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Running Head: TRANSDIAGNOSTIC SCED

Treating Co-morbid Anxiety and Depression in Older Adults Using the Unified Protocol

Ben Hague [1]

Shonagh Scott [3]

&

Stephen Kellett [2, 3]

[1] University of Sheffield, Western Bank, Sheffield, S10 2TN, UK

[2] Centre for Psychological Services Research, ScHARR, The University of Sheffield, Regent Court, 30 Regent St, Sheffield, S1 4DA, UK

[3] Sheffield Social and Healthcare NHS Foundation Trust, Michael Carlisle Centre, 75 Osborne Road, Nether Edge, Sheffield, S11 9BF, UK

Address for correspondence:

Ben Hague, Clinical Psychology Unit, Department of Psychology, University of Sheffield, S10 2TN

TEL: +44 14 222 6570 Email: b.hague1@ sheffield.ac.uk

Abstract

Objectives: This study sought to test the acceptability and effectiveness of a transdiagnostic approach to treating co-morbid anxiety and depression in older adults. **Method** In an A/B single case experimental design, a co-morbidly patient completed 5 daily ideographic measures of anxiety and depression across baseline and treatment and also the HADS at five time points over time. Treatment consisted of an 8-session intervention using the Unified Protocol (UP) conducted in routine practice. **Results** All sessions were attended. Significant baseline-treatment improvements were found in daily structure, mood, confidence and worry, with large associated effect sizes. The shape of change was progressive following initiation of treatment. The patient met recovery criteria by the end of treatment, but with some evidence of anxious relapse at follow-up. **Conclusion** The UP offers promise as an additional approach to treating co-morbid anxiety and depression in older adults and needs to be tested further via more exacting methodologies in larger samples.

Keywords: *Unified Protocol, Single Case Experimental Design, Older adults.*

The majority of the progress in the psychological treatment of emotional disorders has been in the development and testing of treatment protocols for either anxiety or depressive disorders (Barlow, 2010). Whilst the trials of such protocols have understandably excluded patients with co-morbid anxiety in order to ensure internal validity, such co-morbidity is the norm rather the exception in routine clinical practice (Barlow et al., 2004; Clark and Taylor, 2009). Co-morbidity of anxiety and depression in older adults is more common than each disorder independently; 50 % suffering from depression also display some form of anxiety disorder (King-Kallimanis, Gum, & Kohn, 2009). Co-morbidity also increases impairment in daily functioning, severity of symptoms and likelihood of suicide (Lenze, 2003). The Department of Health (2009) highlight that one quarter of older adults living in the community have symptoms of depression and anxiety serious enough to warrant assessment and intervention. Testing of new clinical models that address such co-morbidity are therefore at a premium for patients and services alike.

Recent research evidence suggests greater theoretical and clinical commonalities between anxiety and depression than previously assumed (Ellard, Fairholme, Boisseau, Farchione & Barlow, 2010), and in particular the demonstration of the key role of negative affect (Etkin & Wagner, 2007). In an attempt to meet this recognition a 'transdiagnostic' or 'unified protocol' (UP) has been developed (Barlow et al., 2004). The UP is a manualised, brief cognitive behavioural treatment that formulates deficits in emotion regulation as key maintainers of anxiety and depression (Barlow et al., 2004), through chronic and unsuccessful attempts to avoid or dampen the intensity of negative affects (Ellard et al, 2010). The UP has been tested in two open (Ellard et al., 2010) and one controlled trial (Farchione et al., 2012) with working age patients. The first open trial (*N*=18) noted significant pre to post treatment effects of an early version of the UP, which were incorporated into the second open trial (*N*=15). These results showed that 64% of co-morbid patients achieved

responder status, with gains maintained at follow-up (Ellard et al., 2010). The wait-list controlled Farchione et al., (2012) trial noted that in comparison to controls (*N*=11), UP patients (*N*=26) demonstrated significant reductions in clinical severity of anxiety/depression and symptom interference with everyday life.

