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Might psychological flexibility processes and Acceptance and Commitment Therapy (ACT) apply in adults with painful diabetic neuropathy? A cross-sectional survey

Kitty Kioskli¹

Kirsty Winkley²

Lance M McCracken^{1,3}

¹ King's College London, Health Psychology Section, Psychology Department, Institute of Psychiatry Psychology and Neuroscience, London, United Kingdom

² King's College London, Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, London, United Kingdom

³ Uppsala University, Psychology Department, Uppsala, Sweden

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Correspondence to:

Lance M McCracken
Psychology Department
Uppsala University
Box 1225
751 42 Uppsala
Sweden
Email: lance.mccracken@psyk.uu.se

Highlights:

- Psychological Flexibility is thought to contribute to processes of pain, emotional experiences, and daily activities.
- Pain severity is associated with psychological functioning for people with Painful Diabetic Neuropathy.
- Psychological Flexibility components may improve psychological treatments for people with PDN.

Abstract

Painful diabetic neuropathy (PDN) is a distressing and disabling condition. There is, surprisingly, relatively little research into the role of psychological variables related to PDN. The aim of this study was to investigate the association between psychological flexibility, daily functioning, and distress in people with PDN. This cross-sectional study included 225 participants who were recruited from hospital services and online. In correlation analyses, acceptance of pain was shown to be negatively correlated with pain intensity ($r=-0.21$, $p<0.01$), pain distress ($r=-0.25$, $p<0.01$), functional impairment ($r=-0.38$, $p<0.01$), depression severity ($r=-0.41$, $p<0.01$), and depression impact ($r=-0.41$, $p<0.01$). Cognitive fusion correlated positively with pain intensity ($r=0.14$, $p<0.05$), functional impairment ($r=0.24$, $p<0.01$), depression severity ($r=0.44$, $p<0.01$), and depression impact ($r=0.20$, $p<0.01$). Committed action also correlated negatively with functional impairment ($r=-0.22$, $p<0.01$), depression severity ($r=-0.43$, $p<0.01$), and depression impact ($r=-0.21$, $p<0.01$). In regression analyses, the four variables representing psychological flexibility accounted for significant variance in all the equations except in the case of pain distress. However, in some cases the variance accounted for was less than that accounted for by pain intensity. For example, in the equation for functional impairment, pain intensity accounted for 32.2% of variance, while psychological flexibility accounted for 6.8% of variance. These results suggest that psychological flexibility may play a smaller role, relative to pain intensity, in the context of PDN as compared to the larger populations of chronic, mostly musculoskeletal, pain. The reliability and generalisability of these results need to be established.

KeyWords: painful diabetic neuropathy; cross-sectional survey; psychological flexibility; Acceptance and Commitment Therapy

1. Introduction

The World Health Organization (WHO, 2016) estimates that approximately 422 million adults live with diabetes mellitus (DM) worldwide. If DM is poorly managed, it can lead to complications, such as kidney failure, heart disease, stroke, blindness and neuropathy. The most common type of neuropathy caused by DM is painful diabetic neuropathy (PDN), affecting 25-30% of people with DM (Daousi et al., 2004; Davies, Brophy, Williams, & Taylor, 2006; Geelen et al., 2017). PDN is a complex condition affecting the peripheral nervous system (Treede et al., 2007), resulting in loss of sensation, numbness, and a burning, sharp, electrical, stinging pain in the affected area, which often worsens at night (Bouhassira et al., 2005; Daousi et al., 2004; Davies et al., 2006; Geelen et al., 2017). It is known to negatively affect physical and mental health, to reduce overall quality of life (Benbow, 1998; Fernando et al., 2013; Galer, Gianas, & Jensen, 2000; Gore et al., 2005; Van Acker et al., 2009; Vileikyte et al., 2009), and to impact on work, social life, general activities, and sleep (Geelen et al., 2017). There are few studies of the role of psychological processes in people with PDN (Kioskli, Scott, Kylakos, Winkley, & McCracken, 2019) and these have focused on a narrow set of variables, such as depression and anxiety (Gore et al., 2005), and fears (Geelen et al., 2017).

Forms of cognitive behavioural therapy (CBT) are the most often used psychological treatments for chronic pain. These include contextual forms of CBT, such as Acceptance and Commitment Therapy (ACT) (Hayes, Strosahl, & Wilson, 1999; McCracken & Morley, 2014; McCracken & Vowles, 2014). ACT is a form of CBT that includes methods of acceptance, mindfulness and behaviour change (Hayes, Strosahl, & Wilson, 2003) and explicitly focuses on increasing psychological flexibility (PF; Hayes, Villatte, Levin, & Hildebrandt, 2011). PF is a

model of wellbeing and performance that includes six related processes: acceptance, cognitive defusion, present moment awareness, self-as-context, values, and committed action (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). This is sometimes referred to as a focus on openness to experiences, awareness of the present moment, and engagement in actions that are guided by values and goals (Hayes et al., 2011). The current literature indicates that ACT and closely allied approaches are at least as effective as other psychological approaches for managing chronic pain (Hann & McCracken, 2014).

