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Blended care in the treatment of subthreshold symptoms of depression and psychosis in emerging adults: A randomised controlled trial of Acceptance and Commitment Therapy in Daily-Life (ACT-DL)

Evelyne van Aubel[a],[*],[1], Jindra Myrthe Bakker[a],[b],[1], Tim Batink[b],[c], Stijn Michielse[b], Liesbet Goossens[b], Iris Lange[b], Koen Schruers[b],[d], Ritsaert Lieverse[b], Machteld Marcelis[b],[e], Thérèse van Amelsvoort[b], Jim van Os[b],[f],[g], Marieke Wichers[h], Thomas Vaessen[a], Ulrich Reininghaus[b],[i],[j], Inez Myin-Germeys[a]

[a] Department of Neurosciences, Center for Contextual Psychiatry (CCP), University of Leuven, Leuven, Belgium
[b] Department of Psychiatry and Psychology, School for Mental Health and Neuroscience (MHeNs), EURON, Maastricht University Medical Center, Maastricht, the Netherlands
[c] U-Center, Epen, Netherlands
[d] Department of Health Psychology, Faculty of Psychology, University of Leuven, Leuven, Belgium
[e] Institute for Mental Health Care Eindhoven (GGzE), Eindhoven, the Netherlands
[f] Department of Psychosis Studies, Institute of Psychiatry, King's College London, King's Health Partners, London, England, United Kingdom
[g] Brain Center Rudolf Magnus, University Medical Center Utrecht, Utrecht, the Netherlands
[h] University of Groningen, University Medical Center Groningen, Department of Psychiatry (UCP), Interdisciplinary Center Psychopathology and Emotion Regulation (ICPE), the Netherlands
[i] Department of Public Mental Health, Central Institute of Mental Health, University of Heidelberg, Mannheim, Germany
[j] Center for Epidemiology and Public Health, Health Service and Population Research Department, Institute of Psychiatry, Psychology & Neuroscience, King's College London, London, UK

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ABSTRACT

In this study, the feasibility and efficacy of Acceptance and Commitment Therapy in Daily Life (ACT-DL), ACT augmented with a daily life application, was investigated in 55 emerging adults (age 16 to 25) with subthreshold depressive and/or psychotic complaints. Participants were randomized to ACT-DL (n = 27) or to active control (n = 28), with assessments completed at pre- and post-measurement and 6- and 12-months follow-up. It took up to five (ACT-DL) and 11 (control) months to start group-based interventions. Participants attended on average 4.32 out of 5 ACT-DL sessions. On the app, they filled in on average 69 (48%) of signal-contingent beep-questionnaires, agreed to 15 (41%) of offered beep-exercises, initiated 19 on-demand exercises, and rated ACT-DL metaphors moderately useful. Relative to active control, interviewer-rated depression scores decreased significantly in ACT-DL participants (p = .027). Decreases in self-reported depression, psychotic-related distress, anxiety, and general psychopathology did not differ between conditions. ACT-DL participants reported increased mean NA (p = .011), relative to active controls. Mean PA did not change in either group, nor did psychological flexibility. ACT-DL is a feasible intervention, although adaptations in future research may improve delivery of and compliance with the intervention. There were mixed findings for its efficacy in reducing subthreshold psychopathology in emerging adults. Dutch Trial Register no.: NTR3808.

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1. Introduction

Mental illness poses a significant burden to society (Wittchen et al., 2011) which can only in part be reduced by the current available best practice, such as pharmacotherapy and psychotherapy (Andrews, Issakidis, Sanderson, Corry, & Lapsley, 2004; Huhn et al., 2014). Since it is known that subthreshold symptoms put one at risk for subsequent mental disorder (Karsten et al., 2011; Rössler et al., 2011), it may be of specific interest to implement interventions at an early developmental stage, in terms of both symptom progression and age. Indeed, most mental disorders emerge during late adolescence or early adulthood (Beesdo-Baum et al., 2015; Costello, Copeland, & Angold, 2011; Hamdi & Iacono, 2014; Kessler et al., 2005) and are preceded by suboptimal functioning (Balázs et al., 2013; Bruffaerts et al., 2018; McGorry, Nelson, Goldstone, & Yung, 2010) as well as an admixture of early psychopathology including amongst others affect dysregulation and psychotic experiences (McGorry & van Os, 2013; van Os, 2013; Wigman et al., 2013). That young age is such an important risk factor in the development of psychopathology shouldn't be surprising, given that late adolescence and early adulthood overlaps with a developmental concept known as emerging adulthood (Rey, Arnett, Žukauskienė, & Sugimura, 2014). Indeed, emerging adulthood can be a challenging time for young individuals' mental well-being, since they need to cope with more individual and contextual changes than at any other time in their lives (Schulenberg & Zarrett, 2006). Prevention programs have been shown effective in reducing various mental health problems in emerging adults including anxiety and depression (Conley, Durlak, & Kirsch, 2015; Cuijpers, van Straten, Smit, Mihalopoulos, & Beekman, 2008; Sandler et al., 2014) and cost-effective (Mihalopoulos, Vos, Pirkis, & Carter, 2011), specifically when targeting individuals with subthreshold symptoms (Mihalopoulos & Chatterton, 2015).

Currently, many early interventions are based on traditional cognitive behavioural therapy (CBT). *Acceptance and Commitment Therapy* (ACT) is a more recently developed therapeutic framework (Hayes, Luoma, Bond, Masuda, & Lillis, 2006), aiming to increase psychological flexibility (Ciarrochi, Bilich, & Godsell, 2010). Psychological flexibility is the ability to flexibly adapt behaviour in the service of long-term valued ends while accepting the internal experiences that may arise and it has been coined as an integral part of mental health (Kashdan & Rottenberg, 2010). Research demonstrated that ACT can be equally effective as compared to CBT in treating somatic (e.g. chronic pain, tinnitus) and mental health disorders (e.g. anxiety, depression) (A-Tjak et al., 2015), and the therapy may also be particularly implementable in prevention settings (Biglan, Hayes, & Pistorello, 2008). That is, ACT focuses on how to live life more effectively rather than the elimination of (a specific) psychopathology. It is therefore flexible in addressing coping skills in the general population as well as in individuals reporting subthreshold symptoms. Specifically, since subthreshold symptoms are likely to be diffuse and nonspecific (van Os, 2013) they should avail from a more universal, transdiagnostic intervention. Previous studies have shown the efficacy of various forms of both face-to-face as well as web – or device-based ACT in reducing several broad subthreshold symptoms (Bohlmeijer, Fledderus, Rokx, & Pieterse, 2011; Burckhardt, Manicavasagar, Batterham, & Hadzi-Pavlovic, 2016; Danitz & Orsillo, 2014; Fledderus, Bohlmeijer, Pieterse, & Schreurs, 2012; Jeffcoat & Hayes, 2012; Lappalainen, Langrial, Oinas-Kukkonen, Tolvanen, & Lappalainen, 2015; Levin, Pistorello, Seeley, & Hayes, 2014; Räsänen, Lappalainen, Muotka, Tolvanen, & Lappalainen, 2016) or stress and/or burnout (Ahtinen et al., 2013; Flaxman & Bond, 2010; Frögéli, Djordjevic, Rudman, Livheim, & Gustavsson, 2016; Jeffcoat & Hayes, 2012; Räsänen et al., 2016), when compared to a waiting list control condition. Hence, these studies hint towards the value of ACT as an early intervention. However, when compared to an online mental health education website as active control condition (Levin, Hayes, Pistorello, & Seeley, 2016) no significant effect of ACT online was found. This finding calls for more studies examining the preventative

effects of ACT when comparing it to an active control condition rather than a waitlist condition.

ACT is a third wave behavioural therapy, a new generation of behaviour therapy in which the focus has shifted from the form of psychological phenomena to their context and functions, while making use of many contextual and experiential exercises and metaphors to promote a broader, more flexible repertoire of coping skills (see Hayes, 2016; Hayes, Strosahl, & Wilson, 1999). However, applying these different coping strategies in daily life can be a difficult task. Recent technological advances in *mobile health* (mHealth) may provide an answer to this challenge. That is, mHealth adopts mobile devices, such as personal digital assistant or smartphones, to extend therapy from the therapist's office into daily life (Donker et al., 2013; Lindhiem, Bennett, Rosen, & Silk, 2015). With mHealth *applications* (apps), one can provide evidence-based treatment elements to patients at the moment when they are dealing with difficult experiences in their daily life (Myin-Germeys, Klippel, Steinhart, & Reininghaus, 2016). These so-called *ecological momentary interventions* (EMIs) may thus increase treatment adherence, but more importantly, may also contribute to enhanced coping skill acquisition (Heron & Smyth, 2010). In the context of ACT, mobile devices may help to practice the skills that have been thought in face-to-face sessions within the context of normal daily life.

Indeed, some recent studies describe the extension of ACT with EMI (Batink et al., 2016; Levin, Haeger, Pierce, & Cruz, 2017; Vaessen et al., 2019). In these studies, mHealth apps were developed which participants could use to practice ACT exercises taught during face-to-face group or individual treatment sessions in their own day-to-day environment, by using a dedicated device (Batink et al., 2016; *ACT in Daily Life*, ACT-DL) or a mobile phone app (Levin et al., 2017; ACT Daily; Vaessen et al., 2019; ACT-DL). High degrees of program satisfaction were reported by participants in these studies, and another study (Levin et al., 2017) showed a decrease of depression and anxiety levels. However, these studies did not make use of a randomised controlled trial (RCT) design, neither were they applied to non-help-seeking samples. Thus, no study to date has yet investigated the feasibility and efficacy of group-based ACT enriched with EMI in comparison to an active control condition in a prevention context with a RCT design.

