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RESEARCH ARTICLE

Relationship between outcomes and processes in patients with chronic low back pain plus depressive symptoms: Idiographic analyses within a randomized controlled trial

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Abstract

Objective: This study explored the extent to which within-patient changes in processes targeted in Acceptance and Commitment Therapy (ACT) and Behavioral Activation Therapy for Depression (BATD) are associated with changes within-patient in pain intensity and depressed mood and evaluated the extent that process-outcome relationships differed between patients.

Methods: An idiographic analysis embedded within a randomized controlled trial comparing ACT, BATD, and treatment-as-usual (TAU) was conducted to examine the strength of the relationship between outcomes and process variables in patients with chronic low back pain (CLBP) plus depressive symptoms. Based on data from ecological momentary assessment in patients ($n = 82$), the level of heterogeneity and the pooled effects of these relationships during the intervention period (70 days) were explored.

Results: Overall, a high level of heterogeneity was identified in the relationship between pain intensity or depressed mood and psychological inflexibility or behavioral activation. Individual differences in the relationships between outcomes and process variables were identified in individual people during the intervention period. These individual differences appear independent of the group (ACT, BATD, and TAU) and other definable differences (responders/non-responders, completers/non-completers, and clinical depression/non-clinical depression).

Conclusions: These findings suggest the potential utility of personalizing psychological interventions according to the therapeutic needs of these patients.

Keywords: chronic low back pain; acceptance and commitment therapy; behavioral activation therapy; pain-related outcomes; process variables

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Clinical or methodological significance of this article: Psychological processes and clinical outcomes have been analyzed using group-level data in recent years. There is evidence that longitudinal assessment is useful for conceptualizing individual clinical cases. This study indicates that psychological processes are clearly related to changes in pain intensity and depressed mood. However, the patterns of these relationships are highly heterogeneous. These results highlight the need to personalize patients' interventions according to their individual needs.

1. Introduction

1.1. Chronic low Back Pain and Depression: A Clinical Picture

Chronic low back pain (CLBP) and depression are both highly prevalent and disabling conditions that constitute great challenges for healthcare professionals (Vlaeyen et al., 2018). CLBP is among the most significant contributors to years lived with disability (Chen et al., 2022). Approximately 4% to 20% of the population worldwide suffers from CLBP (Institute for Health Metrics and Evaluation, 2019), and 12% to 72% suffer from depression (Rayner et al., 2016). According to recent studies, the comorbidity between chronic pain and depression is over 60% (Rizvi et al., 2021). The co-occurrence of these conditions is also associated with more treatment resistance than either condition alone (Carlbring et al., 2018). Such comorbidity negatively affects treatment adherence (Mansfield et al., 2016), represents high societal costs worldwide (Dutmer et al., 2019), and requires new approaches for its management (Williams et al., 2020).

1.2. New Forms of Cognitive Behavioral Therapy (CBT)

New forms of Cognitive Behavioral Therapies (CBTs) have been developed in the last decades (McCracken et al., 2022), such as Acceptance and Commitment Therapy (ACT; Hayes, 2004) and Behavioral Activation Therapy for Depression (BATD; Lejuez et al., 2001) that extend and refine critical assumptions of classical CBT. While maintaining an empirical focus, these new methods de-emphasize symptom reduction, predominantly use contextual and experiential change strategies in addition to more didactic ones, and focus mainly on processes of change (McCracken et al., 2022). They also prioritize a holistic promotion of health and well-being, are sensitive to the context and functions of psychological phenomena, not just their form, and are directed toward the construction of broad, flexible, and effective repertoires rather than taking an eliminative approach to narrowly defined problems (McCracken, 2023).

Both ACT and BATD have shown effectiveness and cost-effectiveness in managing chronic pain and depression (Feliu-Soler et al., 2018; Lai et al., 2023; Sanabria-Mazo, Colomer-Carbonell, Borràs, et al., 2023; Sanabria-Mazo, Colomer-Carbonell, Fernández-Vázquez, et al., 2023; Sanabria-Mazo, Colomer-Carbonell, Gandara-Urrutia, et al., 2023). Behavioral activation and acceptance approaches have been recognized as particularly relevant for chronic pain treatment since they encourage patients to engage in meaningful and rewarding activities wheter significant pain is present or not (McCracken et al., 2022). There is also evidence that these approaches help patients develop skills to manage their pain-related behaviors, thoughts, and emotions (McCracken, 2020).

1.3. Emergence of Process-based Therapies

In general, the choice of the most appropriate psychological therapies for chronic pain and depression -as well as other health conditions- derives mainly from the systematic comparison of effect sizes from randomized controlled trials (RCTs; McCracken, 2023). Although RCTs remain the "gold standard" design for evaluating therapeutic effects, an increasing number of researchers and clinicians are warning about the need for a paradigm change (Hofmann & Hayes, 2019). One of the main limitations of RCTs is that the mean effect size of a group is an imprecise and often inaccurate reflection of the intervention's effect on individual people in the group (Fisher et al., 2018).

Traditionally, the logic of evidence-based therapy has been to identify the patient's mental disorder and then deliver an evidence-based therapy protocol that has been shown in RCTs to improve outcomes for that disorder. This paradigm is beset with practical challenges; however, such as the lack of time to administer the full-time protocol, patient comorbidities that do not fit existing syndrome specifications, and variance in response to the ingredients of the protocol (Ciarrochi et al., 2023). The main therapeutic question when moving from a "protocols for syndromes" approach to a "processes for people" approach is "What core biopsychosocial processes should be targeted with this client given this goal in this situation, and how can they most efficiently and effectively be changed?" (Hofmann & Hayes, 2019, p. 287).

Process-based therapy (PBT) is based on the coherent application of evidence-based procedures linked to changeable evidence-based processes to ameliorate problems and promote people's prosperity (Hayes et al., 2020). Key features in the development of ACT such as universalism, multilevel, and multidimensional processes linked to basic principles, idiographic concepts and methods, and an evolutionary approach, have facilitated the development of PBT and its Extended Evolutionary Meta-Model of processes of change (Hayes et al., 2023). These idiographic methods need validation moving forward because traditional methodological and statistical approaches to processes of change, including current approaches to mediation analysis, are based on mathematical assumptions that cannot be met and thus limit progress in this area (Hayes et al., 2022).

1.4. Limitations of Group-based Approaches and Proposal of an Idiographic Approach to Examine Processes of Change

In the dominant current approach, processes of change are studied through mediation analyses relying on aggregated group data. Classical mediation analysis often regards between-person variation as a statistical "error" (Ciarrochi et al., 2023) and is unable to adequately address change processes in psychological therapies because it falsely assumes that therapy change is a linear, unidirectional, and pauci-variate process and that the statistical assumptions are met to extend results to individuals (Hofmann et al., 2020). This approach readily leads to the "ergodic error" because ergodicity is a known and necessary statistical assumption in applying findings from the group to each particular individual (Hofmann et al., 2020), but is vanishingly rare in behavioral science (Sahdra et al., 2023).

