



Shorter communication

Efficacy of an early intervention based on acceptance and commitment therapy for adults with depressive symptomatology: Evaluation in a randomized controlled trial

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ABSTRACT

Objective: The current study examined the efficacy of an early intervention based on acceptance and commitment therapy (ACT) for depressive symptomatology. The ACT intervention is aimed at increasing the acceptance of negative thoughts and emotions and living a mindful and value-based life.

Method: Adults with mild to moderate depressive symptomatology were randomly assigned to the ACT intervention ($n = 49$) or to a waiting list ($n = 44$). The mean age of the participants was 49 years. The majority of the participants was female and of Dutch origin. All the participants completed measures before and after the intervention, as well as three months later at follow-up to assess depression (CES-D), anxiety (HADS-A), fatigue (CIS), alcohol use and acceptance (AAQ-II).

Results: The ACT intervention led to statistically significant reduction in depressive symptomatology (Cohen's $d = .60$). These reductions were maintained at the three-month follow-up. Also significant reductions in anxiety and fatigue were observed. Moreover, mediational analysis showed that the improvement of acceptance during the intervention mediated the effects of the intervention on depressive symptomatology at follow-up.

Conclusion: These findings suggest that an early intervention based on ACT, aimed at increasing acceptance, is effective in reducing depressive symptomatology.

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Introduction

Depression makes a large contribution to the burden of disease worldwide and is the leading cause of the burden of disease in middle- and high-income countries (World Health Organization, 2008). Depression is also associated with high economic costs and increased use of health services (e.g., Cuijpers, Smit, Oostenbrink, et al., 2007; Von Korff, Ormel, Katon, & Lin, 1992). In the last decades many effective treatments for depression have been developed (Cuijpers, Van Straten, Smit, Mihalopoulos, & Beekman, 2008). However, even when the current evidence-based treatments would be optimally implemented, only 40% of the burden of depression will be avoided (Andrews, Issakidis,

Sanderson, Corry, & Lapsley, 2004). Pro-actively offering preventive interventions to people in the community is therefore a necessary complementary strategy for decreasing the burden of disease (Hosman, Jane-Llopis, & Saxena, 2005). Particularly indicated preventive or early interventions are promising (Cuijpers, Smit, & Van Straten, 2007; Cuijpers et al., 2008; Smit, Ederveen, Cuijpers, Deeg, & Beekman, 2006). These interventions aim at people who suffer from clinically relevant symptoms but who do not meet the criteria of a clinical disorder (Mrazek & Haggerty, 1994). The presence of depressive symptomatology can be seen as the most important risk factor for developing a clinical depression (Cuijpers & Smit, 2004). Early interventions in the form of workshops, courses or self-help can be attractive for people who are not in need of psychotherapy or medical treatment as yet (Jorm & Griffiths, 2006).

In the last years several early interventions have been developed (e.g. Lynch, Tamburrino, & Nagel, 1997; Willemsse, Smit, Cuijpers, & Tiemens, 2004). Most interventions are based on cognitive behavior therapy and on the 'Coping with Depression' course in particular (Lewinsohn, Antonucci, Breckenridge, & Munoz, 1984). In this 12-week group course psycho-education is combined with

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several mood management techniques. Cuijpers, Smit, and Van Straten (2007) found a mean effect size of .42 of seven interventions on depressive symptoms.

For early interventions to be effective, a clear model of risk factors and mechanisms in the development of psychopathology is needed (Rapee, 2008). There is growing evidence that in addition to symptoms of depression, experiential avoidance (EA) is such a mechanism involved in depression and other psychopathology. EA has been defined as the unwillingness to remain in contact with experiences such as feelings, thoughts, and bodily sensations, as an attempted means of behavioral regulation (Hayes et al., 2004). A meta-analysis of 32 studies examining the relationship between EA and psychopathology (e.g., anxiety, posttraumatic stress disorder, pain, depression) found a weighted effect size of $r = .42$ (95% CI: .40–.44) (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). Additionally, EA has been found to mediate the effects of maladaptive coping behavior on psychopathology and positive mental health (Fledderus, Bohlmeijer, & Pieterse, 2010; Kashdan, Barrios, Forsyth, & Steger, 2006).