Although trials are frequently recognised as the gold standard in psychotherapy outcome research, their low external validity often limits vital transferability of findings to routine clinical settings (Barkham, Hardy, & Mellor-Clark, 2010). Single case experimental design (SCED) is one in a range of complementary empirical frameworks regarding the scientific evaluation of 'real-world' psychotherapy which places minimal restrictions on inclusion criteria, thus increasing external validity (McMillan & Morley, 2010). In SCED, outcomes are simultaneously measured against patient-centred idiographic measures in time series designs and standardised nomothetic psychometric indices of clinical change (Barkham, Hardy, & Mellor-Clark, 2010). SCED is particularly indicated in the early testing of new clinical models or new applications of extant treatments in novel populations (Morley, 2008). As SCED can also highlight the shape of change during psychological therapy (Kellett, 2007), it is also indicated prior to moving onto group designs in the hourglass model of psychotherapy evaluation (Salkovskis, 2006).

In the present paper, a SCED evaluating the UP treatment of an older adult with a diagnosis of co-morbid depression and anxiety is presented. As no evidence has yet been produced to test the effectiveness of the UP in older adults with co-morbid emotional disorders, the current study is innovative and consistent with the hourglass model of modality evaluation (Salkovskis, 2006). The study hypotheses were H1: that the UP will be well tolerated, H2: UP treatment will reduce the daily experience of anxiety over time in comparison to baseline, H3: UP treatment will increase

daily structure and improve daily mood over time compared to baseline, H4: UP will facilitate a reliable and clinically significant improvement to anxiety and depression.

Method

Design

An A/B SCED evaluated an 8-session UP treatment with a 3-month follow-up. The baseline (A) phase was spread over two assessment sessions (2-weeks duration), reflecting standard assessment times in routine clinical practice (McMillan & Morley, 2010). The overall time series therefore consisted of 70 continuous days of an older adult patient undergoing assessment (A) and treatment (B) testing the Barlow et al., (2004) UP.

Ideographic measurement

Five ideographic anxiety and depression target measures were collaboratively designed at the first session and were then subsequently collected daily across baseline and intervention phases. The three depression measures were (1) structure: '*I feel like there is structure in my day'*, (2) hopefulness: '*I feel hopeful about my husband's progress'* and (3) mood: '*I feel happy*'. The two anxiety measures were (4) confidence: *'I am confident at this point'* and (5) worry: '*thoughts are whirring through my mind'.* All daily ideographic measures were scored 0 'worst ever felt' to 10 'best ever felt.'

Nomothetic measurement

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) was completed at five time points; (1) start of baseline, (2) end of baseline, (3) mid-treatment, (4) end of treatment and (5) at three-month follow-up. The HADS produces a valid and reliable measure of depression

(HAD-D) and anxiety (HADS-A) and is well accepted by patients (Flint & Rifat, 1996) and practitioners alike (Herrmann, 1996). The measure is widely used in older populations as it excludes somatic symptoms and thus avoids the confounding effects of physical illness (Rapp & Vrana, 1989; Yesavage et al., 1983).

Participant

Jan (pseudonym), a 67-year old white-British female was referred for psychological assessment following non-response to a range of medication and support. Jan reported symptoms of hopelessness, low mood, poor concentration and low levels of energy on a daily basis. Jan also described worry characterised as excessive and uncontrollable, intermittent feelings of panic and reported symptoms of agitation, restlessness and poor sleep. She described feeling anxious about everyday tasks and no longer enjoying social activities/contact. The patient reported a lack of structure and purpose to her general daily life and attributed this to a transitional period whereupon her husband had retired from work due to ill health. The patient was a reluctant carer for her partner. Jan's anxious and depressive symptoms had been evident for one year and she described the major impact of such symptoms upon her life. Jan's symptoms met DSM-5 (APA, 2013) criteria for the diagnosis of Major Depression and Generalised Anxiety Disorder. At screening, Jan scored in the moderate to severe range for both the HADS-D (*15*) and HADS-A (*20*).

