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A Feasibility and Pilot Randomised Dismantling Trial of the Efficacy of Self-As-Context During Acceptance and Commitment Therapy

Daniel Stockton[1] · Stephen Kellett[2,3] · Nic Wilkinson[3] · Jen Hague[2] · Paul Bliss[3] · Mike Heaver[3] · Angela Devine[3]

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Abstract

The comparative clinical utility of the components of the psychological flexibility model of acceptance and commitment therapy (ACT) have not been equally evaluated. This study therefore conducted a feasibility and pilot two-arm dismantling trial by quarantining the self-as-context component. Sixteen participants were randomised to either 8 sessions of protocol-based ACT (Full-ACT) or 8 sessions of protocol-based ACT minus self-as-context (ACT-SAC). Process measures (flexibility and decentring) were taken at start of treatment, end of treatment, and at 6-week follow-up. Clinical outcome measures (functioning, anxiety, and depression) were collected on a session-by-session basis. Randomisation was well tolerated, all measures were completed, both interventions were competently delivered, and one adverse effect occurred in the full-ACT arm. Ten participants attended all 8 sessions creating a dropout rate of 37.50%. Clinical change appeared linear in both treatments and that treatment gains were maintained. Findings suggest that a full trial is possible and sample size calculations and methodological improvements are provided for this.

Keyword ACT · dismantling · hexaflex · IAPT · LTC

Acceptance and commitment therapy (ACT) is an action oriented psychotherapy informed by relational frame theory (RFT; Hayes, 2004; Barnes-Holmes et al., 2016) that seeks to define how patients become emotionally enmeshed with internal dialogues, and so take less pleasure from positive environmental contingencies

✉ Stephen Kellett

[1] The Mid Yorkshire Hospitals NHS Trust, Wakefield, UK

[2] Clinical and Applied Psychology Unit, Department of Psychology, University of Sheffield, Sheffield, UK

[3] Sheffield Health and Social Care NHS Foundation Trust, Sheffield, UK

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(Ciarrochi et al., 2010). The main aims of ACT are to then to enable psychological flexibility, to increase connection to the present moment, and to close the gap between personal values and behaviours (Hayes et al., 1999). Psychological flexibility is thought to be achieved through the interaction of six core processes during ACT, defusion, acceptance, contact with the present moment, values, committed action, and self-as-context (Hayes et al., 2012). These components are theoretically modelled in the 'hexaflex' model (Rolffs et al., 2018), and there are a range of in-session and homework exercises that clinically support learning of each component (e.g. Hayes et al., 1999). The evidence base for ACT has been building to suggest that it is a promising and useful psychotherapy across a wide range of mental health problems (for reviews see Hayes et al., 2006a, b; Powers et al., 2009; Ruiz, 2010; Öst., 2014). The recent Gloster et al. (2020) review of the ACT meta-analytic evidence base reported 100 controlled effect sizes across 12,477 participants. ACT was shown to be efficacious across differing diagnoses, was superior to passive controls, treatment as usual, and most active controls.

The ACT model discriminates between three aspects of self; self-as-content, self-as-process, and self-as-context (SAC; Hayes et al., 2012). SAC refers to the contents of psychological experience, self-as-process refers to awareness of the ongoing changing nature of experiences, and self-as-context refers to experiential contact with a persistent and an unchanging perspective from which all experiences are observed (De Houwer et al., 2013). During ACT, patients learn to build awareness of SAC, whilst simultaneously liberating themselves from any over-attachment to a conceptualised self. SAC is independent of content (i.e. thoughts and feelings) and is therefore the place from which such content is observed (Ciarrochi, et al., 2010). SAC facilitates awareness of a self that is stable and constant and reciprocally that negative self-evaluations are therefore transient and temporary (Hayes et al., 1999). Hayes (2011) defined SAC as: "Self-as-context is the coming together and flexible social extension of a cluster of deictic relations (especially I/Here/Now) that enable observation and description from a perspective or point of view. Self-as-context enables or facilitates many different experiences, including theory of mind, empathy, compassion, self-compassion, acceptance, defusion, and a transcendent sense of self."

SAC is presented to patients as a mindfulness extension, which enables them to focus on a stable, grounded, and enduring sense of self, capable of taking flexible perspectives (Godbee & Kansas, 2020). SAC is used for practicing a sense of "I" "here" and "now" across challenging contexts and in the face of ongoing stressors (Hayes et al., 2001). SAC is believed to enable and facilitate engagement with the other core processes of the hexaflex (Hayes, 2004). There is however an on-going debate as to whether SAC is necessary to enable flexibility, or whether it is sufficient to only develop self-as-process (De Houwer et al., 2013; McHugh & Stewart, 2012). Indeed, there is no predefined order for focusing on the components and not all individuals needed to master each of the processes in order to achieve sufficient flexibility (Strosahl et al., 2004). Godbee & Kansas, 2020) reviewed twenty studies of variable methodological quality that had assessed whether SAC could be taught to patients. There was provisional, but very limited, evidence to suggest that SAC could be effectively taught and implemented as a stand-alone

process. The review questioned the use of SAC as a stand-alone process, and encouraged more testing.