The aim of the current study was two-fold. First, it was investigated whether providing a dedicated-device-augmented, group-based, face-to-face ACT therapy (ACT-DL) within a sample of non-help-seeking emerging adults with subthreshold symptoms of depression and/or psychosis is feasible in terms of study design, and the daily use and rated usefulness of (some aspects of) the ACT-DL app on a dedicated device. Given the importance of symptom-reduction within the scope of prevention programs, a second aim of the study was to investigate the preliminary efficacy of ACT-DL on subthreshold depression and distress related to psychotic experiences, anxiety, and general psychopathology in comparison to an active control condition. Even though the theoretical framework behind ACT focuses on psychological flexibility rather than on symptom reduction, the assumption is that symptom reduction may come about by living a life of valued action while letting go of the struggle with difficult internal experiences (Harris, 2006). Furthermore, the study investigated whether ACT-DL would foster a change in psychological flexibility and in *negative affect* (NA) and *positive affect* (PA) in daily life. The latter was of specific interest since low PA and high NA in daily life have been associated with several forms of psychopathology (Barge-Schaapveld, Nicolson, van der Hoop, & DeVries, 1995; Henker, Whalen, Jamner, & Delfino, 2002; Kashdan & Steger, 2006; Kwapil, Brown, Silvia, Myin-Germeys, & Barrantes-Vidal, 2012; Mata et al., 2012; Myin-Germeys, Delespaul, & DeVries, 2000; Myin-Germeys et al., 2009).

Overall, it was hypothesized that: ACT-DL would be (1) a feasible EMI; and (2) would be more efficacious than an active control condition in improving subthreshold symptoms of depression and/or distress related to psychotic experiences (primary outcomes), symptoms of

anxiety, and general psychopathology; increasing psychological flexibility; and decreasing daily-life NA, while increasing daily-life PA (secondary outcomes).

2. Methods

2.1. Design and participants

This trial is a single-blind two-armed RCT with a 1:1 allocation ratio. It was approved by the Medical Ethics Committee of Maastricht University Medical Centre (protocol number: NL41929.068.12/METC 12-2-072) and formed part of a larger registered study (SMARTSCAN) at Maastricht University (Dutch Trial Register no.: NTR3808). Participants were recruited from the general population in the region of Maastricht with advertisements focusing on individuals reporting sub-threshold symptoms of depression and/or psychosis from November 2012 to January 2017. If individuals expressed interest in participating, they received a detailed information letter, followed by a telephone screening to assess for eligibility. Eligible participants were invited for a first session in which they (and additionally a parent or guardian if age < 18) signed informed consent. Inclusion criteria were as follows: (1) age 16 to 25; (2) a total sum score of two or more on the Community Assessment of Psychic Experiences (CAPE (Konings, Bak, Hanssen, Van Os, & Krabbendam, 2006)) positive distress subscale or more than ten on the Montgomery-Åsberg Depression Rating Scale (MADRS (Montgomery & Åsberg, 1979)). As for the CAPE, this cut-off score resides within the idea that psychotic experiences lie on a psychosis continuum, and that the experience of distress in relation to these experiences shifts them towards the pathological end of the continuum (McGorry et al., 2010). Given the focus on mild symptomatology and early intervention in the current study, individuals could as such be included once they reported either one psychotic symptom by which they were quite distressed or two symptoms by which they were a bit distressed. As for the MADRS, the cut-off score is in line with a study showing that a broad definition of remission is defined by a MADRS score of 9 or lower (Zimmerman, Posternak, & Chelminski, 2004). Exclusion criteria were: (1) current treatment for mental health problems; (2) current psychotropic drugs use; (3) significant need for care as assessed by a psychiatrist; and (4) MRI-related contra-indications (MRI

measurements were part of another research question within SMARTSCAN). Data collection and interventions took place at the MHeNS department at Maastricht University.

2.2. Intervention

2.2.1. Experimental condition

The experimental intervention was ACT-DL. The intervention entailed five 90-min weekly face-to-face group-based ACT-sessions with a trained therapist (TB). Table 1 shows an overview of the structure of the ACT-DL intervention. The first four meetings consecutively introduced the following topics: creative hopelessness (the exploration of the individual's unsuccessful attempts to cope with unwanted experiences); acceptance (the active embrace of difficult and disturbing emotions); defusion (taking distance of unwanted cognitions); values and committed action (clarifying what is important, choosing directions one wants to go, and planning how to commit to actions consistent with these values). In the last session, an integration of all skills was made by introducing the concept of psychological flexibility. The topic of mindfulness (making non-judgemental contact with psychological and environmental events) was present throughout all sessions.

At the end of each session, individuals were asked to log into the ACT-DL app that was installed on a dedicated PsyMate™ device (www.psymate.eu) and to take home this device in between therapy sessions. After five training weeks, individuals could do an additional sixth week of practise. Starting one day after login, the PsyMate™ beeped at 8 semi-random moments (once every 1.45 h) throughout the day (between 8.00 and 22.00) for 3 subsequent days. With every beep, participants were asked to fill out a short 31-item questionnaire asking about current mood, context, and activities (see the Measures section for item examples) to enhance mindful awareness. After completion of the questionnaire, the PsyMate™ showed a metaphor in 50% of the beeps. This metaphors was a simple picture to serve as a quick reminder of an ACT coping skill introduced that week in therapy (e.g. creative hopelessness), and individuals were asked to rate on a 7-point Likert scale whether the metaphor was relevant to that specific moment. In the other 50% of questionnaire completion, the PsyMate™ asked whether one was interested in doing an exercise; if 'yes', one could select an exercise related to that same coping skill or a mindfulness exercise, the

Table 1
Structure of the ACT-DL intervention per week.

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
ACT session	Creative Hopelessness (CH)	Acceptance (ACC)	Defusion (DEF)	Values and Committed Action (VCA)	Psychological Flexibility	
Exercises	Option at 4 beeps: - CH (4) - Mindfulness (4)	Option at 4 beeps: - ACC, disturbed emotions? - If yes (3) - If no (4) - Mindfulness (4)	Option at 4 beeps: - DEF, disturbed thoughts? - If yes (3) - If no (4) - Mindfulness (4)	Option at 4 beeps: - VCA (4) - Mindfulness (4)	Option at 4 beeps: - ACC, disturbed emotions? - If yes (3) - If no (4) - DEF, disturbed thoughts? - If yes (3) - If no (4) - Mindfulness (4)	Option at 4 beeps: - ACC, disturbed emotions? - If yes (3) - If no (4) - DEF, disturbed thoughts? - If yes (3) - If no (4) - Mindfulness (4)
Metaphors	CH (4x)	ACC (4x)	DEF (4x)	VCA (4x)	CH (1x) ACC (1x) DEF (1x) VCA (1x)	CH (1x) ACC (1x) DEF (1x) VCA (1x)
Morning List				Prompt to think about 3 values	Prompt to think about 3 values	Prompt to think about 3 values
Evening List				Check whether invested in values	Check whether invested in values	Check whether invested in values

Notes. ACT-DL = Acceptance and Commitment Therapy in Daily Life. In week 2, 3, 5 and 6 selection of an acceptance or defusion exercise prompted participants to specify whether they were experiencing disturbing emotions or thoughts, respectively. If 'yes'; they were redirected to a selection of exercises specifically targeting disturbing experiences, if 'no'; they could choose from more general acceptance/defusion exercises. In week 4–6, the morning questionnaire included an extra item prompting individuals to think about which three values they were going to attend to that day and to come up with specific actions in line with those values. An additional item in the evening questionnaire asked to what extent individuals acted in line with their values that day.

latter being available throughout the whole intervention. If 'no', the In week 2, 3, 5 and 6, the selection of an acceptance of defusion exercise prompted one to specify whether one was experiencing disturbing emotions or thoughts, respectively. If 'no', the PsyMate™ session was aborted until the next beep or until initiation of an exercise. If 'yes'; one was redirected to a selection of exercises specifically targeting these disturbing experiences; one could choose from more general acceptance/defusion exercises (see Batink et al., 2016, p. 6 for examples of metaphors and exercises). In addition to the 8 beeps each day, participants were also asked to fill in a 2-item morning questionnaire upon awakening (asking about sleep quality) and a 7-item evening questionnaire before sleeping (asking general questions about (the implementation of the intervention during) the day). In week 4–6, the morning questionnaire included an extra item prompting individuals to think about which three values they were going to attend to that day and to come up with specific actions that would be in line of those actions. Additionally, an extra item in the evening questionnaire asked about to what extend individuals acted in line with their values that day. On the remaining days until the next therapy session, participants did not receive any beeps to alleviate burden and to practice coping skills in daily life independent of the ACT-DL app. In addition to the signal-contingent beeps, individuals could initiate on-demand exercises at all times, whenever they felt the need to do so. On-demand exercises build up weekly, with ACT exercises on topics of the previous therapy sessions remaining available.

2.2.2. Active control condition

Participants in the active control condition were asked to select, as a group, one of five documentaries, each week with another theme (biography, crime, history, nature, and art). After the selection, they were asked to fill in a short questionnaire asking about how satisfied they were with the group choice, and their prior expectations. After watching the documentary, they were asked to discuss, in pairs, several questions regarding the documentary (e.g., what they thought was the main message and how they could apply this message into their lives), after which a group discussion started with a participant summarizing the answer of the other individual in the pair to one of these questions. Lastly, participants were asked to fill in a short questionnaire regarding their satisfaction with the film selection, and whether the documentary changed how they thought about life. This condition was chosen to control for elements of behavioural activation and social support. That is, participants were encouraged to come to the research department on a weekly basis to enjoy and discuss a documentary with other emerging adults who were struggling with similar mental health complaints.