Ergodicity requires that modeled phenomena be stationary, but change processes cannot be, by definition (Ciarrochi et al., 2023). Ergodicity also requires that the same dynamic model applies to all individuals (e.g., each person has the same within-person central tendency and variability in measured phenomena) when that is extremely unlikely. Therefore, traditional statistical approaches are simply not reliable when generalized to predictions of individual development (Hayes et al., 2022). To avoid the ergodic error and deliver a more legitimately personalized approach (Hayes et al., 2020), the analyst "first validates concepts idiographically based on relationships established against the background of intrasubject variability alone, and then gathers these relations into nomothetic generalizations" (Ciarrochi et al., 2023, p. 6).

1.5. Background on the Relationship Between Outcomes and Process Variables in Patients with Chronic Pain

Pain research has tested processes of change using group-level mediational models, longitudinal analysis, and correlational analysis (McCracken, 2023). The potential of process variables such as psychological inflexibility, pain acceptance, and behavioral activation to mediate the relationship between psychological therapies targeting these processes and outcomes such as pain interference, pain intensity, and emotional disturbances has been investigated (Fang & Ding, 2022; Karayannis et al., 2023; Probst et al., 2018). Nevertheless, this research has focused on group-level effects, that is, on exploring the mean effect of therapies on the outcomes explored, as well as on understanding the mediating effect of process variables on the association between intervention and outcome, based substantially on intersubject variability (Ciarrochi et al., 2023).

Studies based in group data imply that the effect of the interventions and processes applies equally to each person (Ciarrochi et al., 2023; Hayes et al., 2023; Sahdra et al., 2023). If, for example, increases in psychological flexibility are associated with a .30 improvement in outcome at the group level, the same effect is assumed to apply to each individual. This process-outcome assumption begs to be tested, which is the primary purpose of the present study.

1.6. The Impact Study

The IMPACT study, a 12-month, multicenter, single-blind RCT conducted in Spain with 234 patients suffering from CLBP and comorbid depressive symptoms, found that group and remote-delivered forms of ACT or BATD were effective (Sanabria-Mazo, Colomer-Carbonell, Borràs, et al., 2023). At the nomothetic level, both ACT and BATD patients reported significant improvement in pain interference, pain catastrophizing, behavioral activation, and psychological flexibility compared to treatment-as-usual (TAU). This traditional statistical approach does not alone examine the percentages of the sample that improved in the mentioned outcomes, nor whether these effects were significantly heterogeneous.

1.7. Purpose of the Present Study

Previous research at the group or nomothetic level (Fang & Ding, 2022; Karayannis et al., 2023;

Probst et al., 2018) suggests that process variables such as the six facets of psychological inflexibility (i.e., experiential avoidance, lack of contact with the present moment, self as content, fusion, lack of contact with values, and inaction) and behavioral activation are relevant to the improvement of pain-related variables (i.e., pain intensity and emotional disturbances). The main purpose of this study was to use intensive within-participant data to examine the extent to which such processes are linked to outcomes within-person. This idiographic study, embedded within an RCT, will use ecological momentary assessment (EMA) data collected across the 70 days of the IMPACT study, to examine the extent to which within-participant changes in ACT- and BATD-related processes were associated with within-participant changes in pain intensity and depressed mood (pooled effects at the group level), as well as to analyze whether these relationships varied from participant to participant (level of heterogeneity).

This idiographic analysis focuses first on the individual rather than with aggregated estimates based on the assigned study arm (i.e., ACT, BATD, and TAU). This personalized analysis approach allows one aspect of the ergodic assumption to be tested, namely, whether each participant in the group share the same model structure and parameters. This analysis sought to establish the strength of the relationship within each individual between the two main clinical outcomes and each therapeutic process collected with EMA. The main hypothesis was that there would be substantial individual differences in the processes that drive pain intensity and depressed mood beyond the study arm the participant was assigned. If so, measuring the heterogeneity in process-to-outcome relations could be used to personalize interventions in the future. For example, if during therapy for a particular person it was detected that "process A" was significantly more important than "process B" in predicting an outcome, interventions could target the more important process based on that idiographic functional analysis.

2. Method

2.1. Study Design

This study was nested within a 12-month, multicenter, single-blind RCT (IMPACT study) that examined the efficacy of adding a videoconference group-based form of ACT or BATD to TAU for patients with CLBP plus clinically relevant depressive symptoms (Sanabria-Mazo, Colomer-Carbonell, Borràs, et al., 2023). The RCT comprised three study arms: ACT + TAU (hereafter, ACT), BATD + TAU (hereafter, BATD), and TAU alone (hereafter, TAU). The RCT was registered in ClinicalTrial.gov (NCT04140838) and adhered to the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) and the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT).

This research was conducted in the Pain Service of two hospitals in Barcelona (Spain) according to the 1964 Declaration of Helsinki and received approval from the Ethics Committee of the Fundació Sant Joan de Déu (PIC-178-19) and the Hospital del Mar (2019/8866/I). None of the patients received any financial incentive for participating in this study.

2.2. Participants

Adult patients (aged between 18 and 70 years) with a diagnosis of CLBP (> 3 months according to medical history) and depressive symptoms (≥ 10 points out of 27 points according to the Patient Health Questionnaire [PHQ-9 (Spitzer et al., 1999)]) who sought services at the Pain Service of the two hospitals mentioned above were invited to participate in the IMPACT study. All patients were informed of the purpose of the study and confidentiality agreements. Patients who met the eligibility criteria and signed the informed consent form participated in a face-to-face interview conducted by clinical psychologists at the hospitals. The eligibility criteria for the RCT and a complete description of methods are detailed elsewhere (Sanabria-Mazo, Colomer-Carbonell, Borràs, et al., 2023).

A total of 82 people were included in this study from the total sample of 234 recruited for the IMPACT study. Of the potentially eligible patients ($n = 193$), 111 patients were excluded because (1) they did not register a minimum of 50% of the responses in EMA, which corresponded to half of the total evaluation period or (2) because they exhibited no variability on one or more assessment items (see Sanford et al., 2022 for more information). Of the 30 patients excluded by the variability criterion, 14 were from ACT (47%), 10 from BATD (33%), and 6 from TAU (20%). Patients with potentially analyzable data were finally distributed as follows into the three study arms: ACT ($n = 23$), BATD ($n = 27$), and TAU ($n = 32$).

2.3. Therapies

ACT and BATD were delivered in a group format (range: 7–13 participants) and consisted of eight weekly 1.5-hour sessions via videoconference (Zoom Pro). Both therapies were conducted in

parallel and in three waves: October to December 2020 (first wave), February to April 2021 (second wave), and May to July 2021 (third wave). All study patients received TAU. The general characteristics of the therapies are summarized below, and the specific content of the eight sessions is described in Sanabria-Mazo et al. (2020), Sanabria-Mazo, Colomer-Carbonell, Borràs, et al. (2023).