Two treatment intervention studies have specifically evaluated the role of SAC. Luciano et al. (2011) in a small sample ($N = 15$) of troubled adolescents taught SAC to manage problematic private events and evaluated whether impulsivity and mindfulness improved. The defusion plus SAC group had significantly fewer problem behaviours, improved flexibility, and acceptance at post-treatment and also follow-up compared to the defusion only group. Yu et al., (2017a, 2017b) provided a within-group evaluation ($N = 412$) of a rehabilitation-focused ACT program for pain management. Results suggested a role for change in SAC during pain management, as ACT was associated with increased SAC both at post-treatment and 9-month follow-up, with SAC also associated with less depression, pain interference, and occupational adjustment.

A theme of last several decades of psychotherapy outcome research has been the testing of the efficacy of psychotherapies (Roth & Fonagy, 2006). Whilst this approach has proved useful in defining evidence-based treatments, it simultaneously also failed to identify which components of these psychotherapies were essential, redundant, or possibly harmful (Rosen & Davison, 2003). This 'entire package approach' has also been criticised for promoting the proliferation of apparently 'new' psychotherapies that are essentially *re*-packages of extant psychotherapies (Ciarrochi et al., 2010). Therefore, despite extensive outcome research validating psychotherapy as an effective treatment, research has been slow in identifying necessary, effective and active ingredients (Ahn & Wampold, 2001). Proving the utility of these different active ingredients (and the associated in-session definitive technical features) is a key ongoing challenge (Stevens et al., 2000). Research studies need to unpack and compare the components of any psychotherapy 'package' to ascertain their relative and specific contribution (Stevens et al., 2000).

The clinical trial design used to assess the relative importance of treatment components is labelled as either deconstruction or additive trials (Ahn & Wampold, 2001). Dismantling trials compare a whole treatment with treatment minus a specific theoretically important component (see Jacobson et al., 1996 for the definitive example). Additive trials test the impact of providing a specific and supplementary component hypothesised to enhance outcomes (e.g. Propst et al., 1992). Levin et al. (2020) dismantling trial in a student population compared the effects of a full ACT to 'open' (i.e., acceptance and cognitive defusion) or 'engaged' (i.e., values and committed action) components and a waitlist control. Delivering only the 'open' components was somewhat less effective and including both the 'open' and 'engaged' components created greater decreases in cognitive fusion. The current study reported here is the first to use a deconstruction method to examine the efficacy of the SAC component of the psychological flexibility model in an adult clinical sample. Given that the ethical dilemma of extracting a potentially clinically efficacious component, the current study used a feasibility and pilot approach, as the ethical and scientific value of such studies is widely recognised (Arain et al., 2010).

The current study evaluates primary feasibility outcomes relating to safety and acceptability (Leon et al., 2011), whilst also providing a pilot and preliminary

description of secondary clinical outcomes (Rounsaville et al., 2001). The primary feasibility outcomes were to evaluate recruitment methods (i.e. the rate of the study participation being offered and then subsequently taken up, with the aim of 100% take up), whether randomisation was tolerated (i.e. the rate at which participants declined randomisation, with the aim of 0% refusal), to assess the measure completion rate in both arms (i.e. expressed in percentage form, with 100% measure completion being the target), calculate drop-out rates in both arms as a proxy index for treatment acceptability (i.e. expressed as a percentage, with a 15% dropout rate being the aim, based on the Ong et al. (2018) ACT dropout meta-analysis), whether it was safe to deliver deconstructed ACT (i.e. the rate of adverse events in both arms, with an aim of there being no adverse events) and finally whether it was possible to deliver deconstructed ACT (i.e. by comparing session competency scores in each arm). As the feasibility outcomes would index whether it is possible to implement a dismantled ACT intervention during a main RCT, the study therefore conducted a post-hoc power analysis in order to provide sample size requirements for any such a future main trial. The preliminary and pilot comparison of secondary outcomes sought to compare define the shape of change in each intervention and define the rates of reliable and clinically significant change.

Method

Participants

Participants were working age adults (16–65 years) recruited via an Increasing Access to Psychological Therapies (IAPT) service in the UK. Patients referred to the service by general practitioners (GPs) due the presence of anxiety and depression associated with the poor self-management of a long-term physical health condition (LTC). Medical records were accessible and reviewed to ratify the presence of a definitive primary diagnosis of an LTC. In total, 29 patients were referred to the study: 15 males (51.72%) and 14 females (48.28%), with an age range of 18–72 years (mean 46.31, SD 13.09). Study exclusion criteria were diagnosis of 'medically unexplained symptoms' including somatoform disorders (e.g. pain disorder, conversion disorder, body dysmorphic disorder, hypochondriasis) and functional somatic syndromes (e.g. irritable bowel syndrome, chronic fatigue syndrome, fibromyalgia, non-cardiac chest pain, non-epileptic seizures), mental health diagnoses in addition to anxiety or depression (e.g. personality disorder, bipolar disorder, psychosis etc.), currently accessing secondary care mental health services, significant current suicidal risk, current substance misuse, previous contact with mental health services (defined as two or more prior episodes of contact without significant change), inpatient admission for mental health difficulties within the last five years, history of self-injury, and stated reluctance to engage in psychotherapy.