Current treatment options for PDN are mainly pharmacological. There are only four studies of psychological treatments for PDN, including CBT, mindfulness, mindfulness-based stress reduction (MBSR) and thermal biofeedback assisted relaxation (Otis et al., 2013; Nathan et al., 2017; Pfammatter, 2010; Teixeira, 2010). The results from the mindfulness study (Teixeira, 2010) suggested a small between-group effect in the mindfulness group on quality of life ($d=-0.16$, 95% CI: -1.1 - 0.78) and large effect on sleep ($r= 0.53$, 95% CI: 0.048 - 0.813). Evidence from the biofeedback study (Pfammatter, 2010) did not produce any statistically significant results. The CBT study (Otis et al., 2013), an RCT (N=20), showed significant decreases in pain, pain interference and depression levels in the CBT group, at post-treatment and follow-up ($d= 0.68-0.91$), compared to the control group. Results from the MBSR study (Nathan et al., 2017) showed that more than half of participants in the experimental group (19/30) improved in depression, pain interference, quality of life, catastrophizing and function. Overall, their results are promising and, at the same time, due to small sample sizes or small effects, show no clear evidence-based psychological approach for PDN.

Previous studies of chronic pain provide support for the role of PF in relation to well-being and daily-functioning, in people with mixed chronic musculoskeletal pain conditions, (McCracken, Gauntlett-Gilbert, & Vowles, 2007; Vowles, McCracken, & Eccleston, 2008; McCracken & Velleman, 2010) chronic low back pain (Mason, Mathias, & Skevington, 2008), and fibromyalgia (Yu, Norton, Almarzooqi, & McCracken, 2017). Preliminary evidence of this type has led in turn to successful treatment trials of ACT in these conditions (Hann & McCracken, 2014). We simply do not know whether the results from studies of PF in the context of chronic musculoskeletal pain will be replicated in the context of PDN, again, a condition for which there are very few psychological studies, and none focused on PF.

The complex and particularly intractable qualities of PDN are important as motivators for research into the role of PF. The prospects for pain control are practically very limited, even when compared to other pain conditions, and so an approach that supports the capacity to function without pain control, and in the midst of multiple co-morbid symptoms, appears relevant to this condition. However, no published studies have yet explored either the suitability of ACT or the applicability of PF to individuals with PDN.

Finally, there is one more motivation for the study of PDN in a context of many studies of other pain conditions. It appears that neuropathic pain conditions in clinical practice are implicitly regarded as mainly a physical problem with relatively little psychological input (Kioskli et al., 2019), possibly because that pathology underlying the pain appears undeniable. This conclusion is supported by evidence from large cohorts of people seeking specialty treatment for chronic pain where few if any report diagnosis of neuropathic pain (Mason, Mathias, & Skevington, 2008; McCracken & Velleman, 2010; Yu et al., 2017). We

argue that, in order to overcome this bias against access to psychosocial thinking and treatment development for PDN, evidence for the role of psychological factors must be shown in this condition specifically.

The purpose of the present study is to survey people with PDN and examine the role of PF in relation to their daily functioning, including emotional functioning. Our research question is whether PF, here including acceptance, cognitive defusion, committed action, and self-as-context, is relevant and potentially beneficial for people with PDN. We predicted that each process measured here would be relevant and that a potentially important role would be shown in significant correlations between measures of PF and measures of pain and daily functioning in this group, and significant increments of explained variance in multivariate analyses.

2. Methods

2.1 Study design and participants

The current study was a cross-sectional survey of adults with Type 1 and Type 2 diabetes and PDN. Participants were included regardless of any treatment they were receiving. The sample was recruited from pain and diabetes hospital services, from Diabetes UK (DUK), other websites designed to support people with pain, and via social media (i.e. Twitter). The recruitment started on 6 of February 2018 and finished on 6 of May 2018.

2.2 Sample size

A priori estimation was used to determine the required sample size based on several considerations. First, for multiple regression analyses, we based our estimate on similar

studies (Billingham, Whitehead, & Julious, 2013; Chilcot et al., 2015). We also based it on modelling a regression equation with 12 predictors and an effect size (Muller & Cohen, 1989) of $f^2=0.15$ (medium effect), with power set at 0.80. This suggested a need for a sample size of at least 127. Finally, we also considered possible missing data, and the need for an adequate sample size for secondary validity analyses of the instruments being used, as well as sensitivity analyses based on the mode of recruitment. We thus aimed to recruit a minimum of 200 participants.

