Clinical effectiveness of a pain psychology service within an outpatient secondary care setting

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Background

Policy context

Recent audits have highlighted the patchy and often inconsistent services provided for people with chronic pain (English Pain Summit, 2012). Despite the increase in provision of psychological therapies demonstrated by such initiatives as Improving Access to Psychological Therapies (IAPT; Department of Health, 2011), psychological services are often unresponsive to the specific needs of patients with chronic pain (British Pain Society, 2009). It is thus paramount that psychological services specialising in pain develop ways of evaluating service outcomes in a way that is consistent with the needs of patients with chronic pain.

Service description

Referrals to this publicly funded (UK National Health Service) pain psychology service, based within an outpatient secondary care setting, are typically made by Consultants in Anaesthesia and Pain Control (84%), although pain nurse specialists also refer (16%). The service provides psychological therapy to clients experiencing chronic pain, who have difficulties managing pain or the distress associated with their pain. In terms of therapy model, the service has recently undergone a transition: moving away from the delivery of Cognitive Behavioural Therapy (CBT) to an approach based on Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 1999). This reflects the emergent evidence for the utility of ACT with chronic pain, and the clinical interests and experiences of psychologists working within the service. Core to ACT for pain is the notion that people's distress is maintained by focussing on pain relief (i.e., being entirely free from pain) alongside the functional limitations that result from pain (Breivik, Collett, Ventafridda, Cohen & Gallacher, 2006). ACT focuses on helping people to accept the limiting conditions of pain (i.e., to find ways of living alongside pain, rather than struggling to avoid or suppress it), so as to improve their engagement with valued, and previously avoided, activities (Dahl, Wilson & Nilsson, 2004). Consequent to changing the client's relationship with their pain and increasing engagement in personally-meaningful activity, we often secondarily observe a reduction in client distress. However, distress reduction is not

a direct target of the therapy – again, within ACT, a focus on reducing unwanted experiences (pain or associated distress) is considered to be counterproductive.

This is typically the first contact clients have had with mental health services so engagement and developing client-centred goals are prioritised over adherence to fixed protocols. Clients choose between individual or group sessions in partnership with their healthcare professional (NICE, 2011). Individualised person-centred interventions are designed collaboratively with the client following the assessment and formulation sessions. Group sessions focus on psycho-education, values clarification, values-based goal setting and activity scheduling, mindfulness and acceptance-based activities. Components of the group sessions were specifically operationalised and introduced in terms of the ACT model; thus, for example, activity scheduling was presented with a particular emphasis on overcoming avoidance of values-consistent activities.

Evidence-Based Practice and Practice-Based Evidence

Efforts to improve care and cost-efficiency have led to an increasing emphasis on 'evidence-based practice', i.e., therapies supported by randomised control trials (RCTs; Macey, Clarke, Moghaddam, das Nair, in press). RCTs attest to the treatment efficacy of ACT under controlled conditions in comparison with wait-list, control groups and Cognitive Behavioural Therapy (CBT) (e.g., Dahl et al., 2004; Hoffman, Papas, Chatkoff, & Kerns, 2007; Wetherell et al., 2011). However, RCTs do not always paint a consistent picture with respect to treating pain (Eccleston, Williams, & Morley, 2009) and generalising from RCTs to other contexts is problematic – partly due to the selectivity of recruitment to controlled trials, which can mean that participants are poorly representative of populations served by real-world services (Morley, Williams, & Hussain, 2008). So while data from RCTs are used to 'establish the *efficacy* of psychological treatments they do not necessarily provide evidence of *effectiveness:* whether the treatment provides a measurable beneficial effect when delivered to patients in other service contexts' (Barkham & Mellor-Clark, 2003, p. 320). Consequently, data gathered from routine clinical settings or 'practice-based evidence' is thought a necessary complement to evidence-based practice as provided by RCTs (Barkham & Mellor-Clark, 2003; Margison et al., 2000).