2.3.1. **Acceptance and commitment therapy (ACT).** The content of the ACT sessions was based on the Vowles and Sorrell (2007) protocol. ACT itself was developed by Hayes et al. (1999) and is a form of CBT focused on enhancing psychological flexibility, often described as including acceptance of unwanted experiences, and committed goal-directed, and value-based action. Considered more completely, ACT targets six core processes of psychological flexibility include: (1) acceptance, (2) fusion, (3) contact with the present moment, (4) self-as-context, (5) values, and (6) committed action. ACT is an empirically supported treatment for chronic pain (McCracken et al., 2022).

2.3.2. **Behavioral activation therapy for depression (BATD).** The content of the BATD sessions was based on the Lejuez et al. (2001) protocol. This psychological therapy applies learning principles to the pattern of withdrawal or reduced behavioral activity related to depressive symptoms. The purpose of BATD is to reduce depressive symptoms and consequently to enable patients to achieve a satisfying life. It focuses on aspects of activation such as daily monitoring, identification of core life values, selection and planning of valued activities, and social support (Balán et al., 2016). BATD is an effective therapy in patients with depression (Cuijpers et al., 2007) and other health problems, including pain (Lejuez et al., 2011).

2.3.3. **Treatment-as-usual (TAU).** Usual care consisted of the same as in routine clinical practice. Patients randomized exclusively to TAU did not receive any additional active treatment. In Spain, general practitioners usually manage chronic pain in periodic consultations. TAU includes pain relief medication (analgesics, anti-inflammatories, anxiolytics, antidepressants, and/or opioids) and suggestions for aerobic exercise. Complying with ethical agreements, patients in the TAU group were subsequently allowed to receive the therapy (i.e., ACT) that had demonstrated the highest number of responders based on the clinical significance of improvements on the primary outcome upon completion of the study's follow-up assessments (Sanabria-Mazo, Colomer-Carbonell, Borràs, et al., 2023).

2.4. EMA

2.4.1. **Data collection.** EMA data were gathered using Pain Monitor, a smartphone app that was validated in an empirical study by Suso-Ribera et al. (2018). Patients were instructed on how to use the application at the baseline evaluation and were monitored throughout the intervention by an automatic notification system. Data were collected one week before the start of the therapy to assess baseline (7 days), during the eight weeks of therapy (56 days), and one week after the end of therapy (7 days). Patients responded to the notifications they received via the app for 70 days. Items were distributed twice daily using the app (once in the morning, between 8 and 10 am, and once in the evening, between 7 and 9 pm), which notified users via push notifications. To facilitate participation, all patients were given 2 hour daily to log in to the application and respond to each administration. The 2-hour interval and the order of the items were the same in each administration. The response time for each administration was less than 2 minutes.

In total, 9 items related to the objectives of this study were selected for analysis. Of these, 2 items were explored in both daily administrations (i.e., pain intensity and depressed mood) and 7 items in only one (i.e., activity level, experiential avoidance, lack of contact with the present moment, self as content, fusion, lack of contact with values, and inaction). Data were collected at two different time points to increase the probability of obtaining responses from each patient. A substantial percentage of the sample was active at the time of baseline assessment, so providing two response times per day increased the likelihood of receiving at least one response per patient per day, thereby achieving an appropriate balance between the level of detail over time and patient burden. The number of daily administrations was determined considering the results of the systematic review by May et al. (2018) and the meta-analysis by Ono et al. (2019).

The data collected on variables with two daily administrations (i.e., pain intensity and depressed mood) were averaged to obtain a daily response per participant. When missing values were recorded in any of these two daily administrations, the last known value was selected. If there were no responses in either of the two daily administrations, the value was recorded as missing. For more details on all EMA items explored, see Supplementary Table 1.

2.4.2. **Measures.** Sociodemographic and clinical characteristics were assessed with a computer-administered battery of measures, using Research Electronic Data Capture (REDCap) software. An *ad hoc questionnaire* was used to obtain the patient's general information (gender, age, marital status, living arrangement, educational level, and employment status) and clinical characteristics (years of diagnosis and current episode of depression). The *Composite International Diagnostic Interview* (CIDI; Wittchen, 1994) was employed to measure the current episode of depression.

EMA data (outcome and process variables) were captured with the Pain Monitor app. Regarding outcomes, two single *ad hoc items* were used to measure depressed mood and pain intensity. Both items were answered on an 11-point scale ranging from 0 *("no depressed mood or no pain")* to 10 (*"maximum depressed mood or maximum pain")*. Concerning process variables, a single *ad hoc item* was used to measure activity level. This item was answered on an 11-point scale ranging from 0 *("no active")* to 10 *("totally active")*. In addition, six single-items selected from the *Multidimensional Psychological Flexibility Inventory (MPFI;* Rolffs et al., 2018*)* were used to measure daily the six facets of psychological inflexibility (based on the Hexaflex model proposed by Hayes et al., 2011): (1) experiential avoidance, (2) lack of contact with the present moment, (3) self as content, (4) fusion, (5) lack of contact with values, and (6) inaction. The item with the highest factor loading in its corresponding dimension of the MPFI-12 was selected. These single items were answered on a 5-point scale ranging from 0 (*"no agreement"*) to 4 (*"strongly agree"*). Higher scores indicate greater psychological inflexibility in each dimension.

2.5. Data Analysis

2.5.1. **Between-group differences at baseline.** Descriptive analyses were calculated for study measures and were presented as means and standard deviations (SDs) for continuous variables and as frequencies (*n*) and percentages (%) for categorical variables. Baseline differences between groups in sociodemographic and clinical characteristics were examined by applying the analysis of variance (ANOVA) for continuous variables and the χ^2 test for categorical variables. These analyses were performed to find out the specific characteristics of the groups of interest explored in this study.

2.5.2. **Bivariate associations.** An analysis was conducted to observe the strength of simple bivariate associations between outcomes and processes when sampled repeatedly within patients. Between- and within-patient correlations were calculated from longitudinal data using decomposing the observed correlations into a weighted correlation of the means between persons and a pooled within-persons correlation (Pedhazur, 1997). Effect sizes were interpreted using Cohen's conventions. The rule of thumb criterion was as follows: weak (.10), moderate (.30), and large (.50).

2.5.3. **Ergodicity.** In addition to stationarity (which processes of change cannot satisfy, as already mentioned above), the ergodic assumption in multilevel models implies invariant random coefficients; adding random slopes to a random intercept model should not make them differ significantly from similar slopes across patients (Sanford et al., 2022). χ^2 tests of varying slopes for multilevel analyses with random slopes against random intercepts only with processes as predictors and observations nested within patients were calculated to test the ergodicity of the relationship between outcomes and processes, to see whether or not between-patients results accurately apply to within-patient actual behaviors.