Design

The design was a randomised and controlled dismantling trial. The follow-up period was 6 weeks following treatment completion. Ethical approval was granted (contingent on monitoring adverse incidents; ref: 144363) and also the trial was registered (ref: NCT03925259). Participants were randomised to either full-ACT (i.e. the full hexaflex approach) or ACT-SAC (i.e. ACT minus the self-as-context component of the hexaflex). The GraphPad (2005) computer randomisation software package was used to allocate participants to the study arms. As participants were recruited over time, a pairwise randomisation method ensured an even distribution across the study arms. Suresh's (2011) review of online randomisation resources for clinical trials found that Graphpad produced unbiased randomisation sequences. Participants were blind to their allocation. It was impossible to blind therapists to allocation, as they had to know whether to include or exclude the SAC module. ACT process measures were completed at assessment, final therapy session and at 6-week follow-up. Outcome measures were collected at assessment, each session, and at 6-week follow-up.

Adverse Event Monitoring

Due to the ethical concern of potentially withholding an active ingredient, then adverse event monitoring was used to assess safety issues. Duggan et al. (2014) define 'harm' during psychotherapy trials as any sustained deterioration directly caused by the intervention. Deterioration needs to be sustained, as this enables patients to experience temporary discomfort as an authentic aspect of psychological change during any therapeutic work. Patient safety was therefore monitored by defining an adverse event as either (1) dropping out from treatment or (2) a sustained reliable deterioration over three consecutive sessions on any of the three clinical outcome measures (see measures section).

Therapists and ACT Treatments

Therapists consisted of one clinical psychologist, two final-year trainee clinical psychologists (one of whom was also a British Association of Behavioural and Cognitive Psychotherapy, BABCP, accredited psychotherapist), and four BABCP accredited cognitive-behavioural psychotherapists. Therapists had to have completed a minimum of a two-day introductory ACT course to be eligible for the study. Participants in either arm received 8 sessions of ACT. A treatment protocol comprising of eight modules in the Full-ACT arm was developed by the research team. Each module comprised a series of in-session metaphors and change methods, as well as guidance on how to discuss specific components. There was some degree of flexibility by which therapists introduced modules (Strosahl et al., 2004). By end of treatment, all mandatory change methods and metaphors in that arm had to be covered and this was monitored in weekly clinical supervision. Modules were as follows: creative hopelessness, acceptance, defusion, present-momentness, self-as-context, values,

and committed action. The ACT-SAC arm removed the self-as-context module, and therefore, more time was spent in the other modules. Therapists delivering ACT-SAC were instructed to avoid any reference to SAC or to support discussions regarding SAC processes in any other of the modules as far as possible. Where aspects of SAC are inevitably present in other modules (e.g. when discussing the concept of acceptance and when carrying out acceptance-based exercises), then processes such as 'noticing thoughts' were discussed, but not from a SAC perspective or with the aim of creating more stable SAC.

Treatment Competency

In order to assess treatment competency and the feasibility of delivering a deconstructed version of ACT, then sessions were audiotaped. A minimum of one full-taped session per participant was reviewed in order to assess treatment competency. Sessions were rated by two therapists with a minimum of intermediate ACT training, in addition to supervisor training in ACT. These raters did not treat patients in the study and used the ACT core competency rating scale—short version (ACT-CCRS-S; Luoma et al., 2007) to rate sessions. This is a 30-item scale assessing competency across seven domains, six of which relate to hexaflex components, with the remaining item related to therapeutic stance. All items are scored on a 7-point Likert scale, with full scores ranging from 30 to 210.

Process Measures

In order to assess participant's ability to engage in psychological flexibility, self-report process measures were completed at session 1, session 8, and at 6-week follow-up. The process measures indexed to two aspects of psychological flexibility: (a) general psychological flexibility and (b) 'decentring' (a higher-order process that predicts connection with self-as-context; McCracken et al., 2014).

Acceptance and Action Questionnaire II (Bond et al., 2011)

The Acceptance and Action Questionnaire II (AAQ-II) is a 7-item measure of psychological inflexibility (score range 7–49) and is based on the widely researched Acceptance and Action Questionnaire (Hayes et al., 1999). The AAQ-II has sound psychometric properties (Bond et al., 2011).

Experiences Questionnaire (Fresco, Moore, van Dulmen, Segal, Teasdale, Ma, & Williams, 2007)

The Experiences Questionnaire (EQ) is a 20-item measure of decentring and rumination. Only the EQ-decentering scale was used in the current study; this contains 11 items and so scores ranged from *11* to *55*. The EQ has been shown to have good convergent and discriminant validity and has good internal consistency (Fresco, et al., 2007). The EQ-decentring scale has been cross-culturally validated and can

detect changes in decentring abilities after mindfulness-based interventions (Soler et al., 2014).

