**Background:** Despite the prevalence of comorbid anxiety and depression in older adults in clinical services, the evaluation of suitable clinical models is unfortunately rare. **Aims:** This study sought to test the acceptability and effectiveness of a trans diagnostic CBT approach to treating comorbid anxiety and depression in older adults in a routine clinical setting. **Method:** In an A/B single-case experimental design, a patient completed five daily idiographic measures of anxiety and depression across baseline and treatment and the HADS, including 3-months post-treatment. Treatment consisted of an eight session trans diagnostic CBT intervention developed based upon the Unified Protocol (UP). **Results:** At the end of treatment, significant baseline-treatment improvements were found in the experience of daily structure, mood, confidence, and worry and associated effect sizes were large, with all sessions attended. The shape of change in idiographic measures was progressive following the start of treatment. The Hospital Anxiety and Depression Scale (HADS) showed that the patient met recovery criteria by the end of treatment, with some evidence of anxious relapse at follow-up. **Conclusion:** A relatively short-term trans diagnostic CBT offers promise as a treatment approach to mixed anxiety and depression in older adults, but needs to be tested further using more rigorous methodologies and greater numbers of patients.

Keywords: Trans diagnostic CBT, Unified Protocol, Single-case Experimental Design, Older adults.

**Introduction**

The Department of Health (2009) highlight that one quarter of older adults (65+) living in the community have symptoms of depression and anxiety serious enough to warrant assessment and intervention. Comorbidity 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). Comorbidity also increases impairment in daily functioning, severity of symptoms and likelihood of suicide (Lenze, 2003). The majority of the progress in the psychological treatment of emotional disorders has however, been in the development and testing of treatment protocols for either anxiety (Wolitsky-Taylor, Castriotta, Lenze, Stanley, & Craske, 2010) or depressive disorders alone (Wilson, Mottram, & Vassilas, 2004). Whilst the trials of such protocols have understandably excluded patients with comorbid anxiety in order to ensure internal validity, testing of new clinical models that address such comorbidity are therefore at a premium for patients and services alike (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010).

Recent research evidence suggests greater theoretical and clinical commonalities between anxiety and depression than previously assumed (Harvey, Watkins, Mansell, & Shafran, 2004), and in particular the demonstration of the key role of negative emotions (Etkin & Wagner, 2007). In an attempt to meet this recognition a ‘unified protocol’ (UP) has been developed (Barlow et al., 2011). 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., 2011); through chronic and unsuccessful attempts to avoid or dampen the intensity of negative affect (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 comorbid patients’ significant benefit from treatment, 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 randomised-controlled 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). SCED is particularly indicated in the early testing of new clinical models or new applications of extant treatments in novel populations (Morley, 2007).

In the present paper, a SCED evaluating trans diagnostic CBT treatment of an older adult (65+) with a diagnosis of comorbid depression and anxiety is presented. Core principles of the UP model would be incorporated into a relatively short-term therapy contract to reflect the practice-based reality of UK service delivery for moderate depression and anxiety (National Institute for Health and Clinical Excellence, 2009). The current study is innovative, as no evidence has yet been produced to test the effectiveness of trans diagnostic CBT in older adults with comorbid emotional disorders. The study hypotheses were H1: that the UP will be well tolerated, H2: UP treatment will improve symptoms of anxiety over time in comparison to baseline, H3: UP treatment will improve symptoms of depression 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 trans diagnostic CBT treatment based on the UP protocol with a 3-month follow-up. The baseline (A) phase was spread over two assessment sessions (2-weeks duration), reflecting the standard assessment period 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) using the Barlow et al., (2011) UP. Assessment and treatment was delivered by a Trainee Clinical Psychologist (first author), also accredited as a CBT therapist, and received weekly supervision by a Consultant Clinical Psychologist (third author), also trained in CBT. Treatment was delivered in an out-patient older adult NHS setting in Northern England.

**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. From the post-war generation, Jan described herself as typically active, reporting no physical or cognitive impairments to her functioning. No previous psychiatric history was reported. At the time of referral, 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 chronic physical 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*).

**Idiographic measurement**

Five idiographic anxiety and depression target measures were collaboratively designed by Jan and the therapist 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 idiographic 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 and practitioners alike (Flint & Rifat, 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).

**Formulation**

Figure 1 presents Jan’s formulation, informed by the UP model (Barlow et al., 2011) 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 that countering emotional avoidance would reduce suffering (Barlow et al., 2011).