2.5.4. **iARIMAX analysis.** Given that the ergodicity assumption was not met, as expected, a meta-analytical procedure recently introduced by Ciarrochi et al. (2023) was carried out. The time series nature of the data allows the results to be analyzed through ARIMAX models with the processes as exogenous variables, consisting of linear regressions with ARIMA models for the error terms (Hyndman, 2010). Therefore, these models can be thought of as removing the noise from the data (including the trend, autoregressive effects, and moving average) while keeping a beta signaling for the strength of the relationship between outcomes and processes. Here, an idiographic version (iARIMAX) consists of fitting a separate model for each patient, pooling the betas with their standard errors across the individuals, and meta-analyzing them to get the pooled effects and estimate their heterogeneity.

2.5.5. **Software.** Analyses were computed with Statistical Package for the Social Sciences (SPSS, v29) for descriptive data and with R version 4.3.0 for all the other analyses (R Core Team, 2023). Specifically, the R library lme4 1.1-32 (Bates et al., 2015) was used for the multilevel analyses, the statsBy function in the R package psych 2.3.3 (Revelle, 2023) to compute correlations between

measures at both the within-patients and between-patients levels, the iARIMAX models were computed with the auto.arima function in the R package forecast 8.21 (Hyndman et al., 2023), and the library metafor 4.2-0 (Viechtbauer, 2010) was used to proceed with the meta-analyses.

3. Results

3.1. Preliminary Analysis

3.1.1. **Baseline sociodemographic and clinical characteristics.** A total of 82 patients met the eligibility criteria for this study, of which 23 had been assigned to ACT, 27 to BATD, and 32 to TAU. Most patients were middle-aged women who had completed secondary education. They mostly lived with their partner and were in paid employment at the start of this study. According to the CIDI diagnostic criteria, about three-quarters of the sample had a current episode of depression. The mean time with diagnosed chronic pain was greater than 10 years. No significant between-group differences in sociodemographic and clinical characteristics were found. Supplementary Table 2 presents the initial characteristics of patients at the group level and Supplementary Table 3 presents the individual characteristics of the patients in each arm.

3.1.2. **Within and between correlations between outcomes and processes.** To explore how processes were associated with the outcomes at the participant level over time, and how these relationships were related to those of other patients, within- and between- patients' correlations were preliminarily computed. Supplementary Table 4 presents within-patients and between-patients bivariate correlations between outcomes (i.e., *depressed mood* and *pain intensity*) and process variables (i.e., *activity level*, *experiential avoidance*, *lack of contact with the present moment, self as content, fusion, lack of contact with values*, and *inaction*). If there was a significant relationship, it suggests associations (which may be positive or negative) between the outcome and process variables over time, either within-patients or between-patients.

As for within-patient correlations, in the ACT (n = 23), BATD (n = 27), and TAU (n = 32) samples, *depressed mood* showed significant positive associations with *self as content*, *fusion*, *lack of contact with values*, and *inaction*, as well as significant negative associations with *activity level*. In turn, *pain intensity* demonstrated a significant positive association with *lack of contact with the present moment*. Regarding between-patient correlations, *depressed mood* exhibited significant positive associations with *self as content*, *fusion*, *lack of contact with values*, and *inaction*, as well as significant negative associations with *activity level*. Moreover, *pain intensity* displayed a positive association with *self as content*, *lack of contact with values*, and *inaction*, as well as significant negative associations with *activity level*.

3.1.3. **Exploration of ergodicity.** The extent to which the links between outcomes and process variables differed significantly within a patient across all outcomes was preliminarily analyzed in relation to ergodicity. To conduct multilevel analyses, all observations were nested within the patient. A comparison was explored between two multilevel models for each relationship between outcomes and process variables, one assuming random intercepts and the other assuming both random intercepts and slopes. If there was a significant difference, it suggests that the slopes between outcome and process variables varied among patients.

As shown in Table I, seven process variables were examined (*activity level* and the six psychological flexibility processes) across two outcomes (*depressed mood* and *pain intensity*). Of the 21 associations of processes of change with depressed mood, all of the 10–90 percentile confidence intervals of the distribution of betas contained zero. This means that the ergodic assumption that the same dynamic model applied to all was violated in all 21 associations. The results differed for *pain intensity* where 13 of the 21 associations did not violate this part of the ergodic assumption. These include *activity level* and *lack of contact with values* in the ACT sample, *lack of contact with the present moment*, *self as content*, *lack of contact with values*, and *inaction* in the TAU sample, and all 7 variables in the BATD sample. Thus, overall, for 29 of the 41 process-to-outcome relationships (71%), idiographic analyses appear necessary to explicate them.

3.4. Main Analysis

3.4.1. **Testing for the pooled effects and heterogeneity.** The within-patient coefficients between the outcome and process variable were examined using a meta-analytic procedure. This approach estimates the pooled effects, as well as the heterogeneity of these effects across patients. The pooled effects (beta and *SE*) suggest the positive or negative association between the outcomes and process variables of the patients explored in each of the arms of this study (ACT, BATD, and TAU). I^2 represents the percentage of total variability (level of heterogeneity) of the association between

Table I. Betas and range of within-person associations between process measures and outcomes (examined by applying multilevel analyses).

		ACT ($n = 23$)		BATD ($n = 27$)		TAU ($n = 32$)	
		Outcomes		Outcomes		Outcomes	
Process variables	Statistic	Depressed mood	Pain intensity	Depressed mood	Pain intensity	Depressed mood	Pain intensity
Activity level	10%	−0.47	−0.11	−0.41	0.01	−0.42	−0.11
	Average	−0.14	−0.03	−0.15	0.05	−0.19	0.03
	90%	0.10	0.06	0.10	0.09	0.07	0.24
	Slopes vary	54.00**	5.72	34.92**	1.90	81.61**	16.81**
Experiential avoidance	10%	−0.39	−0.06	−0.36	−0.06	−0.33	−0.10
	Average	0.05	0.05	0.00	0.03	0.09	0.00
	90%	0.68	0.20	0.35	0.13	0.93	0.08
	Slopes vary	93.35**	3.80*	82.88**	1.29	62.19**	10.53**
Lack of contact with the present moment	10%	−0.50	−0.17	−0.42	−0.03	−0.40	0.04
	Average	0.00	0.13	0.05	0.06	0.13	0.11
	90%	0.66	0.42	0.65	0.18	0.67	0.20
	Slopes vary	60.12**	23.65**	165.08**	2.57	85.81**	5.33
Self as content	10%	0.20	−0.23	−0.04	−0.05	0.24	−0.20
	Average	0.63	−0.06	0.48	0.04	0.62	0.01
	90%	1.14	0.06	1.08	0.11	1.05	0.18
	Slopes vary	57.83**	8.35*	105.22**	1.72	43.52**	3.68
Fusion	10%	0.25	−0.12	0.03	−0.11	0.38	−0.20
	Average	0.62	0.08	0.48	0.03	0.71	0.03
	90%	1.02	0.30	1.01	0.14	1.13	0.29
	Slopes vary	22.51**	8.42*	106.21**	2.98	72.66**	7.95*
Lack of contact with values	10%	0.25	0.01	0.13	−0.09	0.32	−0.04
	Average	0.68	0.16	0.50	−0.01	0.60	0.03
	90%	1.31	0.32	1.04	0.05	0.87	0.11
	Slopes vary	55.03**	4.04	109.04**	1.44	27.76**	1.72
Inaction	10%	0.21	−0.11	0.13	0.02	0.33	−0.02
	Average	0.63	0.10	0.49	0.02	0.52	0.10
	90%	1.29	0.37	1.01	0.03	0.72	0.24
	Slopes vary	58.55**	27.17**	79.24**	0.01	21.21**	5.50