Clinical outcome measures

Three self-report outcome measures were completed on a session-by-session basis, and at 6-week follow-up (i.e. creating nine time-points in a full dataset). A key treatment target of ACT with LTCs is to enable engagement in values-based living, whilst accepting the limitations caused by the LTC (Prevedini et al., 2011). Therefore, the Work and Social Adjustment Scale was selected as the primary clinical outcome measure, due to its ability to index the impact of the LTC on functioning. Measures of depression and anxiety were also included as secondary outcome measures in order to measure changes in mental health symptomology.

Work and Social Adjustment Scale (Mundt et al., 2002).

The Work and Social Adjustment Scale (WSAS) is a five-item measure of the impact of a health condition on five facets of daily functioning (work, home management, social leisure activities, private leisure activities, and close relationships). Items are scored on a 9-point rating scale from *0* to *8* with a score range of *0–40*. Severity ratings are categorised as severe functional impairment (> 20), significant functional impairment (10–20), and subclinical (< 10). WSAS caseness is defined as scores of ≥ 10. The WSAS is sensitive to differences in disorder severity and is a sensitive to measuring change (Purdie et al., 2012).

Patient Health Questionnaire (Spitzer et al., 1999).

The PHQ-9 is a nine-item measure, widely used within primary and secondary care settings to detect depression. Items are scored on a 4-point scale from *0* to *3* with a score range of *0–27*. Severity ratings are categorised as severe (> 20), moderately severe (15–20), moderate (10–14), mild (5–9), and remission (< 5). Caseness is defined as scores of ≥ 10, and the amount of pre to post treatment change needed to demonstrate statistically reliable change is defined as ≥ 6 (Gyani et al., 2011). Sensitivity and specificity have been identified at 92% and 80% respectively at the > 10 cut off point (Gilbody et al., 2007).

Generalised Anxiety Disorder Assessment (Spitzer et al.,; 2006).

The Generalised Anxiety Disorder Assessment (GAD-7) is a seven-item severity measure of generalised anxiety. Items are scored on a 4-point scale from *0* to *3* with a score range of *0–21*. Severity ratings are categorised as severe (> 15), moderate (10–14), mild (5–9, and remission (< 5). Caseness is defined as scores of ≥ 8, and the amount of pre to post treatment change needed to demonstrate statistically reliable change is defined as ≥ 4 (Gyani et al., 2011). Applying a threshold score of 10 affords 89% sensitivity and 82% specificity (Swinson, 2006). The GAD-7 has also

demonstrated sensitivity and specificity for the detection of other anxiety disorders (e.g. panic disorder, social anxiety disorder; Kroenke et al., 2007).

Analysis strategy

Recruitment and retention in treatment is summarised using a consort diagram. *T*-tests were used to analyse for any differences between competency ratings taken from sessions in the two arms. Reliable and clinically significant change rates (RCSC) were used to evaluate outcomes on a case-by-case basis. For the clinical outcome measures, RCSC rates were calculated using the assessment and treatment termination session outcomes, via the reliable change index (RCI; Jacobson & Truax, 1991). RCSC is defined as the probability that change observed is actually due to measurement error is less than 5% and additionally whether the patient is in a non-clinical population following treatment (Evans et al., 1998; Jacobson & Truax, 1991). There are no published RCI rates for the WSAS, and so this was calculated using Evans et al. (1998) metric (formula: Standard Error of difference = *SD* of a clinical population $\sqrt{2}$ $\sqrt{}$ [1 – test–retest reliability of measure]). Based on normative properties taken from Mundt et al. (2002), the critical value was calculated as 5.88, and so patients had make an assessment to termination change of 6 on the WSAS for the change to be considered reliable. Patients were categorised as 'recovered' (reliable improvement plus movement from caseness to non-caseness), 'improved' (reliable improvement, no change in caseness), 'deteriorated' (reliable deterioration), or 'harmed' (reliable deterioration plus movement from non-caseness to caseness). Patients making no reliable change in either direction represent 'stasis.' The shape of change in the two treatments are summarised via session-by-session outcome graphs.

Results

Feasibility and acceptability

The consort summary is reported in Fig. 1. In terms of feasibility of recruitment, twenty-nine patients were screened for suitability, of which 11 (37.9%) failed to meet inclusion criteria. Eighteen (62.1%) patients were assessed, of which two (11.1%) were deemed not appropriate. No single participant refused being randomised. All pre, post, and follow-up measures were completed by those participants that had reached those stages. Of the 16 participants that began treatment, four (25%) dropped out within the first four sessions and two (12.5%) dropped out between sessions 5–8. Ten (62.5%) attended all eight sessions and so completed full treatment: 6 in full-ACT and 4 in ACT-SAC. There were no differences between completers and non-completers with regards to gender (completers 40% male, 60% female; non-completers 50% male, 50% female; $U = 27$, $p = 0.79$) or age (completers' mean age = 40.5 (SD = 14.48); non-completers' mean age = 47.5 (SD = 15.76); $U = 22.0$, $p = 0.43$).

