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Bringing light into darkness: A multiple baseline mixed methods case series evaluation of Augmented Depression Therapy (ADepT)

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ABSTRACT

Two core features of depression are elevations in negative valence system (NVS) functioning and reductions in positive valence system (PVS) functioning. Existing psychological treatments have focused on the NVS and neglected the PVS, which may contribute to sub-optimal outcomes. The present mixed methods multiple randomised baseline case series preliminarily evaluates Augmented Depression Therapy (ADepT), a novel depression treatment targeting PVS and NVS disturbance, that aims both to reduce depression and enhance wellbeing. Eleven clinically depressed participants were recruited. Intensive time series analyses showed that 7/11 participants improved on both wellbeing and depression. Reliable and clinically significant improvement was observed for 9/11 participants on at least one of these outcomes (and also across a range of other PVS and NVS outcomes). Group level analyses showed significant pre to post change on all outcomes. Benchmarking analyses indicated these effect sizes were at least comparable (and for some PVS outcomes superior) to existing treatments. Gains were largely sustained over one-year follow-up. Qualitative interviews indicated ADepT was feasible and acceptable. These findings provide preliminary support for ADepT as a novel depression treatment. Further evaluation, directly comparing ADepT to existing treatments using randomised controlled trial designs, is now required.

1. Introduction

Depression is a prevalent, recurrent and debilitating condition, which leads to marked economic and social costs, and is predicted to become the leading worldwide contributor to disability by 2020 (Andrews & Titov, 2007; Judd, 1997; Kruijshaar, Barendregt, Vos De Graaf, Spijker, & Andrews, 2005; Layard et al., 2006; Moussavi et al., 2007; Singleton, Bumpstead, O'Brien, Lee, & Meltzer, 2003; Üstün, Ayuso-Mateos, Chatterji, Mathers, & Murray, 2004). Existing psychological and pharmacological interventions for depression are not optimally effective, with approximately only half of individuals responding (showing at least a 50% reduction in symptoms) and many exhibiting residual depression symptoms and functional impairment after treatment (Cuijpers, van Straten, Andersson, & van Oppen, 2008; Rush, 2015; Sheehan, Harnett-Sheehan, Spann, Thompson, & Prakash, 2011). It remains unclear if existing treatments are superior to placebo, except in cases of severe depression (Cuijpers et al., 2014b, 2014a; Fournier et al., 2010). Even in those who fully recover during acute treatment, subsequent rates of relapse are high (Vittengl, Clark, Dunn, & Jarrett, 2007). Enhanced treatments are needed to reduce symptom severity and to improve functionality, allowing individuals to lead the best life they can alongside depression.

One way forward is to acknowledge that depression is not a homogeneous diagnostic entity and instead is better considered in terms of a constellation of distinct underlying functional dimensions, each requiring different intervention strategies (Insel et al., 2010). The two symptoms required for a diagnosis of depression are either a pervasive depressive mood or a loss of pleasure and interest in all or most activities (anhedonia). These symptoms can be seen as emergent properties of disruptions to two underlying and partly dissociable neurobiological dimensions in depression (Carver & White, 1994; Gray, 1987; Insel et al., 2010; Paulus et al., 2017; Watson, Wiese, Vaidya, & Tellegen, 1999). Up-regulation of the negative valence system (NVS) results in elevated withdrawal from punishing stimuli and increased negative affect (NA) experience. Down-regulation of the positive valence system (PVS) reduces approach to rewarding stimuli and inhibits

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positive affect (PA) experience.

Whilst it has long been recognised that NVS elevations are prognostically important in depression, it is now increasingly acknowledged that PVS reductions also predict acute symptom severity, poor treatment response, and a chronic, relapsing future course (Spijker, Bijl, De Graaf, & Nolen, 2001; Uher et al., 2012, McMakin et al., 2012; see reviews by Dunn & Roberts, 2016; Dunn, in press). To treat depression effectively it is therefore likely to be necessary to target disturbances in both the PVS and the NVS. However, existing psychological treatments primarily focus on NVS elevations and neglect the PVS (Dunn, 2012; Dunn & Roberts, 2016). For example, informal content analysis suggests that Cognitive Therapy (CT; Beck, Rush, Shaw, & Emery, 1979) predominantly targets the modification of negative thinking to reduce negative mood (Dunn, in press).

Consistent with the assertion that existing approaches have neglected the PVS, treatment has been shown to be more effective at lowering NA than building PA in routine practice (Brown, 2007; Kring, Persons, & Thomas, 2007; Naragon-Gainey, Gallagher, & Brown, 2013). Similar findings have emerged when reanalysing existing RCTs (Dunn et al., in press). The CPT2 trial (DeRubeis et al., 2005) compared 16 weeks of cognitive therapy and antidepressant medication in the treatment of depression and the CPT3 trial (Hollon et al., 2014) investigated the efficacy of antidepressant medication alone versus combined cognitive therapy and antidepressant medication in treating depression to remission. Secondary analyses revealed that reductions in PA were more marked than elevations in NA prior to treatment; there was a smaller repair of PA relative to NA during treatment; and disturbances were greater in PA versus NA at the end of treatment (Dunn et al., in press).[1]

To improve depression outcomes, enhanced treatments need to be developed that simultaneously target both the PVS and the NVS (Dunn, 2012; Dunn & Roberts, 2016; Wood & Tarrier, 2010), focusing on underlying psychological mechanisms that elevate NA and reduce PA. When deciding how to measure treatment outcomes, it is also imperative to consider what 'recovery' from depression means from a client perspective. The key element of recovery to clients is enhanced functioning in valued life domains (i.e. a reduction in the disability burden of depression) and increased wellbeing (the capacity to experience pleasure, meaning and social connection in life; Keyes, 2005) (Demyttenaere et al., 2015; Zimmerman et al., 2006). This resonates with the 'recovery' literature, emphasising that recovery involves a positive focus on being able to live a life that enhances wellbeing and functioning (Slade, 2010), often alongside mental illness (Anthony, 2003). Given the chronic, relapsing course of depression, focusing on functional recovery of this kind rather than complete cure may feel a more realistic goal for many clients. The goal-setting literature also emphasises the importance of identifying approach rather than avoidance goals (Elliot, Sheldon, & Church, 1997; Roskes, Elliot & DeCru, 2014), meaning it may be preferable to target building wellbeing rather than symptom relief. It is known that functional improvement can often lag behind symptomatic improvement (Rush, 2015; Sheehan et al., 2011, 2017). Therefore, enhanced treatments need to target both symptom relief *and* enhanced functioning and wellbeing, helping individuals learn to live well alongside depression. Such an approach is likely to have high acceptability to clients, potentially reducing drop-out during treatment (estimated to be greater than 25% during CT; Hans & Hiller, 2013; Fernandez, Salem, Swift & Ramtahal, 2015).

Augmented Depression Therapy (ADepT) has been developed to target PVS and NVS deficits in depression simultaneously. ADepT is a fifteen session individual therapy for acute depression (with five optional booster sessions in the year post treatment). To help foster positive recovery, ADepT co-targets reduction of depression symptoms *and* enhancement of wellbeing/functioning. Following MRC guidance regarding the development of complex interventions (Craig et al., 2008), the ADepT protocol was constructed by: i) co-designing the intervention with service-users and other key stakeholders to maximise uptake (Concannon et al., 2012; Cooper, 1999; Muller, 2012); ii) translating findings from basic science research characterising PVS deficits in depression (cf., Clark, 2004); and iii) integrating elements of best practice from existing treatment approaches. The co-design process followed the principles of Intervention Mapping (Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, 2011) and involved an iterative process of stakeholder consultation, literature review, and analysis of the local context, during which a preliminary logic model of the intervention was tested and revised. We used proven elements from existing treatments to target NVS function. Basic science findings were used to identify those underlying mechanisms impairing PVS function which ADepT should target (cf. Dunn, 2017). The mechanisms targeted included: elevated use of dampening appraisals when feeling positive (Burr, Javiad, Jell, Werner-Seidler, & Dunn, 2017; Dunn et al., 2018; Werner-Seidler, Banks, Dunn, & Moulds, 2013); reduced attentional and mnemonic processing biases to positive information (e.g., see Winer & Salem, 2016; Matt, Vazquez & Campbell, 1992; Dunn, Stefanovitch, Buchan, Lawrence, & Dalgleish, 2009); reductions in experiential processing (e.g., see Gadeikis, Bos, Schweizer, Murphy, & Dunn, 2017; Teasdale, 1999); and reductions in self-compassion and kindness (e.g. see Hofmann, Grossman, & Hinton, 2011). These mechanisms can all be seen as subtypes of avoidance of positive emotion experience (e.g. Bardeen, Tull, Stevens, & Gratz, 2014; Gilbert, McEwan, Catarino, Baião, & Palmeira, 2014; Jacob, Ower & Bucholz, 2013).