Formulation

Figure 1 presents Jan's formulation using the UP model (Barlow et al., 2004) which contextualised current emotional distress and symptomatology as couched in the early life experiences of loss and abandonment, which had created a *forced independence* maladaptive coping strategy. Such developmental influences did not teach the patient how to manage emotions

and she described the need to cope with deep feelings of sadness, anxiety, anger and guilt across her entire adult life. Critically, when her husband retired it changed interpersonal patterns and associated behavioural routines (based upon interpersonal distance) that had been relied upon for years in the attempt to manage emotions. Figure 1 maps the unintended consequences of the client's coping strategies that only served to prolong her emotional suffering. For example, the patient pushed her husband to increase his activity (an emotion-driven behaviour) only for this to increase conflict and so maintain anxiety and depression. The formulation highlighted the key role of emotion in on-going unhelpful patterns and also provided hope in that working towards acceptance and creating personally valued goals would reduce suffering (Barlow et al., 2004).

Please insert Figure 1 here

Intervention

Treatment consisted of delivery of the UP (Barlow et al., 2004). Treatment therefore consisted of the following, (1) validation of extant coping strategies through the formulation, (2) understanding the adaptive properties of emotions, (3) identifying and modifying maladaptive emotion-driven behaviors, (4) countering emotional avoidance and emotionally-driven behaviours via behavioural experiments, (5) working towards valued-driven behaviour and (6) accomplishments, maintenance, and relapse prevention

Data analysis

Stability of ideographic baseline data was assessed through graphical representations and the addition of trend lines. Running totals were calculated for all ideographic measures to account

for missing data points and smooth out the data for visual inspection. Two time series analyses compared baseline to treatment ideographic measures scores; percentage of data exceeding the median (PEM; McMillan & Morley, 2010) and non-overlap of all pairs (NAP; Parker & Vannest, 2009). PEM was employed to account for vulnerability to outliers (McMillan & Morley, 2010) and is particularly indicated when autocorrelation is present in time series data (Manolov, Solanas & Leiva, 2010). Estimates of treatment effects based on PEM used the Wendt (2009) criteria; <70% indicates questionable or ineffective treatment, 70-90% indicates a moderately effective treatment and >90% indicates a highly effective treatment. Due to error susceptibility in PEM, non-overlap of all pairs (NAP) was also employed as an ideographic measure analysis method. Mann-Whitney U-tests assessed for any significant difference between baseline and treatment phases in the ideographic measures. Reliable and clinically significant change analyses (Evans, Margison, & Barkham, 1998; Jacobson & Truax, 1991) assessed change over time on the HADS. A patient meeting caseness at assessment would need to score below 7 on the HADS-D and below 9 on the HADS-A at post-treatment to be *clinically* improved and lose at total of 8 points on the HADS-A and 5 points on the HADS-D to be considered *reliably* improved. Patients who simultaneously achieve *clinical and reliable* change are labelled as 'recovered' in practice-based research (Barkham, Stiles, Connell & Mellor-Clark, 2012).

Results

The patient attended all scheduled sessions and completed all collaboratively agreed homework (such as the behavioural experiments), indicating that the UP was well tolerated (hypothesis 1). Figures 2 to 6 contain the graphs (hypotheses 2 and 3) of the ideographic measures comparing baseline to treatment study phases. Visual inspection of trend lines do indicate a slight

improvement occurring during the baseline phase across most measures (except happiness, which deteriorated during the baseline). Baselines did not increase monotonically and an equal number of individual baseline scores reduced rather than improved (e.g. daily structure, confidence and happiness). Trajectories on the outcome graphs therefore indicate an acceleration of positive change during UP treatment in terms of daily structure, worry and confidence. In terms of mood (the ideographic measure of happiness) the UP appeared to reverse the downward trend evident in the baseline. However, the improvement evident during baseline concerning hopefulness (connected to the husband) reversed during UP treatment.

Please insert Figure 2 -6 here

In order to contextualise the graphical results, Table 1 reports the means and SDs across the baseline and UP treatment phases for ideographic measures, with associated analyses of change. These results demonstrate a significant improvement between baseline and treatment phases in terms of the patient's daily structure, mood, confidence and worry. PEM and NAP results indicate that all measures (except hopefulness*)* show a high proportion of non-overlapping data between baseline and treatment phases, indicating clinical change during the treatment phase. The effect size analysis of the PEM results would indicate large effect sizes for structure (91%), mood (97%), confidence (97%) and worry (97%).