2.3 Procedure

Ethical approval was gained for this study (Surrey Research Ethics Committee, 29/1/2018. Ref: 17/LO/2047). Informed consent was obtained from all participants, described below in more detail.

The inclusion criteria for this study were aged 18 years or more, living in the UK, having either a confirmed or self-reported diagnosis of diabetes mellitus (DM), having suffered from PDN for the last three months or more, having the ability to take part in the study, and the ability to provide informed consent. Diabetes and neuropathy diagnosis were assessed, using two participant self-report questions and the validated screening questionnaire, Douleur Neuropathique 4 (DN4). DN4 was not administered to the whole sample, but to a subgroup of participants, as it was not initially a high priority concern to obtain this kind of screening data, and in order to reduce the length of the survey. Participants recruited from the hospital services also had a physician's diagnosis.

Potential participants who were not able to understand verbal explanation or written information in English were excluded from the study, as no resources were available to

translate the survey or to produce and validate the standardized measures being used in other languages.

Participants were recruited either online or face-to-face through hospital services. In particular, within the hospital services, participants were identified by diabetes and pain clinical care teams. A member from our research team then approached the potential participants, in the relevant outpatient clinics, explained the study and answered questions. Participants who agreed to take part then gave consent and received the recruitment pack. A total of 120 participants were initially approached in person. Of the 120 invited this way, 60 did not meet the inclusion criteria (N=25 not being diagnosed with diabetes, N=35 suffering from neuropathy due to other causes than diabetes), and 38 declined to take part. Reasons for non-participation included, the length of the questionnaires (N=16), not being able to understand written information in English (N=10), and some eligible participants declined to give a reason (N=12). A total of 14 completed the pen-and-paper version of the presented survey. Two out of the 14 participants did not adequately complete the questionnaire and were excluded. In total 12 participants were recruited from hospital services.

Online recruitment was conducted through sending targeted online invitations to diabetes organisations with an online presence and through social media. An email was sent to the charity Diabetes UK (DUK), explaining the study and the inclusion criteria of participants and asking to publicise it through any available means, such as special interest forums and their website. Within the email, there was also a link to the online version of the survey. DUK posted the link on the recruitment page (<https://www.diabetes.org.uk/research/take-part-in-research>) and forum. Recruitment was also done via Twitter and two discussion forums

sponsored by charity supported websites, 'Pain Support' (<http://painconcern.org.uk/how-we-help/forum/>) and 'Pain Concern' (<https://painsupport.co.uk/>). Particularly, 130 people were recruited from DUK's website, 40 from DUK's forums, 7 from Twitter, 17 from Pain Support forum and 19 from Pain Concern forum. In total 213 participants were recruited from online sites. This dual method of recruitment, in clinic and online, was aimed at including a wider sample of people suffering from PDN and achieving the targeted sample size.

2.4. Measures

The participants who agreed to take part in the survey completed a series of psychometrically validated assessment measures. The following additional variables were assessed through self-report questions: age, gender, ethnicity, education, work status, marital status, type of diabetes, presence of neuropathy, duration of pain, and specific pain locations. The survey was administered via paper or a widely available survey platform, Bristol Online Survey (BOS, <https://www.onlinesurveys.ac.uk/>). This is an easy to use portal to create a survey and used by many institutions. BOS is flexible and does not require any technical knowledge to set-up the survey or collect the data.

2.4.1. Chronic Pain Acceptance Questionnaire (CPAQ-8)

The CPAQ-8 is a measure of acceptance of chronic pain. It includes engagement in activities while experiencing pain and willingness to experience pain without trying to control or avoid it (McCracken, Vowles, & Eccleston, 2004; McCracken, & Velleman, 2010). CPAQ-8 is based on the 20-item questionnaire, and this version consists of 8 items and has also been fully validated (Fish, McGuire, Hogan, Morrison, & Stewart, 2010). Items are rated on a scale

from 0 (never true) to 6 (always true). Higher scores reflect greater acceptance of pain. In the current sample, the CPAQ-8 demonstrated good internal consistency (Cronbach's $\alpha = 0.87$).

2.4.2. Cognitive Fusion Questionnaire (CFQ-7)

The CFQ-7 is a measure of cognitive fusion (Gillanders et al., 2014). Cognitive fusion refers to a domination of cognitive influence over direct experiential influence on behavior, and a lack of separation between the content of the thoughts and the situations or people to which they refer. Cognitive defusion, on the other hand, is the ability to see thoughts as just thoughts, and not as essential reflections of events as they are directly experienced. The CFQ-7 consists of seven items rated on a 1 (never true) to 7 (always true) point scale. An early version of the CFQ has been validated in chronic pain samples based on significant predicted correlations with acceptance and daily functioning in people with chronic pain (McCracken, DaSilva, Skillicorn, & Doherty, 2014). The updated version was used in the present survey. In the current sample, the CFQ-7 demonstrated good internal consistency (Cronbach's $\alpha = 0.95$).