2.2.3. Randomisation and blinding

Whenever enough participants completed the baseline to form a group for the group sessions (2–10 individuals), the research coordinator flipped a coin to randomise them as a group. In order to balance out season effects between the two conditions, the next complete group was automatically assigned to the other condition. The research coordinator informed participants on where and when they were expected for their group session to keep assessors blind at all times. They were not informed on the particular interventions they could be allocated to, they were only aware of when and where they would get treatment for their mental health complaints.

2.3. Measures

2.3.1. Data collection

Data were collected at baseline, post-measurement, and at 6- and 12-month follow-up. Because the data were part of a larger study (SMARTSCAN), they were collected at two time points before [baseline 1 (B1) and 2 (B2) with on average 26 days (SD = 18) in between] and after [post 1 (P1) and 2 (P2) with on average 13 (SD = 8) days in between] the six-week intervention. Some measures were collected at B1 and P1 (CAPE, STAI), some at B2 and P2 (IDS-SR, SCL90, FIT-60). The MADRS was collected during both B1&2 and P1&2. Participants were instructed on the *experience sampling method* (ESM) procedure (infra) on B2 and P1, after which they carried the PsyMate™ for 15 and 7 days respectively. During the follow-up only the IDS-SR, CAPE, STAI and SCL90 were assessed (see Fig. 1).

2.3.2. Feasibility measures

Feasibility of study design was assessed through the average time participants had to wait until they started their allocated treatment, and through average attendance rates, as well as numbers and proportion of participants completing training. Feasibility of the use and usefulness of (some aspects of) the ACT-DL app on the PsyMate™ was investigated in terms of number of filled out beeps and (on-demand) exercises, and participant ratings on the usefulness of the metaphors.

2.3.3. Primary outcome measures

Montgomery Åsberg Depression Rating Scale (MADRS (Montgomery & Åsberg, 1979),). The MADRS is a 10-item semi-structured interview, in which interviewers indicate the severity of symptoms of depression over the last week on a 7-point scale (range 0–60) based on individuals' responses to open interview questions as well as observations during the interview. After the interview, interviewers filled in a blinding-checklist to control for deblinding, in which they reported whether they were suspicious about the allocation of the participant under assessment, and if so, whether they were sure about it. An experienced psychiatrist trained interviewers and reliability meetings were held during which the scoring of videotaped interviews
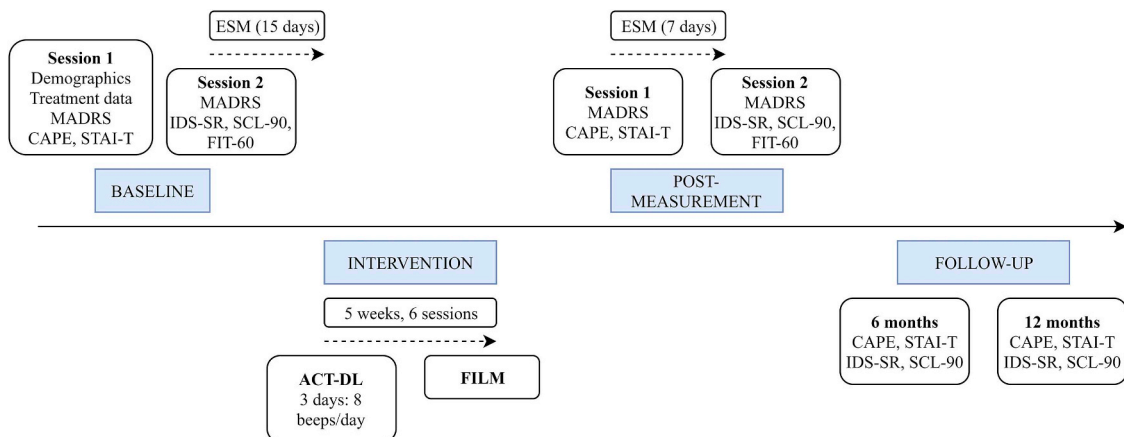

Fig. 1. Data collection.

was discussed: *inter-rater reliability* (IRR) was calculated using the scores of raters who attended a minimum of 50% of the reliability meetings, with median imputation of missing scores. A fair level of IRR was found (ICC = 0.44) (Cicchetti, 1994).

Inventory of Depressive Symptomatology, Self-Report (IDS-SR (Rush, Gullion, Basco, Jarrett, & Trivedi, 1996)). The IDS-SR is a 30-item questionnaire assessing depressive symptom severity during the last 7 days. Participants scored 28 items on a 4-point scale (range 0–84).

Community Assessment of Psychic Experiences (CAPE (Konings et al., 2006),). The CAPE is a 42 item self-report scale, designed to assess psychotic experiences during the last three months in the general population. It includes dimensions of positive (20 items; e.g. "Do you ever feel as if you are being persecuted in some way?"), negative (14 items; e.g. "Do you ever feel that you are not a very animated person?") and depressive (8 items; e.g. "Do you ever feel sad?") items. Each item consists of a 4-point frequency score ("How often did you have a certain feeling, thought or experience in your life?" 0 never – 1 sometimes – 2 often – 3 nearly always), and if a score of ≥ 2 on this item, a 4-point distress score ("How distressed were you by this experience?" (0 not distressed – 1 a bit distressed – 2 quite distressed – 3 very distressed). For the current analyses, only the weighted (mean) score of the positive distress items was used (range 0–3), with individuals reporting no psychotic symptoms left out of the analysis.

2.3.4. Secondary outcome measures

State-Trait Anxiety-Inventory (STAI-T (Spielberger, 1983),). The STAI-T is a 20-item self-report questionnaire assessing the disposition to feel stress, worry and discomfort the last few weeks. Each item is scored on a 4-point Likert scale assessing frequency (ranging between never/rarely-almost always; range 20–80).

Symptom Checklist (SCL-90 (Derogatis, 1977),). The SCL-90 is a multidimensional self-report scale including 90 items, each measured on a 5-point scale of distress (ranging between 'not at all' to 'extremely'). Psychopathology during the last week is assessed with items that load on eight (agoraphobia, anxiety, depression, somatic complaints, obsessive-compulsive complaints, distrust and interpersonal sensitivity, hostility, and sleeping problems) symptom dimensions (Arrindell & Ettema, 1981, 2002). The current paper used the total sum score on all items to assess general psychopathology.

Flexibility Index Test (FIT-60, Batink, Jansen, & de Mey, 2012; Batink & Delespaul, 2015). The FIT-60 is a self-report questionnaire that measures psychological flexibility and six underlying ACT components: acceptance, defusion, self as context, present moment, values, and committed action (10 items per component). The FIT-60 consists of 60 items scored on a 7-point scale (range 0–360).

NA affect and PA in daily life. Momentary NA and PA was measured with the ESM, a structured, random time-sampling diary technique allowing to distinguish fine-grained patterns in the daily lives of participants, while reducing the risk of retrospective bias (Csikszentmihalyi & Larson, 1987; Myin-Germeys et al., 2018). Before and after the intervention participants carried a dedicated device with the PsyMate™ ESM app (similar to the ACT-DL app but without follow-up exercises and metaphors) installed that beeped ten times a day at semi-random moments within blocks of 90 min, between 07:30 h and 22:30 h. At each beep, participants completed a 46-item beep-questionnaire including Likert-type or multiple-choice items on current mood (e.g.: "I feel cheerful"), context (e.g.: "Who am I with?") and activities (e.g. "What am I doing?"), with answers being rated on a 1–7 Likert scale or chosen from multiple options. For the current study, only mood items were used to calculate PA and NA. PA was computed by averaging the items "cheerful", "relaxed", "satisfied", "enthusiastic", and "energetic" per participant and beep moment, and similarly, NA was calculated similarly by averaging the items "down", "insecure", "lonely", "anxious", and "guilty". After person-level-centring the items, Cronbach's alphas were .74 and .82 (baseline) and .77 and 0.81 (post-measurement) for NA and PA respectively.

Self-reporting of improvement. In addition to the instruments used above, participants were asked to what extent their problems had changed after the intervention (either ACT-DL or control), ranging from much better to much worse. Next, they were asked to what extent the research had contributed to this change.

2.4. Statistical methods

All analyses were conducted in Stata version 14.2 (StataCorp, 2015). Missing items in questionnaires (not ESM) were imputed with the average of all non-missing items (computed within subscales if existing) if > 80% of necessary items were completed, except for the SCL-90, in which we made use of the manual's guidelines for handling of missing data (Arrindell & Ettema, 2002). Condition (control = 0, experimental = 1) differences at baseline were examined with the REGRESS command for quantitative variables (age and questionnaire sum-scores), the LOGIT command for dichotomous variables (gender, education and medication use in the past) and MIXED for ESM variables (NA and PA).

2.4.1. Sample size

The sample size calculation was based on expected fMRI-related changes, since these were the primary study parameters to answer the research question on treatment effects within SMARTSCAN. Based on previous fMRI research in participants with mental disorder (Desmond & Glover, 2002), it was calculated that 25 participants would be required to detect pre-post differences in BOLD signals with a conservative alpha. However, this number was increased to account for the following issues that could limit the difference in effect size of both interventions: (1) a sample with subthreshold psychopathology; (2) the implementation of an active component in the control condition; (3) the anticipation of approximately 10% withdrawal at baseline and 10% during the trial. As such, $2 \times 33 = 66$ participants were planned to become randomised. Aiming for a medium effect size (Cohen's d = 0.5) on fMRI-changes and setting alpha at .05 and T:C = 1, with groups of 33 participants each, the calculation using the SAMPSI command yielded a power of .86.