So, early interventions targeting EA and clinically relevant symptoms of depression are warranted from a public mental health perspective (Biglan, Hayes, & Pistorello, 2008). One intervention that has been specifically developed for targeting EA in patients with depression is acceptance and commitment therapy (ACT). ACT is a form a behavioral therapy that focuses on decreasing EA and increasing value-based behavior (Hayes, Strosahl, & Wilson, 1999). Several studies have shown medium to large effects of clinical ACT treatments on depression (e.g., Forman, Herbert, Moitra, Yeomans, & Geller, 2007; Lappalainen et al., 2007).

However, to our knowledge, no studies have been conducted on the efficacy of ACT as an early community intervention for people with clinically relevant depressive symptoms. A group course based on ACT was developed, called “Living to the full” and was proactively offered to the general public. This paper presents the results of a randomized controlled trial with a waiting list as a control group, in which the efficacy of this ACT intervention was assessed for reducing depressive symptomatology. In addition, we were also interested in symptoms of anxiety and fatigue, and the degree of alcohol use. A secondary goal of this paper was to test the effects on EA as an important process factor of ACT.

Method

Procedure and participants

The group intervention was designed as an early intervention for adults of 18 years and older with mild or moderate psychological distress. Study participants were recruited from March to May 2008 through press articles, leaflets and posters, and through psychologists at seven mental health institutions in the Netherlands. In these advertisements the target group of the intervention was described as people who want to live more fully but who are hindered by depressive symptoms. 140 individuals responded and were assessed for eligibility by trained psychologists in clinical face-to-face interviews. Participants with more severe psychological distress and therefore in need of therapeutic treatment were excluded and referred to a mental health institution. Other exclusion criteria were: (a) currently undergoing treatment at a mental health institution; (b) started less than three months ago with psychopharmacological treatment; (c) reporting no psychological complaints or symptoms; or (d) missing two or more sessions of the intervention. 47 individuals were excluded on the basis of these criteria. After signing informed consent, the remaining 93 participants were randomly assigned to the ACT intervention ($n = 49$) or to a waiting list ($n = 44$). An independent researcher carried out the block

randomization for the two groups with stratification on gender and age (<50 and ≥ 50 years), using a computer-generated random sequence of numbers. Participants completed measures on three occasions: at baseline (T0), post-treatment at two months (directly after the intervention) (T1), and follow-up at 5 months after baseline (T2). Fig. 1 provides an overview of the flow of participants. There were 75 (80.6%) participants who filled out the questionnaires three times. The drop-out rate for the intervention was 14.3% (7 out of 49). Table 1 shows an overview of the participants' characteristics. The mean age of the study participants was 49 years (range = 24–71). The majority was female (81.7%) and of Dutch origin (91.4%). They varied in education: 26.9% had less than 13 years of education, 39.8% more than 16 years and 33.3% in-between. Furthermore, 46.2% was married and 52.7% had a paid job.

Measures

All assessments included a primary measure of depression, secondary measures of anxiety, fatigue and alcohol use and EA as a process measure.

Primary measure

Center for Epidemiologic Studies Depression Scale (CES-D). The CES-D (Radloff, 1977) is a 20-item questionnaire that measures depressive symptoms in the general population. Respondents rate on a 4-point scale ranging from *hardly ever (less than 1 day)* (0) to *predominantly (5–7 days)* (3) to what extent they had experienced depressive symptoms in the previous week. Summation of the scores results in a total score ranging from 0 to 60. A score of 16 or higher is considered to indicate the presence of clinically relevant depressive symptoms. The CES-D showed adequate psychometric properties (Radloff, 1977). The Dutch translation showed similar psychometric properties in a group of elderly people in the Netherlands (Haringsma, Engels, Beekman, & Spinhoven, 2004). The scale showed high internal consistency in this study ($\alpha = .88$, T0).

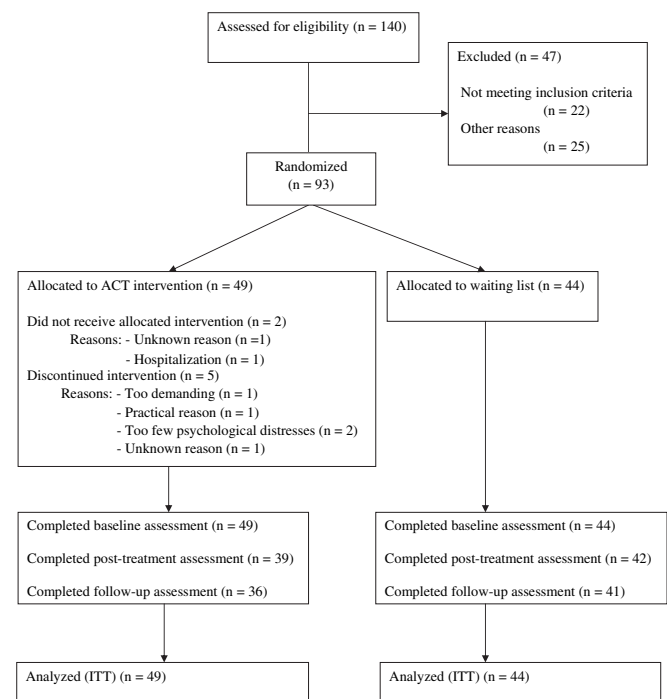


Fig. 1. Flow of participants.