An effective and efficient first step in evaluating and refining a novel psychological treatment is to conduct a case series (Kazdin, 2011; Morley, 2017). Case series methods can: assess treatment acceptability and feasibility; provide preliminary evidence of effectiveness and proof-of-concept; help refine and optimise the protocol; and establish if the treatment is likely to be implementable in the target context. Generalisability can be assessed by evaluating if findings replicate across a series of individual cases, this begins to control for threats to external validity and to assess whether findings are generalizable. Intensive time series data are typically collected and analysed at the individual participant level to visually ascertain whether there is within-person change in slope and level from a baseline phase to the intervention. Where a sufficient number of data points are collected, these individual time series analyses also have adequate power to test statistically the efficacy of an intervention for an individual participant (Borckardt et al., 2008). Use of a randomised multiple baseline design (randomising individuals to different lengths of baseline phase before starting treatment; effectively turning case series into rigorous experimental design) beings to control threats to validity. In particular, it helps to differentiate between a genuine treatment effect and natural recovery over time or other confounding factors (Kratochwill & Levin, 2010). These time series analyses can also be supplemented with reliably and clinically significant change analyses. These can determine the proportion of individuals who improve to a greater extent than measurement error on the scale and beyond a minimum amount that indicates a meaningful degree of change (Jacobson & Truax, 1991). Case series can also highlight treatment non-responders, who may otherwise be hidden within the overall effect of a group-based design.

Given the lack of an internal control condition in case series designs, it can be helpful to benchmark the treatment effects against some external comparator (Borckardt et al., 2008). Conventional group level statistical tests can be run to estimate effect sizes, which can be

[1] Similar findings emerge when looking at the broader constructs of wellbeing versus symptom relief and personality change. For example, there is more robust relief of symptoms of mood disorders than improvements in wellbeing following Acceptance and Commitment Therapy (Trompetter, Lamers, Westerhof, Fledderus, & Bohlmeijer, 2017) and CBT. Behavioural Activation only generates a medium effect size for wellbeing outcomes (Mazzucchelli, Kane, & Ress, 2012). Moreover, psychological treatments bring about bigger changes in neuroticism (related to negative affect) than they do extraversion (related to positive affect) (see systematic review by Roberts et al., 2017).

compared against existing randomised control trial (RCT) outcomes for other depression interventions. Case series can be further enhanced by incorporating qualitative methods, allowing for detailed exploration of patient views on feasibility, acceptability, efficacy, mechanisms of action and ways in which the treatment can be improved (Onghena, Maes, & Heyvaert, 2018; O'Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013). While quantitative analyses can provide numerical precision, qualitative analyses can ensure descriptive precision (Kitchenham, 2010; Onghena et al., 2018). Further, alongside a careful examination of participant characteristics and extra-therapeutic events, qualitative analysis can help identify reasons why a treatment did not produce change in a particular individual and for whom a treatment might be contraindicated.

We therefore ran a randomised multiple baseline case series evaluation of ADepT, including both quantitative and qualitative methods. We set *a priori* continuation rules allowing us to proceed to pilot trial evaluation of ADepT only if:

1. 60% of clients show at least reliable improvement pre to post in depression or wellbeing
2. < 30% of clients show reliable clinical deterioration pre to post in depression or wellbeing
3. > 60% of clients complete a minimum adequate dose of acute treatment (over 50% of acute dose; 8 or more sessions)
4. Clients on average attend > 60% of scheduled acute sessions (on average at least 7.5 sessions per client)
5. > 60% of clients and therapists rate treatment as acceptable, that they are satisfied with the treatment, and that they would recommend it to friends and family
6. ADepT treatment participation does not lead to serious negative consequences for participants (unexpected, clearly trial- or treatment-related serious adverse reaction)
7. At least large pre to post effect sizes emerge on depression and wellbeing (Hedges g > 0.8; cf. Cohen, 1988)

Further, the case series outcomes were benchmarked against existing trial data to examine how NVS (depression and anxiety symptoms, negative affect) and PVS (positive affect, anhedonia, and wellbeing) outcomes compared to existing treatments. While this was not pre-specified as a continuation rule, the expectation was that ADepT would lead to broadly comparable NVS effects, and superior PVS effects, relative to current best practice.

2. Method

2.1. Setting and design

The case series was conducted at the Accessing Evidence Based Psychological Therapies (AccEPT) clinic, University of Exeter (see: https://www.exeter.ac.uk/mooddisorders/acceptclinic/), utilising a randomised multiple baseline mixed methods case-series design. Participants were recruited by writing to clients on local Improving Access to Psychological Therapy (IAPT) Services high intensity waiting lists for depression therapy or via NHS or self-referral to the AccEPT clinic. Participants were randomised to different baseline assessment length (between three and eight weeks), with a random sequence generated by a computer-based package. The acute intervention phase consisted of up to fifteen weekly sessions. Participants completed measures of depression and wellbeing each week in the baseline and acute treatment phase. In addition, participants also completed a longer battery of measures at randomisation, pre-treatment, post-treatment, and two months after completing acute treatment. An ethics amendment was sought after the original study was completed to follow-up participants approximately one year later (after the optional booster sessions had been completed). We followed guidelines in the design, analysis and reporting of case series to ensure the method was applied optimally (Kratochwill et al., 2013, 2010; Smith, 2012; Tate et al., 2016).

2.2. Participants

Consecutive referrals that met study inclusion criteria took part in the study. Inclusion criteria were: being aged over 18 years; currently experiencing a major depressive episode based on a Structured Clinical Interview for Diagnosis (SCID-I; First, Spitzer, Gibbon, & Williams, 1994); and scoring in the clinical range of the PHQ-9 with marked anhedonic features (PHQ-9 total score ≥ 10; item one measuring anhedonia score ≥2). Participants were required to describe depression as their primary presenting problem and have sufficient knowledge of written and spoken English to be able to make use of the therapy and to complete research assessments without the need of a translator. Exclusion criteria included: a history of bipolar disorder or organic brain change; currently receiving any other psycho-social therapy; substance abuse that compromised ability to use therapy; and current marked risk to self (self-harm or suicide) that could not be safely managed in the clinic setting. Taking psychotropic medication was not an exclusion criterion in this study and a majority of participants were prescribed anti-depressants.

Sample size estimations for intensive time series analysis (our primary analysis method) do not follow a formal power analysis approach. However, guidelines recommend a minimum of three replications of the intervention effect (Kratochwill et al., 2010). To increase confidence in the generalisability of the findings, we asked three different therapists to deliver the treatment, aiming for each to treat at least three cases. For the secondary group level analyses (used to generate effect sizes for benchmarking purposes), we aimed to be powered to detect a large effect size in the key pre-post analysis (based on the continuation rule that ADepT needed to demonstrate a large effect size on the primary outcome variables). We therefore intended to recruit at least 13 participants. We only included participants in the final analyses who remained above the clinical cut-off for depression at the end of the baseline phase (PHQ-9 ≥ 10) and showed a stable pattern of depression and wellbeing during the baseline phase. This is because instability in the baseline phase can bias the conclusions reached in both visual and statistical analyses (Kratochwill et al., 2010). We used reliable change for the PHQ-9 (≥6 points) and wellbeing (≥7 points) as the cut-off to indicate the baseline was not stable.

Participants gave written informed consent prior to participation. The original study (and the amendment to follow-up participants at one year) was approved by Frenchay NHS ethics committee (reference number 15/SW/0352). Participants were given an honorarium of £10 for each of the research assessments they completed (a maximum of £60).

2.3. Intervention

ADepT is an integrationist approach that combines novel intervention elements translated from basic science alongside existing strategies from established treatments, including CT (Beck et al., 1979; Kuyken, Padesky, & Dudley, 2011; Moore & Garland, 2003), Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson, 2011), Behavioural Activation (BA; Martell, Dimidjian, & Herman-Dunn, 2013), Mindfulness Based Cognitive Therapy (MBCT; Segal, Williams, & Teasdale, 2012), and positive psychology approaches (Bryant & Veroff, 2007; Sin & Lyubomirsky, 2009).

ADepT aims to enhance wellbeing (positive mood, meaning and social connection), to optimise functioning and to reduce symptoms of depression. It is a solution-focused, values-based, cognitively augmented behavioural activation approach, consisting of up to 15 acute treatment sessions and up to 5 optional booster sessions (scheduled flexibly in the year following acute treatment to sustain longer-term recovery). Each session lasts 60 min, with the exception of the initial assessment which can last up to 90 min. Sessions are scheduled weekly

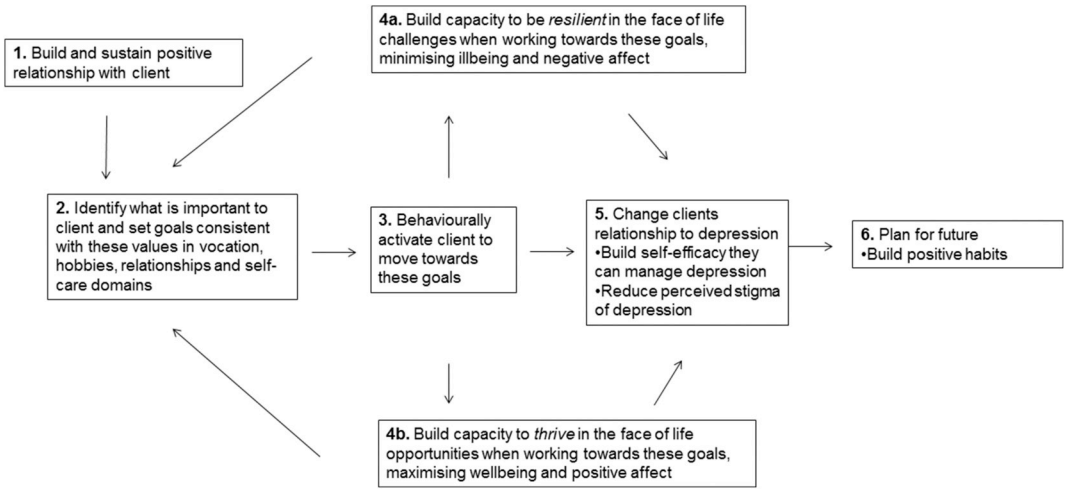

Fig. 1. Logic model of ADepT.

and are delivered face-to-face, although therapists are encouraged to be flexible about timing and delivery format to meet client needs. Each session follows a typical CT structure, consisting of: mood review, agenda setting, home-practice review, working through each agenda item, and client summary and feedback. Figure One presents the logic model underpinning ADepT (see also Dunn et al., 2019 for further details of ADepT protocol).