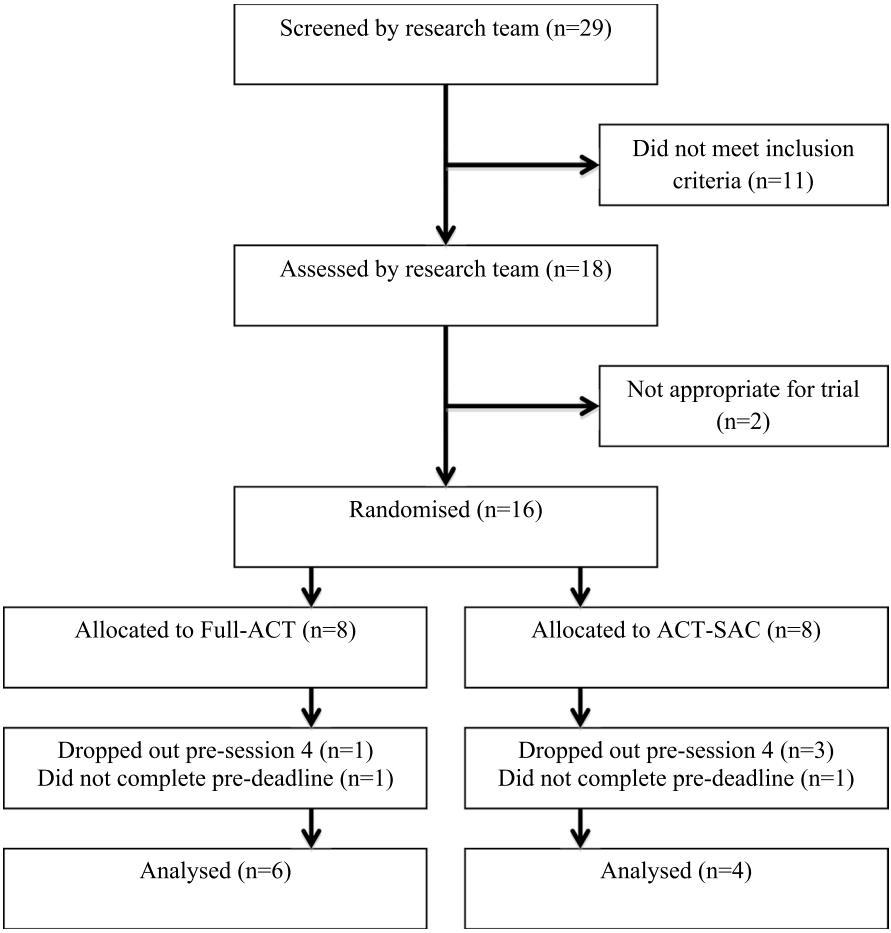

Fig. 1 Participant pathway summary

Treatment Competency

Of the seven therapists, three had a Full-ACT session rated and four had an ACT-SAC session rated. Scores on the ACT-CCRS-S are shown in Table 1 and show that there was no difference between the competency ratings of the sessions completed in either the Full-ACT arm or the ACT-SAC arm. Scores also indicate a high and consistent level of clinical competence across components, indicating that it was possible to deliver a dismantled version of ACT. The SAC competency score was lowest, as the session sampled may have been in the ACT-SAC arm and therefore the therapist would not have discussed SAC processes.

Table 1 ACT competency ratings

Subscale	Possible score range	Full-ACT Mean (SD)	ACT-SAC Mean (SD)	Between groups comparison
Therapeutic stance	6–42	32.70 (1.53)	33.25 (0.5)	$t(5) = .73$, $p = .5$
Acceptance	5–35	26.70 (0.58)	28.00 (1.83)	$t(5) = 1.2$, $p = .29$
Cognitive fusion	5–35	25.70 (4.04)	25.75 (2.75)	$t(5) = .03$, $p = .98$
Present momentness	4–28	20.00 (3)	20.75 (2.22)	$t(5) = .38$, $p = .71$
Self-as-context	3–21	14.33 (1.53)	-	-
Values	3–21	17.33 (2.31)	16.75 (1.9)	$t(5) = .37$, $p = .73$
Committed action	4–28	22.33 (1.53)	23.00 (0.82)	$t(5) = .76$, $p = .48$
Total	Full-ACT 30–210 ACT-SAC 27–189	159 (11.79)	147.5 (7.85)	-

Safety

The dropout rate was 37.50% (i.e. 10 of the 16 participants attended all 8-sessions). One participant in the Full-ACT met the criterion for an adverse event, as they had had sustained deterioration on the GAD-7 (at sessions 3, 4, and 5).

Sample Characteristics

The ten participants completing full treatment were made up of four men and six women (Full-ACT 1/6 male, 5/6 female; ACT-SAC 3/4 male, 1/4 female). This completer sample had a mean age of 40.2 (SD = 14.9), and there was no difference between the arms with regards to age (ACT mean = 38.33 [SD = 15.83], ACT-SAC mean = 43 [SD = 15.14]; $U = 6.5$, $p = 0.26$), with Levene's test of error variance being non-significant ($F(1,9) = 1.07$, $p = 0.33$). Completers were white British (9/10) and Asian (1/10). The LTCs were inflammatory bowel condition (2/10), post-surgical complications (2/10), deep vein thrombosis (1/10), temporomandibular joint disorder (1/10), skin condition (1/10), respiratory condition (1/10), degenerative disc disease (1/10), and multiple sclerosis (1/10).