Table 1
Characteristics of participants.

Characteristic	All participants (n = 93)		ACT (n = 49)		Waiting list (n = 44)	
	n	%	n	%	n	%
<i>Gender</i>						
Female	76	81.7	42	85.7	34	77.3
Male	17	18.3	7	14.3	10	22.7
<i>Age (M, SD)</i>	49.02 (10.70)		48.84 (11.34)		49.23 (10.07)	
<i>Marital status</i>						
Married	43	46.2	25	51.0	18	40.9
Divorced	18	19.4	10	20.4	8	18.2
Widowed	3	3.2	0	0	3	6.8
Never married	29	31.2	14	28.6	15	34.1
<i>Race</i>						
Dutch	85	91.4	46	93.9	39	88.6
Other	8	8.6	3	6.1	5	11.4
<i>Education</i>						
<13 Years of education	25	26.9	14	28.6	11	25.0
13–16 Years of education	31	33.3	16	32.6	15	34.1
>16 Years of education	37	39.8	19	38.8	18	40.9
<i>Daily activities</i>						
Paid job	49	52.7	26	53.1	23	52.3
No job	44	47.3	23	46.9	21	47.7

Secondary measures

Hospital Anxiety and Depression Scale-Anxiety subscale (HADS-A). The HADS-A (Zigmond & Snaith, 1983) is a 7-item questionnaire that assesses the presence and severity of anxious symptoms. Respondents rate on a 4-point scale ranging from *not at all* (0) to *often* (3) to what extent they had experienced anxiety symptoms in the previous week. The total HADS-A scores range from 0 to 21. The Dutch translation showed good psychometric properties (Spinhoven et al., 1997). Bjelland, Dahl, Haug, and Neckelmann (2002) showed that an optimal balance between sensitivity and specificity was achieved when caseness was defined by a score of 8 or above. The scale showed high internal consistency in this study ($\alpha = .83$, T0).

Checklist Individual Strength (CIS). The CIS (Vercoulen, Alberts, & Bleijenberg, 1999) is a Dutch 20-item questionnaire and measures four aspects of fatigue: subjective fatigue, concentration, motivation and activity. Only the subscale of subjective fatigue (8 items) was measured in this study, because this scale indicates the severity of fatigue. Respondents rate on a 7-point scale ranging from *yes, that is correct* (1) to *no, that is not correct* (7) to what extent they had felt fatigue in the last two weeks. The summation of the scores gives an indication of the severity of fatigue: <27 indicates normal fatigue, 27–35 indicates heightened fatigue and >35 indicates severe fatigue. The CIS showed good convergent and discriminant validity, and showed high internal consistency in this study ($\alpha = .93$, T0). *Alcohol use* was measured by assessing the number of standard units of alcohol consumed in the preceding week. Respondents rated how many standard units they drank during each of the last 7 days. These were summated to calculate the weekly alcohol consumption.

Process measure

Acceptance and Action Questionnaire-II (AAQ-II). The AAQ-II (Bond et al., submitted for publication) is a 10-item measure of EA. The AAQ-II assesses on a 7-point scale ranging from *never true* (1) to *always true* (7) the subject's willingness to be in contact with negative private events, the acceptance of these events, and whether they can live according to their values. Summation of the scores results in a total score ranging from 10 to 70, whereby a higher score indicates higher acceptance and less EA. The Dutch AAQ-II showed a good factor structure in a general and clinical

population in the Netherlands and good internal consistency in the current study ($\alpha = .86$, T0) (Jacobs, Kleen, de Groot, & A-Tjak, 2008).

Intervention

ACT

The intervention 'Living to the full' consists of eight two-hour weekly sessions. It is a group-based intervention with on average seven participants per group. The intervention was provided by seven teams of two licensed psychologists. These psychologists work at prevention departments of mental health care institutes. All psychologists received a three-day training that was given by two clinical psychologists with ample experience in ACT.