2.3.1. Therapist style

Therapists are encouraged to make judicious use of warmth, humour, positive feedback, gratitude and self-disclosure to build a positive relationship with clients and to make each session enjoyable where possible (logic model box 1). A solution-focused, coaching stance is taken, intentionally focusing on pockets of resilience and thriving to enhance client agency whenever possible ('thickening the positive narrative'; De Shazer & Coulter, 2012). Clients are supported to see their depression as a normal part of life and something they can proactively manage, meaning they are able to live a life they wish to lead even alongside periods of low mood (logic model box 5). Therapists utilise techniques to enhance memorability and generalisability of sessions throughout (attention recruitment, categorisation, evaluation, application, repetition, practising remembering, use of cue based reminders, and praising recall; see Harvey et al., 2014). Clients are also given handouts summarising key therapy content to ensure long term recall of session content (logic model box 6).

2.3.2. Early sessions

Session 1 assesses depression and presents the ADepT rationale, in particular that the treatment aims to build wellbeing in important life domains and sees depression as a barrier to achieving this goal. Clients are given a simplified version of the logic model underpinning the intervention, which the therapist tailors and personalises to them. Sessions 2 to 5 help clients establish what is important to them in life (their values) in vocation, relationship, hobbies and self-care domains; set behavioural goals consistent with these values; and break these goals down into 'action-steps' (logic model box 2).

A key element introduced in this early phase values work is a modified values 'bullseye' tool that is co-developed with the client (cf. Lundgren, Luoma, Dahl, Strosahl, & Melin, 2012). In later sessions, clients report if they are completing the action steps they specified and if they are moving closer to the bullseye in each life domain. Values, goals and action-steps are updated in an ongoing fashion as therapy proceeds. This tool serves many of the functions of a conventional therapy formulation (synthesis of client experience with theory; normalisation of presenting issues; promoting client engagement; making goals seem manageable; guiding selection, focus and sequence of treatment; identifying strengths and building resilience; monitoring outcomes; guiding supervision; (see Kuyken, Padesky, & Dudley, 2008) without having any emphasis on psychopathology. This values work can either involve reconnecting clients to previous values they have neglected while depressed and/or helping clients build new values in areas of life they have not considered before. Often there is an emphasis on distinguishing between what is intrinsically important to clients, versus what values may have emerged as a reaction to depression or external pressures.

2.3.3. Middle sessions

Sessions 5–12 behaviourally activate clients to work towards the goals set on the values tool (logic model box 3). To maximise the likelihood that these goals are completed, clients are encouraged to recognise if they have the capability, opportunity and motivation to carry out each action step (known to be key underlying determinants of behaviour change; Michie, Van Stralen, & West, 2011). If they lack any of these determinants, coaching approaches are used to build them in session. As they work towards these goals, clients are supported to understand how depressogenic patterns of thinking and behaviour hinder them from fully embracing opportunities to enhance PA (thriving; maximising PVS activation) and coping with challenges to minimise NA (being resilient; minimising NVS activation) (boxes 4a and 4b in the logic model). The therapist supports the client to recognise and then 'act-opposite' to a range of depressogenic mechanisms including: avoidance, rumination, self-criticism, negative processing biases, and neglect of sensory experience.

A mapping tool is introduced to facilitate this process of pattern recognition and modification (a modified 'hot cross bun'; cf. Padesky & Mooney, 2012) in the middle phase of therapy. Clients are encouraged to map out a 'depressed me' (how depression makes them cope), then develop an 'alternative me' (alternative ways of coping to maximise chances of goal attainment) and commit to behavioural experiments to test out the 'alternative me' (cf. Padesky & Mooney, 2012). This can involve reconnecting clients to their existing strengths (cf. Ghielen, van Woerkom & Meyers, 2017) or developing new skills as appropriate. This mapping occurs at the 'micro' rather than 'macro' level. The emphasis is on understanding the fine details of what helped or hindered in a specific context rather than at an abstract, general level. The focus of these maps is the present and future, with far less attention paid to historical insights than in mainstream CT. Therapists aim to model and actively reinforce a (realistically) positive and future-oriented cognitive and interpersonal style (Macleod, 2017; Vilhauer, 2014; Verplanken, 2006; Wood & Neal, 2007).

Therapists use a mixture of cognitive change, role-play, skills training and problem-solving techniques to help clients build new positive patterns of response. Cognitive change work predominantly adopts a 'utility' rather than 'truth' perspective (thinking/attending in way that maximises the chances a goal is achieved rather than evaluating whether particular ways of thinking/attending are realistic). Other tools used in this middle phase of therapy include a positive journal (where clients record moments of resilience and thriving occurring in their everyday life) and brief training in mindful engagement with the external senses during everyday activity (both as a way to enjoy every day 'simple pleasures' and as a way to regulate negative mood at times of stress).

2.3.4. End and booster sessions

Sessions 13–15 develop a wellbeing plan, to help clients continue to move towards positive recovery. Therapy is framed as the start of this process. The intention is for clients to consolidate skills they have learned and build a habit of maintaining and tracking progress towards valued goals. By doing so, in the event of a future drop in mood, clients will have well-rehearsed, and increasingly automated, positive coping strategies to deploy (logic model box 6). The wellbeing plan involves working through a series of handouts consisting of: a review of progress made in therapy (including celebrating progress); setting goals for the future on the bullseye tool; considering what could help or hinder achieving these goals; and developing concrete steps outlining how to respond to any signs of relapse or mood lift. Sessions 16–20 are optional booster sessions, focusing on managing any mood dips, 'thickening the positive narrative' around successes, and reviewing and updating the wellbeing plan and values bullseye tool as required.

2.3.5. Similarities and differences with other approaches

The systematic emphasis on thriving (making the most of opportunities to enhance positive affect and PVS function) distinguishes ADepT from CBT and MBCT (which predominantly focus on NVS regulation). ADepT is similar to ACT in that it focuses on the pursuit of valued activities. However, the ACT stance is to engage in these activities regardless of unwanted experiences that may occur and with little attempt to alter symptoms. In contrast, ADepT explicitly focuses on trying to enhance wellbeing and PA and reduce NA and symptoms whilst engaging in these valued activities. ADepT also has overlap with Behavioural Activation approaches (Martell et al., 2013), but with more of an explicit emphasis on clarifying values and targeting cognitive mechanisms that may sabotage resilience and thriving during planned activities.

2.3.6. Therapists and supervision

Treatment was delivered by three therapists. Therapist one was the first author of this study and the intervention developer (a doctoral level clinical psychologist; BD). Therapist two was a doctoral level clinical psychologist. Therapist three was a BABCP accredited nurse therapist. Group supervision was provided weekly for 60 min in group format (led by BD).

2.4. Measures

2.4.1. Diagnostic interview

The Structured Clinical Interview for DSM-IV-TR Axis I Disorders (SCID-I; First et al., 1994) was used to assess whether participants met criteria for a Current Major Depressive Episode and to rule out current or past mania or psychosis at intake. At one-year follow-up, participants also underwent a diagnostic interview to assess if they had met criteria for a major depressive episode in the period of time since completing acute treatment using The Longitudinal Interval Follow-up Evaluation (LIFE, Keller et al., 1987). The interviewer was not blind to treatment phase.

2.4.2. Weekly measures

The 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS; Tennant et al., 2007) was used to index wellbeing and the 9-item Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001) was used to measure depression symptom severity. Both measures have been shown to be sensitive to change during treatment (Kroenke, Spitzer, Williams, & Lowe, 2010; Maheswaran, Weich, Powell, & Stewart-Brown, 2012) and had acceptable reliability in the current sample (see supplementary materials Section S1 for full descriptions, reliability co-efficients, and normative data). These measures were filled in weekly, either via post or online.

2.4.3. Acceptability

After the acute treatment phase was completed, participants were invited to take part in a qualitative interview (lasting approximately 45 min) to explore their experience of ADepT treatment. A particular focus of the qualitative interviews was to examine if the wellbeing, solution-focused emphasis of ADepT was feasible and acceptable to clients, given concerns that such an approach could be experienced as "PollyAnna-ish" (see Dunn, 2012). A pragmatic stance was adopted (stimulating the combination of action and reflection to solve 'real world problems'; Feilzer, 2010; Biesta, 2010). The interviews were conducted by the research team and the qualitative analysis was completed by the first author (BD). The interviews followed a topic guide to ensure that all areas were covered, but this was used flexibly so as to allow other issues of importance to participants to be fully examined (see Supplementary Materials Section S4). At the end of this interview, participants also quantitatively rated the acceptability of the intervention (from 1 = not at all acceptable to 5 = extremely acceptable); how satisfied they were with the intervention (from 1 = not at all satisfied to 5 = extremely satisfied); and whether they would recommend this treatment to friends or family suffering from depression (from 1 = not at all likely to 5 = very likely). Qualitative interviews were audio-recorded and then transcribed. Thematic analysis of the interviews was conducted using a Framework approach, involving the coding and sorting of textual units according to both deductive and inductively-derived categories, and the use of matrices to review the coded data, investigate commonalities and differences and search for patterns (Ritchie, Spencer, & O'Connell, 2003; Gale, Heath, Cameron, Rashid, & Redwood, 2013).