Process and Clinical Outcomes

All participants met caseness criteria on each of the three clinical outcome measures at assessment. With regard to functioning (WSAS), all participants remained above caseness at treatment termination, and at follow-up, this had reduced to 4/6 for Full-ACT and 3/4 for ACT-SAC. At treatment termination depression caseness reduced to 3/6 for Full-ACT and 1/4 for ACT-SAC. At follow-up, no participants were above depression caseness in Full-ACT and ACT-SAC remained at 1/4. At treatment termination, anxiety caseness had reduced to 3/6 for Full-ACT and 2/4 for ACT-SAC, and at follow-up, this reduced to

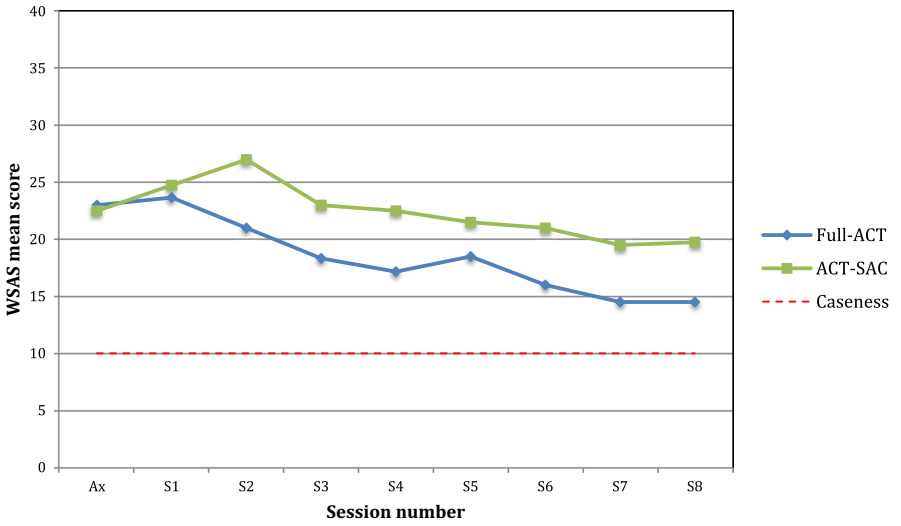

Fig. 2 Session by session WSAS scores in the arms

Table 2 Process and clinical measure scores at assessment, termination, and follow-up

	Arm of the study	*N*	Assessment mean (SD)	Termination mean (SD)	Follow-up mean (SD)
AAQ	Full-ACT	6	42.00 (4.34)	32.83 (6.8)	26.33 (6.92)
	ACT-SAC	4	36.58 (12.97)	25 (14.58)	21.50 (15.63)
EQ	Full-ACT	6	27.83 (8.8)	34.83 (5.23)	37.33 (4.08)
	ACT-SAC	4	26.75 (7.5)	36 (8.12)	40.5 (9.57)
WSAS	Full-ACT	6	23.00 (8.17)	14.50 (5.13)	12.67 (5.82)
	ACT-SAC	4	22.50 (5.8)	19.75 (7.14)	15.25 (11.44)
PHQ-9	Full-ACT	6	14.33 (2.73)	8.00 (2.76)	6.00 (1.67)
	ACT-SAC	4	17.50 (6.03)	8.50 (9)	8.25 (7.18)
GAD-7	Full-ACT	6	13.17 (4.22)	8.33 (3.88)	5.67 (2.58)
	ACT-SAC	4	11.75 (6.4)	6.50 (6.8)	5.50 (6.45)

2/6 for Full-ACT and 1/4 for ACT-SAC. At treatment termination, one participant had 'deteriorated' in the ACT-SAC arm on the WSAS, and one participant 'deteriorated' in the Full-ACT arm on the GAD-7. The shape of change in the clinical outcomes in the two arms is displayed Fig. 2 (WSAS), 3 (PHQ-9), and 4 (GAD-7) and shows that clinical change appeared to be linear regardless of type of treatment. The assessment, termination, and follow-up means (SDs) for the process measures and clinical outcome measures are presented in Table 2. The follow-up scores suggest that the gains made during treatment were maintained regardless of treatment.

Effect sizes and Post Hoc Power Analysis

Effect sizes were calculated for assessment to termination change scores between the study arms using the Rosenthal (1991) metric ($r = Z/\sqrt{N}$) and compared with Cohen's (1992) between-group effect size parameters (small: ≥ 0.2, medium: ≥ 0.5, large: ≥ 0.8). A small between-arm effect size was observed for functioning (0.20) and depression outcomes (0.39), but not for anxiety outcomes (0.05) or changes on the AAQ (0.07) or EQ (0.05). Assuming a small effect size of $d > 0.2$, a significance of $\alpha = 0.05$, and two study arms providing data at three time points (assessment, treatment termination, and follow-up), a total sample size of $N = 312$ (i.e. $N = 156$ in each study arm) would give 80% power to accurately test differences between Full-ACT and ACT-SAC on the WSAS in a main trial (Fig. 3).