The intervention is based on six core processes of ACT: willingness to experience negative emotions and thoughts, cognitive defusion, contact with the present moment, self as context, values, and committed action (Hayes et al., 2006). In session 1, the basic principles of ACT are explained and participants are encouraged to think about what they really want in life. This is a first exploration of their values. In sessions 2 and 3, the participants reflect on the avoidance and control strategies they are using and whether these strategies are effective in the long run. In sessions 4, 5, and 6, the participants learn how to come into contact with their present experiences, without trying to avoid or control them. Cognitive defusion and experiencing self as context are practised. In the last two sessions, the focus is on becoming aware of the most important personal values and making decisions based on these values. In all sessions participants learn mindfulness skills based on mindfulness-based stress reduction (Kabat-Zinn, 1990, 1994).

Waiting-list control

Study participants assigned to the waiting list received no intervention. After the study ended, these participants were invited to take part in the ACT intervention.

Statistical analyses

The statistical analyses were done using SPSS 17. Independent-samples *t*-tests and chi-square tests were conducted to examine differences between the treatment conditions at baseline.

Intention-to-treat analyses were conducted with the use of SPSS Missing Value Analysis to impute all missing data on the continuous measures with the expectation-maximization (EM) method. This method computes missing values based on maximum likelihood estimates using observed data in an iterative process (Dempster, Laird, & Rubin, 1977). The total percentage of missing data was 10.47% due to unanswered items (.43%) or incomplete assessments (10.04%). These missing values at baseline, post-treatment and follow-up were imputed. Hence, all participants that were randomized were included in the statistical analyses. A comparison of results based on the imputed intention-to-treat sample versus the observed data revealed similar outcomes. Therefore, only the results from the intention-to-treat analyses are reported.

All measures had a normal distribution, except for the measure of alcohol use. To describe this measure, the measure of alcohol consumption was transformed into a dichotomous variable using the current Dutch guideline (Health Council of the Netherlands, 2006), according to which a weekly alcohol consumption of 21 or more standard units per week (for men) and 14 or more (for women) was defined as alcohol misuse. For analyzing, the difference in reported alcohol use between baseline and post-treatment and follow-up was calculated. The non-parametric Mann–Whitney test was used to assess whether this change in alcohol use was different between the ACT group and the waiting-list group. To measure the effects for the other measures, analysis of covariance (ANCOVA) were conducted with the baseline scores as covariates. Comparisons were two-tailed and interpreted with a significance of $p < .05$.

Effect sizes at post-treatment and follow-up were calculated with Cohen's d using the means and the pooled standard deviations of the measurements of the conditions. To interpret Cohen's d an effect size of $d = .2$ was considered small, $d = .5$ was considered medium and $d = .8$ was considered large (Cohen, 1992).

In order to examine whether a reduction in EA (or an improvement in acceptance) during the intervention would mediate the effects of the intervention on depressive symptomatology at follow-up mediational analysis with bootstrapping procedures ($n = 5000$ bootstrap resamples) were used to assess the indirect effect of the mediational pattern outlined by Preacher and Hayes (2008). As prescribed, an indirect effect was considered significant in the case zero was not contained in the 95% confidence interval.

Results

Baseline characteristics

The means and standard deviations for the measures of depression (CES-D), anxiety (HADS-A), fatigue (CIS) and EA (AAQ-II) are presented in Table 2. There were no significant differences at baseline between the ACT group and the waiting-list group for any of the demographic variables or outcome measures, indicating a successful randomization.

The baseline scores of the participants on depression, anxiety and fatigue consistently show clinically relevant symptoms in at least two-thirds of the sample. The scores on acceptance are considerably lower than was found in a general Dutch population (Jacobs et al., 2008), meaning that the participants score high on EA. Most participants reported a safe use of alcohol, and 29 participants drank no alcoholic beverages. In the ACT intervention 8 participants were reporting alcohol misuse and on the waiting list 10 participants.

Intervention attendance

The average number of sessions attended by ACT participants that started with the intervention ($n = 47$) was 7.06, with a range of 2–8. There were 27 ACT participants that attended all the sessions.

Treatment adherence

At the time of the study, a standard measure of therapist adherence was not yet available. However, the therapists at every mental health institution were asked to note in a logbook after every session whether they performed all parts of the session. In total, 88.1% of all the exercises and 92.7% of all the mindfulness exercises were performed in the 8 sessions.