2.4.4. Extended assessment measures

At intake, pre-treatment, post-treatment, two-month follow-up, and approximately one -year follow-up, participants completed an extended battery of measures. In addition to the WEMWBS and PHQ-9, participants completed four further measures. The 5-item Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002) was used to assess functional impairment resulting from depression. The past week version of Positive and Negative Affect Scale (PANAS; Watson, Clark, & Tellegen, 1988) was used to measure levels of positive and negative affect (measures of PVS and NVS respectively). The 7-item Generalized Anxiety Disorder scale (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) was used to measure anxiety symptom severity, given depression is frequently comorbid with anxiety. The 14-item Snaith Hamilton Pleasure Scale (SHAPS; Snaith et al., 1995) was used to measure anhedonia severity, reporting the continuous scoring recommended by Franken, Rassin, and Muris (2007). Reliability was acceptable for all measures (see supplementary materials Section S1 for full descriptions and reliability coefficients). These measures were either administered via post or in a face-to-face interview conducted by a member of the research team (EW).[2] The mean interval from final acute

[2] This extended battery also included the Behavioural Activation for Depression Scale (BADS) as a measure of behavioural activation, the short-form of the Recovery Assessment Scale (RAS-SF) as a measure of recovery

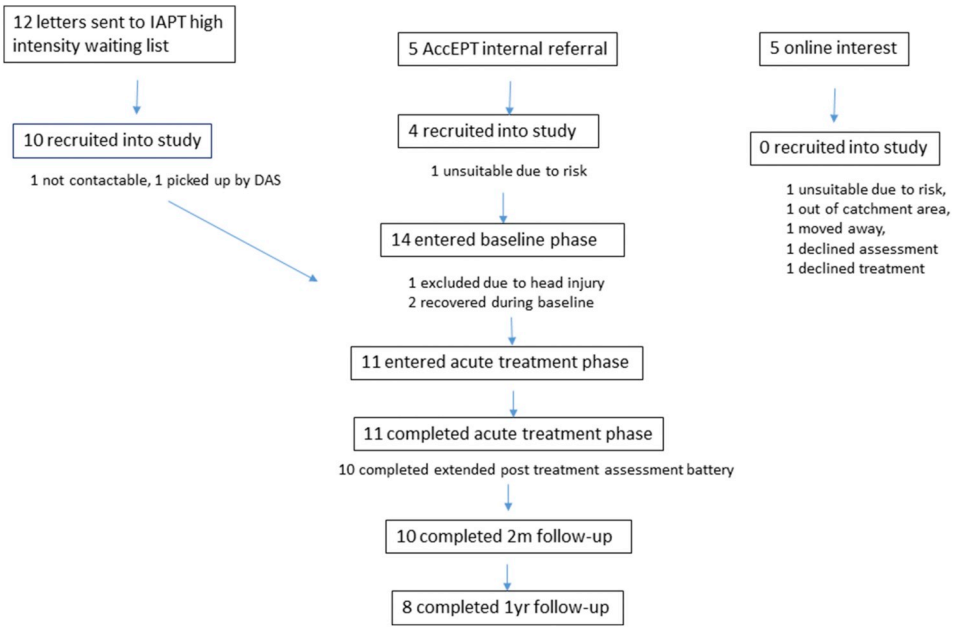

Fig. 2. Consort diagram for case series.

therapy session to one-year follow-up was 406 days (SD = 92.42, range = 241 days–492 days).

3. Results

3.1. Recruitment, data completeness and demographic characteristics

Fig. 2 presents the consort diagram for the case series. Fourteen participants entered the case series but three were excluded (P1 and P2 as they recovered during the baseline phase [PHQ-9 change > 6 points and scoring < 10 at pre-treatment]; P14 because it became apparent that their primary presenting problem was a head injury[3]). All remaining 11 participants had complete PHQ-9 and WEMWBS data for each weekly assessment, apart from P10 (no treatment week seven data) and P13 (no baseline week two data). We substituted these two missing values with the average of the two values either side of them. Complete extended assessment data at pre, post and two-month follow-up were available for ten out of eleven participants (P4 did not complete post-treatment and follow-up assessments). We substituted the post-treatment PHQ-9 and WEMWBS scores for P4 with weekly measures taken at session 15. Nine out of eleven participants took part in the post-treatment qualitative interview. Eight out of eleven participants were contactable after one-year for the additional follow-up, all of whom agreed to take part. P4, P9, P13 could not be contacted at one-year follow-up, all of whom had showed reliable improvement on the PHQ-9 during acute treatment.

Table 1 summarises client demographic and clinical characteristics at intake. The sample were aged between 20 and 70, were predominantly female, were mostly not employed, and all were of White British ethnic origin. None declared themselves as having a disability. Mean depression severity was in the moderately severe range, mean anxiety severity was in the moderate range, and mean WSAS severity was in the severe range. Mean WEMWBS score was well below general population averages (mean for 7020 UK adults from Health Survey for England 2011 data = 51.61; SD = 8.71); mean SHAPS score was well above general population averages (mean for 50 members from the Dutch general population = 20.2, SD = 4.4; Franken et al., 2007); and mean PANAS PA was well below, and PANAS NA was well above, general population averages (mean for 2,527 general adult population: PA = 31.72; SD = 7.38; NA = 17.04, SD = 6.68; Crawford et al., 2009). The sample predominantly had recurrent depression (mean of 8 episodes, with mean age of first onset in their twenties), with three participants having attempted suicide in the past at least once. Eight out of eleven individuals were taking anti-depressants, none of whom reported a change in medication during the baseline phase and three of whom reported a change during acute treatment. One individual switched medications and two individuals individualsreduced or stopped medications, meaning this is unlikely to have inflated treatment response (unless the medications were serving an iatrogenic function). Ten out of eleven individuals had undergone previous psychological treatment (a combination of counselling, high intensity CBT, low intensity CBT, low intensity BA, and MBCT), none of which overlapped with treatment in the present study. Therapist one treated three cases and therapists two and three each treated four cases.

3.2. Acceptability and feasibility of ADepT

Detailed thematic analyses of the qualitative interviews is presented in the supplementary materials (Section S4). Here we summarise key findings from this analysis. Nine out of eleven clients perceived ADepT to have been very helpful, finding the future-oriented wellbeing focus unexpected but beneficial and leading to improvements in depression.

(*footnote continued*)
orientation, the Response to Positive Affect scale (RPA) as measure of positive appraisal, the positive scale of the Affective Control Scale (ACS-P) to measure fear of positive affect, and the ICEPOP Capability measure for adults (ICECAP-A) as an additional measure of wellbeing. For the sake of brevity, analyses of these data are reported in the supplementary materials (Section S3). There were significant improvements during treatment on the BADS, RAS-SF, ICECAP-A, and dampening scale of the RPA, which were largely sustained over one-year follow-up. There was no significant change in fear of positive emotions on the ACS-P, or amplifying appraisals on the RPA.

[3] These three participants all continued with acute ADepT therapy but were excluded from subsequent analyses. The two participants (P1 and P2) who were excluded from the case series analyses on the basis of recovering during the baseline both completed a full dose of acute treatment and rated it as acceptable. They were both in recovery for depression and anxiety at the end of treatment. The participant with a head injury (P14) completed a modified treatment, before being referred onto specialist head injury services.

Table 1
Participant demographic and clinical characteristics.

P.	Age	Sex	PHQ	GAD-7	WEM-WBS	WSAS	SHAPS	PA	NA	First Onset	# Epis-odes	Ther-apist	Previous therapy	Primary medication	Emplo-yment
3	47	F	23	16	29	25	37	15	42	13	10*	1	C, MBCT	Duloxetine 60 mg[a]	U
4	34	M	14	16	29	28	29	14	28	18	7*	2	C, CBT	Sertraline 50 mg	U
5	27	F	26	20	36	33	28	27	45	12	10	3	LI- CBT	Citalopram 20 mg[b]	U
6	43	M	11	8	34	28	34	24	28	13	8*	2	LI-CBT	Sertraline 150 mg	U
7	58	F	13	9	37	31	22	20	23	15	15	3	None	Duloxetine 60 mg[c]	R
8	48	F	20	14	34	28	34	23	31	46	3	3	C, LI-CBT	None	E
9	33	M	11	7	28	26	30	18	23	27	2	1	LI-BA	Fluoxetine 20 mg	E
10	31	F	19	12	25	34	44	11	36	18	10	2	LI-CBT	Fluoxetine 20 mg	E
11	64	F	17	16	32	–	36	12	25	50	10	3+	C	None	R
12	22	F	13	17	33	23	31	20	33	12	10	1	LI-BA	Fluoxetine 20 mg	E
13	21	M	19	13	23	32	32	16	33	21	2	2	LI-BA	None	S
M	38.91	–	16.91	13.45	30.90	28.80	32.45	18.18	31.54	22.27	7.91	–	–	–	–
SD	14.24	–	4.97	4.11	4.48	3.62	5.66	5.13	7.27	13.52	4.09	–	–	–	–

Note- P. = participant id Previous therapy: C = counselling; MBCT = Mindfulness Based Cognitive Therapy; LI-CBT = low intensity CBT; LI-BA = low intensity BA. Therapist: + booster sessions completed by therapist 1, due to therapist 3 becoming ill. Medication status: a - Duloxetine replaced with mirtazapine 15 mg mid treatment; [b] - Stopped taking citalopram mid treatment; [c] - Reduced dose of duloxetine to 40 mg mid treatment; * = previous suicide attempt. Employment: U = unemployed; R = retired; E = employed; S = student.