Please insert Table 1 here

In terms of psychometric outcome (hypothesis 4), figure 7 demonstrates HADS scores over treatment phases. The graph demonstrates that anxiety and depression were below the clinical cut-off by the end of UP treatment, with the slight relapse in anxiety and depression at follow-up creating a 'hockey-stick' style outcome pattern. Baseline to end of treatment outcomes indicate a patient that had 'recovered' in terms of both anxiety (RCI = 4.31, $p < 0.05$ and termination score in the normal range) and depression (RCI = 5.39, $p < 0.05$ and termination score in the normal range) during treatment. The final HADS-A score at follow-up was just in the clinical range, indicating clinically significant deterioration in anxiety. The HADS-D score remained in below the clinical cut-off at follow-up. The treatment to follow-up deteriorations evident on the HADS did not meet reliable deterioration criteria for either anxiety (RCI = 4.31, n.s.) or depression (RCI = 5.39, n.s.).

Please insert Figure 7

Discussion

This study reported the first attempt to test the UP in co-morbid older adults in routine practice. The SCED methodology provided a uniquely person-centred analysis of change of an older adult struggling with co-morbid anxiety and depression, with the UP formulation emphasising the key role of emotional avoidance in the maintenance of on-going difficulties. The patient's choice of ideographic measures appeared to reflect the reality of the everyday toll of co-morbid anxiety and depression. Taken as whole, the results would be described as mixed. Despite a reliable and clinically significant reduction in HADS anxiety and depression during treatment (meeting recovery criteria), there was some evidence of (non-reliable) relapse over the follow-up

period in terms of anxiety, as the patient was in the clinical range at follow-up. This vital follow-up evidence created the marked 'hockey-stick' outcome pattern in the HADS. In terms of ideographic change, the baseline-treatment comparisons noted significant improvements to daily structure, self-confidence and mood and a significant reduction to the intensity of daily worry. The associated effect sizes for these improvements to structure, mood, confidence and worry were large and would indicate effective UP treatment (Wendt, 2009).

No previous SCEDs of the UP have been completed in adults or older adults and therefore the results also throw light on the shape of change during UP treatment. For the ideographic measures that significantly improved, the graphing of the outcome data illustrated that progress was fairly stable and progressive across the treatment phase, with an absence of sudden gains. Clinically, it is interesting to note that the patient did feel less hopeful after UP treatment – despite this being a statistically non-significant change. The UP appeared to enable the patient to better understand the adaptive properties of emotions, with treatment helping to address emotional avoidance and counter emotionally-driven behaviours. This actually enabled the patient to appropriately accept her husband's retirement and place less emphasis on her husband's health as the sole marker for her own on-going well-being and recovery (Barlow et al., 2004). Loss of hope was therefore consistent with UP treatment and the acceptance of reality by the patient.

The findings from the present research are important in advancing the treatment of co-morbid anxiety and depression in later life and suggest that a single transdiagnostic approach can be well tolerated. The style of the UP appears to have high face validity with co-morbid patients and in the current study all scheduled session were attended indexing this. Clinicians can also feel supported and contained by the modularised and structured clinical approach, with specific activities to complete at certain junctures during therapy. The skill in applying any evidenced-based

psychotherapy is to always adapt and mould the method to the presentation of the patient, whilst remaining consistent to the evidence-base. This solves the clinical dilemma of either slavish adherence to protocols versus messy eclecticism. In the current study the person-centred UP formulation aided in this process of the patient's emotional distress being heard and understood. Obviously, further research is indicated concerning the acceptability and effectiveness of transdiagnostic approaches with older adults, guided by the hourglass model of psychotherapy evaluation (Salkovskis, 2006). In terms of the head of the UP older adult evaluation hourglass, the next indicated steps concern testing the UP with more controlled SCEDs (such as a withdrawal design or testing against a phase of disorder-specific CBT) and other small N evaluations. Testing the acceptability and effectiveness of UP group delivery is also indicated.