Primary outcome

The results of the ANCOVA as well as the corresponding effect sizes are presented in Table 2. An ANCOVA covarying the baseline assessment of depression, showed significant differences between the groups at post-treatment and at follow-up with more reduction in depression in the ACT intervention compared to the waiting-list

Table 2
Means and standard deviations for measures (baseline to follow-up) and results of ANCOVA and Cohen's d for intervention effects.

Measures	ACT ($n = 49$)		Waiting list ($n = 44$)		F (dt)	p	d
	M	SD	M	SD			
<i>Primary outcome</i>							
CES-D baseline	23.94	9.91	26.11	9.12			
CES-D post-treatment	15.94	10.37	22.07	9.99	9.19 (1,92)	.003	.60
CES-D follow-up	14.78	9.49	21.17	10.71	9.30 (1,92)	.003	.63
<i>Secondary outcomes</i>							
HADS-A baseline	9.65	4.39	11.09	3.91			
HADS-A post-treatment	7.13	4.19	9.71	3.44	7.94 (1,92)	.006	.67
HADS-A follow-up	6.66	3.74	8.74	3.72	4.23 (1,92)	.043	.56
CIS baseline	39.49	11.82	40.52	11.80			
CIS post-treatment	33.80	11.85	39.85	11.31	8.24 (1,92)	.005	.52
CIS follow-up	34.52	11.94	40.32	11.89	7.84 (1,92)	.006	.49
<i>Process measure</i>							
AAQ-II baseline	36.83	11.29	36.68	8.63			
AAQ-II post-treatment	42.98	8.92	37.87	8.54	10.47 (1,92)	.002	.59
AAQ-II follow-up	44.66	10.27	38.39	8.69	14.17 (1,92)	.000	.66

Note. ACT = Acceptance and Commitment Therapy, CES-D = Center for Epidemiologic Studies Depression Scale, HADS-A = Hospital Anxiety and Depression Scale-Anxiety subscale, CIS = Checklist Individual Strength, AAQ-II = Acceptance and Action Questionnaire-II.

group. Results for Cohen's *d* showed medium effect sizes at post-treatment and at follow-up.

Secondary outcomes

A significant difference between the groups was observed for anxiety at post-treatment and follow-up with a greater decrease in anxiety in the ACT intervention. Results also showed that the ACT group had more reduction in fatigue at the post-treatment and at follow-up compared to the waiting-list group. Medium effects sizes were found at post-treatment and at follow-up for the secondary outcomes.

A Mann–Whitney test, using the dichotomous criterion for alcohol misuse, showed no effects of the ACT intervention on alcohol misuse from baseline to post-treatment and follow-up.

Process outcome

Participants in the ACT intervention showed a greater reduction in EA (or improvement in acceptance), both at post-treatment and at follow-up compared to the waiting-list group. Medium effect sizes were found at post-treatment and at follow-up.

Mediational analyses with EA

The results of the mediational analysis are presented in Table 3. Step 1 in Table 3 shows that, controlling for CES-D and AAQ-II at baseline, the ACT intervention significantly reduced depressive symptomatology at follow-up. Step 2 in Table 3 shows that the improvement of AAQ-II from baseline to post-treatment significantly predicted scores on the CES-D at follow-up. The treatment effect is reduced with 43% and becomes non-significant. Mediational analysis, following Preacher and Hayes (2008) showed that the mediating effect of improvement of AAQ-II from baseline to post-treatment is significant ($p < .05$), with bootstrapping values between -4.10 and $-.67$.

Discussion

Depression is one of the most prevalent disorders in the world. In order to reduce this prevalence, a public mental health approach is needed in addition to effective treatment in clinical settings (Hosman et al., 2005). In this study it was found that a small-group course based on acceptance and commitment therapy (ACT) has beneficial effects on depressive symptoms and may be useful in such a public mental health approach. Among ACT participants the average level of depressive symptomatology decreased significantly to a level below the cut-off score (16) for clinical relevant levels of symptoms (Radloff, 1977), while among the waiting-list control group depressive symptoms remained well above this cut-off score. This effect was maintained at three-month follow-up. As the presence of clinically relevant depressive symptoms is known

to be an important risk factor for clinical depression (Cuijpers & Smit, 2004), this outcome suggests that early treatment with ACT may decrease the risk of developing a (next) full clinical depression. This risk is also associated with experiential avoidance (EA) (Biglan et al., 2008; Hayes et al., 2006; Kashdan et al., 2006). The ACT intervention specifically targeted EA. In this respect it is meaningful that medium effect sizes were found on EA, and that a reduction in EA during the intervention mediated the treatment effect on depressive symptoms at three-month follow-up. This implies that longer term effects of ACT are mediated by the effects on EA. This finding corroborates the underlying theoretical model on which ACT is built.