2.4.3. Committed Action Questionnaire (CAQ-8)

The CAQ-8, is an eight-item measure of committed action, a facet of PF (McCracken, 2013; McCracken, Chilcot, & Norton, 2014). Committed action is the ability to persist with actions that are guided by goals, including when this runs into discouraging experiences and to change these actions when they are shown to be ineffective. Responses to the items were rated from 0 (never true) to 6 (always true). Out of the eight items four are positively keyed and four negatively keyed. Scores from the CAQ-8 have demonstrated relations with

measures of acceptance, and of emotional, physical, and social functioning in people with chronic pain, supporting construct validity (McCracken, Chilcot, & Norton, 2014). In the current sample, the CAQ-8 demonstrated good internal consistency (Cronbach's $\alpha = 0.81$).

2.4.4. Douleur neuropathique 4 (DN4)

Presence of neuropathic pain was assessed with a screening measure called DN4. It consists of four interview questions and has also been psychometrically validated as a self-report measure (Bouhassira et al., 2005). It has a specificity of 83% and sensitivity of 90% (Spallone et al., 2012). In the current sample, the DN4 demonstrated adequate internal consistency (Cronbach's $\alpha = 0.75$). This questionnaire was only administered to a subsample (N=75), to reduce the length and burden of the survey. The subsample was selected from their response to a question at the end of the survey asking if they would be willing to take part in further research, if they answered 'yes', we contacted them and asked them to respond to the DN4. The purpose was to validate the self-report method for determining the diagnosis of PDN used in the full sample.

2.4.5. Pain Scale

Pain intensity and pain-related distress were assessed through four validated questions using 0 (no pain/distress) to 10 (worst possible pain/distress) numerical ratings. Participants were asked to rate their pain right now and in the past week, and how distressing their pain is right now and in the past week (Jensen, Turner, Romano, & Fisher, 1999; Von Korff, Ormel, Keefe, & Dworkin, 1992). In the current sample the reliability, of pain intensity and pain distress scale, was calculated with the Spearman-Brown formula, due to the fact that

each scale has only two items and is was $r = 0.86$ in each case (Eisinga, Grotenhuis, & Pelzer, 2012).

2.4.6. Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a widely used, reliable and validated, measure used as an index for depression severity. It includes ten items based on DSM-IV. The first nine items reflect severity of depression symptoms and each is rated on a scale from 0 (not at all) to 4 (nearly every day). The last item, item ten, is a measure of impact of depression and is rated from 'not difficult at all' to 'extremely difficult' - this item was used as an additional variable to study here because within the psychological flexibility model the impact of symptoms of functioning is regarded as a particularly important potential outcome in treatment. The higher score for the sum of the nine items indicates higher levels of depression severity (Kroenke, Spitzer, & Williams, 2001). In the current sample, the PHQ-9 demonstrated good internal consistency (Cronbach's $\alpha = 0.84$).

2.4.7. Self Experiences Questionnaire (SEQ)

The SEQ is a 15-item self-report measure of self-as-context, within the PF model (Yu, McCracken, & Norton, 2016). This "contextual self" is defined as a sense of self that is not based upon self-evaluations and is separate from one's thoughts and feelings. This could also be referred as, taking a point of view on one's psychological experiences, seeing oneself as distinct from one's psychological experiences, or as "perspective taking". All items are rated on a scale from 0 (never true) to 6 (always true). All items are positively keyed, and higher scores indicate higher PF. The construct validity of the SEQ has been supported in demonstrated significant expected correlations with acceptance, committed action, and

decentering, and with depression and daily functioning in people with chronic pain (Yu et al., 2016). In the current sample, the SEQ demonstrated good internal consistency (Cronbach's $\alpha = 0.98$).

2.4.8. Work and Social Adjustment Scale (WSAS)

The WSAS is a five-item, reliable and validated self-report measure of impairment in work and social functioning, or as we label here, "functional impairment" (Mundt, Marks, Shear, & Greist, 2002). WSAS items refer to work, home management, social and private leisure, and relationships. Each item is rated from 0 (no impairment) to 8 (very severe impairment). The validity of the WSAS is supported by significant correlations with measures of psychiatric symptoms and it is shown to be sensitive to the effects of treatment (Mundt et al., 2002). In the current sample, the WSAS demonstrated good internal consistency (Cronbach's $\alpha = 0.93$).