*Please insert Figure 1 here*

**Intervention**

A total of eight intervention sessions were delivered of trans diagnostic CBT informed by the UP (Barlow et al., 2011). Between-session-tasks were assigned after each session, in addition to completion of idiographic measurement. Treatment focused of the following: (1) two sessions collaborating on the formulation (Figure 1), and validation of extant coping strategies (2) one session understanding the adaptive properties of her sadness, anxiety, and anger (3) two sessions identifying and monitoring her maladaptive emotion-driven behaviors, such as her rumination and hyper-vigilance toward her husband’s health, (4) three sessions countering emotional avoidance and emotionally-driven behaviours, (5) one session working towards valued-driven behaviour, and (6) one session with a focus on accomplishments, maintenance, and relapse prevention. For Jan, exits included anchoring in the present in her house (countering rumination), resuming reading in the house as a valued activity, and taking steps to volunteer in the community. No adjustments were made to the content of the UP, but adaptations to suit therapy for older adults. For Jan this included slower paced sessions, focusing on behavioural to suit her cultural norms, and setting home visits when Jan could not access transport via her husband.

**Data analysis**

Stability of idiographic baseline data was assessed through graphical representations and the addition of trend lines. Running totals were calculated for all idiographic measures to account for missing data points and smooth out the data for visual inspection. Two time series analyses compared baseline to treatment idiographic 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 idiographic measure analysis method. Mann-Whitney U-tests assessed for any significant difference between baseline and treatment phases in the idiographic 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.’ Similarly, patients that experience reliable deteriorations and go from a non-case to a case are considered ‘harmed’ in psychotherapy outcome research (Kellett et al., in press).

**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 idiographic measures comparing baseline to treatment study phases. Visual inspection of trend lines do indicate an improvement (though non-significant) 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 idiographic 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 idiographic 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. However, the treatment to follow-up deteriorations evident on the HADS, did not meet the criteria for a reliable deterioration in terms of anxiety (RCI = 4.31, *p = ns*) or depression (RCI = 5.39, *p = ns*).

*Please insert Figure 7*

**Discussion**

This study reported the first attempt to test trans diagnostic CBT treatment informed by the UP model in a comorbid older adult patient via a SCED. The SCED methodology provided a uniquely person-centred analysis of change for an older adult struggling with comorbid 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 idiographic measures appeared to reflect the reality of their everyday struggle with comorbid anxiety and depression. Taken as whole, the results could be described as mixed. Despite a nomothetic reliable and clinically significant reduction in 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 the idiographic change, the baseline-treatment comparisons did note significant improvements to daily structure, self-confidence and mood and significant reduction to intensity of daily worry. The associated effect sizes for these improvements to structure, mood, confidence and worry were large and would indicate effective trans diagnostic CBT 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 treatment. For the idiographic 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 treatment – despite this being a statistically non-significant change. The UP principles 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., 2011). 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 comorbid anxiety and depression in later life and suggest that a single trans diagnostic approach can be well tolerated and was generally clinically effective. The style of the UP has high face validity with comorbid patients and in the current study the treatment was well tolerated and all scheduled session were attended. Clinicians can also feel supported by the modularised and structured clinical approach, with specific activities to complete at certain junctures. 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 trans diagnostic 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 trans diagnostic approaches with older adults, and particularly the full 18-session modules outlined in the UP manual (Barlow et al., 2011) requires evaluation in older adults. Testing the UP with more controlled SCEDs (such as a withdrawal design or testing against a phase of disorder-specific CBT) and small N evaluations is indicated, before progressing to evaluation of larger scale designs of UP with comorbid older adults.

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 is much 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, and that assessment in not technically or interpersonally ‘neutral’ and often has a therapeutic action in and of itself (McMillan & Morley, 2010). The idiographic 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 effectiveness of the UP in an older adult. 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 trans diagnostic CBT treatment informed by the UP model with an older adult with comorbid 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). Trans diagnostic approaches appear to have the potential to offer additional treatment choice for older adults with comorbid problems, who are at risk of attrition and relapse when treated with disorder-specific psychological models (NICE, 2009; Rybarczyk et al., 1992). Comorbidity 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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Table 1

*Anxiety and depression during baseline and treatment phases*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Idiographic 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*.*

Try not to feel bad

Increases and prolongs…

*Life experience / vulnerability factors*

Adopted,

Raised an only child, learned to rely on self,

Both parents died when Jan in her 20’s,

Internalised experiences “people will only leave me”,

Raised kids alone,

Husband retires, carers role

*Emotional experience*

Sadness, Anxiety,

Resentment,

Guilt

*GOAL: to feel better*

*Safety seeking / emotionally driven action*

Hyper vigilance to husband’s ill-health,

Push partner to get active,

Change medication to fix problem,

Rumination

Avoid house

*Consequence*

Conflict with partner,

Increased hopelessness with lack of fix,

No energy,

Loneliness

*EXIT*

Work step by step towards: personally valued goals,

Promote self-efficacy

*EXIT*

Understand and tolerate emotions;

“Separate own happiness from progress of husband”,

Enjoy own company in the house,

To have time for self

Reduces suffering of…

*Figure 1.*Trans diagnostic CBT formulation of Jan’s presenting distress

*Figure 2 - 6.* Jan’s running totals (*1, 2, 3; 2, 3, 4 ...n₁, n₂, n₃*) for five idiographic recorded daily during baseline and intervention

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