Note: * $p < .05$, ** $p < .01$. Average = Fixed effect, Beta relationship process measures and outcomes. χ^2 tests of varying slopes for multilevel analyses with random slopes against random intercepts only with processes as predictors and observations nested within patients have been calculated to test the ergodicity of the relationship between outcomes and processes.

outcome and process variables according to patients in each arm and Q^2 is used to test whether this level of heterogeneity is statistically significant. In standard meta-analytic analyses values of I^2 below 25% reflect low levels of heterogeneity, from 25% to 50% moderate, between 50% and 75% high, and above 75% very high.

For some agencies (e.g., the National Institute for Health and Care Excellence guidelines in the United Kingdom), relying on reporting of central tendencies is discouraged when I^2 values are .5 or above. The level of heterogeneity reflected the extent to which the strength of the association between outcomes and process variables varied during the intervention period (70 days, of which approximately 56 days corresponded to the 8 therapy sessions) in the patients of each of the arms.

As shown in Table II, across all three samples, I^2 values ranged from 66% to 96% in the relation between *depressed mood* with process variables, demonstrating a very high level of heterogeneity during the intervention period. Q^2 values were highly significant ($p < .001$) in all cases. The level of heterogeneity in the association between *pain intensity* with process variables was more variable. All levels of heterogeneity above 15% for I^2 were significant ($p < .05$), regardless of the study arm, and using that as a cutoff for *pain intensity*, 6 of 7 associations were significantly idiographic in the ACT sample, 5 of 7 in the BATD sample, and 4 of 7 in the TAU sample.

Thus, overall, for both outcomes, 36 of 42 associations (86%) of the process to outcome associations were significantly heterogeneous using I^2 and Q^2 as metrics. Of those 42 associations, 30 of them (71%) exceeded levels that would permit reporting of and reliance on central tendency values in standard meta-analysis. For more information, supplementary Tables 5, 6, and 7 display the percentage of patients showing different magnitudes

Table II. Average (pooled) within-person relationships between arms (ACT, BATD, and TAU), variables (outcome and process measures), and level of heterogeneity (Heter) of that relationship (examined by applying the iARIMAX analyses).

	ACT ($n = 23$)				BATD ($n = 27$)				TAU ($n = 32$)			
	Pooled		Heter		Pooled		Heter		Pooled		Heter	
Outcomes	Beta	SE	I^2	Q^2	Beta	SE	I^2	Q^2	Beta	SE	I^2	Q^2
Link between depressed mood and process variables												
Activity level	−0.08	0.09	95.97	837.84	−0.11	0.05	95.03	369.17	−0.14	0.06	93.02	902.13
Experiential avoidance	0.00	0.11	89.78	329.81	−0.04	0.05	66.25	60.99	0.03	0.09	88.29	174.10
Lack of contact with the present moment	−0.01	0.12	85.97	286.98	0.01	0.08	87.94	120.19	0.03	0.07	84.60	148.88
Self as content	0.47	0.10	83.28	192.43	0.35	0.09	89.47	167.83	0.39	0.06	68.81	94.68
Fusion	0.54	0.10	87.10	223.09	0.33	0.09	88.24	167.12	0.47	0.06	74.17	112.82
Lack of contact with values	0.53	0.13	93.20	448.07	0.43	0.09	90.99	175.30	0.50	0.11	92.05	462.33
Inaction	0.51	0.09	80.09	88.57	0.33	0.07	89.24	178.03	0.43	0.06	72.88	110.91
Link between pain intensity and process variables												
Activity level	0.03	0.06	86.83	155.34	0.08	0.04	73.75	131.41	0.04	0.04	79.52	194.08
Experiential avoidance	0.08	0.10	84.07	170.16	−0.05	0.07	77.38	94.82	−0.01	0.03	0.00	27.02
Lack of contact with the present moment	0.08	0.14	91.59	328.64	0.00	0.04	17.99	34.94	0.02	0.03	0.01	31.44
Self as content	−0.06	0.04	0.00	19.04	0.04	0.04	13.57	23.39	−0.04	0.04	17.86	45.90
Fusion	0.00	0.07	58.86	54.55	−0.02	0.05	34.03	39.37	−0.03	0.04	20.32	46.52
Lack of contact with values	0.12	0.13	87.18	173.26	−0.01	0.04	8.94	30.91	−0.08	0.04	19.46	44.76
Inaction	0.09	0.07	64.53	54.10	−0.06	0.05	41.13	45.86	0.00	0.04	12.99	48.19

Note: * $p < .05$. All Q^2 tests of heterogeneity are highly significant, $p < .0001$. The time series nature of the data allows the results to be analyzed through ARIMAX models with the processes as exogenous variables, consisting of linear regressions with ARIMA models for the error terms.

(< −.31, −.30 to −.21, −.20 to −.11, −.10 to .10, .11 to .20, .21 to .30, and > .31) of the relationship (beta) between outcomes and process variables.

3.4.2. **Reviewing from an idiographic approach the different associations between outcomes and process variables.** The above analyses provided clear evidence that there are individual differences in the link between outcomes and process variables in the three samples. Therefore, a review of these associations from a personalized approach is necessary to understand some of these patterns. To do this, for each therapy (ACT and BATD), three patient samples were compared for each of the following conditions: responded (i.e., at least one point reduction in the Brief Pain Inventory-Interference Scale [BPI-IS] after completing therapy) or did not respond to the therapy, completed (i.e., attended ≥ 6 out of 8 sessions) or did not complete the therapy, and met or did not meet criteria for a diagnosis of depression (according to CIDI criteria). Finally, in the TAU sample, this same comparison was made between three patients who met the diagnostic criteria and three who did not meet the criteria for a diagnosis of depression.