Perhaps of greatest importance to clinicians is that evaluating treatment using some form of aggregated global measure (e.g., group mean), while informative, does

not tell us about the utility of the treatment for *individual clients*. Indeed, group-level effects can mask important individual-level differences: even in the context of overall (group average) improvement, some clients may show no change or even deterioration (Davies & Sheldon, 2011). The present study makes use of Reliable Change Index (RCI) and Clinically Significant Change (CSC) analyses (Jacobson, Roberts, Berns, & McGlinchey, 1999; Jacobson & Traux, 1991). These analyses enable evaluation in terms of individual outcomes – permitting consideration of idiographic context, whilst retaining the objective and standardised advantages of statistical analyses (Barlow & Nock, 2009). RCI analysis determines whether an individual-level change in scores is statistically reliable – i.e., whether change is greater than could be accounted for by measurement imprecision (Connell & Barkham, 2007; Wise, 2004). CSC analysis determines whether an individual-level change constitutes a change in clinical status – e.g., whether change moves the individual from being within a 'clinical' range of scores to being within a 'normal' or 'recovered' range (Jacobson et al., 1999; Morley & Dowzer, 2014). Reliable Change is considered a necessary condition for Clinically Significant Change: To be considered clinically meaningful, an apparent transition between population distributions must be of a magnitude that is statistically reliable. British studies employing this methodology (although not using CORE-10) for chronic pain sufferers show that following ACT 75% of patients demonstrated reliable improvement on at least one key measure, with medium (0.67) to large effect sizes (1.76) (Vowles & McCracken, 2008). Following CBT, Morley, Williams & Hussain (2008) found that 49% of patients demonstrated reliable improvement on at least one key measure (PSEQ): based on the sum of those showing reliable change only (32%) plus those showing CSC (which requires reliable change as a precondition; 17%). The Morley study found pre-post effect sizes (*d*) ranging from 0.26 to 0.73 (i.e., small to medium magnitudes)

This evaluation follows on from one conducted in 2012-13 (Macey et al., in press) and was deemed necessary as part of the service's commitment to continuous evaluation, accountability, and transparency (DOH, 2010). Demonstrating effectiveness is also necessary for future planning, and evaluations are used to make continual improvements to clinical data recording. However, good quality care includes not only clinical effectiveness but improving the service user experience. In line with guidance, this evaluation reports client satisfaction data alongside outcome

data in order to provide a more rounded view of service quality and effectiveness, and to improve service-user experience (NICE, 2011).

Aims

This service evaluation aims to:

1. Examine individual level outcomes, using RCI and CSC methodology, for all clients discharged during financial year (FY) 2013-14
2. Report satisfaction data
3. Consider changes to data collection to improve auditing and subsequently benefit future service planning.

Methods

The service evaluation was approved under local governance procedures and informed by BPS ethical guidelines (Cooper, Turpin, Bucks & Kent, 2005). The data reported here were routinely collected by the service.

Inclusion criteria

As clinical work is continuous and clients may be referred in one FY but complete treatment in another FY it was decided to include clients identified as discharged during FY 2013-14 irrespective of their referral date. This also ensured that clients assessed in earlier service evaluations (e.g., Macey et al., in press) were not duplicated here.

Audit Sheets

The data were available in an anonymised database collated from service audit sheets completed by clinicians for each discharged patient. Information included: gender, referrer, presenting problem, number of sessions attended, the outcome of initial contact, CORE-10 data, and employment status.

Outcome measures – CORE-10

The CORE-10 is a brief outcome measure comprising 10 items (Connell & Barkham, 2007) drawn from the CORE-OM (Evans et al., 2000). The measure is designed to tap into a pan-theoretical 'core' of users' distress (Connell & Barkham, 2007), including symptoms of anxiety and depression (commonly experienced by

sufferers of chronic pain; Breivik et al., 2006), associated aspects of life and social functioning, and risk to self. The items are scored on a 5-point scale ranging from 0 ('not at all') to 4 ('most or all the time'). Total scores range from 0-40, with higher scores indicating more problems and/or greater distress. The scale has good internal reliability with an alpha of 0.82 (CI 0.79-0.85) (Connell & Barkham, 2007). It correlates well with standardised measures of anxiety, depression, and overall mental health, and is responsive to change (Connell & Barkham, 2007).