2.4.2. Feasibility

Descriptive statistics including relevant parameters including averages, standard deviations, ranges, percentages, and frequency distributions were used to assess delivery of and attendance to the interventions and the use of the ACT-DL app, and t – and chi-square statistics were calculated to assess significant differences between conditions for continuous and categorical feasibility outcomes respectively. Repeated measures mixed models were fitted using the MIXED command with time, defined in study weeks, as the independent variable. The weekly within-subject number of beeps, beep-exercises, on-demand exercises, metaphor usefulness, and the ratio of yes-beep-exercises to total-beep-exercises were modelled as the dependent outcomes. The ratio was calculated as the weekly within-subject amount of beep-exercises to which participants said yes, divided by the weekly total within-subject amount of beep-exercises that week.

2.4.3. Efficacy

Repeated measures mixed models with a fixed effect for the intervention were designed to analyse the treatment effects for the ACT-DL condition compared to the active control condition for both primary and secondary outcomes. In the models in which the non-ESM questionnaire outcomes (scores of MADRS, IDS-SR, CAPE, STAI-T, SCL-90 and FIT-60) were the dependent variables, the within-subject variance-covariance matrix of each model was set to unstructured, which means that every time point in the analyses could have its own variance and that each pair of time points could have its own covariance. In models with ESM outcomes (NA and PA) as dependent variables, random intercepts and random slopes were added and the variance-covariance

structure of these random effects was set to unstructured. In addition, within each time point (baseline and post-measurement), it was assumed that the within-subject error variance-covariance matrix had an autoregressive (AR) structure (of the exponential type), which allowed the models to account for unequally spaced time values.

With these models, conditions were assessed on how treatment outcomes changed over time (Condition x Time), and, if unchanged per condition, whether treatment outcomes changed over time within the entire sample (Time), with standardized beta coefficients (β) indicating the magnitude of the effects. In addition, the CONTRAST command was used in a first step to perform joint omnibus tests of the interaction and main effects making use of the chi-square statistic (χ^2) with the degrees of freedom (df) reflecting the number of time points in the analysis. Secondly, it was used to assess between condition effects.

All models were fitted using restricted maximum likelihood estimation (REML), with data assumed to be missing at random (MAR). Residuals were checked for normal distribution. If residuals were non-normally distributed, variable transformations (e.g. log, inverse) were performed and residuals checked for improvement.

3. Results

3.1. Descriptives

Table 2 displays condition averages on demographic, clinical and outcome measures at baseline. No significant differences between conditions were found, although the ACT group showed a trend towards lower anxiety (STAI-T: p = .056) and higher PA (p = .056) at baseline. Visual inspection of residual distribution of the MADRS, IDS-SR, SCL-90 (all slight positive skew and kurtosis), STAI-T (slight negative kurtosis), and CAPE (slight positive skew) only showed slight deviations from normality. However, all models' residuals except for those with the FIT-60, NA and PA as the outcomes were non-normally distributed as tested with Shapiro-Wilk tests. Neither transforming (log,

inverse, etc.) the MADRS, nor the CAPE improved the distribution of the residuals. These outcomes should therefore be interpreted with caution. A reciprocal transformation of the SCL-90 and a square root transformation of the IDS-SR and STAI-T improved normality of the distribution of the residuals, however sensitivity analysis on both the original and the transformed scores showed that there were no differences in either Condition, Time, or Condition x Time effects. Hence, Fig. 3 and Tables 4–7 provide information on the change of the untransformed scores within both conditions. Sensitivity analyses without outliers, defined as outcome scores greater than 3 standard deviations from the mean, were run for all models, and showed no differences in effects in comparison to the models with outliers.

3.2. Feasibility

3.2.1. Participant recruitment and study design

The final sample consisted of 53 emerging adults with subthreshold symptoms of depression and/or psychosis. Fig. 2 displays the participant flow in the study. In total 1561 individuals responded to advertisements, many of whom were excluded via information exchange through email contact, decided not to participate after reading the information letter, or did not provide us with their telephone number. In total, 398 individuals were screened by telephone after which 89 turned out to be eligible for the current study and were invited for a first session. Based on this first session 11 participants were excluded because they did not meet inclusion criteria. Another 23 participants withdrew from the study due to various reasons (see Fig. 2), resulting in the randomisation of 55 participants after the second baseline session (28 to the film condition, 27 to the ACT-DL condition). Two individuals who were randomized in the ACT-DL condition were not able to participate in the scheduled meetings. The resulting 53 participants came back for the post-measurement, after which there was a withdrawal of 18% and 12% at 6 months and of 25% and 20% at 12 months in the film and the ACT-DL condition respectively.

Table 2
Baseline characteristics of the sample.

Measure	Film	ACT-DL	p
Demographics			
Age (mean, sd, range)	21.36 (2.39) 18 - 25	20.64 (2.46) 16 - 24	.29
Female (number, %)	19 (68%)	21 (84%)	.18
High education (number, %)	25 (89%)	21 (84%)	.57
Psychotropic medication use in the past			
Antidepressants	2 (7%)	1 (4%)	.63
Anxiolytics	1 (4%)	0 (0%)	.
Antipsychotics	0 (0%)	1 (4%)	.
Other	5 (18%)	5 (20%)	.84
Symptom measures (mean, sd, range)			
MADRS-inclusion	15.43 (4.85) 4 - 24	16.22 (4.14) 10 - 27	.53
MADRS-scan session	14.14 (4.33) 5 - 21	13.44 (7.42) 2 - 33	.67
IDS-SR	25.14 (9.83) 5 - 42	21.72 (10.07) 5 - 46	.22
CAPE, positive distress[1]	3.42 (3.35) 0-16	3.21 (2.97) 0-10	.83
STAI-T	52.39 (8.49) 32 - 69	46.8 (12.17) 23 - 69	.06
SCL-90	170.66 (41.73) 103 - 256	167.03 (52.61) 101-316	.78
Psychological flexibility (mean, sd, range)			
Total	169.21 (32.97) 110 - 248	182.38 (44.02) 115 - 262	.22
ESM measures (mean, sd_b, sd_w, range)			
Negative Affect	2.24 (.78 - .83) 1-7	2.18 (.75 - .89) 1-7	.52
Positive Affect	3.75 (.62 - .97) 1-7	4.16 (.76–1.06) 1-7	.06

Notes. sd = standard deviation; [1] = sum score; sd_b = standard deviation (between); sd_w = standard deviation (within); % = percentage.
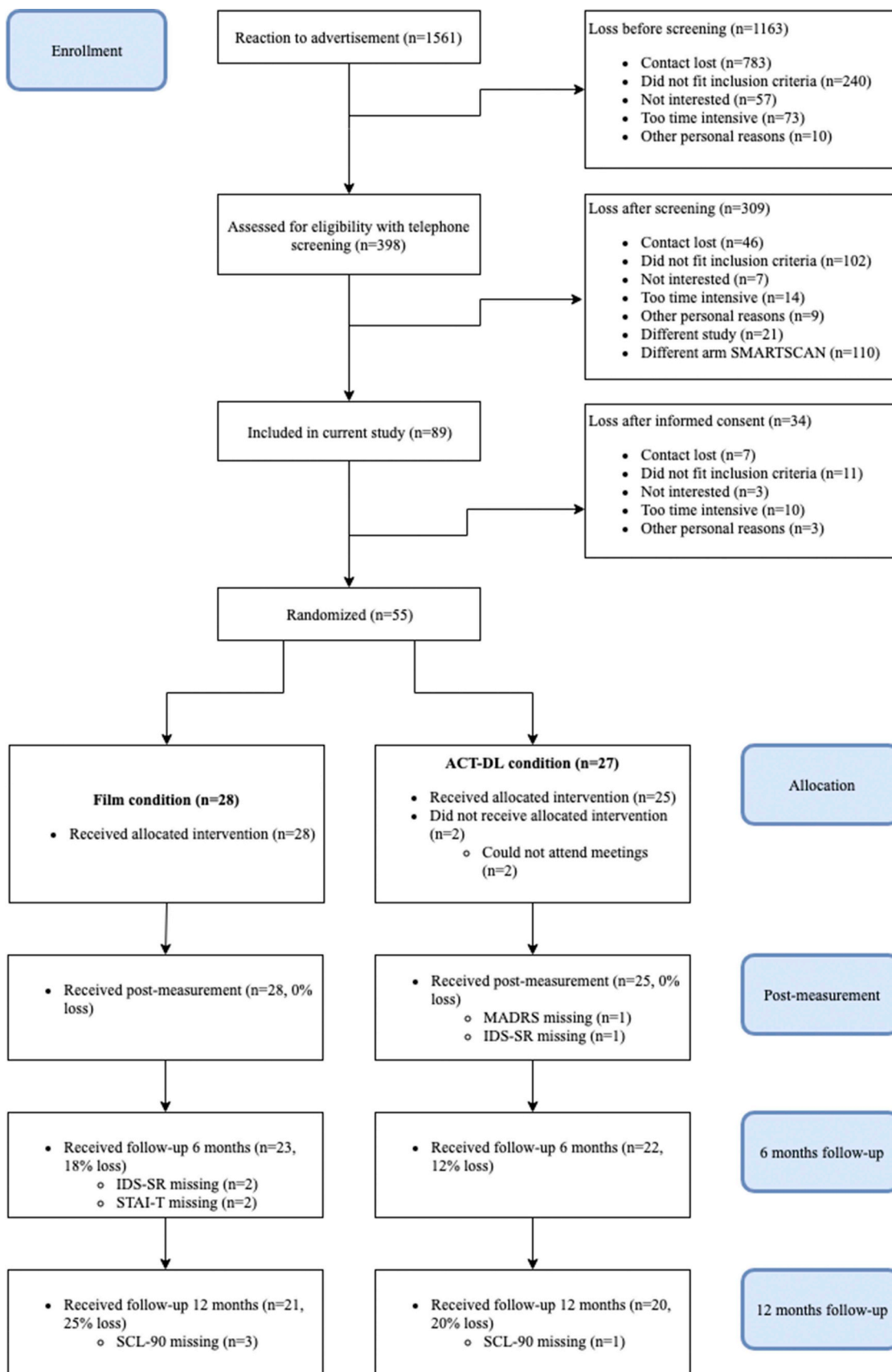
Fig. 2. Participant flow of the study.