Table 2
Sessions attended and client ratings of treatment acceptability, satisfaction with treatment, and whether they would recommend treatment to friends and family.

Measure	P.3	P.4	P.5	P.6	P.7	P.8	P.9	P.10	P.11	P.12	P.13	Mean (SD)
Acute sessions attended (out of maximum 15)	15	15	15	15	15	15	11	15	15	15	15	14.64 (1.21)
Booster sessions attended (out of maximum 5)	2	0	5	1	1	5	0	4	1	0	3	2.00 (1.94)
Acceptability ratings	4	–	5	5	4	5	4	4	5	4	–	4.44 (0.53)
Satisfaction ratings	4	–	5	4	4	5	4	4	5	5	–	4.44 (0.53)
Recommend ratings	5	–	5	5	5	5	5	4	5	5	–	4.89 (0.33)

Note – P. = participants; Acceptability of the intervention rated from 1 (not at all acceptable) to 5 (extremely acceptable); satisfaction with intervention rated from 1 (not at all satisfied) to 5 (extremely satisfied); and whether they would recommend this treatment to friends or family suffering from depression rated from 1 (not at all likely) to 5 (very likely).

One client saw depression as a secondary consequence of fibromyalgia, which they did not feel the therapy had addressed. Another client wanted concrete advice about a life issue, and was disappointed the therapist explored this Socratically rather than providing answers. A number of clients reported developing a new relationship to depression during ADepT, seeing it as just one part of them that they could learn to control to maximise their resilience (i.e., leading to meaningful changes in self-identity). Aspects of ADepT that were viewed as particularly helpful included: the establishment of a positive, caring therapeutic relationship; identifying and living according to their values; building self-care; engaging with simple everyday pleasures; socially reconnecting; having clear goals; and having a practical focus. The handouts and exercises were viewed as constructive, although the volume of homework felt overwhelming to some clients (in clients where English was not the first language or who had dyslexia). Booster sessions were seen as useful, even though not all clients felt the need to take them up. Areas to improve in the ADepT protocol identified by clients included redrafting some handouts to be clearer, further emphasising social reconnection, and taking life stage into account more explicitly. Barriers to engagement included negative previous experiences of talking therapy, depression reducing motivation, and practical life issues. The three clients whose depression had not remitted during acute treatment all gave positive feedback about the treatment, identifying clear behavioural gains they had made despite only partial or no symptomatic relief.

Table 2 reports number of sessions attended in the acute treatment phase and optional booster phase and participants quantitative' ratings of ADepT. Indicating ADepT was acceptable to clients, four were extremely satisfied and five were very satisfied with treatment. Four rated the treatment as extremely acceptable and five rated the treatment as very acceptable. Eight participants would be extremely likely to recommend ADepT and one would be likely to recommend ADepT. Further suggesting ADepT is acceptable, ten out of eleven participants completed the full dose of 15 acute sessions. The other participant chose to stop treatment after eleven sessions, having made a full recovery (PHQ-9 = 0 and GAD-7 = 2 at final treatment session) and met their treatment goals. A minimum adequate dose was defined as attending at least 50% of sessions and all participants exceeded this criteria.

Eight out of eleven participants made use of the ADepT optional booster sessions (attending on average 2 sessions, SD = 1.94). Of those participants who engaged with boosters but did not complete all five, all agreed with their therapist at which point to terminate the booster phase (typically at the point they had met their treatment goals and/or stayed well for an extended period of time). Of those who did not engage with any booster sessions, two participants declined as they felt they were currently well and had no need of further sessions at the end of acute treatment (both with PHQ-9 score < 10 at post treatment). One participant initially accepted the offer of booster sessions but then withdrew prior to the first scheduled booster as they felt they were well and had no need of further sessions.

Table 3
Time series analyses for patient health questionnaire (PHQ-9) and the Warwick-Edinburgh mental wellbeing scale (WEMWBS).

	3	4	5	6	7	8	9	10	11	12	13
PHQ-9											
pAR(Lag1)	0.51	0.13	0.26	0.20	0.33	0.65	0.53	0.05	0.71	−0.07	0.34
Level	-.21	-.31	-.18	-.44	-.29	-.35	-.64	-.49	-.55	-.33	-.42
Slope	-.28,	-.62*	-.20	-.58*	-.58*	-.84*	-.83*	-.39	-.88*	-.19	-.70*
WEMWBS											
pAR(Lag1)	0.54	0.08	0.37	0.87	0.29	0.72	0.29	0.30	0.47	0.48	0.218
Level	.18	.29	-.01	.74	.45	.57	.52	.25	.49	.53	.27
Slope	.61	.56*	-.14	.93*	.62*	.90*	.66*	.26	.83*	.45	.58*

Note-pAR(Lag1) = autocorrelation estimate. * = fit of model significantly greater than chance at $p < .05$.

3.3. Time series analyses of weekly depression and wellbeing data

Simulation-modelling analysis (SMA; Borckardt, 2006) was used to examine statistically the baseline and acute treatment time series data for PHQ-9 and WEMWBS, whilst taking into account the auto-correlation inherent in time series data of this kind (results summarised in Table 3). We focused on both level and slope of change (Kratochwill et al., 2010). Significant differences in level and/or slope indicate an intervention effect for each individual participant. Given that therapeutic interventions for depression are lengthy and rarely result in an immediate improvement in symptoms (especially in treatment resistant cases), an intervention effect is more likely to be observed in the slope analysis than the level analysis. Level change analysis examines if there is a difference in mean level during the baseline and intervention phase. Slope change analysis examines the fit of the data to an *a priori* specified model of a flat slope during baseline and then a linear improvement during acute treatment. SMA generates Pearson's correlation coefficients to indicate the extent of fit with these models. Multiple simulations of data streams sharing the same characteristics as the observed data (same degree of autocorrelation and same length of the two phases) are then run to determine the probability of obtaining the observed correlation with the *a priori* level-change and slope-change (using conventional p value cut-offs to indicate significance). We did not include the intake assessment point in the time series analyses, as for some participants there was more than a week gap between intake assessment and the start of the baseline period.

Autocorrelation between time measures (using a phase lag of one) varied between −.07 and .71 for PHQ-9 and between 0.08 and 0.87 for WEMWBS. No participants showed a significant difference in mean level of either outcome in the treatment relative to the baseline phase. For both PHQ-9 and WEMWBS, the fit of the slope change model was significantly greater than would have been expected by chance for seven out of eleven participants (P4, P6, P7, P8, P9, P11, P13), indicating significant linear improvement over time. The supplementary materials Section S2 reports visual analysis of these time series data, with Supplementary Figure 1 plotting weekly levels of depression and wellbeing for each participant. This visual analysis reached broadly similar conclusions to the SMA analysis, with the same seven participants appearing to improve on both outcomes. However, the pattern of change was not clearly linear, with significant variability over time within and between participants. This likely reflects the fact that mid-treatment clients were moving from a position of avoidance to interacting with potential opportunities and challenges in life. Further, clients were refining new skills to manage these opportunities and challenges, making it very likely they would experience more variability in mood in this part of treatment. According to case series guidelines, to demonstrate an intervention effect there needs to be either a significant change in slope *or* level (Kratochwill et al., 2010), which is replicated at least three times. This analysis meets this criterion, although is only considered moderate evidence as it was not demonstrated for each individual case.

3.4. Reliable and clinically significant change analyses

Following Jacobson and Truax (1991), we looked at the proportion of individuals showing reliable change (RC) and reliable and clinically significant change (R + CSC) at each follow-up period, relative to pre-treatment levels. We focused on both improvement and deterioration to identify benefits and harm. Reliable change was computed for each measure by dividing the magnitude of change observed during the course of therapy by the standard error of the difference score. Clinically significant change analyses used criterion c (participants are closer to comparison than clinical mean) for all measures apart from the WSAS. As no healthy comparison group values were available for the WSAS, criterion a (falling more than two standard deviations away from the clinical group mean in the direction of clinical improvement) was instead deployed for this measure. The Leeds Reliable Change Indicator Excel tool (Morley & Dowzer, 2014) was used to conduct these analyses. This requires the user to enter reliability estimates and mean (SD) values for a clinical and comparison sample. The pre-treatment assessment point in the present sample was used to define clinical group values for each measure. Reliability estimates (test-retest reliability where available and otherwise internal reliability) and comparison sample values were derived from relevant scale validation papers (see Supplementary Materials Section S1 for full details).