In total, 42 patients were selected to visualize the relationship between outcomes and process variables during the intervention period. As mentioned above, the individual characteristics of these patients are detailed in Supplementary Table 3. To facilitate the interpretation of the figures, statistically significant relationships between outcome and process variables are shown in green, and non-significant ones in red. The bottom triangle of the plots represents the pooled effects of all process variables about the outcomes explored in each patient. Figures 1 and 2 show the strength of this association in responder and nonresponder patients. Examples of the remaining conditions are displayed in Supplementary Figures 1 to 4.

3.4.2.1. ***Associations between outcomes and process variables in responders.*** In ACT patient 7, a significantly positive association was found between *pain intensity* with *fusion* and between *depressed mood* with *experiential avoidance*, *lack of contact with the present moment*, *self as content*, *fusion*, and *lack of contact with values*. In this same patient, a significantly negative relationship was detected between *depressed mood* with *activity level*. Meanwhile, in BATD patient 38, a positively significant association was recognized between *depressed mood* with all process variables; nevertheless, there was no significant relationship between *pain intensity* with any of the process variables.

3.4.2.2. ***Associations between outcomes and process variables in non-responders.*** In ACT

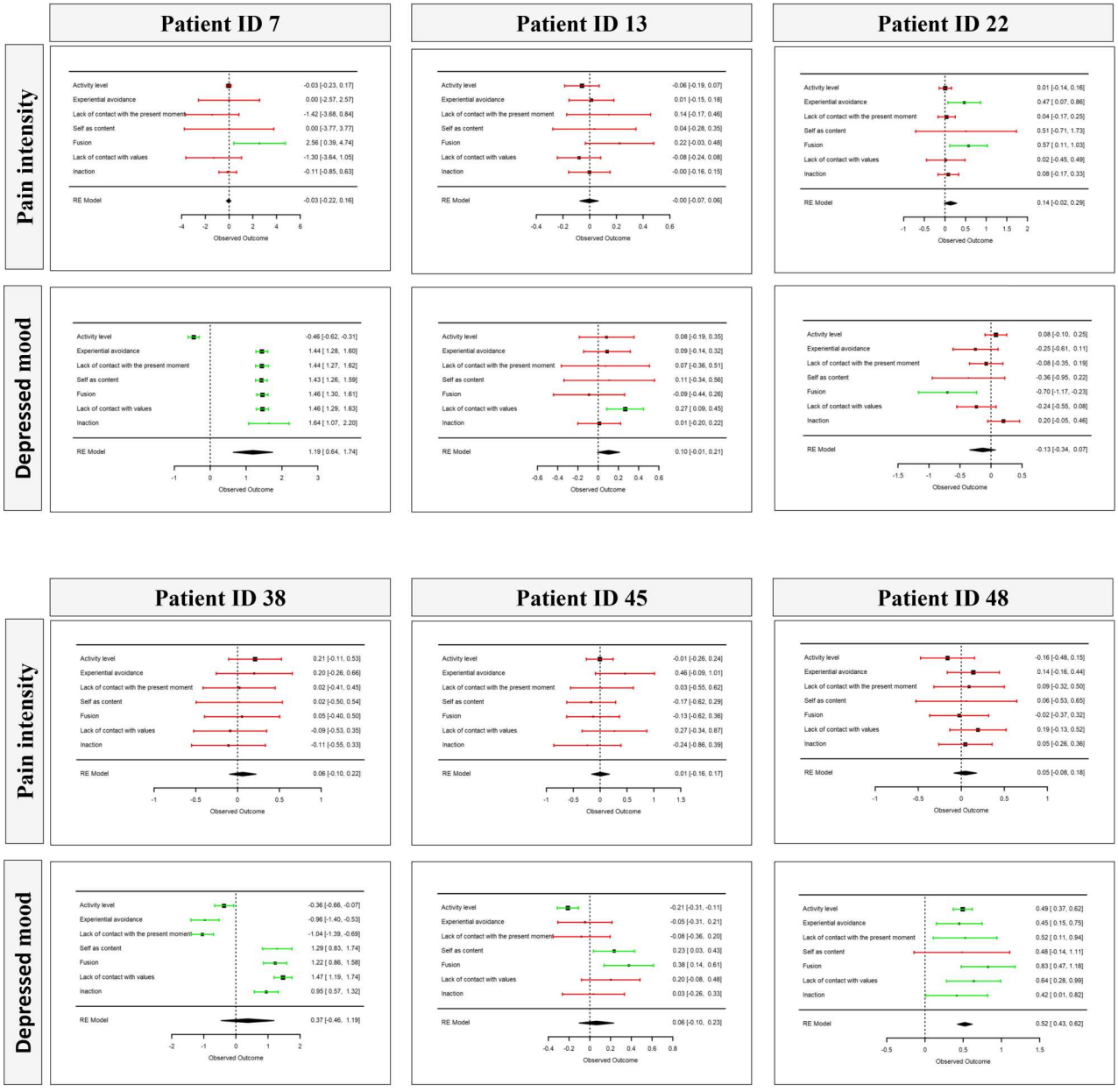

Figure 1. Strength of the relationship between outcomes and process variables for three responder patients in ACT (IDs 7, 13, and 22) and three in BATD (IDs 38, 45, and 48). Note: To facilitate the interpretation of the figures, statistically significant relationships between outcome and process variables are shown in green, and non-significant ones in red.

patient 8, a significantly positive association was identified between *depressed mood* with *fusion*; nevertheless, there was no significant association between *pain intensity* with any of the process variables. Meanwhile, in the pattern of BATD patient 31, a positive relationship was detected between *depressed mood* with *self as content*, *fusion*, and *inaction* and negative with *activity level* and *lack of contact with the present moment*.

3.4.2.3. ***Associations between outcomes and process variables in completers.*** In ACT patient 15, a significantly positive association was found between *pain intensity* with *activity level* and *inaction* and negative with *lack of contact with the moment present* and *fusion*. In this same patient, a significantly positive relationship was detected between *depressed mood* with *self as content*, *fusion*, *lack of contact with values*, and *inaction* and negative with *activity level* and *experiential avoidance*. Meanwhile, in the pattern of BATD patient 26, a significantly negative association was identified between *pain intensity* and *inaction* and between *depressed mood* and *self as content*.