After the second baseline measurement, it took on average 3 months (sd = 2) with a range of 6 days–11 months to start the film intervention, and 3 months (sd = 1) with a range of 3 days–5 months to start the ACT-DL intervention (t(51) = 0.66; p = .513). Participants attended the film sessions (3.71 out of 5 (sd = 0.85)) significantly less (t (51) = -2.91; p < .01) compared to the ACT sessions (4.32 out of 5 (sd = 0.63)). What is more, the proportion of participants who completed all 5 sessions differed significantly by allocated intervention (χ^2(1, N = 53) = 4.49, p < .05), with 14% of the participants in the film condition completing all sessions in contrast to the ACT-DL condition, where this percentage was 40%.

3.2.2. Use and usefulness of (some aspects of) the ACT-DL app

Detailed information on the use of the ACT-DL app is presented in Table 3. Participants completed on average 69 (48%) of 144 programmed beeps (72 exercises/metaphors) throughout the course of the intervention period (i.e. 6 weeks). Of these beeps, 32 (47%) beeps were followed by a metaphor, providing participants with a visual cue reminding them of what they learned in therapy. Thirty-seven (53%)

beeps were followed by a question asking whether they were interested in doing an exercise. As to the latter, participants responded on average with 'yes' 15 (41%) times, and with 'no, later' 22 times (59%). The average rated usefulness of the metaphors (range 1–7) was rated as 3.49 (sd(between) = 0.99, sd(within) = 1.58). Frequency distributions of momentary ratings of metaphor usefulness throughout the whole intervention period showed that for 50% of the times where participants were provided with a metaphor, they perceived it as less than moderately useful (scores 1–3), 17% as moderately useful (score 4) and 33% as more than moderately useful (scores 5–7). Whereas for 21% of the times the metaphor was rated as "not useful at all", 5% of the times the metaphor was rated as "very useful". Participants, in addition, initiated on average 19 exercises on their own accord (i.e., without a beep signal) throughout the whole intervention period. The amount of weekly beeps (b = −.70; p < .01), actual executed beep-exercises (b = −0.32; p < .01), ratio of yes-beep-exercises to total-beep-exercises (b = −0.02; p < .05), and on-demand exercises (b = −0.79; p < .01) dropped significantly throughout the weeks. The usefulness ratings of the metaphors (b = 0.02; p = .66) remained stable.

Table 3
Use and usefulness of the ACT-DL app in terms of beeps, beep-exercises, beep-metaphors and on-demand exercises.

	n		Mean (SD) Range					
	Total	ACT-DL	1 - CH	2 - ACC	3 - DEF	4 – VCA	5 – PF	6 – ADD
Beeps								
Completed	1722	68.88 (28.51)	14.42 (5.28)	12.38 (6.27)	12.09 (4.78)	12 (5.20)	11.17 (5.44)	10.13 (5.74)
		21–120	5–23	2–22	5–20	2–21	1–23	1–19
Beep-exercises	918							
Yes	372	14.88 (9.21)	3.79 (1.86)	2.95 (2.20)	3.1 (1.77)	3.1 (1.62)	2.9 (2.05)	2.5 (1.64)
		4–42	1–7	1–10	1–7	1–7	1–9	1–6
No	546	–	–	–	–	–	–	–
Beep-metaphors	804							
Usefulness		3.49 (bs = .99; ws = 1.58)	3.49 (bs = .98; ws = 1.58)	3.29 (bs = 1.46; ws = 1.24)	3.42 (bs = 1.15; ws = 1.59)	3.50 (bs = 1.57; ws = 1.40)	3.81 (bs = 1.38; ws = 1.41)	3.40 (bs = 1.34; ws = 1.26)
On demand	469	18.76 (17.28)	6.45 (4.87)	4.95 (3.08)	4.79 (3.63)	4.35 (2.71)	3.09 (2.31)	4.89 (5.82)
		1–70	1–18	1–10	1–12	1–8	1–9	1–18

Notes. ACT-DL = Acceptance and Commitment Therapy in Daily Life; CH = Creative Hopelessness; ACC = Acceptance; DEF = Defusion; VCA = Values and Committed Action; PF = Psychological Flexibility; ADD = Additional training week; bs = between subject standard deviation; ws = within subject standard deviation. Total stands for the total amount of beeps, beep-exercises and beep-metaphors throughout the whole ACT training across all participants (n = 25).

Table 4
Repeated Measures Mixed Models of Treatment Effects on Primary Outcome Variables.

Outcome	Fixed effects						Omnibus test of fixed effects			
			β	SD	95% CI	P-value		df	χ^2	P-value
MADRS	Condition		.15	.19	−.22; .52	.424	Condition	1	.45	.501
	Time	Post	−.41	.17	−.75; −.07	.019	Time	1	29.52	.000
	Condition x Time	Post	−.56	.25	−1.06; −.06	.027	Condition x Time	1	4.89	.027
IDS-SR	Condition		−.33	.26	−.84; .18	.211	Condition	1	.5	.481
	Time	Post	−.40	.18	−.75; −.05	.025	Time	3	11.89	.008
		FU6	−.51	.21	−.91; −.10	.015	Condition x Time	3	2.1	.553
		FU12	−.65	.25	−1.14; −.16	.010				
	Condition x Time	Post	.14	.26	−.37; .65	.584				
		FU6	.04	.30	−.54; .62	.895				
		FU12	.49	.36	−.22; 1.20	.173				
CAPE, pos. distr.[1]	Condition		−0.11	0.27	−0.65; 0.42	0.677	Condition	1	0.01	0.906
	Time	Post	−0.01	0.21	−0.42; 0.40	0.962	Time	3	22.39	0.000
		FU6	−0.65	0.24	−1.12; −0.18	0.007	Condition x Time	3	2.27	0.519
		FU12	−0.54	0.28	−1.09; 0.02	0.058				
	Condition x Time	Post	0.24	0.31	−0.37; 0.85	0.433				
		FU6	0.25	0.34	−0.41; 0.91	0.462				
		FU12	−0.15	0.40	−0.94; 0.65	0.719				

Notes. MADRS (Montgomery & Åsberg, 1979), Montgomery Åsberg Depression Rating Scale; IDS-SR (Rush et al., 1996), Inventory of Depressive Symptomatology, Self-report; CAPE pos. distr. (Konings et al., 2006), Community Assessment of Psychic Experiences, positive distress cores; [1] = weighted (mean) score; β = standardized beta-coefficient; SD = standard deviation; 95% CI = 95% confidence-interval (α = 0.05); χ^2 = chi-square statistic.

3.3. Efficacy

3.3.1. Depression and distress related to psychotic experiences (primary outcomes)

The repeated measures mixed models provided partial support for the hypothesis that ACT-DL would decrease subthreshold symptoms of depression more than active control (see Table 4 and Fig. 3). A significant Condition x Time effect in the MADRS model (χ^2 = 4.89, p = .027) was found, with a steeper decrease in scores in the ACT-DL condition from pre – to post-measurement (β(SD) = −0.56(0.25)) compared to the decrease in the film condition (β(SD) = −0.41(0.17)). A subsequent sensitivity analysis was run to rule out deblinding effects during MADRS assessment. Of the 83 interviews during which the blinding-checklist was administered (missing data of 22 interviews), the interviewer reported 23 times (28%) to be sure or suspicious about the allocation, which was correct in 21 cases. When executing the same analysis while excluding the data of the 43 interviews in which no blinding check was performed (n = 22) or when the interviewer was

deblinded (n = 21), the Condition x Time effect remained significant (χ^2 = 5.22, p = .022).

In contrast, there was no significant Condition x Time effect for self-reported depression (IDS-SR), nor for self-reported distress related to psychotic experiences (see Table 4 and Fig. 3). The main effect for Time did reach significance for both the IDS-SR scores (χ^2 = 11.89, p = .008) and CAPE scores (χ^2 = 22.39, p = .000), with scores changing equally in both conditions. That is, IDS-SR scores changed significantly from baseline to post-measurement (β(SD) = -0.40(0.18)), as well as from baseline to follow-up of 6 months (β(SD) = -0.51(0.21)), and of 12 months β(SD) = -0.65(0.25)). For the CAPE scores, there was only a significant decline from baseline to follow-up of 6 months (β(SD) = -0.65(0.24)).

Note that symptom levels of depression (interviewer-rated and self-reported) and distress related to psychosis in either condition were not significantly different from each other at any time point in the study (see Table 6).

Table 5
Repeated Measures Mixed Models of Treatment Effects on Secondary Outcome Variables.