Discussion

The present study conducted a pilot and feasibility dismantling trial of ACT, with self-as-context (SAC) as the hypothesised quarantined component, using a sample of participants with anxiety or depression in the context of an LTC. The type of LTC varied widely in the sample. In terms of the primary feasibility outcomes, participants accepted the rationale for the study, were willing to be randomised, and the follow-up completion rate was high. There were 100% collection rates for all measures and so data collection appeared acceptable for both therapists and patients. However, there were a large number of inappropriate referrals (37.93%, $n = 11$ out of 29) and therefore more detailed inclusion/exclusion guidance for clinicians referring into future trials would be useful. With regard to number of eligible patients, there were 18 suitable referrals within a three-month period from the 15 clinicians

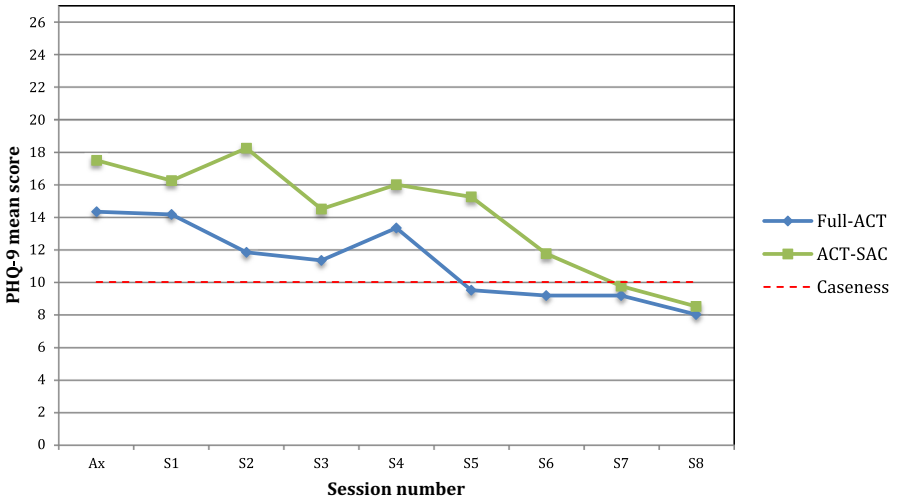

Fig. 3 Session by session PHQ-9 scores in the arms

who referred into the study. The timescale for recruitment to an adequately powered main trial would be 52 months on this evidence to reach the indicated sample size of $N = 312$ participants. The decision to conduct the study with an LTC population was due to the IAPT LTC service offering ACT as an intervention, and this not being the case in more general IAPT services.

Ethical approval was contingent on monitoring adverse incidents. The drop-out rate (37.50%) was a concern as this rate more than doubled the mean weighted drop-out rate of 15.8% (95% CI: 11.9%, 20.1%) reported in the Ong et al. (2018) meta-analysis of ACT acceptability. The dropout rate did not mean however that the trial had to be halted prematurely and dropouts were spread evenly across both early and late treatment stages and also across both treatment arms. The sustained reliable deterioration in anxiety (GAD-7) experienced by one participant in the Full-ACT arm did meet criteria for an adverse event—but the patient did also go onto complete treatment. The competency analysis indicated that therapists did not experience problems delivering the dismantled treatment and there were no differences shown in the competency scores in each of the arms of the trial. Definitive conclusions cannot be made regarding the utility and efficacy of the SAC component of the ACT hexaflex model from such a small study as this (Fig. 4).

A consideration regarding the internal validity of the present study concerned whether SAC could be entirely quarantined from overall ACT, in order to successfully implement the aims of the study. The extraction of SAC was aimed to be achieved by removing any element of explicit teaching and discussion of SAC, by removing the SAC module. However, implicit learning of SAC may still have occurred experientially during sessions through engaging in learning of other ACT processes such as cognitive defusion. This is because this essentially involves the same process of distancing or detaching from relational responding (De Houwer