In terms of methodological problems with the current research, trend lines indicated some improvement within the baseline period for four out of five of the idiographic SCED measures. This instability in baselines means that change as a result of intervention are harder to evidence with confidence. Unstable baselines are common in SCED (Kellett, 2007) and frequently reflect the fact that the patient has been offered some hope through contact, that assessment is not technically or interpersonally 'neutral' and often has a therapeutic action in and of itself (McMillan & Morley, 2010). The ideographic data was only collected during baseline and treatment phases and the study would have been much improved by the collection of time series data across the follow-up period. This would have usefully contextualised the slight increase in anxiety observed on the HADS-A at follow-up and also been a good test of the durability of the UP. As previously stated, the design of the current A/B SCED study was the most basic variant of the methodology and could have been improved by removal, addition or randomisation designs. All the data was self-report and evaluation efforts would have been improved with the addition of clinician-rated outcome

measures. An interesting additional data source could have been collecting a time series from the husband of the patient's anxiety and depression over the course of assessment and treatment (or a behavioural measure of frequency of conflict). The most obvious limit to any SCED is the degree to which results generalise to other patients.

In conclusion, this study is the first to assess the effectiveness of the UP with an older adult with co-morbid anxiety and depression. Despite acknowledged methodological limitations, this study offers initial encouragement concerning the adoption and further testing of the UP within older adult populations. No adjustments were made to the content of the UP, but the normal adjustments made to the delivery of any talking therapy with older adults were observed (e.g. slowing of pace). Transdiagnostic approaches appear to have the potential to offer additional treatment choice for older adults with co-morbid problems, who are at risk of attrition and relapse when treated with disorder-specific psychological models (NICE, 2009; Rybarczyk et al., 1992). Co-morbidity is the norm and not the exception in clinical services and there is much work to do clinically, organisationally and research-wise to meet this clinical need.

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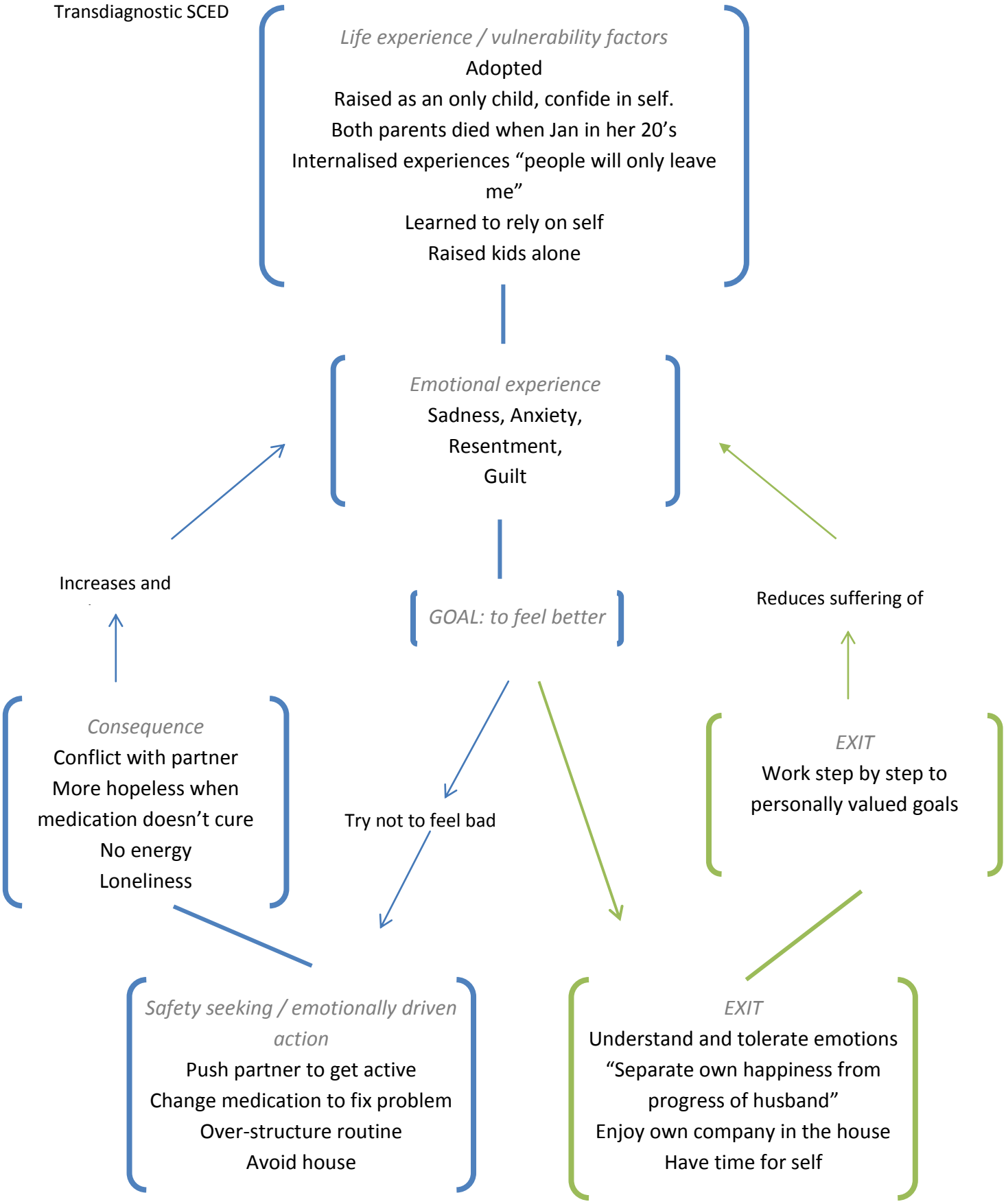