2.5 Statistical Analyses

The collected data were analysed with the Statistical Package for Social Science (version 18.0 IBM, SPSS). Limited missing data in the standardized inventories were substituted by mean imputation. The total sample size was 225 participants. Descriptive statistics, including means and standard deviations (SDs) for continuous variables and frequencies and percentages for categorical variables, were calculated for the sample.

All standardized measures were scored according to their standard instructions. The variables consisting the PF facets were: acceptance of chronic pain (CPAQ-8), cognitive fusion (CFQ-7), committed action (CAQ-8), and self-as-context (SEQ). The dependent

variables of the study were pain and pain-related distress (pain scale), functional impairment (WSAS), depression (PHQ-9), and depression impact (PHQ-9 item 10). Preliminary analyses included *t*-tests and correlation analyses examining relations between the pain outcomes and functioning variables and the PF variables with individual's background characteristics.

Three sets of analyses were conducted to address the main purpose of this study. The first set included correlation analyses between the four PF variables, with pain, functional impairment, and depression variables. These analyses were conducted to first identify significant unadjusted relationships between these variables in order to then proceed to a multivariate approach with linear, hierarchical, multiple regressions. Multiple regression analyses were designed both to consider and statistically control the role of age, education, sex, pain duration, and pain intensity, and to examine the proportion of variance accounted by acceptance of chronic pain, cognitive fusion, committed action, and self-as-context, uniquely and combined, in relation to the measures of participant's functioning.

3. Results

3.1 Sample Characteristics

A total of 225 people participated in this survey. Mean age of all participants was 52.05 (SD=12.06) years. Women represented 64.9% of the sample and white ethnicity 82.2%. Mean years of education was 14.98 (SD=3.76) and mean years pain duration was 7.16 (SD=9.02). Employment status was categorized as follows: full-time employment (24%), employed part-time due to pain (22%), employed part-time due to other reasons (13%), retired (24%), unemployed due to pain (10%), and full-time student (7%). Mean DN4 score was 7.15 (SD

=2.39) and 92.7% exceeded the cut-off, an overall score of 4, for neuropathic pain. The 12 participants recruited from hospital services and 213 from online did not differ on background variables or the measures of psychological flexibility or pain outcome measures and were treated as one sample.

3.2 Preliminary analysis

Each primary variable was examined for normality by using histograms, Q-Q plots, and indices of skewness and kurtosis. None of the primary measures in this study produced significantly skewed distributions or outliers expected to adversely affect correlation-based analyses. The total scores of all measures were considered normally distributed. See Table 1 for means, ranges and standard deviations for the primary study variables.

Pain intensity and distress variables differed significantly by gender, with men reporting higher scores of pain intensity, $t = -3.09, p < 0.01$, and pain-related distress, $t = -2.86, p < 0.01$. Participants of white ethnicity reported lower scores in terms of committed action, $t = -2.64, p < 0.01$, functional impairment, $t = -2.96, p < 0.01$, and self-as-context, $t = -3.82, p < 0.01$, than the non-white group of participants. Employed participants scored significantly lower in terms of committed action, $t = -2.73, p < 0.01$, functional impairment, $t = -2.97, p < 0.01$, and self-as-context, $t = -3.44, p < 0.01$ variables than those who are not employed.

Preliminary correlation analysis showed that age was correlated with committed action, depression severity, and self-as-context, $r = -0.23, p < 0.01$; $r = 0.19, p < 0.01$, and $r = -0.24, p < 0.01$ respectively. Years of education was found to be correlated with all primary variables except cognitive fusion, including pain intensity: $r = 0.20, p < 0.01$; acceptance of pain: $r = -0.16, p < 0.05$; committed action: $r = -0.20, p < 0.01$; depression severity: $r = 0.21, p$

< 0.05; functional impairment: $r = 0.21, p < 0.01$; self-as-context: $r = - 0.14, p < 0.05$. Duration of pain was not significantly correlated with any of the variables.

Table 1: Means and standard deviations for standardized psychological flexibility variables, health and functionality outcome variables ($N = 225$).

| | Possible Range | Sample Mean | Standard Deviation |
|---------------------------------------|----------------|-------------|--------------------|
| Pain intensity (Rating Scales) | 0-10 | 4.31 | 2.24 |
| Pain distress (Rating Scales) | 0-10 | 4.52 | 2.43 |
| Functional impairment (WSAS) | 0-40 | 17.67 | 11.48 |
| Depression severity (PHQ-9 items 1-9) | 0-27 | 12.05 | 7.00 |
| Depression impact (PHQ-9 item 10) | 0-3 | 1.83 | 0.64 |
| Acceptance of pain (CPAQ-8) | 0-48 | 25.01 | 4.88 |
| Cognitive fusion (CFQ) | 7-49 | 24.33 | 11.06 |
| Committed action (CAQ-8) | 0-48 | 21.08 | 8.16 |
| Self-as-context (SEQ) | 0-90 | 40.98 | 21.17 |

3.3 Correlation analyses

The four primary PF variables were not found to be correlated with each another at a level that would suggest problems of multicollinearity in regression analyses ($r < .80$, Grewal, Cote, & Baumgartner, 2004). In fact, the highest correlation between these variables was $r = .54$. Please see Table 2.

