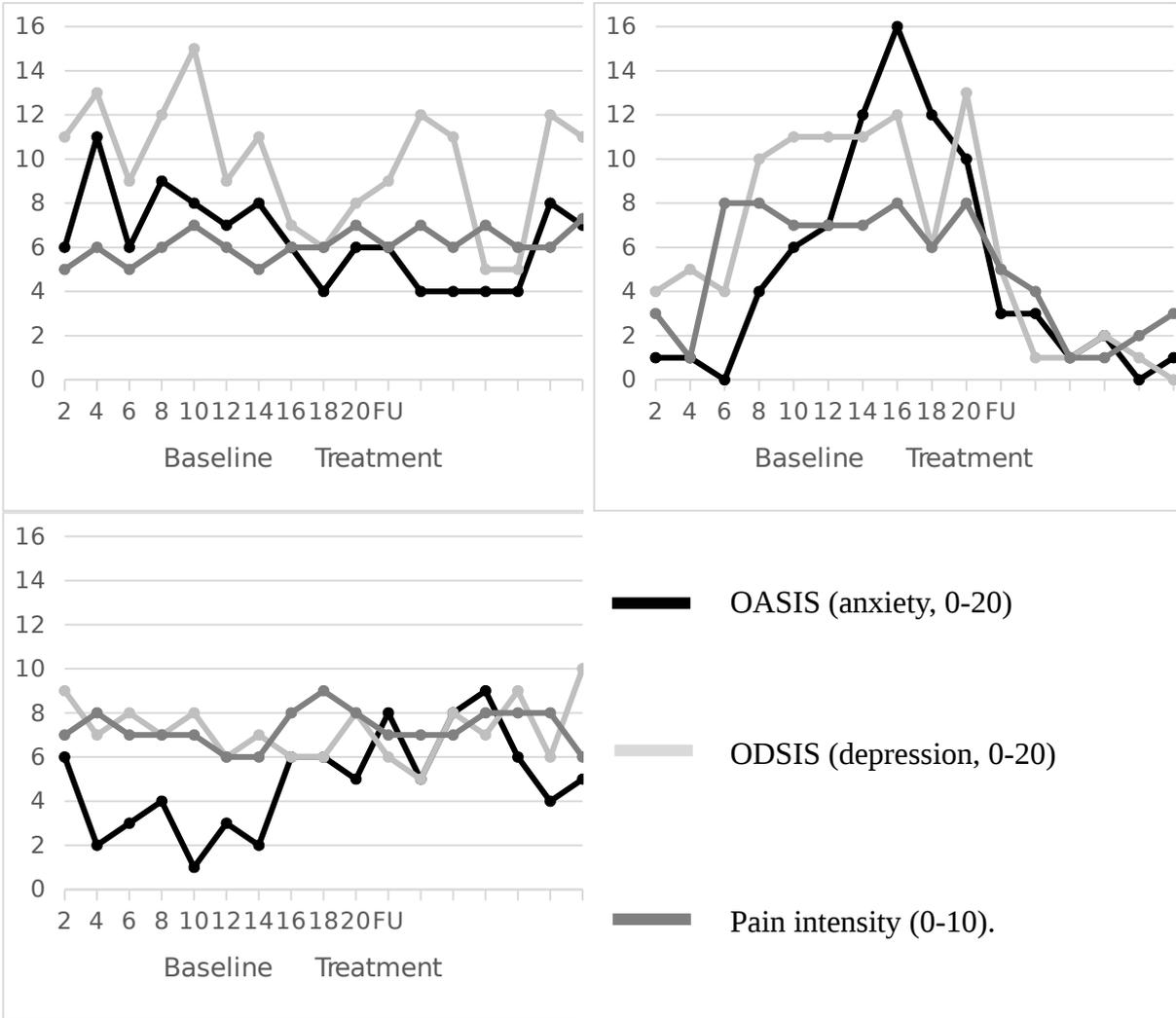
	thoughts	estimation and catastrophizing		awareness
		• The importance of		• Find participant’s own example
6	Emotional avoidance	cognitive flexibility	• Nature and consequences of	• Identifying emotional avoidance
7	Emotion-driven behaviors (EDB)	emotional avoidance	• The nature and consequences of EDBs	• Identifying EDBs • Unhelpful EDBs, alternative behaviors • Testing and evaluating alternative behaviors
8	Emotional experiences and physical sensations	emotions	• Physical sensations and emotions • Introduction to emotional exposure	• Evoke emotions with music • Exposure to physical pain sensation • Creating a hierarchy for emotional exposure
9	Emotional exposure	emotional exposure	• Rationale for emotional exposure	• Highlight bodily sensations as part of emotional experiences. Find participant’s own examples. • Remind participant of helpful techniques from earlier weeks. • Discuss hierarchy.
10	Maintaining planning	exposure	• Repetition of principles • Setbacks	• Emotional exposure • Evaluating progress • Formulation of new goals
				• Remind of upcoming MINI and follow-up

-
- Planning future development
-

Note. ¹ Every week: positive reinforcement, clarifying treatment content, help to plan the coming week.