Figure 1. Transdiagnostic formulation of Jan's presenting distress

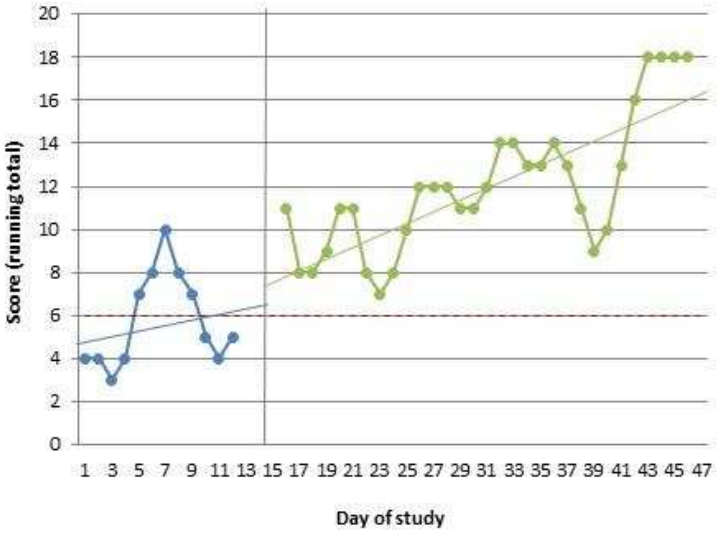

Figure 2. Daily structure over baseline and UP treatment

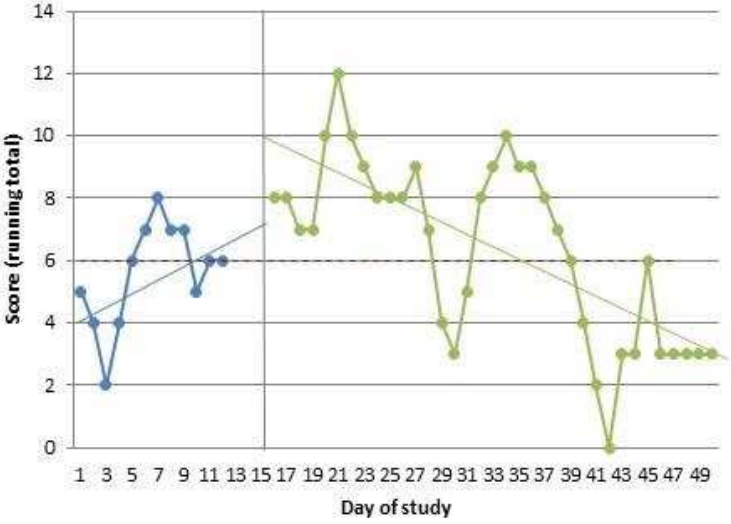

Figure 3. Hopefulness over baseline and UP treatment

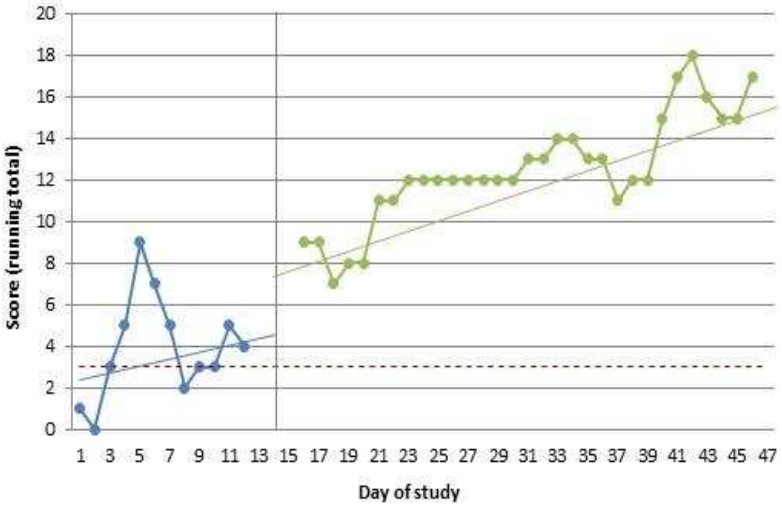

Figure 4. Confidence over baseline and UP treatment

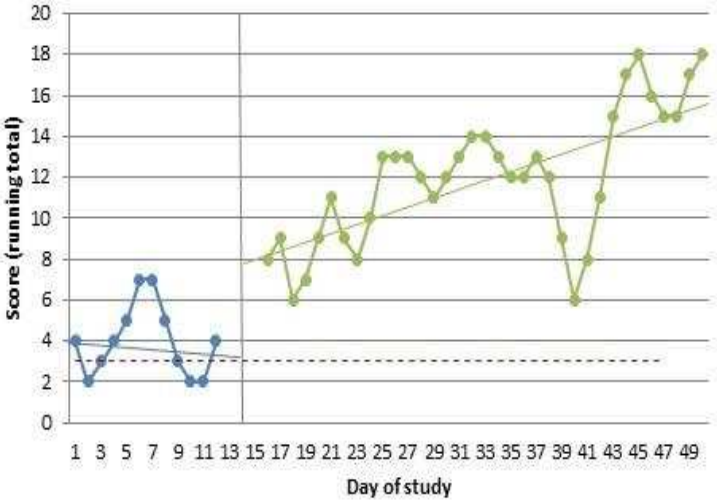