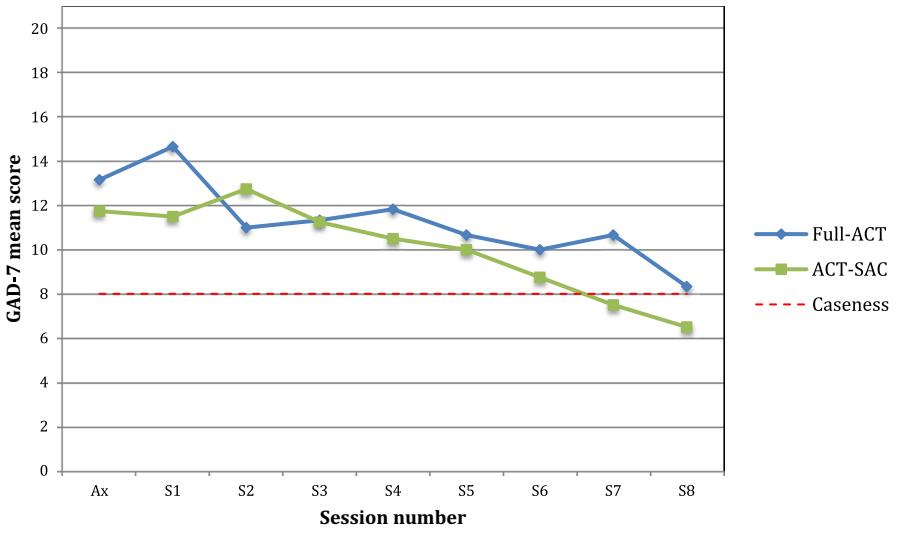

Fig. 4 Session by session GAD-7 scores in the arms

et al., 2013). SAC is often unwittingly omitted in ACT interventions due to confusion about this process and low therapist confidence in delivering interventions targeting this process (Luoma et al., 2007; Westrup, 2014). Indeed, some theorists have argued that only self-as-process needs to be targeted to create sufficient psychological flexibility to promote valued living (McHugh & Stewart, 2012). Future studies attempting to dismantle SAC from ACT should both remove the module and then audit session content to confirm that SAC has been removed from other therapeutic processes, which might be (unintentionally or intentionally) targeted by other components of the hexaflex (e.g. the defusion exercises). The rating of session recordings and coding of sessions to assess the frequency and form of SAC dialogue to definitively demonstrate whether SAC was effectively quarantined would be a useful research endeavour and would improve the methodological quality of any future dismantling study (Ahn & Wampold, 2001).

Theoretically and methodologically, dismantling studies of the middle-level processes of the hexaflex are clearly therefore a challenge. Definitive quarantining one of the middle-level processes is difficult because the work on the other processes implicitly touches on the eliminated process, and also, theoretically, the hexaflex middle-level processes are not defined in a way that differentiates the processes. Indeed, middle-level processes are all interrelated in the hexaflex, as the lines within the model indicate (Rolffs et al., 2018). Future studies may therefore prefer to rather split the hexflex left and right and so compare (a) defusion, willingness, and SAC versus and (b) values and action. This could be completed in a crossover design, so that all participants ultimately receive all the components. Indeed, this has already been achieved in a single case design (Villatte et al., 2015).

A key limitation of the present study was the small sample size, and this may have inflated the reported effect sizes used in the power analysis (Ellis, 2010). Billingham et al. (2013) reviewed sample sizes in pilot trials and found a median sample size per arm of 30, with a range of 8–114 participants. Johanson & Brooks (2010) did recommend a sample size of 12 participants per arm for pilot trials. As the current study was below the average (Billingham et al., 2013) and below the recommended (Johanson & Brooks, 2010) sample size, then appropriate due caution should therefore be exercised when drawing conclusions regarding the findings of the present admittedly small study. No psychometric properties have been reported for the ACT-CCRS-S, and therefore, the assessment of treatment competency in this study was suspect and also limited to a single session assessment. Future studies should consider the use of a more validated measure, such as the Drexel ACT/tCBC Adherence and Competence Rating Scale (McGrath, 2012) and also broaden the assessment of competency across a higher number of sessions. As diagnostic assessment was not an aspect of study methodology, future studies would benefit from using structured diagnostic interviewing. The process measure used aimed to capture changes in SAC (the EQ) also measured a higher order process (decentring), which is comprised of SAC and cognitive defusion (McCracken et al., 2014). The 29-item self-experiences questionnaire (SEQ; Yu et al., 2017a, b), the 10-item self-as-context scale (SACS; Zettle et al., 2018), and the 60-item multidimensional psychological flexibility inventory (MPFI; Rolffs et al., 2018) will therefore be valuable additions to the method of any future dismantling study. These measures were not considered

in the current study, due to the ethical approval being achieved after the publication of the measures. Finally, in terms of limitations, the protocol for the study was subject to scientific review prior to ethical review and approval, in which the feasibility and pilot outcomes were specified. However, the specific target rates for each feasibility outcome were generated post hoc, as was the dropout rates benchmark, because at the time of the study design the meta analytic evidence was not available (Ong et al., 2018).

In terms of clinical implications of the study, then findings suggest that building better acknowledgement of a permanent and stable sense of self can be the position from which LTCs can be observed and experienced (De Houwer et al., 2013), so decentring from 'over-idealised and perfectionistic' physical or psychological functioning. SAC in physical health settings presents the challenge of teaching patients to transcend personal psychological content related to their LTC to facilitate better acceptance of that content (Atkins & Styles, 2016). SAC in an LTC context encourages patients to shift from judging to observing daily fluctuations in physical functioning (Ciarrochi, et al., 2010), in the effort to build better distress tolerance (Foody et al., 2015). The increases in psychological flexibility would suggest that ACT for LTCs clinically enable patients to better connect with the present moment and create behavioural consistency with their personal values (Moran, 2015). Offering follow-up and booster support sessions grounded in the hexaflex appears useful.

To conclude, in order to quarantine and test the clinical utility of SAC during ACT, LTC patients with concurrent mental health difficulties were randomised into either Full-ACT or ACT-SAC, with both treatments lasting for 8 sessions and delivered in routine practice. Results of this small pilot and feasibility study indicate that a main dismantling trial would be safe and feasible; however, the indicated methodological changes should be observed, methods be implemented to minimise dropout, and adverse events should continue to be monitored in order to ensure patient safety. The role and utility of the SAC component of the hexaflex appear to remain open to debate and future testing in larger studies is therefore indicated.

Declarations

Conflict of Interest The authors declare no competing interests.

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