Correlations between acceptance of pain, cognitive fusion, self-as-context, and committed action and pain intensity with pain-related distress, functional impairment, depression severity, and depression impact are included in Table 3. Pain intensity positively correlated with pain distress, $r=0.87$, $p<0.01$, functional impairment, $r=0.57$, $p<0.01$, depression severity, $r=0.51$, $p<0.01$, and depression impact, $r=0.40$, $p<0.01$. Acceptance of pain negatively correlated with pain intensity $r=-0.21$, $p<0.01$, pain distress, $r=-0.25$, $p<0.01$, functional impairment, $r=-0.38$, $p<0.01$, depression severity, $r=-0.41$, $p<0.01$, and depression impact, $r=-0.41$, $p<0.01$. Cognitive fusion positively correlated with pain intensity $r=0.14$, $p<0.05$, functional impairment, $r=0.24$, $p<0.01$, depression severity, $r=0.44$, $p<0.01$, and depression impact, $r=0.20$, $p<0.01$. Additionally, committed action negatively correlated with and functional impairment, $r=-0.22$, $p<0.01$, depression severity, $r=-0.43$, $p<0.01$, and depression impact, $r=-0.21$, $p<0.01$. Lastly, self-as-context negatively correlated only with depression severity, $r=-0.31$, $p<0.01$.

Table 2: Primary correlation analysis among psychological flexibility variables ($N=225$).

| | 1 | 2 | 3 | 4 |
|-----------------------|-------|--------|-------|---|
| 1. Acceptance of pain | - | | | |
| 2. Cognitive fusion | -.25* | | | |
| 3. Committed action | .40** | -.42** | | |
| 4. Self-as-context | .27** | -.20** | .54** | - |

* $p < .05$, two-tailed

** $p < .01$ two-tailed

Table 3: Correlations between psychological flexibility variables, health and functioning, and pain.

| | Pain intensity | Pain distress | Functional impairment | Depression severity | Depression impact |
|--------------------|----------------|---------------|-----------------------|---------------------|-------------------|
| Pain intensity | - | .87** | .57** | .51** | .40** |
| Acceptance of pain | -.21** | -.25** | -.38** | -.41** | -.41** |
| Cognitive fusion | .14* | .12 | .24** | .44** | .20** |
| Committed action | -.05 | -.12 | -.22** | -.43** | -.21** |
| Self-as-context | -.05 | -.07 | -.07 | -.31** | .00 |

* p < .05, two-tailed

** p < .01 two-tailed

3.4 Multiple regression analyses

Multiple regression analyses were conducted to examine the unique and combined role of PF variables, after adjusting for individuals' characteristics and pain intensity, in relation to the measures of health and functioning: pain-distress, functional impairment, depression severity, and depression impact. Hence four regression equations were conducted.

The potential predictors were tested hierarchically in each of these equations. Participants' age, gender, education and duration of pain were firstly tested and retained in the equations when significant (first block, $p < 0.05$ to enter, $p > 0.10$ to remove). Afterwards, the pain intensity average score was entered to control its contribution to the prediction of each criterion variable (second block). Finally, acceptance of pain, cognitive fusion, committed action, and self-as-context scores were entered together in a single block to examine their contribution. The regression results are shown in Table 4.

Education was entered and retained as a significant predictor at entry into all the equations. However, the regression coefficient for education did not remain significant in the final step of all the regression equations. It should be noted that education accounted for modest

increments of variance at entry, no more than 7.7%. Gender and duration of pain were not significant predictors at entry in the equation for depression impact, depression severity or functional impairment. Gender was a significant predictor of pain distress, with men experiencing more pain distress than women, explaining 3.1% of variance. Gender did not remain significant in the final step of the regression equation. Finally, age was a significant predictor of both depression impact and depression severity and accounted for a 3.0% and a 2.3% increment of variance, respectively. As age increased, depression impact and depression severity also increased. Age remained significant only in the final step of depression impact regression equation.