Figure 5. Mood over baseline and UP treatment

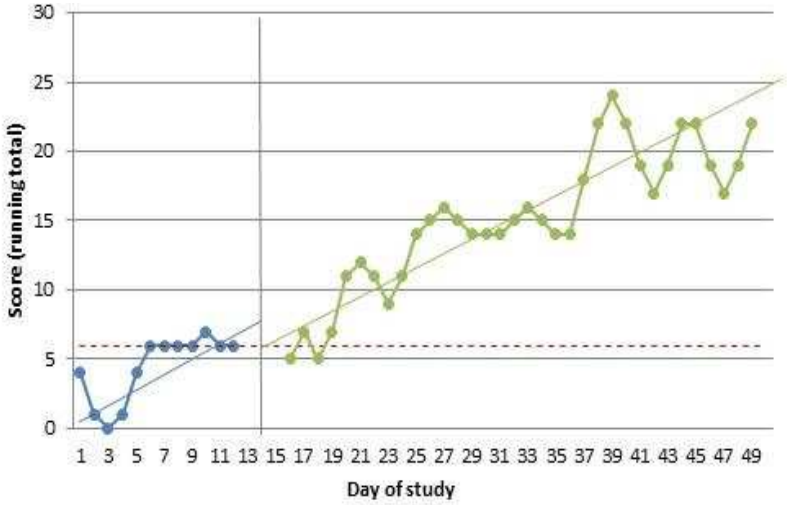

Figure 6. Worry over baseline and UP treatment

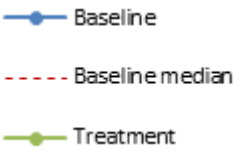

Table 1

Anxiety and depression during baseline and treatment phases

Ideographic measure	Baseline Mean *(SD)*	UP treatment Mean *(SD)*	Non-overlap of all pairs (NAP) %	Percentage of data exceeding median (PEM) %	*Z*