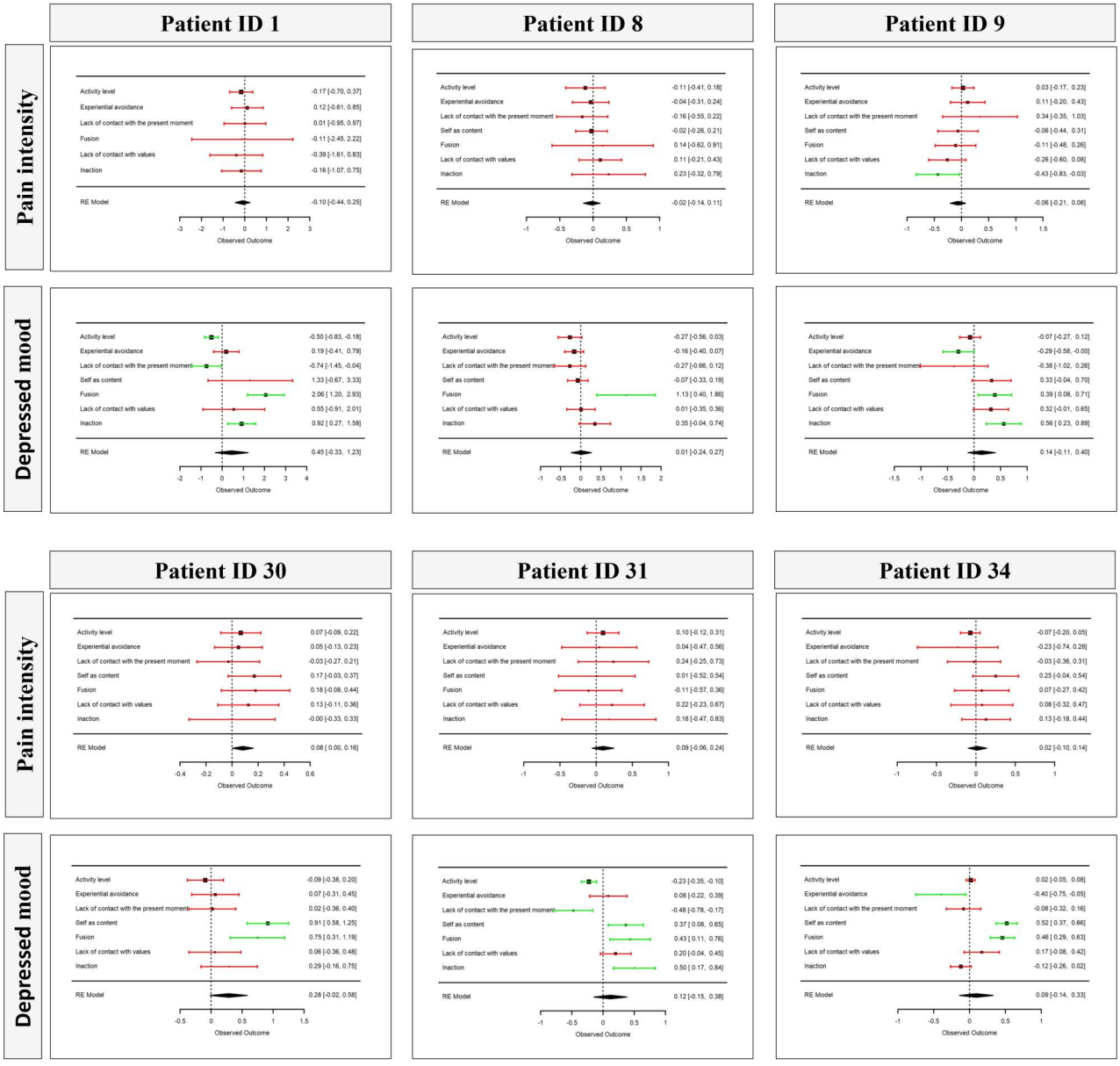

Figure 2. Strength of the relationship between outcomes and process variables for three non-responder patients in ACT (IDs 1, 8, and 9) and three in BATD (IDs 30, 31, and 34). Note: To facilitate the interpretation of the figures, statistically significant relationships between outcome and process variables are shown in green, and non-significant ones in red.

3.4.2.4. ***Associations between outcomes and process variables in non-completers.*** In ACT patient 4, a significantly positive association was detected between *depressed mood* with *self as content, fusion*, and *inaction*; however, there was no significant association between *pain intensity* with any of the process variables. Meanwhile, in the pattern of BATD patient 24, a significantly positive relationship was found between *pain intensity* with *self as content*. In this same patient, a significantly negative relationship was identified between *depressed mood* and *experiential avoidance* and a positive association with *lack of contact with values*.

3.4.2.5. ***Associations between outcomes and process variables in clinical depression.*** In ACT patient 20, a significantly negative association was found between *pain intensity* with *experiential avoidance* and *self as content*. In this same patient, a significantly positive relationship was detected between *depressed mood* with *self as content* and *fusion* and negative with *lack of contact with the present moment* and *lack of contact with values*. In the pattern of BATD patient 25, a significantly negative association was identified between *pain intensity* with *experiential avoidance* and positive, between *depressed mood* with *lack of contact with the present moment* and *self as*

content. Meanwhile, in TAU patient 71, a significantly positive association was recognized between *depressed mood* with *activity level*, *lack of contact with the present moment*, *lack of contact with values*, and *inaction;* nevertheless, there was no significant association between *pain intensity* with any of the process variables.

3.4.2.6. ***Associations between outcomes and process variables in non-clinical depression.*** In ACT patient 19, a significantly positive association was detected between *pain intensity* with *fusion* and *inaction*. In this same patient, a significantly positive relationship was found between *depressed mood* with *self as content* and *inaction* and negative with *experiential avoidance*. In the pattern of BATD patient 49, a significantly positive association was identified between *depressed mood* with *self as content*, *fusion*, and *lack of contact with values*; however, no significant association was found between *pain intensity* with any of the process variables. Meanwhile, in TAU patient 68, a significantly positive association was recognized between *pain intensity* with *experiential avoidance* and negative with *lack of contact with values*. In this patient, all the associations between *depressed mood* were significantly positive with process variables, except for the association with *activity level*.

In general, most of the relationships between *pain intensity* and process variables were non-significant. In the above examples, several cases of significant association between depressed mood and the process variables were identified, which for some patients were positive, for others negative, and for others positive and negative. The bottom triangle of the plots of the selected patients demonstrated variability during the intervention period in the pooled effects detected between process variables concerning *pain intensity* and *depressed mood*.

4. Discussion

This study investigated processes of change and their relations with outcome, idiographically, in participants from a three-arm trial of ACT versus BATD versus TAU for people with CLBP plus depressive symptoms. The processes examined included six facets of psychological inflexibility, as typically targeted in ACT, and activity level, as typically targeted in BATD. The outcomes examined included pain intensity and depressed mood. Based on the main analyses, focused on calculating pooled effects for process-outcome relations, and heterogeneity estimates for these, the overwhelming pattern in the data was very high heterogeneity. This was particularly the case for the ACT and BATD arms and more so for depressed mood as an outcome. For the participants in ACT and BATD, 13 out of 14 I^2 values were greater than 80%, reflecting very high heterogeneity. Further analyses of the individual relations between each therapy process and the outcomes of pain intensity and depressed mood generally showed that the range of values generally fell in the expected direction; nevertheless, these ranges were remarkably wide, and individual within persons slopes were significantly different in 29 of 42 cases. The ranges of within person relations between the process variables and outcome clearly show that an assumption of ergodicity, that group results will reflect the individual people, is unwarranted in these data.