Outcome			Fixed effects				Omnibus test of fixed effects			
			β	SD	95% CI	P-value		df	χ^2	P-value
STAI-T	Condition		−.45	.23	−.90; .00	.050	Condition	1	.69	.405
	Time	Post	−.42	.15	−.70; −.13	.004	Time	3	16.8	.001
		FU6	−.71	.20	−1.10; −.31	.000	Condition x Time	3	2.13	.546
		FU12	−.54	.22	−.98; −.10	.016				
	Condition x Time	Post	.26	.21	−.15; .68	.218				
		FU6	.34	.29	−.21; .90	.227				
		FU12	.40	.32	−.23; 1.03	.215				
SCL-90	Condition		−.07	.26	−.59; .44	0.779	Condition	1	.02	.896
	Time	Post	−.25	.15	−.53; .04	0.094	Time	3	8	.046
		FU6	−.27	.16	−.57; .04	0.087	Condition x Time	3	2.49	.477
		FU12	−.29	.20	−.69; .10	0.149				
	Condition x Time	Post	.24	.21	−.18; .66	0.267				
		FU6	−.06	.22	−.50; .39	0.805				
		FU12	−.02	.29	−.58; .55	0.956				
FIT-60	Condition		.36	.28	−.18; .90	.192	Condition	1	2.51	.113
	Time	Post	.20	.16	−.12; .51	.217	Time	1	3.77	.052
	Condition x Time	Post	.06	.23	−.40; .52	.793	Condition x Time	1	.07	.793
NA	Condition		−.10	.18	−.46; .25	.579	Condition	1	.25	.620
	Time	Post	−.15	.10	−.35; .05	.144	Time	1	.3	.586
	Condition x Time	Post	.38	.15	.09; .67	.010	Condition x Time	1	6.55	.011
PA	Condition		.27	.15	−.03; .57	.079	Condition	1	1.35	.246
	Time	Post	.07	.08	−.09; .23	.376	Time	1	.14	.704
	Condition x Time	Post	−.19	.12	−.43; .04	.111	Condition x Time	1	2.55	.111

Notes. STAI-T (Spielberger, 1983), State-Trait Anxiety Inventory – Trait; SCL-90 (Derogatis, 1977), Symptom Checklist; FIT-60 (Batink & Delespaul, 2015; Batink et al., 2012), The Flexibility Index Test; PA, Positive Affect; NA, Negative Affect. PA and NA were measured with the ESM; β = standardized beta-coefficient; SD = standard deviation; 95% CI = 95% confidence-interval (α = 0.05); χ^2 = chi-square statistic.

Table 6
Means, SDs, and Estimated Differences (95% CI, p-value) between treatment conditions (ACT-DL versus Film) for primary outcome variables.

Outcome		Film		ACT-DL		Estimated difference with 95% CI and p-value		
		Mean	SD	Mean	SD	Δ	95% CI	P-value
MADRS	Pre	15.45	.81	16.39	.86	.94	−1.37; 3.25	.424
	Post	12.90	1.14	10.34	1.21	−2.56	−5.82; .70	.123
IDS-SR	Pre	25.14	1.88	21.72	1.99	−3.42	−8.79; 1.94	.211
	Post	20.96	1.76	19.04	1.89	−1.92	−6.98; 3.14	.457
	FU6	19.81	2.28	16.80	2.30	−3.01	−9.35; 3.32	.351
	FU12	18.30	2.53	20.07	2.63	1.77	−5.39; 8.92	.628
CAPE, pos. distr.[1]	Pre	1.14	0.12	1.06	0.14	−0.08	−0.45; 0.29	0.677
	Post	1.13	0.15	1.22	0.15	0.09	−0.33; 0.51	0.675
	FU6	0.69	0.16	0.78	0.15	0.09	−0.34; 0.53	0.672
	FU12	0.77	0.17	0.59	0.16	−0.18	−0.63; 0.28	0.440

Notes. MADRS (Montgomery & Åsberg, 1979), Montgomery Åsberg Depression Rating Scale; IDS-SR (Rush et al., 1996), Inventory of Depressive Symptomatology, Self-report; CAPE pos. distr. (Konings et al., 2006), Community Assessment of Psychic Experiences, positive distress cores; [1] = weighted (mean) score; SD = standard deviation; Δ = estimated mean group differences; 95% CI = 95% confidence interval (α = 0.05).
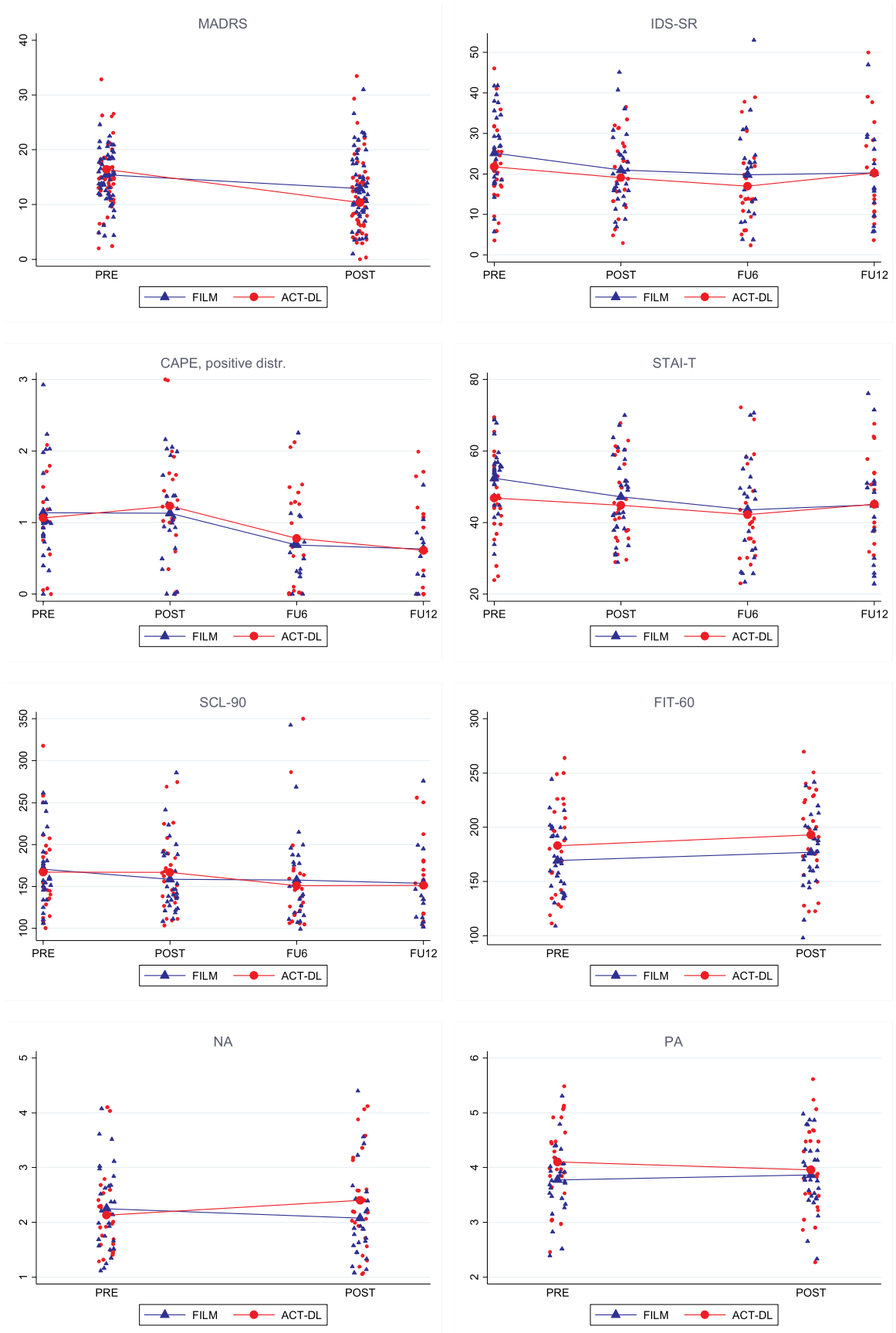
(caption on next page)

Fig. 3. Mean scores for the film and ACT-DL condition.

Notes. MADRS (Montgomery & Åsberg, 1979), Montgomery Åsberg Depression Rating Scale; IDS-SR (Rush et al., 1996), Inventory of Depressive Symptomatology, Self-report; CAPE pos. distr. (Konings et al., 2006), Community Assessment of Psychic Experiences, positive distress cores; STAI-T (Spielberger, 1983), State-Trait Anxiety Inventory – Trait; SCL-90 (Derogatis, 1977), Symptom Checklist; FIT-60 (Batink & Delespaul, 2015; Batink et al., 2012), The Flexibility Index Test; PA, Positive Affect; NA, Negative Affect; PA and NA were measured with the ESM; CAPE scores are weighted (mean) scores.

3.3.2. Anxiety and general psychopathology (secondary outcomes)

The hypothesis that ACT-DL would lead to less anxiety (STAI-T) and less general psychopathology (SCL-90) in comparison to active control was not supported by the results of the repeated measures mixed models, with no significant Condition x Time effects (see Table 5 and Fig. 3). There were however significant Time effects for both STAI-T scores (χ^2 = 16.8, p = .001) and SCL-90 scores (χ^2 = 8, p = .046). Only the anxiety scores declined significantly from pre – to post-measurement (β(SD) = −0.42(0.15)), as well as from baseline to follow-up of 6 (β(SD) = −0.71(0.20)) and of 12 months (β(SD) = −0.54(0.22)). Neither anxiety, nor general psychopathology scores in either conditions were significantly different from each other at any time point (see Table 7).

3.3.3. Psychological flexibility (secondary outcome)

The fitted repeated measures mixed model showed no support for the hypothesis that ACT-DL would foster more psychological flexibility than active control. There was no significant interaction effect for psychological flexibility scores (FIT-60) (Table 5 and Fig. 3), nor was there a main effect of time. Conditions were not different from each other at post-measurement (Table 7).

3.3.4. NA and PA in daily life (secondary outcomes)

The last hypothesis regarding our secondary aim was that ACT-DL would lead to less NA and to more PA in daily life than active control (Table 5 and Fig. 3). In contrast to our expectation, a significant Condition x Time effect suggested that NA scores changed differently over time (χ^2 = 6.55, p = .011), with an increase in these scores in the ACT-DL condition from baseline to post-measurement (β(SD) = 0.38; p = .010). The change from baseline to post-measurement in PA scores (PA) was not different between groups, nor was there a main effect of time. Conditions were not different from each other at post-measurement, neither in NA nor in PA (Table 7).