Table 4 summarises the results of these analyses. For the PHQ-9, RC was observed for eight out of eleven participants (73%) and R + CSC was observed for seven out of eleven participants (64%) at the post-treatment assessment point. For the WEMWBS, RC was seen for seven out eleven participants (64%) and R + CSC improvement was seen for six out of eleven participants (55%) at the post-treatment assessment point. These improvements were preserved for a majority of participants at each subsequent follow-up point for both primary outcome measures (RC > 50%; R + CSC > 38%).

There were also gains for a majority of participants at all time points for WSAS functioning (RC ≥ 50%, R + CSC ≥ 40%) and PANAS positive and negative affect (RC ≥ 60%, R + CSC ≥ 50%). GAD-7 improvements at post and two-month follow-up assessment were observed for a smaller proportion of participants (RC ≥ 30%; R + CSC ≥ 30%) but there were GAD-7 gains for a majority of participants at one-year follow-up (RC = 75%; R + CSC = 75%). Only a minority of participants showed clear improvement for SHAPS anhedonia at each time point (RC ≥ 30%; R + CSC ≥ 20%). There was little evidence of reliable deterioration except that P5 deteriorated on the WEMWBS at two-month follow-up and

Table 4
Depression, wellbeing, anhedonia, anxiety, and functioning measures at each phase (and percentage showing reliable and clinically significant change).

	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	RC (CSC)
PHQ-9												
Pre	18	18	24	11	14	19	11	15	17	12	20	–
Post	14	8**	25	5**	9**	9**	0**	9**	0**	8	10*	73% (64%)
2mFU	16	–	26	4**	10	7**	4**	12	0**	7**	14*	60% (50%)
1yFU	10*	–	23	7	16	5**	–	9**	2**	10	–	50% (38%)
WEMWBS												
Pre	32	29	36	28	39	31	31	31	36	42	21	–
Post	36	31	31	52**	51**	45**	49**	36	63**	50**	37*	64% (55%)
2mFU	30	–	25+	53**	47**	47**	38*	32	63**	52**	38*	70% (50%)
1yFU	47**	–	34	51**	52**	55**	–	36	63**	46	–	63% (63%)
WSAS												
Pre	28	23	30	27	27	29	25	36	16	19	27	–
Post	21	11**	33	13**	23	12**	13**	24*	0**	10**	15**	73% (64%)
FU	28	–	32	6**	29	11**	13**	22*	0**	17	25	50% (40%)
1yrFU	17*	–	31	12**	31	7**	–	21*	0**	11**	–	75% (50%)
GAD-7												
Pre	15	17	19	8	9	14	7	9	15	19	12	–
Post	12	13	18	3**	4**	10	2**	7	0**	8*	8	45% (36%)
2mFU	14	–	20	2**	9	5**	4	7	0**	17	10	30% (30%)
1yrFU	9*	–	18	2**	4**	4**	–	7	0**	14*	–	75% (50%)
SHAPS												
Pre	29	27	27	32	23	39	31	43	31	26	32	–
Post	28	–	32	28	15**	20**	24	36	14**	17**	28	40% (40%)
2mFU	32	–	31	28	24	20**	26	29*	14**	19	28	30% (20%)
1yFU	24	–	27	22**	16	19**		28*	14**	20	–	50% (38%)
PA												
Pre	20	17	27	23	21	16	21	17	16	21	14	–
Post	19	–	26	30**	30**	31**	33**	20	42**	36**	24*	70% (60%)
2mFU	16	–	22+	29**	19	32**	28**	14	41**	34**	22*	60% (50%)
1yrFU	37**	–	19+	34**	26**	39**	–	23*	39**	34**	–	88% (75%)
NA												
Pre	41	28	39	25	21	41	17	32	31	36	23	–
Post	42	–	41	16**	28	20**	16**	22**	13**	16**	20**	70% (70%)
2m FU	34*	–	46	12**	21	21**	19	22**	12**	23**	22**	70% (60%)
1yrFU	28*	–	35*	18**	32+	16**	–	22**	10**	32	–	75% (50%)

Note – PHQ-9 = Patient Health Questionnaire; WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale; WSAS = Work and Social Adjustment Scale; GAD-7 = Generalized Anxiety Disorder Assessment; SHAPS = Snaith Hamilton Pleasure Scale; PA = Positive affect subscale of the Positive and Negative Affect Scale; NA = Negative affect subscale of the Positive and Negative Affect Scale. * = reliable change (relative to pre-assessment); ** = reliable and clinically significant change (relative to pre-assessment); + = reliable deterioration. RC (CSC) = % of participants with data showing reliable change (clinically significant change). Clinically significant change used criterion c for PHQ-9, WEMWBS, GAD-7, SHAPS, PA and NA and criterion a for WSAS (as comparison sample normative data were not available for this measure).

PANAS positive affect at two-month and one-year follow-up. P7 also deteriorated at one-year follow-up on PANAS negative affect.

3.5. Recovery analyses

Next we examined the proportion of clients showing clinical levels of symptoms on the PHQ-9 and GAD-7 at each time point. According to recent meta-analyses, a PHQ-9 score of 10 has 85% sensitivity and 89% specificity for diagnosing major depressive disorder (Manea, Gilbody, & McMillan, 2012) and a GAD-7 score of 8 has 83% sensitivity and 84% specificity for diagnosing generalized anxiety disorder (Plummer, Manea, Trepel, & McMillan, 2016). Scoring beneath these cut-off values is used to indicate clinical 'recovery' in UK IAPT services (from where the present sample was predominantly recruited). At intake and pre-treatment, all eleven participants (100%) reported clinically significant levels of depression and ten out of eleven (91%) participants reported clinically significant levels of anxiety. Depression recovery criteria were met by eight out of eleven (73%) participants at the post-assessment, five out of ten (50%) participants at two-month follow-up assessment, and four out of eight (50%) participants at one-year follow-up assessment. Anxiety recovery criteria were met by five out of eleven (45%) participants at post-assessment, five out of ten (50%) participants at two-month follow-up, and five out of eight (63%) participants at one-year follow-up. UK IAPT services additionally report the proportion of clients showing reliable improvement, defined as at least a six point drop on the PHQ-9 and at least a four point drop on the GAD-7 during acute treatment. Seven out of eleven participants (64%) met criteria for reliable improvement on the PHQ-9 and eight out of eleven participants (73%) met criteria for reliable improvement on the GAD-7.

The diagnostic interview at one-year revealed that six out of eight participants [75%] interviewed had not relapsed during the follow-up period and therefore met criteria for sustained recovery. Of the two participants who had met diagnostic criteria during the follow-up period, both of these had scored above the PHQ-9 caseness cut-off immediately post treatment (PHQ-9 post-treatment was 14 for P3 and 25 for P5), indicating they had not fully responded to acute treatment. P5 met criteria for a current major depressive episode at one-year follow-up on the SCID and continued to score above the PHQ-9 cut-off. P3 was no longer in episode according to the SCID (although her PHQ-9 score was 10, so just above the caseness cut-off).

3.6. Group level analysis

Fig. 3 plots mean levels for each outcome measure at each assessment period. Total raw scale scores are plotted for all measures, with the exception of the PANAS which has been converted into Z-scores (relative to general population normative data) to aid interpretation of the magnitude of PA versus NA change. General population average levels and cut-offs for clinical caseness are super-imposed on the Figures to help interpret the extent to which intake deficits are 'normalised' during treatment.

We conducted complete case analysis, rather than intention to treat analysis, as it was not possible to implement multiple imputation (the model would not converge; see McNeish, 2017). There is a balance between controlling for type I and type II error in small sample research of this kind, with use of non-parametric approaches and correction for multiple comparisons potentially inflating type II error, whereas use of parametric approaches and non-correction for multiple comparisons potentially inflates type I error. We chose to use parametric analysis, as inspection of the paired differences scores suggested an approximately normal distribution of change scores. As we had clear *a priori* hypotheses about each measure, we chose not to control for multiple comparisons. Instead, we restricted the number of comparisons being run by first conducting a series of repeated measures ANOVA on each outcome variable (with time as the within-subjects factor: intake, pre, post and two-month follow-up) and only proceeding to pairwise comparisons in cases where the ANOVA for that measure was significant. We did not include the one-year follow-up outcomes in the repeated measures ANOVAs as this assessment was a post-hoc amendment to the protocol and data were only available for eight participants. Including the one-year follow-up data in the ANOVA would have significantly reduced statistical power.

Fig. 3. Mean scores for depression (a), wellbeing (b), WSAS (c), SHAPS anhedonia (d), PANAS positive and negative affect (e) and anxiety (f) at each assessment point.
Note – Data are mean (one SEM values). Y axes are raw score values, with the exception of the PANAS which is Z score units (to allow visual comparison of repair of NA versus PA). Raw plots of the PANAS data are Supplementary Fig. 2.

As intended, there was a main effect of time for PHQ-9, $F(3,27) = 20.32$, $p < .001$, $\eta_p^2 = .69$, WEMWBS, $F(3,27) = 11.82$, $p < .001$, $\eta_p^2 = .58$, WSAS, $F(3,24) = 11.71$, $p < .001$, $\eta_p^2 = .59$, GAD-7, $F(3,27) = 10.61$, $p < .001$, $\eta_p^2 = .54$, PANAS PA$(3,27) = 8.56$, $p < .001$, $\eta_p^2 = .49$, PANAS NA, $F(3,27) = 7.97$, $p = .001$, $\eta_p^2 = .47$, and SHAPS, $F(3,27) = 8.68$, $p < .001$, $\eta_p^2 = .49$.