Client satisfaction questionnaire

The service-designed 'satisfaction questionnaire' required a response ranging from 0-4 for each of the following items (where higher scores indicated more favourable ratings):

1. "How good was the service?" (0 = 'very poor', 4 = excellent)
2. "How good was your psychologist at listening to you?" (0 = 'very poor', 4 = 'excellent')
3. "To what extent were you shown respect by your psychologist?" (0 = 'never', 4 = 'always')
4. "How likely are you to recommend the service to a friend or relative?" (0 = definitely not', 4 = 'definitely'; based on the 'family and friends test'; Cain, 2013)

Analytic approach

Reliable change refers to the extent to which change falls beyond that likely based on the measurement variability of the measure. For the CORE-10 the RCI derived by the scale's authors was used (Connell & Barkham, 2007): calculated as a reliable change criterion of 5.9, rounded up to 6.0 for ease of measurement. Therefore a client must improve by 6.0 or more from pre- to post-therapy to be able to demonstrate that they have made reliable improvement.

To establish whether a client has made a clinically significant change, CSC criteria established by Cornell & Barkham (2007) were again employed. These authors calculated that a cut off of 10/11 be used where 10 is in the non-clinical range and 11 in the clinical range. In other words, to achieve clinically significant

improvement a client must (reliably) change from a pre-therapy score of 11 or above to a post-therapy score of 10 or below (i.e., showing a reduction in distress).

By using these established cut-offs we are able to make direct comparisons with a previous evaluation (in terms of proportions showing reliable and clinical change) which adopted the same criterion (e.g., Macey et al., in press). The combination of RCI and CSC criteria also enables patients to be classified into one of five possible outcomes at post-treatment (Connell & Barkham, 2007; Davies & Sheldon, 2011):

1. Clinically significant improvement: improvement from pre-treatment that meets both RCI and CSC criteria.
2. Reliable improvement: improvement from pre-treatment that meets RCI but not CSC criteria.
3. No change: magnitude of any change is within expected range due to measurement error.
4. Reliable deterioration: deterioration that meets RCI criterion but not criterion for CSC.
5. Clinically significant deterioration: deterioration that meets both RCI and CSC criterion.

Findings

During the FY 2013-14, 58 adults (67% females) were discharged from the service. The main reasons for referral were depression (91%), anxiety (38%), relationship difficulties (21%), trauma (12%), other (12%), self-harm (5%), and anger (3%)[1]. The outcomes of initial contact were 17% assessed and subsequently discharged; 12% assessed and referred onto other services; 21% "opted-out" (decided not to pursue treatment or dropped out of treatment[2]); and 50% (n = 29) completed individual and/or group treatment. Information on ethnic origin and age was unavailable.

Attendance rates

[1] Percentages exceed 100% as patients were referred for more than one difficulty.
[2] For 2014-15 these are recorded as separate categories. The service is now collecting more detailed information on these outcomes.

For the 58 discharged clients, the average number of assessment sessions attended was 2 (*SD* = 1.4).

Only one patient dropped out of treatment. Of the 29 treatment completers 76% completed individual therapy; 17% group therapy and 7% both. The average number of individual treatment sessions attended was 15 (*SD* = 5.3); for group therapy, average attendance was 6 sessions (*SD* = 3.0). Overall this sub-group attended an average of 14 (including assessment and treatment) sessions (ranging from 2 to 23, *SD* = 5.8).

Outcome data: CORE-10

Of the 58 discharged clients, 52% (*n* = 30) had only pre CORE-10 data; 48% (*n* = 28) had pre- and post-data but as one client scored below the (normative) cut-off "clinical" score at pre-treatment s/he was excluded from analysis (Morley & Dowzer, 2014) leaving 27 clients (46%) with useable pre- and post-data scores, all of whom were treatment completers.

Independent t-tests showed no significant differences between the pre-treatment CORE-10 scores of (1) therapy completers versus "opted-out" patients or (2) those who did versus did not have post-treatment data.

Table 1 and Figure 1 show the results of the reliable and clinically significant change analyses from pre-treatment to post-treatment (at the 95% confidence interval) for the CORE-10 outcome data of 27 treatment completers. The pre-treatment mean for this group was 25.2 (*SD* = 6.1); the post-treatment mean was 13.8 (*SD* = 7.3) (pre-post effect size *d* = 1.87).