The pain intensity variable was a significant predictor at entry and remained significant in all the equations. In the equation for functional impairment, pain intensity had the largest regression coefficient and the ΔR^2 value, higher than that of the four PF variables combined, reflected 32.2% of the variance. In the equation for depression severity, pain intensity once again had the largest regression coefficient and the ΔR^2 value, close to that of the four PF variables combined, reflected 23.3% of the variance. In the equation for pain distress, pain intensity had the largest regression coefficient and the ΔR^2 value, higher than that the four PF variables combined, reflecting 67.1% of the variance. In the equation for depression impact, pain intensity had the largest regression coefficient and the ΔR^2 value, close to that of the four PF variables combined, reflected 13.2% of the variance.

The combination of the four variables representing PF variables accounted for a significant increment of variance in all the equations except in the case of pain distress. In the equation for functional impairment, PF variables accounted for 4.5% of the variance, although only

the coefficient for acceptance of pain was significant. In the case of depression severity, acceptance of pain, cognitive fusion and committed action had significant regression coefficients and the variance accounted for was 7.5%. In the case of the pain distress, no significant regression coefficient was found from among the PF variables. In the case of depression impact, acceptance of pain and self-as-context had significant regression coefficients and the variance accounted for was 11.4%.

Standardized regression coefficients and the squared semi-partial correlation coefficients reveal the relative role of the four separate processes when considered together. Mean proportions of unique variance contributed (sr^2) from all the equations were as follows: acceptance of pain, 0.033, cognitive fusion, 0.011, committed action, 0.008, pain intensity, 0.294, and self-as-context, 0.011.

Table 4: Multiple regression analyses of psychological flexibility variables with measures of health and functioning.

| Block | Predictor | Beta (final) | ΔR^2 (block) | sr^2 | Adjusted total R^2 |
|------------------------------|-----------------------|--------------|----------------------|--------|----------------------|
| <i>Pain distress</i> | | | | | |
| 1 | Duration of education | .100** | .061** | .009 | |
| 2 | Gender | -.015 | .031* | .000 | |
| 3 | Pain intensity | .851** | .671** | .642 | |
| 4 | Acceptance of pain | -.012 | .003 | .000 | |
| | Cognitive fusion | -.027 | | .001 | |
| | Committed action | -.072 | | .003 | |
| | Self-as-context | .034 | | .001 | .757** |
| <i>Functional impairment</i> | | | | | |
| 1 | Duration of education | .081 | .045** | .006 | |
| 2 | Pain intensity | .532** | .322** | .264 | |
| 3 | Acceptance of pain | -.218** | .068** | .037 | |
| | Cognitive fusion | .062 | | .003 | |
| | Committed action | -.075 | | .003 | |
| | Self-as-context | .053 | | .002 | .417** |
| <i>Depression severity</i> | | | | | |
| 1 | Duration of education | .061 | .042** | .003 | |
| 2 | Age | .079 | .030* | .006 | |
| 3 | Pain intensity | .436** | .233** | .178 | |
| 4 | Acceptance of pain | -.158** | .187** | .019 | |
| | Cognitive fusion | .228** | | .041 | |
| | Committed action | -.165* | | .015 | |
| | Self-as-context | -.064 | | .003 | .473** |
| <i>Depression impact</i> | | | | | |
| 1 | Duration of education | .173** | .077** | .027 | |
| 2 | Age | .131* | .023* | .015 | |
| 3 | Pain intensity | .314** | .132** | .092 | |
| 4 | Acceptance of pain | -.313** | .126** | .075 | |
| | Cognitive fusion | .000 | | .000 | |
| | Committed action | -.136 | | .010 | |
| | Self-as-context | .237** | | .039 | .334** |

* $p < .05$, two-tailed, ** $p < .01$, two-tailed

4. Discussion

PDN is a complex condition and one of the most distressing complications of DM (Galer et al., 2000; Selvarajah et al., 2014). Despite this, existing studies of psychological variables mainly focus on pain intensity as outcome in relation to depression and anxiety without exploring the other potentially therapeutic psychological processes. For the first time in a study of PDN, facets of PF were carefully assessed, using validated questionnaires, and examined in relation to standard measures of pain and functioning.

This study demonstrated significant correlations between PF variables and functional impairment, depression severity, and depression impact in people with PDN. These results are consistent with the results of previous studies that support the role of PF in people with general, usually musculoskeletal, pain, including studies particularly focused on acceptance of pain (Mason et al., 2008; McCracken, 1998; Nicholas & Asghari, 2006; Viane et al., 2003), cognitive defusion (McCracken, DaSilva, Skillicorn, & Doherty, 2014), mindfulness (McCracken, MacKichan, & Eccleston, 2007) and value-based action (McCracken et al., 2007), and committed action (McCracken, 2013).