We resolved these main effects of time by running pairwise comparisons for each measure using paired sample t-tests. As intended, there was no significant difference for any measure from the intake to pre assessment (indicating a stable baseline phase), ps > .12. There was also significant improvement intake to post, ps < .01, intake to two-month follow-up, ps < .03, pre to post, ps < .02, and pre to two-month follow-up, ps < .05. The one exception was that the pre to two-month follow-up comparison for PANAS PA was not significant, p = .16. There was no significant change from post to two-month follow-up for any measures, ps > .10, with the exception further improvements in PANAS PA over that time period, p = .01 (indicating benefits were sustained or extended during the follow-up period).

We then went on to look at the differences between each of the earlier assessment points and the one-year follow-up assessment on the subset of eight individuals who had complete data with paired sample t-tests. As intended, one-year follow-up levels were significantly improved relative to intake and pre-treatment, ps < .03, but did not differ relative to post-treatment or two-month follow-up, ps > .13, for PHQ-9, WEMWBS, PANAS PA, and WSAS. A similar pattern emerged for the SHAPS and GAD-7, with the exception that symptom levels had further significantly improved from two-month follow-up to one-year follow-up, ps < .04. For PANAS NA, one-year follow-up levels were only trend lower than pre-treatment NA levels, p = .054, but otherwise the pattern was the same as for PHQ-9, WEMWBS, PANAS PA and WSAS.

3.7. Benchmarking analysis

We benchmarked the group level case series outcomes against effect sizes from routine practice collected in the same service setting and high quality RCTs of best practice that had included the same measures of PVS and NVS function. We selected the CPT2 trial (16 week outcomes for depression, PA and NA in the CT arm; DeRubeis et al., 2005), the CPT3 trial (six month outcomes for depression, PA, NA in the combined CT and anti-depressant medication arm; Hollon et al., 2014), the COBRA trial (six month PHQ-9 depression GAD-7 and anxiety outcomes following CBT and BA at six months; Richards et al., 2016), the COBALT trial (six month PHQ-9 depression and GAD-7 anxiety following CBT at six months; Wiles et al., 2013), and routine IAPT outcomes (pre-post outcomes for PHQ-9 depression, GAD-7 anxiety and WSAS functioning for combined high and low intensity treatment; Zahra et al., 2014; pre-post outcomes for WEMWBS wellbeing for high intensity treatment) for benchmarking.

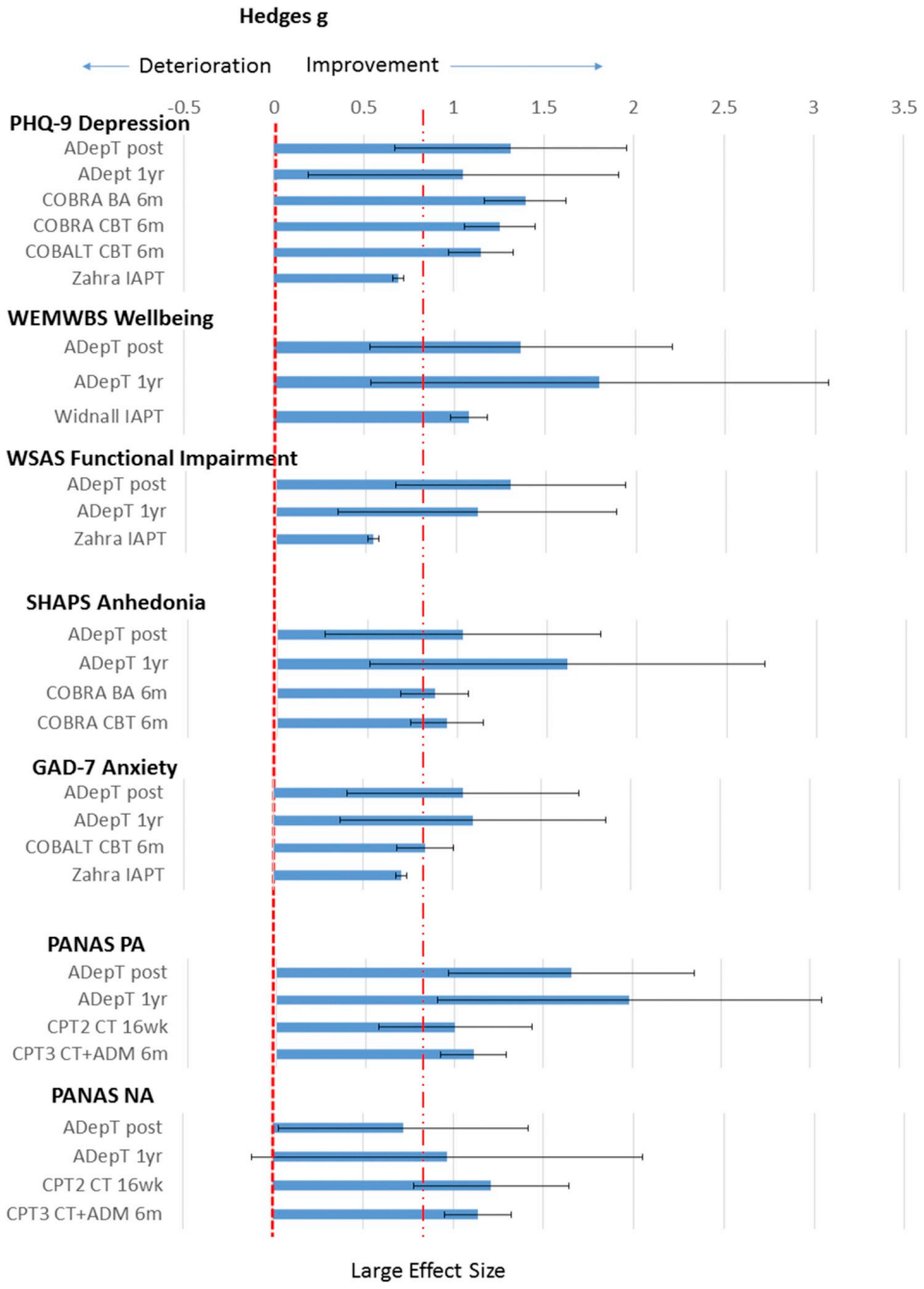

Fig. 4. Benchmarking ADepT effect sizes against other datasets.
Note – Effect size estimates are Hedges g_{av} (using small sample correction), with 95% confidence intervals.

Fig. 4 plots the pre to post and pre to one-year effect sizes on each outcome measure in the case-series against outcomes from these other datasets. For all measures at both time points, effect sizes following ADepT were large (Hedges g, correcting for small sample sizes, > 0.8). Reflecting the sample size in the case series, the 95% confidence intervals of the effects were broad and crossed zero. Visual inspection of mean effect sizes tentatively suggests ADepT outcomes were comparable to existing trials for depression, anxiety, and NVS outcomes, but potentially superior to existing trials for wellbeing, anhedonia and PVS outcomes. ADepT outcomes also appeared superior to routine IAPT service outcomes for anxiety, depression, and functional impairment.

4. Discussion

This multiple randomized baseline case series evaluated the acceptability and clinical efficacy of Augmented Depression Therapy (ADepT), a novel psychological treatment that aims to target positive valence system (PVS) and negative valence system (NVS) deficits simultaneously so as to both reduce symptoms of psychopathology and build wellbeing in depressed clients.

Participants were willing to enter the case series and there was a high degree of engagement with ADepT. All participants completed acute treatment with a planned discharge and a majority of participants

attended some booster sessions. Given high dropout rates in individual CBT for depression (estimated to be greater than 25%; Hans & Hiller, 2013; Fernandez, Salem, Swift & Ramtahal, 2015), the retention rates in the case series are encouraging. Participants rated ADepT as acceptable, that they were satisfied with it, and would recommend it to friends and family. The qualitative interviews revealed that the well-being focus of ADepT was acceptable to and valued by clients, with no evidence that it was experienced as "PollyAnna-ish" (cf. Dunn, 2012).

There was preliminary but nevertheless promising evidence of clinical effectiveness on the primary outcome measures, with triangulation in findings across analytic methods. At the individual level, time series analyses showed significant improvement on depression and wellbeing for 7/11 participants. Reliable improvement was observed for 8/11 participants on depression and 7/11 participants on wellbeing (9/11 participants improving on at least one of these measures). There was also reliable improvement for most participants on secondary outcome measures of functional impairment, anhedonia, PA and NA. Recovery analyses found that 7/11 participants scored beneath clinical cut-offs for depression at post-treatment. Group level analyses found significant improvements on all outcome measures, all of a large effect size (albeit with broad confidence intervals due to the small sample size). Gains were mostly preserved (and for wellbeing and anhedonia enhanced) at follow-up.

Benchmarking analyses indicated that depression and anxiety mean effect-sizes in the case series were broadly comparable to those observed in existing CBT and BA trials (e.g., DeRubeis et al., 2005; Hollon et al., 2014; Richards et al., 2016) and were superior to routine IAPT care (e.g., Zahra et al., 2014). Mean effect sizes for ADepT for PVS outcomes (anhedonia and positive affect) were larger than those found in previous trials of BA and CBT (DeRubeis et al., 2005; Hollon et al., 2014; Richards et al., 2016), suggesting ADepT has potential to lead to step-wise improvements in the capacity to treat PVS deficits. Importantly, these bench-marking analyses take into account a range of non-specific factors (expectancy effects from being involved in research, benefits of a positive therapeutic alliance, spontaneous recovery) that could be biasing interpretation, as these comparison datasets are also subject to these non-specific effects. Therefore, where ADepT shows a larger effect size than these other treatments, it is plausible this is specifically related to treatment. Again, the small sample size (and as a result broad confidence intervals around the effects reported), mean these bench-marking results need to be interpreted cautiously.