TABLE 1 and FIGURE 1 ABOUT HERE

In terms of meeting the different outcome criteria: no clients showed reliable deterioration; 19% demonstrated no reliable change (i.e., change could not be distinguished from measurement error); 81% achieved reliable improvement, and 44% made a clinically significant improvement (i.e., improvement that met both RCI and CSC criteria).

In comparison to 2012-13 (Macey et al., in press) the percentage of clients demonstrating reliable improvement was higher in FY 2013-14 (Table 2). Proportions showing clinically significant change or no change remained at similar levels.

TABLE 2 ABOUT HERE

Functional outcomes

Employment data were available for the 29 treatment completers. Significant changes in employment status were observed ($p < .001$, two-tailed Fisher's exact test): with a greater proportion engaging in unpaid employment/education, and a smaller proportion off sick, after treatment (Table 3).

TABLE 3 ABOUT HERE

Patient satisfaction data

Of the 58 discharged clients, 37 completed the satisfaction questions (response rate 64%). The service scored highly, with 86% of clients rating both the psychologist's ability to listen and the overall service they received as "excellent", and 97% rating the psychologist as "always" being respectful. Moreover, 95% were "definitely likely" to recommend the service.

Discussion

Summary

Returning to the aims of this evaluative study, analysis of individual-level outcomes demonstrated that – in cases where data were available – most clients achieved reliable improvements (measured in terms of reduced distress). Moreover, clients evidenced post-treatment changes in functional outcomes, including improved health status and engagement in voluntary work or educational activities. Comparison with data from the previous financial year (2012-13) suggested that client outcomes improved in 2013-14 (increase in proportion of clients achieving reliable amelioration of distress); this apparent improvement coincided with a shift in treatment model – away from CBT, towards an ACT-based approach – but it is difficult to attribute cause. The service met a number of NICE quality standards (2011) concerning the "relational" aspects of care deemed important to clients such as being treated with respect by staff who listen.

Critique

The reduction in number of clients discharged from FY 2012-13 is noteworthy, and warrants further contextualisation. This reduction reflects workforce change within the service: Since 2012-13, specialist psychology input has reduced by 33% (from 1.2 to 0.8 Whole Time Equivalent); the total number of discharged clients has reduced by a similar proportion (30%; from 83 to 58). Thus, the shift in service-focus (from CBT to ACT) and observed increments in client outcomes (proportion achieving reliable improvement) were accomplished whilst maintaining similar levels of client throughput relative to staff time.

Since 2012-13 the service has reduced its number of outcome measures due to significant overlap in how they previously assessed generalised distress (Macey et al., in press). With only one brief outcome measure (thereby minimising client burden) this may have contributed to higher completion rates of the measure at pre-therapy, compared to previous years (Macey et al., in press). However, it is argued that the CORE-10 provides insufficient sensitivity for early decision making (Halstead, Youn & Armijo, 2013) and, importantly, no service can be fully evaluated through the use of one outcome measure alone – thereby limiting the conclusions here.

The functional outcomes data provided some important additional evidence for the effectiveness of the service and suggests that the introduction of a new therapy model, namely ACT, could be responsible for improvement in some of the clinical outcomes. The fit between ACT as a therapeutic approach and patients with chronic pain has been well documented and links back to a principal aim of ACT: which is to help individuals engage with valued, and previously avoided, activities. Moreover, returning to paid or unpaid activities has a high public health impact.

However, the longer term effectiveness of the service remains unclear and the minimal collation of demographic information limited our ability to assess the population mix or whether there were any systematic biases in the findings attributable to demographic characteristics. Furthermore, we know little of the “opted-out” group, e.g., reasons for drop-out or their scores at “ending”.