Daily structure	1.85 (1.14)	3.97 (1.30)	89	91	-3.867*
Hopefulness	1.92 (1.40)	2.05 (1.40)	54	42	-0.425
Confidence	1.31 (1.38)	4.00 (1.31)	94	97	-4.832*
Mood	1.38 (1.26)	3.90 (1.50)	89	97	-4.319*
Worry	1.54 (1.13)	4.87 (2.12)	96	97	-4.591*

*p<0.001; negative *Z* values indicate higher scores in treatment compared to baseline.

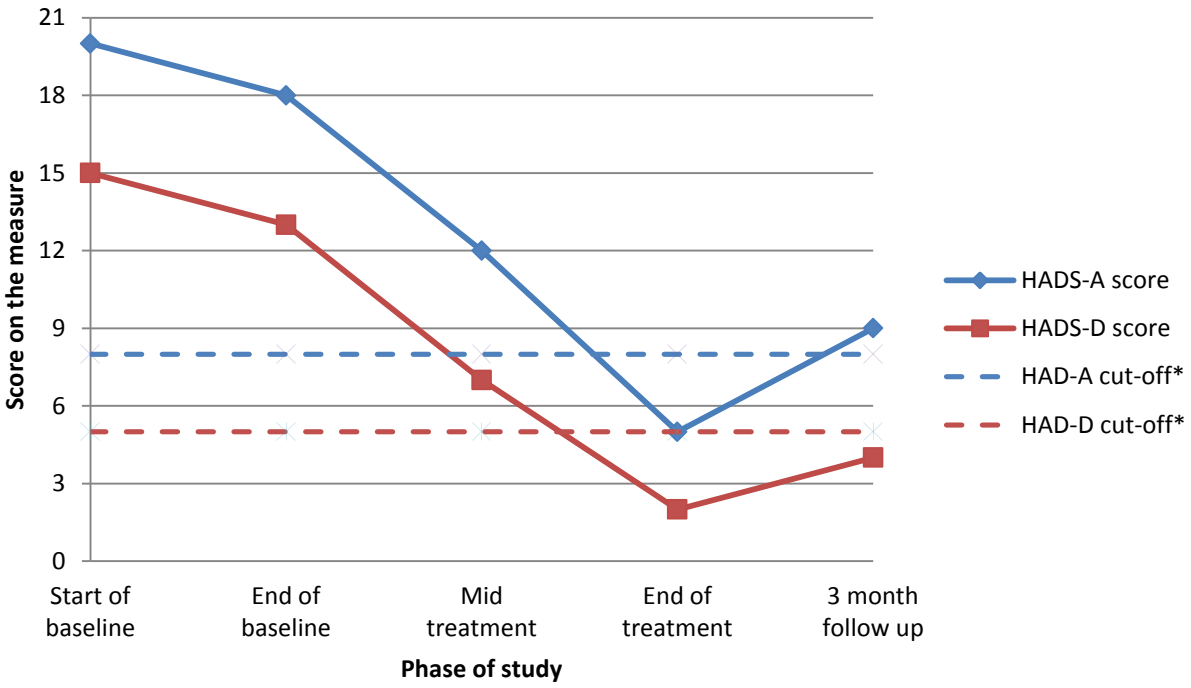

Figure 7. HADS during baseline, treatment and 3 –month follow up