A significantly different picture is seen in simple bivariate correlations presented here depending on whether these correlations are calculated within participants over time or between people. Whether it is the ACT, BATD, or TAU group, the relations between pain intensity and depressed mood are substantially different between and within-person, and the same is true for the relations of process variables with outcomes or with other processes. One immediately apparent difference is that the results from the between-person analyses invariably give a stronger estimate of relationships than did idiographic analyses. In essence, individual response patterns were hidden in the "error terms" used in normative analyses.

In a set of additional analyses that focus on selected individual cases, once again, the pattern reflects substantial individual variability. The results of these analyses are depicted in forest plot style graphs of 42 people mainly from the ACT and BATD arms selected as treatment completers, non-completers, meeting criteria for diagnosable depression, or not. A smaller number of TAU cases are shown about meeting or not meeting the criteria for a diagnosis of depression. Visual inspection of these results once again shows a clear pattern of high heterogeneity.

Significant processes of change differ for pain intensity as an outcome versus depression mood as an outcome. For pain intensity as an outcome, only a minority of the selected cases show any processes that demonstrate significant relations. On the other hand, 39 of the 42 cases (93%) show patterns of significant relations between the processes and depressed mood. In all but one of these, it is two or more processes, typically more than two, that reach this level. Clearly, no two cases show a similar pattern of process-outcome relations; however, in treatment, these idiographic patterns could be key to effective personalized intervention. Idiographic analyses suggest that each person is different in the number and

strength of processes that appear relevant and in which ones seem to appear to be most prominent.

The results of the analyses shown graphically for the 42 individuals appear highly informative. They allow one to observe whether the pattern of relations of processes with outcome depends on which outcome, treatment type, positive response to therapy, completion of therapy, or meeting criteria for a diagnosis of depression. Other than the stronger results for relationships between processes of change and depressed mood, it is difficult to discern clear nomothetic patterns. Curiously, even the TAU cases show interesting multivariate patterns of relations. Once again heterogeneity prevails, meaning that results are highly individual. Advanced statistical means (e.g., see Sanford et al., 2022) and larger samples may be needed to cluster idiographic patterns into nomothetic groupings – what has been referred to as an "idionomic" approach (Hayes et al., 2022).

It was not necessarily expected that results for the role of processes about pain intensity would be weaker than the relations for depressed mood; nevertheless, this is the case here. In retrospect perhaps this could have been predictable, as pain intensity is not a direct target for change in ACT, nor in BATD, notwithstanding that an indirect effect is sometimes found (McCracken et al., 2022). These results may mean that if one is very serious about moving pain intensity as an outcome, as opposed to pain interference, one ought to choose different processes of therapeutic change than the ones featured here (McCracken, 2023).

4.1. Limitations and Considerations

The current study is not without limitations, and several important ones need to be mentioned. First, less than half of the originally enrolled participants were included in the current analyses. This is a secondary study that needed to accommodate the primary study design, which itself had to accommodate itself to the COVID-19 pandemic. Greater initial attention to the methods used here might have led to a higher proportion of participants retained. Second, in retrospect, the daily EMA measure could have been better designed. The researchers opted for a rating scale ranging from 0 to 10 for the pain intensity, depressed mood, and activity level items, but utilized a scale of 0 to 4 for the psychological inflexibility items. They were constrained by the rating scale used in the measure from which these items were sourced, rather than harmonizing the rating scale. In addition, due to the specific characteristics of the outcomes and process variables, different time scales were used. These decisions present a potential confound when comparing the activity level and inflexibility processes and may have imposed a ceiling on the magnitude of correlations that could be found for the psychological inflexibility items. Third, a limited set of processes is included here, and there could have been others at work. A more comprehensive set could be used in the future. Fourth, a strength of the analyses here is that they can track multiple processes in time uniquely for each person. However, they are not able to determine nonlinear or bidirectional relations or complex associations between processes. Such approaches are still under development and may require larger samples, and for this reason, this study uses the currently available approach closest to the objective being explored. Finally, it is relatively new and uncertain territory to look at individual results that appear to differ and to determine how much difference is unreliability and how much is substantive. Heterogeneity indices and multilevel model analysis were used here. Although these methods seem appropriate and useful, the question of how much difference is significant remains a major challenge.

Regarding considerations, it is relevant to clarify that although the primary outcome of the RCT was pain interference, this study focused specifically on two outcomes of great interest to the CLBP population: pain intensity and depressed mood. This decision was made for two main reasons: (1) there is a need to provide evidence on pain intensity, which is a well-defined primary outcome in a large number of RCTs in the chronic pain population (see Schneider, Junghaenel, Ono, et al., 2021, Schneider, Junghaenel, Broderick, et al., 2021; Stone et al., 2021); and (2) the impact on pain interference was divided into three different dimensions (social, work, and leisure activities), which made it problematic to analyze and report individuals' relationships between processes and outcomes succinctly. These data will be explored, through other approaches, in future research.

4.2. Conclusions

In summary, it seems undeniable that the process of change, including facets of psychological inflexibility and activity level are related to changes in pain intensity and depressed mood in participants in an RCT looking at ACT, BATD, and TAU in people with CLBP plus depressive symptoms. Nevertheless, what is shown here is that the patterns of these relations are highly individual. What this seems to mean is that processes of change cannot be examined "in general" and at best traditional analyses can only be used as starting points for a more idionomic approach (Hayes et al., 2022). In this study, people

demonstrated highly unique patterns of change in specific processes over time, changes that differ in the particular processes involved, and in the strength of the relation of each with the particular outcome of interest. In short, processes of change are properties of people in association with therapies, not uniform properties of treatments cut off from those they serve.

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Disclosure Statement

No potential conflict of interest was reported by the author(s).

Supplemental Data

Supplemental data for this article can be accessed doi:10.1080/10503307.2024.2382429.

Data Availability Statement

The data supporting this study's findings are available from the corresponding author upon reasonable request.

Statement of Ethics

This study has been approved by the Ethics Committee of the Fundació Sant Joan de Déu (PIC-178-19) and Hospital del Mar (2019/8866/I). None of the patients received any financial incentive for participating in this study. All participants provided written informed consent.

Author Contributions

Juan P. Sanabria-Mazo: conceptualization, data curation, software, formal analysis, methodology, visualization, and writing the original draft. Iago Giné-Vázquez: conceptualization, formal analysis, methodology, visualization, and writing – review & editing. Paula Cristobal-Narváez, Carlos Suso-Ribera, Azucena García-Palacios, Lance M. McCracken, Steven C. Hayes, and Stefan G. Hofmann: writing – review & editing. Joseph Ciarrochi: conceptualization, supervision, and writing – review & editing. Juan V. Luciano: conceptualization, funding acquisition, investigation, project administration, supervision, and writing – review & editing.

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