Services implementing ACT-based approaches might consider using theory-specific (i.e., ACT) measures to assess treatment effectiveness, such as the Chronic Pain Acceptance Questionnaire (McCracken, Vowles, & Eccleston, 2004). However, such measures come with both strengths and weaknesses. On the one hand, using ACT-specific measures may allow comparisons to be made with wider ACT literature

(including efficacy studies) and permit examination of whether theorised core processes are evinced within practice-based evidence. On the other hand, any changes evidenced by ACT-specific self-report measures may partly reflect socialisation to the ACT model. Moreover, measurement of process constructs, like 'acceptance', might be perceived to lack relevance or meaning to clients and service managers. Patients want to see tangible reductions in the level of distress they experience. Service managers want to see patients who are no longer presenting to services in distress. The problem is that patients' strategies for reducing distress can be limited and sometimes unworkable, focused on medical solutions that may not be available. The ACT model outlines an alternative approach, with implications for a different measurement strategy – placing emphasis on change in theorised core processes (including 'acceptance') and values-consistent behaviour, rather than distress reduction per se (although, as observed here, distress reduction often occurs secondarily). However, further to congruence with the treatment rationale, measurement strategies must be reconciled with stakeholder expectations regarding outcome evaluation, and consideration of burden to respondents.

Client satisfaction response rates were comparable with larger surveys (e.g., Care Quality Commission, 2013) and supported the favourable outcome data. The satisfaction questionnaire was brief and allowed for swift elicitation of readily-interpretable quantitative data. However, some of the questions may need revising. For example, clients may misunderstand that they are being asked to recommend a specific service/provider, and studies show that patients sometimes express annoyance and objection to this question (Graham & MacCormick, 2012). In addition, whilst pre- and post-intervention satisfaction measures may provide a broad picture of patient experience, they are not able to provide ongoing information regarding patient satisfaction on a session-by-session basis (Duncan et al., 2003). Considering the importance of alliance factors on clinical outcome (Orlinsky, Grawe & Parks, 1994), this may be an important issue for the service to address to increase engagement with treatment.

Finally, the data provide a "snapshot" of individual experiences of care but may be unrepresentative of the views of those who did not complete the questionnaire. Additionally, the reasons for non-completion (e.g., literacy difficulties) are unknown. As questionnaires were anonymised it was also not possible to match satisfaction data to outcome data. Therefore, we cannot rule out the possibility of a

systematic bias contributing to an inflated picture of satisfaction (e.g., clients with positive outcomes may have been more likely to complete the satisfaction questionnaires).

For the reasons stated above, it is difficult to say with any finality whether the results could provide a benchmark for other psychological services in pain. However, future studies could compile the outcome data from the service over an extended period of time in order to generate enough data to statistically benchmark the findings against the results from RCTs in pain. This will enable an assessment of whether practice-level data corresponds to evidence-based practice generated from more formal research designs.

Recommendations

The results of the present study indicate a number of ways by which pain management clinical psychology services can improve their evaluation practices and use practice-based evidence to improve the quality of patient care. Some of the ways include:

- Following clinical trials guidelines (Dworkin et al., 2005), psychology services should evaluate treatments for pain across at least two domains. For instance, pain intensity or severity (e.g., 0 to 10 numerical rating scale), impact of pain on daily functioning (e.g., Brief Pain Inventory Short Form; Cleeland & Ryan, 1994[3]), emotional functioning (e.g., Beck Depression Inventory), or ratings of overall improvement (e.g., Patient Global Impression of Change scale; Dworkin et al., 2005).
- Services should consider introducing ACT approaches alongside traditional CBT for pain management
- Personal idiographic measures, such as Goal Attainment Scaling, could be used to make interventions more bespoke (Ottenbacher & Cusick, 1990).
- Capturing information on the reasons why patients choose to 'opt out' of treatment could help to identify shortcomings in the referral or treatment process.

[3] Since this evaluation the service is now using the Brief Pain Inventory

- Recording numbers of attended and missed sessions will allow for comparisons between the service offered and the service taken up, thus aiding economic evaluations of service utilisation
- Recording demographics, such as age and ethnicity, help identify patterns of service access. Service demographics can be benchmarked against local and national characteristics for the relevant patient population in order to improve social inclusion and facilitate service adaptation to patient need.
- Collecting patient feedback on a regular, sessional basis – using a brief, easy to complete measure, such as the Session Rating Scale (Duncan et al., 2003) – is likely to maximise patient involvement in the therapeutic process and thus increase positive outcomes and minimise patient drop-out.