Appendix B: Results for the three participants not included in the main results

Figure B 1 Graphs for visual inspection, participants 6-8



Note. FU= 3-month follow-up. Numbers on x-axis indicate weeks; the vertical line indicates treatment start.

Similarly to the other participants, visual inspection shows some variability. For participant 6 baselines scores appear to be stable or increasing somewhat. Participant 7 has a steep incline during baseline which peaks at week 4 of treatment. This coincides with her reporting to have lost her income (sick-leave money) during baseline, which was reinstated during treatment.

Participant 8 shows a clear downward slope already during baseline on both anxiety and depression.

Feasibility and patient satisfaction

Participants 6, 7, and 8 were active online, reporting 51, 55, and 43 exercises. They finished the whole treatment in 14 weeks and two days (6, 8) and in 10 weeks, 1 day (7) and filled in the follow-up 3 months later. They were very satisfied with the treatment, would recommend it to a friend and reported improvement in 4 (6), 3 (7) and 2 (8) areas targeted by the treatment.

Table B 1 Results from repeated measurements on anxiety (OASIS) and depression (ODSIS) for drop-outs

	Participant	% of scores ≥8 ¹ during baseline	% of scores ≥8 ¹ during treatment	Baseline Mean (sd)	Treatment Mean (sd)	Change in mean	NAP	NAP CI 90%	Tau-U
OASIS	6	60	27	8.0 (2.1)	6.0 (1.2)	- 2.0	0.82* ^a	0.11<>1	0.64
	7	0	36	1.5 (1.7)	6.5 (5.3)	+ 5.0	0.19	0.04-1	-0.61
	8	0	27	3.2 (1.9)	6.7 (2.1)	+ 3.5	0.20	0.07<>1	-0.6
ODSIS	6	100	66	12.0 (2.2)	8.6 (2.7)	- 1.4	0.84* ^a	0.15<>1	0.67
	7	25	45	5.8 (2.9)	6.7 (5.0)	+ 0.9	0.42	-0.41-0.73	-0.16
	8	60	27	7.8 (0.8)	6.7 (1.2)	- 1.1	0.39	0.02<>1	0.55

Note. ¹scores ≥8= indicate clinical levels of anxiety. *significant at .05-level. **significant at .01-level. ^a moderate effect. NAP= Nonoverlap of All Pairs.

Only participant 6 has NAP-scores in the medium range, both p<.05. Tau-U scores indicate questionable effects for all participants. Two participants reached diagnostic criteria for depression (6, 7) and generalized anxiety disorder (GAD, 7) before treatment. At follow-up, participant 6 no longer reached diagnostic criteria for depression and participant 7 no longer reached diagnostic criteria for GAD.

Table B 2 Results from repeated measurements of pain intensity and pain coping problems (ÖMSPQ)

Participant	Baseline M (sd)	Treatment M (sd)	<Mean change	NAP 90%	NAP CI	Tau-U	ÖMPSQ
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							Pre	Mid	Post	FU
6	5.8	6.2	+0.4	0.35	-0.24<>0.82	0.29	7	6.2	5.5	6.3
7	5	5.1	+0.1	0.55	-0.48<>0.66	0.09	7.3	8.2	5.9	4.1
8	7.2	7.5	+0.3	0.39	-0.24<>0.68	0.22	6.7	7.1	6.9	6.4

Note. ÖMPSQ= pain functioning. *significant at .05-level. **significant at .01-level. NAP= Nonoverlap of All Pairs. Tau-U= percent of data showing improvement between phases. FU= follow-up.

Mean changes across phases on pain intensity show either no change or increases. NAP and Tau-U scores do not indicate an effect. Scores on pain coping show no marked changes and posttreatment mean scores remain on levels high enough to indicate problems (≥ 5), except for participant 7 scoring just under the cut-off at follow-up.