3.3.5. Self-reporting of improvement

Eighteen (64%) individuals in the control condition and 20 (80%) individuals in the ACT-DL condition (χ^2 = 1.61 p = .205) reported that they felt improved after the intervention. Of the people who reported

improvement (n = 38), two (11%) individuals in the control condition and 14 (70%) in the ACT-DL condition (χ^2 = 12.70 p= < .001) thought that the study had contributed to this change.

4. Discussion

The first aim of the current study was to investigate whether EMI-augmented ACT was a feasible intervention to conduct in a prevention context, in terms of its study design and its daily life use and rated usefulness of (some aspects of) the ACT-DL app on the PsyMate™. It was found that for some participants, it took a relatively long time to start their allocated intervention. Attendance rates were high, especially in the ACT-DL intervention. Furthermore, user evaluations showed that participants did indeed use the daily life component of the ACT intervention. On average, participants rated the ACT-DL metaphors as moderately useful throughout all weeks with frequency distributions showing that 50% of the metaphors were rated as below moderately useful, and 21% of the metaphors rated as not useful at all. These findings suggest that ACT-DL is a feasible intervention in a sample of non-help-seeking emerging adults, but that it could potentially benefit from some alterations in its form and content.

The second aim of the study was to investigate the efficacy of ACT-DL on psychopathology, psychological flexibility, and daily-life NA and PA in comparison to an active control condition. Interestingly, interviewer-rated depression scores in the ACT-DL condition had a steeper decrease over time in comparison to an active control condition, but self-reported symptoms of depression, psychosis-related distress, anxiety, and general psychopathology decreased to an equal extent in both conditions. Furthermore, daily-life NA progressed in the opposite direction of what was expected, with an increase in these outcomes in the ACT-DL condition as opposed to a decrease in the active control condition. There was no increase in psychological flexibility in either condition, nor was there a change in daily-life PA.

4.1. Feasibility of ACT-DL

As to the feasibility of the study design, a first important finding was that participants had to wait a relatively long time until sufficient

Table 7

Means, SDs, and Estimated Differences (95% CI, p-value) between treatment conditions (ACT-DL versus Film) for secondary outcome variables.

Outcome		Film		ACT-DL		Estimated difference with 95% CI and p-value		
		Mean	SD	Mean	SD	Δ	95% CI	P-value
STAI-T	Pre	52.39	1.96	46.80	2.08	−5.59	−11.19; .01	.050
	Post	47.17	2.20	44.84	2.33	−2.33	−8.60; 3.95	.467
	FU6	43.54	2.82	42.26	2.85	−1.29	−9.14; 6.56	.748
	FU12	45.66	2.89	45.05	2.98	−.61	−8.74; 7.51	.883
SCL-90	Pre	170.66	8.91	167.03	9.43	−3.63	−29.07; 21.80	.779
	Post	158.54	8.35	166.60	8.83	8.06	−15.75; 31.88	.507
	FU6	157.48	11.31	151.12	11.85	−6.36	−38.46; 25.74	.698
	FU12	155.26	10.40	151.84	10.49	−4.42	−33.36; 24.52	.765
FIT-60	Pre	169.21	7.25	183.07	7.77	13.86	−6.97; 34.68	.192
	Post	176.82	7.16	193.05	7.57	16.23	−4.20; 36.65	.119
NA	Pre	2.25	.14	2.13	.15	−.12	−.53; .29	.579
	Post	2.08	.17	2.40	.18	.33	−.15; .80	.184
PA	Pre	3.78	.13	4.11	.14	.33	−.04; .69	.079
	Post	3.87	.14	3.96	.15	.09	−.31; .50	.647

Notes. STAI-T (Spielberger, 1983), State-Trait Anxiety Inventory – Trait; SCL-90 (Derogatis, 1977), Symptom Checklist; FIT-60 (Batink & Delespaul, 2015; Batink et al., 2012), The Flexibility Index Test; PA, Positive Affect; NA, Negative Affect; PA and NA were measured with the ESM; SD = standard deviation; Δ = estimated mean group differences; 95% CI = 95% confidence interval (α = 0.05).

baseline measurements were conducted to start the group-based interventions. Related to this, it was relatively difficult to plan the sessions for five consecutive weeks. The young individuals often had irregular schedules or difficulties with transportation. These practical issues suggest that the face-to-face group-format of the current ACT-DL intervention itself might not be suitable in a population of non-help-seeking emerging adults. Indeed, the set-up of different therapy groups may be much easier in help-seeking individuals who have reached out for professional help to specialised mental health care organisations. In this particular study, participants were recruited from the general population with posters and flyers inquiring about their mental health. This made the influx of participants in the study more random and less localised within a particular mental health service. One possibility to tackle these practical challenges in this population might be to alter the group-based intervention sessions to individual sessions. Nevertheless, attendance rates were relatively high in both conditions, suggesting that participants did have a positive attitude towards these group-based interventions.

Another possibility might be to make this intervention purely web- or device-based, to reduce the threshold to attend treatment. Indeed, another important finding was that participants did use the PsyMate™ to integrate ACT in their daily lives with an average of 69 beeps (49%), 15 beep-exercises and 19 on-demand exercises throughout the entire intervention. However, compliance rates to the 31-item beeps in the current study were lower than in other studies, regardless of comparing these rates to studies that used longer 42 – to 52 – item pen – and pencil ESM questionnaires (Rintala, Wampers, Myin-Germeys, & Viechtbauer, 2019), or to other mhealth intervention studies that used shorter ESM questionnaires (Depp et al., 2015; Kramer et al., 2014). This relatively low compliance in turn led to fewer possibilities for participants to get a follow-up exercise. In addition, only in 41% of cases did participants opt to do a beep-exercise, potentially because they may have felt burdened by the previous questionnaire. What is more, the use of the ACT-DL app did decline significantly over the course of the intervention period, and the average usefulness of the ACT-DL metaphors was moderate throughout all weeks, with the percentage of metaphors endorsed higher scores of usefulness being lower than those endorsed lower scores.

These rates, together with the metaphor ratings, may also point in the direction of participants not liking some parts of the intervention or losing initial interest and motivation to use the ACT-DL app, which is in line with previous research on user engagement in mHealth (Michie, Yardley, West, Patrick, & Greaves, 2017; Vandelanotte et al., 2016; Woldaregay et al., 2018). However, there was only a small decline in absolute numbers, and it might as well be possible that individuals used the PsyMate™ less because they were better able to implement the learned skills into their daily lives directly. Furthermore, the large variability in user data suggests that the app was more useful for some participants than for others. Future research needs to look into specific design and usability preferences in this population of non-help-seeking individuals to further optimise and personalise the app's content and format in order to increase compliance rates over a longer period. As to the compliance, it would be of additional interest to investigate whether specific baseline and/or therapy-related factors such as perceived working alliance with the therapist are related to EMI-uptake. This information would not only be useful to know for which individuals these new types of interventions work best, but also, if the client-therapist relationship influences compliance, this may be a strong argument to provide EMIs as part of blended care and not as a stand-alone.

Unfortunately, a limitation of the current study is the lack of an evaluation questionnaire, in which participants could have expressed the usefulness of the ACT-DL intervention and whether or not they would change certain characteristics of it. As such, it remains unclear which component of the ACT-DL training (whether the face-to-face meetings-, the group element, or (parts of) the daily life implementation) the participants found more useful. No research to date specifically examined treatment preferences of young individuals reporting subthreshold symptoms. It would perhaps be informative to conduct more qualitative research by organising discussion sessions with stakeholders. Older adults prefer group interventions over web-based interventions (Van Zoonen et al., 2015). However, since younger adults likely are more familiar with online activities, this will have to be examined specifically in this age group.

4.2. Efficacy of ACT-DL

Related to the preliminary efficacy of ACT-DL on psychopathology, interviewer-rated depression scores had a steeper decline in the ACT-DL condition in comparison to an active control condition. This result was not found in self-reported depression scores, which declined to an equal extent in both conditions. On first thought, the discrepancy between the interviewer-rated versus the self-reported scores could have been explained by confirmation bias (Lilienfeld, Ritschel, Lynn, Cautin, & Latzman, 2014), which means that the interviewers would have interpreted information in such a way that it confirmed the preliminary hypothesis that ACT-DL would lead to a stronger reduction. However, interviewers were blind in the current study and blinding checks were performed. Even after excluding the 25% of the interviews in which deblinding occurred, sensitivity analysis yielded the same results. This in line with a meta-analysis (Cuijpers, Li, Hofmann, & Andersson, 2010), showing that the difference in effects for clinician-rated versus self-reported symptoms within intervention studies was not dependent on whether assessors were blinded or not, since in both cases effects were larger for clinician-rated symptoms.

Secondly, it is possible that an interview is more sensitive to intervention-induced changes than a standardized and validated self-report questionnaire. When participants were asked directly whether they thought they improved, 64% in the film condition and 80% in the ACT-DL condition thought they did (p = .205). This non-significant difference seems to mirror the non-significant condition differences in specific symptom questionnaires in change over time. However, of the people who reported improvement (n = 38), 11% in the film condition and 70% in the ACT-DL condition thought that the study had contributed to this change (p < .001). This could be the result of a confirmation bias on the side of the participants, but the ACT-DL intervention might as well have induced subtle changes in depressive symptoms in the participants, and the in-depth questions of the interviews might have picked up these subtleties.

Last, it should be mentioned that since the MADRS was assessed twice before, and twice after the intervention, analyses on this measure had more power than those with the self-report measure of depressive symptoms (IDS-SR), corroborating the finding that MADRS depression scores did indeed decrease to a greater extent in individuals who were treated with ACT-DL.