Overall, it is anticipated that the implementation of such measures will help optimise clinical psychology services in pain management settings.

Biographical Details

Dr Kerry Sheldon is a HCPC-registered Clinical Psychologist. This work was completed as part of her Doctoral Training in Clinical Psychology. She currently works in an Older People's Mental Health Service for Rotherham, Doncaster and South Humber NHS Foundation Trust. She is also an Associate Lecturer for the Open University. Her career includes working for the Probation service, managing a NHS research department, teaching undergraduate and postgraduate psychology, criminology and forensic psychology as well as consultancy work for Pearson's Education Limited.

Dr Simon Clarke is an HCPC-registered Practitioner Psychologist. He works as clinical psychologist in pain management services at King's Mill Hospital, Mansfield, UK for Nottinghamshire Healthcare NHS Trust as a research clinical psychologist for the Arthritis Research UK Pain Centre at the University of Nottingham.

Dr Nima Moghaddam is a Chartered Clinical Psychologist and HCPC-registered Practitioner Psychologist. He works on the Trent Doctoral Programme in Clinical Psychology at the University of Lincoln.

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Table 1.

Pre- and post-treatment CORE-10 scores, change scores and Reliable Change Index (RCI) and Clinical Significant Change (CSC) outcomes (n = 27).

Patient Code	Pre-score	Post-score	Change score	Meets RCI[4] / improved or deteriorated		Meets CSC[5]
1	26	29	-3	No	-	-[6]
2	16	7	9	Yes	Improved	Yes
3	13	4	9	Yes	Improved	Yes
4	29	11	18	Yes	Improved	No
5	22	6	16	Yes	Improved	Yes
7	31	10	21	Yes	Improved	Yes
9	14	7	7	Yes	Improved	Yes
11	24	10	14	Yes	Improved	Yes
14	30	10	20	Yes	Improved	Yes
15	28	11	17	Yes	Improved	No
16	32	15	17	Yes	Improved	No
17	19	12	7	Yes	Improved	No
19	25	26	-1	No	-	-
20	25	21	4	No	-	-
23	30	23	7	Yes	Improved	No
28	30	19	11	Yes	Improved	No
31	32	10	22	Yes	Improved	Yes
34	19	7	12	Yes	Improved	Yes
35	16	8	8	Yes	Improved	Yes
37	25	10	15	Yes	Improved	Yes
41	34	29	5	No	-	-
49	24	17	7	Yes	Improved	No
52	22	5	17	Yes	Improved	Yes
54	27	11	16	Yes	Improved	No

[4] To achieve reliable improvement, a client must improve by 6.0 or more points from pre- to post-therapy.
[5] To achieve clinically significant change, a client must change from a pre-therapy score of 11 or above to a post-therapy score of 10 or below.
[6] Some columns are blank as only patients who make a reliable change can make a clinically significant change (Morley & Dowzer, 2014).

55	35	16	19	Yes	Improved	No
56	23	18	5	No	-	-
58	29	22	7	Yes	Improved	No

Table 2.

CORE-10 Results over time

FY	RCI	CSC	No reliable change	Reliable deterioration
2013-2014 n = 27	81% (22)	44% (12)	19% (5)	0% (0)
2012-2013 n = 56	66% (37)	39% (22)	32% (18)	2% (1)