In addition to depressive symptoms, the intervention showed similar effects on symptoms of anxiety and fatigue. The reduction in fatigue is an important finding, because fatigue is related to both poorer psychological and physical health (Cardol, Bensing, Verhaak, & de Bakker, 2005). These findings suggest that an early intervention based on ACT may play a role in reducing a broad spectrum of psychological distress. This is consistent with earlier studies that found that EA is related to a wide variety of measures of psychopathology (Hayes et al., 2006). No significant reduction in alcohol use was found. Possibly, this outcome is due to low statistical power on this secondary outcome, as 18 of 93 participants reported hazardous alcohol consumption, and a binary outcome measure was used in the analyses.

This study corroborates the findings of earlier studies that showed that ACT is effective in substantially reducing depressive symptomatology of community dwelling people (Forman et al., 2007; Lappalainen et al., 2007). The results also support findings from previous studies that early interventions implemented as a course (e.g. the Coping with depression course) can substantially reduce depressive symptomatology (Cuijpers, Smit, Oostenbrink, et al., 2007). To our best knowledge this is the first study that explored the effects of a similar course based on ACT.

It was recently discussed that early interventions, in order to have a large impact on public mental health, should have a number of characteristics (Cuijpers, Van Straten, Warmerdam, & Van Rooy, 2010). An intervention should be offered in a framework that reduces the stigma associated with depression, because this is one of the main reasons people are unwilling to participate. Furthermore, the intervention should also focus on other mental illnesses for reaching larger groups for preventive services. We think that ACT is especially suited for these types of early or indicated preventive interventions. First, ACT is based on a positive health model and not on a disease model (Hayes et al., 1999). This allows an intervention to be framed positively more easily. Second, ACT targets a risk factor, EA that is relevant for various mental illnesses and thus may have a broad trans-diagnostic impact (Hosman et al., 2005). This was confirmed by our study. However, more elaborate studies are needed to substantiate this claim. Another interesting focus for future studies is the question whether early treatments are more effective in participants who are at risk of a first-time depressive episode than in participants with a history of chronic or recurrent episodes.

Limitations

Several important limitations have to be pointed out. First, no diagnostic instruments were used in the study, so it was unclear how many participants suffered from a mental disorder before and after the intervention. Also, our study relied on self-report measures and used no clinician ratings. Second, the number of participants using psychopharmacological treatment longer than three months prior to baseline and changes in psychopharmacological doses was not assessed. Third, the use of a waiting list as a control group is sub-optimal because confounding by nonspecific

Table 3

Hierarchical regression analysis of CES-D at follow-up on intervention, baseline CES-D, baseline AAQ-II, and improvement of AAQ-II between baseline and post-treatment.

CES-D (T2)	Step 1 Beta	Step 2 Beta
Intervention group (comp: control group)	-.228**	-.130
Baseline CES-D (T0)	.682***	.568***
Baseline AAQ-II (T0)	.117	-.177
Improvement in AAQ-II (T1–T0)		-.419***
Explained variance (adjusted R^2)	.474	.568 ^a

** $p < .01$; *** $p < .001$.

^a Significant improvement in R^2 change ($p < .05$).

factors cannot be controlled for. This implies that the effects on the outcome and process measures cannot be assigned to the specific ACT components. Furthermore, we did not assess the outcomes of participants in the waiting list after they had received the intervention because we included a three-month follow-up period for both the intervention group and waiting-list group and because of budgetary restraints. However, performing a post-treatment assessment in the waiting-list group would add further evidence of the efficacy of the intervention if it can be shown that depressive symptoms were reduced to a similar level as the intervention group at post-treatment. Fourth, due to the relative short follow-up period data on sustained effects are not yet available. Fifth, treatment adherence was not assessed by independent evaluators who have been trained to assess reliability.

Conclusion

Despite the limitations, it can be concluded that the findings provide initial support for efficacy of an early intervention based on ACT within a public mental health approach. The intervention Living to the full has now been implemented in about 50% of Dutch mental health care institutes. Further research is needed to determine the efficacy of this intervention, for example among different populations. This research should preferably include the use of diagnostic instruments, an active control group and a longer follow-up period.

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