In this study, we found mostly small correlations between PF and the dependent variables, functional impairment, depression severity, and depression impact, and relatively larger correlations between pain and some of these same variables, particularly so for functional impairment, less for the depression variables. While PF appears as a plausible contributor, pain severity generally appears to play a more important role in relation to daily functioning in PDN. This result is different in this sense from studies of other populations where the role of PF facets in daily functioning and wellbeing appears greater and the role of pain itself

appears smaller, including studies of mixed pain conditions (McCracken & Velleman, 2010; McCracken & Zhao-O'Brien, 2010), low back pain (Mason et al., 2008), fibromyalgia (Wicksell et al., 2012; Yu, Norton, Almarzooqi, & McCracken, 2017) and headache (Almarzooqi, Chilcot, & McCracken, 2017; Foote, Hamer, Roland, Landy, & Smitherman, 2015). Taking into account that the role of PF is smaller than expected, this could be due to as yet unidentified differences in the experience of neuropathic pain. There are so few psychological studies in neuropathic pain, however, it is too soon to confirm the current results or propose an explanation.

Studies investigating outcomes following treatment have demonstrated a moderate-sized negative relationship between changes in PF variables and pain interference (Wicksell, Ahlqvist, Bring, Melin, & Olsson, 2008) and pain-related anxiety, depressive symptoms, physical and psychosocial disability (McCracken & Gutiérrez-Martínez, 2011; McCracken & Jones, 2012; Vowles, McCracken, & O'Brien, 2011). These results suggest that if PF is increased this would lead to the improvements in a wide range of outcomes. It remains to be seen if this would happen in PDN.

Regression analyses here show that PF variables may play a significant role in functional impairment, depression severity and depression impact, even when other relevant factors are considered, including background variables and pain intensity. Acceptance of pain appeared to contribute the greatest proportion of variance among the PF variables. In general, this suggests that these variables may afford a route toward improved functioning that is independent of pain severity in this population.

It may be worth mentioning that compared to previous pain research our sample was older (by approximately 10 years) (i.e. McCracken, & Velleman, 2010), but it was consistent with PDN research (i.e. Geelen et al., 2017). Participants in the current study were more likely to be employed either part-time or full-time, and they reported a lower level of acceptance of pain than other studies. The sample recruited from hospital services and online did not appear to differ. It remains the case, however, that the applicability of the current results to specific subpopulations with PDN will need to be further examined.

As far as we are aware, only four studies of psychological treatments have been conducted including individuals with PDN, most of them were either small in scale or produced limited results (Otis et al., 2013; Nathan et al., 2017; Pfammatter, 2010; Teixeira, 2010). Clearly more research needs to be done, including into the structure and mode of delivery and into the choice of treatment methods. It appears reasonable, based on present findings, to next incorporate the components of PF into a pilot or feasibility trial.

ACT has been applied successfully to individuals with chronic pain and has growing support (Hann & McCracken, 2014; McCracken & Morley, 2014; Veehof, Trompetter, Bohlmeijer, & Schreurs, 2016). We know in particular that online treatment is increasingly used. A brief online treatment for chronic pain in general, based on ACT, has been demonstrated feasible within a mixed specialty pain treatment population in the UK (Scott, Chilcot, Guildford, Daly-Eichenhardt, & McCracken, 2018). This type of delivery format and similar content could provide efficient means for further treatment development for PDN.

This study addresses new questions and produces new findings. At the same time, it has a number of limitations. Because of the cross-sectional design and reliance on self-report

measures, it can include biases. Self-reports may include some participants not reporting their actual behaviour and views, which may compromise the accuracy of the results. Also, it did not include either analysis of variables over time or an experimental manipulation. No conclusions about causal relations between PF and functioning are possible. Furthermore, the questionnaire was also accessed online anonymously. This means diagnoses could not be verified. This also makes it possible for participants to access it more than once, although the length of the questionnaire certainly would discourage participants from doing this. Also, recruitment among those seeking treatment in the hospital services was limited (10%). It is possible that results may have been different if that recruitment had been more successful. Lastly, our results cannot be automatically generalized to any specific groups within the larger population of people with PDN, groups characterized by specific ethnicity, age, comorbidities, and other factors. If the sample had been different in any of these ways, the results could have been different.

In conclusion, based on the collected data of this cross-sectional observational study, facets of PF are associated with pain, emotional experiences, and difficulties experienced in daily life activities of individuals with PDN. Meanwhile, the unexpected relatively larger role that pain intensity appears to play in the PDN population calls for replication. If a significant role for pain itself is confirmed as reliable, perhaps we need to search more vigorously for effective remedies for pain itself. Further study of psychological factors in general in the context of PDN is encouraged to support the design and evaluation of psychological treatments for individuals suffering from PDN, a condition that has been the subject of very few psychological treatment studies. A psychological treatment focusing on psychological

flexibility, rather than on symptom control, may represent an important new option, an addition to the current almost complete reliance on analgesic medication only.

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