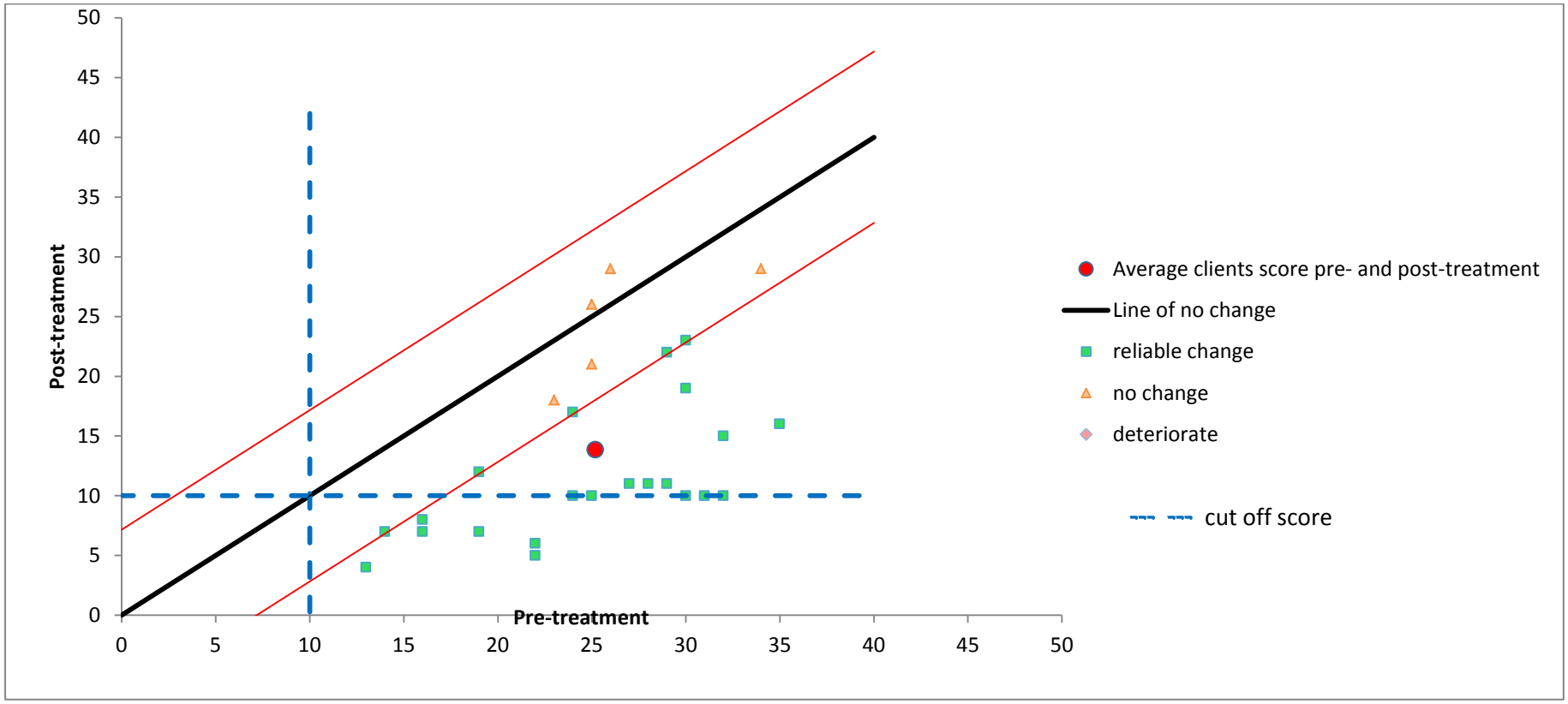
Table 3.

Functional outcomes pre- and post-treatment (n = 29)

Treatment Status	Paid work	Further ed.	Voluntary	Sick	Unemployed	Retired	Unknown
Pre	21%	0%	0%	45%	14%	17%	3%
Post[4]	24%	14%	31%	28%	7%	17%	0%

Percentages do not total 100%; some service users engaged in unpaid work, educational courses and/or retirement simultaneously.

Figure 1. Reliable and clinically significant change analyses from pre-treatment to post-treatment at the 95% confidence interval for the CORE-10 outcome data of 27 treatment completers.



This figure displays data from patients at pre-treatment (x-axis) and post-treatment (y-axis). For a patient with the same score on both occasions (i.e., no change in score), the data point will fall on the main diagonal axis (solid line). Any point not on the main diagonal indicates some change. The parallel lines on either side of the main diagonal are the 95% confidence intervals for the error of measurement; any data point that falls between these lines is not significantly different from the main diagonal, i.e., no significant change has occurred. Data points outside the confidence interval indicate that a client's score has reliably changed (improved or deteriorated). The blue vertical and horizontal dotted lines indicate a clinically meaningful score on the CORE-10. Patients to the right of the pre-treatment (vertical dotted line) cut off score were above the clinical criterion at pre-treatment. Patients below the (horizontal dotted line) cut off score were below the clinical criterion at post-treatment.