It is important to examine if treatment response varies as a function of intake depression severity. A significant pre-post improvement for WEMWBS and PHQ-9 in time series analysis was shown for four out of five participants in the mild PHQ-9 range (10–14); for two of three participants in the moderately severe range PHQ-9 range (15–19); and for one out of three participants in the severe range (> 19). While further evaluation is required, this suggests better responses at the less severe end of the sample in the current version of the protocol and that some adaptations to the protocol may be required for severely depressed clients.

While outcomes were generally promising, two participants did not respond optimally despite engaging fully with the acute treatment sessions. P3 failed to show reliable improvement in depression and wellbeing immediately post-treatment, but did engage with some of the booster sessions and showed significant gains on both outcomes at one-year-follow-up. P5 also failed to show reliable improvement for either primary outcome measure immediately post-treatment. Despite attending all of the booster sessions, this client reported no further improvement in wellbeing or depression at subsequent follow-ups (and showed deterioration on wellbeing at two-month follow-up). Despite these mixed outcomes, both clients rated the treatment as acceptable and in qualitative interviews reported having made meaningful behavioural changes as a result of engaging in sessions.

The sample were predominantly cases of moderate to severe, treatment resistant depression, with comorbid anxiety, recruited from NHS waiting lists. In particular, most had not responded to prior antidepressant or other psychological therapies delivered as part of their routine care. They are therefore representative of patients seen in routine NHS care (e.g. Zahra et al., 2014) and comparable to those treated in existing trials that we used for benchmarking purposes (Richards et al., 2016; DeRubeis et al., 2005; Hollon et al., 2014). There were no obvious differences in outcomes between therapists, preliminarily suggesting effects are not carried by particular therapists and that the protocol is likely generalizable to different workforces.

The case series met the pre-specified continuation rules in full. Nine out of eleven participants showed reliable improvement from pre to post treatment on the PHQ-9 and/or WEMWBS (82%; exceeding the 60% target). No clients showed clinically significant deterioration pre to post treatment on either the PHQ-9 or WEMWBS (0%; falling beneath the 30% target). All eleven clients completed a minimum adequate dose of treatment (100%; exceeding the 50% target). 161 out of a possible 165 acute treatment sessions offered across clients were attended (98%; exceeding the 60% target). All participants rated ADepT treatment as acceptable, were satisfied with ADepT, and would recommend ADepT to friends and family (100%; exceeding 60% target). There were no serious adverse consequences for participants that were clearly trial or treatment related. Pre-post effect sizes for depression and wellbeing were both large in magnitude (Hedges $g > 0.08$).

The bespoke continuation rules used in the present case series were *a priori* set to be liberal, as this was the first iteration of the ADepT protocol and the treatment was not expected to be fully optimised at this stage. In later stages of evaluation of subsequent iterations of ADepT, more stringent continuation rules will be applied (whereby ADepT will need to be at least as effective as current practice in a pilot trial before proceeding to definitive trial). It is noteworthy that the present case series results clearly exceeded these liberal continuation rules, suggesting ADepT has potential to meet more stringent continuation rules in later development phases. On this basis, it seems valid to proceed to further evaluation of ADepT.

It is helpful to consider whether ADepT is likely to add value to existing depression treatment options, given that there is already a plethora of depression therapies all with broadly equal (but sub-optimal) efficacy. To add value new therapies need to strike a balance between innovation and building on what has come before. A position of extreme novelty, where a treatment discards attempts to repair thinking, behaviour and affect using proven intervention elements from existing treatments, is unlikely to be optimally effective, acceptable to key stakeholders, and implementable (as it will not capitalise on existing skills in the workforce). However, a therapy that simply renames and repackages existing treatment elements without any novelty is unlikely to lead to sufficient improvements in outcome to warrant extensive investment. ADepT attempts to find a position of optimal novelty by enhancing existing treatment elements from CBT, ACT and mindfulness approaches to target PVS and NVS disturbances ('horizontal innovation') and ensuring these are deployed to target wellbeing and positive recovery as well as symptom relief (living well alongside mental illness; 'vertical innovation'). Shifting the emphasis to enhancing wellbeing and functioning has potential to represent a radically trans-diagnostic treatment approach.

Ultimately, establishing the value in ADepT is an empirical question. Existing treatments like BA and CBT are relatively ineffective at repairing PVS disturbance and broader wellbeing deficits (Dunn et al., in press). The present case series suggests ADepT has potential to lead to stepwise gains in PVS and wellbeing. While other treatments are also being developed to target PVS disturbance with promising preliminary results (Chakhssi, Kraiss, Sommers-Spijkerman, & Bohlmeijer, 2018; Chaves, Lopez-Gomez, Hervas, & Vazquez, 2017; Craske et al., 2019; Geschwind, Arntz, Bannink, & Peeters, 2019; Ruini & Fava, 2012; Taylor, Lyubomirsky, & Stein, 2017), ADepT in our view is unique in its joint focus on both PVS *and* NVS regulation. RCTs now need to be

conducted that compare ADepT against other treatments.

A key part of the ADepT rationale is that it aims to build wellbeing *and* reduce depression, in part based on the logic that these are orthogonal constructs (Keyes, 2005). However, there was considerable symmetry in the pattern of response across the PHQ-9 measuring depression and the WEMWBS measuring wellbeing in the present study (i.e. participants either improved on both or neither measure). Inspection of the individual items of the WEMWBS and PHQ-9 indicates there is substantial overlap in their content (although clear difference in whether items are positively or negatively phrased). This echoes recent findings that the WEMWBS is not clearly distinct from symptom measures (Bohnke & Croudace, 2016). It may be that the PHQ-9 and the WEMWBS are not ideal measures of symptoms and positive recovery respectively and there is a need to develop better tools to measure these constructs. Consistent with this position, in the qualitative interviews, some clients described improvements in values-consistent functioning that were not captured by either measure (for example, the two non-responders both described behavioural gains they had made during treatment). Alternatively, it may be that wellbeing and depression are better viewed as opposite ends of a single underlying bipolar dimension (running from depression to neutral to wellbeing). Even if this is the case, in our view there is still merit in measuring wellbeing outcomes given clear evidence of the benefits of setting approach rather than avoidance goals to bring about behavioural change (Elliot et al., 1997). Further, client definitions of recovery from depression focus more on desired positive outcomes than symptom relief (Zimmerman et al., 2006) and participants in the case series reported particularly valuing the wellbeing focus of ADepT.

There are a number of limitations that need to be held in mind regarding the present findings. First, the lead author was treatment developer, supervisor and one of the therapists, meaning that there is potential for allegiance biases. Second, treatment fidelity was not assessed (as no fidelity tool currently exists). Third, the time series slope analyses fitted a linear model of change during treatment (followed SMA guidance; Borckardt, 2006), although visual inspection of the data suggested a non-linear, variable pattern of change. The effect of this non-linearity would go against our experimental predictions (of a significant intervention effect), so will have inflated type II rather than type I error. Fourth, the small sample means that the effect sizes have wide confidence intervals and are likely to be positively biased (although Hedges small sample correction was used to minimize this). Fifth, the group level analyses were under-powered (as we did not recruit the intended completer sample size of 13) and we did not correct for multiple comparisons as a result (to balance the risk between type I and type II error). It is noteworthy that across the board the group level analyses were all clearly significant for key comparisons, meaning it is very unlikely that this pattern would have emerged solely due to random error or inflated type I error. Further, the time series analyses on the primary outcome measures were adequately powered and were systematically replicated across a number of participants. Sixth, DSM-IV rather than DSM-V instrumentation was used to assess depression. While no major changes were made to diagnostic criteria for depression in the shift from DSM-IV to DSM-V, the bereavement exclusion was removed and additional specifiers of 'with anxious distress' and 'with mixed features' were added. We did not exclude any eligible participants on the basis of the bereavement criteria in DSM-IV, meaning that our diagnoses align with those that would have been reached under DSM-V. However, we did not capture the additional specifiers. Seventh, the Caucasian, predominantly middle aged sample recruited from a single site in the South West of England lacked diversity. It remains to be established if these effects will generalise to other populations. Eighth, while the post treatment quantitative and qualitative data suggested ADepT was acceptable and feasible, we did not capture participants'views of the approach after their first treatment session (for example, using the Credibility/Expectancy Questionnaire; Devilly & Borkovec, 2000). Finally, we did not pre-register the case series protocol (although we report data on all outcome measures collected using a variety of analytic procedures, therefore minimising risk of p- or measure-hacking). These issues will be partly addressed by an ongoing pilot randomized trial comparison of ADepT versus CBT (Dunn et al., 2019).

In summary, this case series provides preliminary evidence that ADepT is an acceptable intervention to clients that is likely to lead to improvements in PVS and NVS and by doing so lead to enhanced wellbeing and reduced depression symptoms. The case series met all the continuation rules, indicating ADepT is ready to proceed to more rigorous evaluation via randomized controlled trial methodology.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.brat.2019.103418.

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