Besides an equal decline in self-reported depression scores in both conditions, there were no differences in how self-reported symptoms of psychosis-related distress, anxiety and general psychopathology changed over time. It is possible that a psychological placebo effect occurred (Baskin, Tierney, Minami, & Wampold, 2003; Wampold, Minami, Tierney, Baskin, & Bhati, 2005), in which the control component of social contact and behavioural activation in the film condition were sufficient to induce a positive effect on the subthreshold symptoms of the participants. The social contact within group therapy might foster a feeling of "universality" (Yalom & Leszcz, 2005), disconfirming the feeling that people are unique in their problems, and a "normalization" of symptoms. Feeling isolated in experiencing symptoms of psychopathology may be associated with shame and self-stigma, possibly increasing distress (Rüsch et al., 2014). The realization that other individuals in the group sessions applied for study participation for similar reasons could have normalized symptoms, which in itself might have been enough to reduce distress.

It is also possible that the form or duration of the ACT-DL intervention was not suited for this population. The protocol of this intervention was fine-tuned based on a feasibility study in a clinical population (Batink et al., 2016), and hence might not generalize to a population of emerging adults with subthreshold symptoms. A previous study showed that an early intervention implementation of ACT with minimal and online contact with a counsellor was enough to reduce depression, anxiety, and fatigue, as well as increase positive mental health (Fledderus et al., 2012). The ACT-DL protocol involved both regular meetings as well as performing exercises with the use of the PsyMate™ at home, and this might not have matched the participants' experienced level of need for care. Indeed, it seems that in prevention, more intervention is not necessarily better (Hetrick, Cox, Witt, Bir, & Merry, 2016; Stice, Shaw, Bohon, Marti, & Rohde, 2009), but how much preventive care is effective for which population remains to be investigated.

Third, it was found that neither the experimental, nor the control condition increased on psychological flexibility. In ACT, a shift is made from experiential avoidance as a dysfunctional coping mechanism to a more functional form of coping, namely acceptance. This entails a shift from avoiding, controlling or changing unwanted negative experiences to getting in touch with, living through and accepting them (Hayes et al., 2006). Implementing alternative strategies (e.g. acceptance and defusion) requires changing automatic patterns that probably have been active for years, and that often lead to short-term relief (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996). In other words, this process will take time. As such, an increase in psychological flexibility may take longer than the six-week period ACT-DL intervention, meaning that a significant improvement in flexibility in the experimental condition relative to the control group condition would only have become apparent at 6 – and 12-months follow-up. This argumentation is corroborated by the increase in absolute flexibility scores at post-measurement, as well as by a recent ACT-inspired intervention in adolescents with depression showing that psychological flexibility did only increase significantly from baseline to 3 months follow-up (Blom et al., 2017). Unfortunately, a limitation of the current study was that we did not have a follow-up questionnaire on psychological flexibility. There is a clear need for future studies looking more deeply into how ACT-related processes unfold over time, and whether the development of these processes facilitate improvements in functioning, quality of life, and symptom distress.

A fourth remarkable finding is the increase in daily life NA in the ACT-DL condition after the intervention as opposed to the film condition. This pattern was also found in the initial stability in self-reported psychosis-related distress at post-measurement. In line with the above-introduced argumentation that a shift from experiential avoidance to acceptance is a time-consuming process that may be preceded by the initial development of an increased awareness of unpleasant thoughts or emotions, it is possible that the many prompts within the ACT-DL condition indeed ensured that individuals became more aware of their negative feelings and psychotic experiences. This in turn could then explain the initial higher reporting of these symptoms and distress related to them. However, merely being aware of one's negative experiences is not what the intervention aims for. Ultimately, this process should result in beneficial outcomes. In the case of psychosis-related distress, absolute scores started to decrease again after the end of intervention until the follow-up of 12 months, with scores at the end of the study being lower than they were at baseline, suggesting improvement. It is possible that young individuals only learn at a later stage after treatment how to cope functionally with negative experiences and positive symptom distress and only then get the time and space to invest in what is truly important for them (Hayes et al., 2006). A limitation of the current study is that there was no follow-up data to investigate how NA changed over time, neither whether this would potentially be mirrored in increased psychological flexibility over time. These results argue for ongoing ACT training in daily life after face-to-face therapy sessions have ended.

Finally, the finding that ACT-DL does not affect PA is of interest in the context of the concept of well-being. In the literature, two forms of well-being are often discerned; hedonic and eudemonic (Ryan & Deci, 2001), with the former referring to the experience of pleasure (related to PA), and the latter to whether one lives in accordance with their deeply held values. Even though these forms of well-being are related by positively reinforcing each other (Kashdan, Biswas-Diener, & King, 2008), they can also be separated in that they seem to correlate with different neurobiological systems (Fredrickson et al., 2013). It seems that ACT-DL, at least in the short term, does not affect the hedonic component of well-being. A previous study has shown that ACT can increase flourishing, a measure including both hedonic and eudemonic well-being (Bohlmeijer, Lamers, & Fledderus, 2015).

4.3. Limitations

Some limitations of the current study will have to be taken into account when interpreting the results. First, the sample size in this study was based on effect sizes for fMRI measures rather than on primary outcomes in this study. Although the anticipated sample size for these fMRI measures was almost reached, this does not imply that the sample size was large enough for the measures of interest in this study, and this could potentially have inflated Type-II error. Secondly, since the study did not include a condition that received an ACT intervention without the daily-life add-on component, it is impossible to dissect whether the daily-life add-on component benefited, or potentially even obstructed, the efficacy of ACT. Future clinical trials comparing regular face-to-face ACT training with blended and device- or web-based only ACT might tackle this limitation. In line with the above, it is not fully clear whether the equal decline of self-reported psychopathology in both groups was a mere effect of time. As such, another possibility for a future trial would be to add a third arm with a passive control condition (e.g. waiting list) to investigate the potential beneficial effects of not only the ACT-DL intervention, but also of the active control condition. Third, the timing of the assessment sessions before and after the intervention varied a lot, which might have introduced extra noise in the measurements. This mainly had to do with planning and scheduling issues. However, the number of days between assessments did not differ significantly between both conditions. Fourth, there were difficulties to recruit participants and to find suitable dates to conduct group sessions. Adherence rates to the ACT-DL app were lower than in other studies and in-the-moment visual cues of ACT metaphors were scored as below moderately useful in 50% of the cases. These challenges suggest that future studies may want to consider a different recruitment strategy and set-up of the study, as well as optimise the ACT-DL app to increase compliance. Unfortunately, the study lacked an extensive evaluation questionnaire to assess whether participants thought the intervention was useful and whether they felt that it could benefit from some adaptations. Lastly, ACT is theorised to foster increased psychological flexibility (Hayes et al., 1999), which helps individuals in living in the present moment allowing thoughts and feelings as they are, while behaving consistently with their valued goals (Hayes et al., 2006). As such, the anticipated outcome of ACT is not decreased psychopathology per se, but rather an improvement in psychosocial functioning (Gaudiano, Nowlan, Brown, Epstein-Lubow, & Miller, 2013; Petersen, Krafft, Twohig, & Levin, 2019), quality of life (Forman, Herbert, Moitra, Yeomans, & Geller, 2007), as well as an increased well-being (Bohlmeijer et al., 2015). Indeed, alternative measures of functioning, quality of life and other aspects of well-being may have been more informative therapy outcomes independent of psychopathology. The latter is in line with the finding that individuals in the ACT condition were more likely to attribute their reported improvements to the group sessions than those in the control condition, which suggests that these young individuals did benefit from ACT, although likely on outcomes different from the ones assessed in the current study.

5. Conclusion

This is one of the first studies to implement ACT in an EMI-form (ACT-DL) and to apply it as an early intervention in non-help-seeking emerging adults with subthreshold symptoms of depression and distress related to psychotic experiences, and the first to compare it to an active control condition in this setting. It shows that ACT-DL is a feasible intervention in terms of treatment adherence, both to the group sessions and the ACT-DL app on the PsyMate™. However, in terms of delivery of the training and compliance and rated usefulness of the ACT-DL app, the intervention in this specific population might benefit from some alterations such as the use of an individual format or the use of a purely device- or web-based design. Although mixed findings were found regarding its effectivity, the current study did show that ACT-DL, in comparison to an active control condition, was beneficial in reducing interviewer-rated depressive symptomatology.

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CRediT authorship contribution statement

Evelyne van Aubel: Methodology, Software, Formal analysis, Data curation, Writing - original draft, Writing - review & editing, Visualization. **Jindra Myrthe Bakker:** Conceptualization, Methodology, Software, Formal analysis, Investigation, Data curation, Writing - original draft, Writing - review & editing, Visualization. **Tim Batink:** Conceptualization, Methodology, Validation, Investigation. **Stijn Michielse:** Conceptualization, Methodology, Investigation, Writing - review & editing. **Liesbet Goossens:** Conceptualization, Project administration. **Iris Lange:** Conceptualization, Methodology, Investigation. **Koen Schruers:** Conceptualization, Methodology, Supervision, Project administration, Funding acquisition. **Ritsaert Lieverse:** Conceptualization, Methodology, Supervision, Project administration, Funding acquisition. **Machteld Marcelis:** Conceptualization, Supervision, Project administration. **Thérèse van Amelsvoort:** Conceptualization, Writing - review & editing, Project administration. **Jim van Os:** Conceptualization, Writing - review & editing, Supervision, Project administration, Funding acquisition. **Marieke Wichers:** Conceptualization, Methodology, Writing - review & editing, Supervision, Funding acquisition. **Thomas Vaessen:** Writing - review & editing. **Ulrich Reininghaus:** Methodology, Writing - review & editing. **Inez Myin-Germeys:** Conceptualization, Project administration, Writing - review & editing.

Declaration of competing interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brat.2020.103592.

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