Original article

Effects of momentary self-monitoring on empowerment in a randomized controlled trial in patients with depression

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A B S T R A C T

Background: Interventions based on the experience sampling method (ESM) are ideally suited to provide insight into personal, contextualized affective patterns in the flow of daily life. Recently, we showed that an ESM-intervention focusing on positive affect was associated with a decrease in symptoms in patients with depression. The aim of the present study was to examine whether ESM-intervention increased patient empowerment.
Methods: Depressed out-patients ($n = 102$) receiving psychopharmacological treatment who had participated in a randomized controlled trial with three arms: (i) an experimental group receiving six weeks of ESM self-monitoring combined with weekly feedback sessions, (ii) a pseudo-experimental group participating in six weeks of ESM self-monitoring without feedback, and (iii) a control group (treatment as usual only). Patients were recruited in the Netherlands between January 2010 and February 2012. Self-report empowerment scores were obtained pre- and post-intervention.
Results: There was an effect of group × assessment period, indicating that the experimental (B = 7.26, $P = 0.061$, $d = 0.44$, statistically imprecise) and pseudo-experimental group (B = 11.19, $P = 0.003$, $d = 0.76$) increased more in reported empowerment compared to the control group. In the pseudo-experimental group, 29% of the participants showed a statistically reliable increase in empowerment score and 0% reliable decrease compared to 17% reliable increase and 21% reliable decrease in the control group. The experimental group showed 19% reliable increase and 4% reliable decrease.
Conclusions: These findings tentatively suggest that self-monitoring to complement standard antidepressant treatment may increase patients' feelings of empowerment. Further research is necessary to investigate long-term empowering effects of self-monitoring in combination with person-tailored feedback.

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1. Introduction

Electronic momentary assessment with the experience sampling method (ESM) allows for precise and prospective monitoring of emotions. ESM consists of repeated assessments of affective experience and context in the flow of daily life [1,6,22]. These momentary assessments may reveal subtle repetitive and relevant patterns of experience in response to environmental and mental challenges [10,39]. Research employing ESM has shown the relevance of these patterns for the understanding of mental ill health [34,36,31,35,4], and highlights the relevance of focusing on moments of positive affective experiences in predicting resilience against psychopathology [5,37,17] and treatment response [42,13]. These momentary assessments may also be used at an individual level, as input for personalized feedback on dynamic patterns of emotions [8,40,33,41].

ESM-intervention, by transforming implicit, moment-to-moment emotional reactivity to explicit, visualized configurations, may help increase self-awareness of, and control over, daily life

dynamics that may impact on depression. In contrast, antidepressant pharmacotherapy, as a single intervention, does not provide incentives for patients to actively engage in their treatment; yet mobilizing patient engagement in the treatment and decision making process may enhance treatment adherence, patient satisfaction and patient empowerment [28,25,27,30]. ESM-intervention has the benefit that it can be easily implemented in standard mental health care and does not require much additional investment of clinicians; even more, ESM provides ecologically valid and detailed information on fluctuations in the individual's mental state that may be utilized to optimize treatment effects e.g. by individualizing the delivery of psychological interventions [19].

Recently, it has been shown that the efficacy of traditional psychopharmacological treatment of major depression can indeed be enhanced using ESM-derived person-tailored daily life feedback on patterns of positive affect [20]. It was demonstrated that this ESM-intervention was associated with a linear decrease in depressive symptoms in the six months following the intervention, a pattern not observed in the other two conditions. The present study further examined the effects of this ESM-intervention by investigating its effects on patients reported empowerment. With ESM-intervention, mental health problems may be better monitored and managed with the participation of the patient him/herself, giving the patient an active role in the treatment process and mobilizing individual resources. One of the potential mechanisms explaining the impact of person-tailored daily life feedback thus may involve patient empowerment. Empowerment is recognized as a dynamic, contextually-driven multidimensional construct that can be conceived of as a social process of enhancing an individual's ability to meet their own needs, solve their own problems, and mobilize the necessary resources in order to feel in control of their own lives [14,43]. Person-tailored daily life feedback may thus increase patient empowerment in the sense of having better information, more informed choices and thus enhanced shared decision-making [34,15]. However, the effects of actively involving patients with depression in the data collection and interpretation of daily life mental states on patient empowerment have not been examined.

2. Aims of the study

This study examined whether providing patients with tools to self-monitor their own mental states increases experienced empowerment. It was hypothesized that self-monitoring combined with person-tailored daily life feedback increases patient empowerment.

3. Methods

3.1. Participants

For the current randomized controlled trial (registered in the Dutch trial register, www.trialregister.nl, trial id: NTR1974) [20], participants were recruited between January 2010 and February 2012 via mental health care facilities in or near the Dutch cities of Eindhoven and Maastricht, and through local advertisements. The study was approved by an institutional review board (Medical Ethics Committee of Maastricht University Medical Centre; id: NL26181.068.09/MEC 09-3-013) and all participants provided written informed consent before their enrolment.

Participants were considered eligible when they were between 18 and 65 years of age; a DSM-IV-TR diagnosis of depressive episode (assessed with the Structured Clinical Interview for DSM-IV Axis I Disorders [SCID-I] [11]) with current or residual symptoms (17-item Hamilton Depression Rating Scale (HDRS)

score of >7 [16]); treated with antidepressants or mood stabilizers. Participants were excluded if they met criteria for a non-affective psychotic disorder according to DSM-IV or if they reported a (hypo) manic or mixed episode within the past month.

3.2. Design

A randomized controlled trial was conducted with three parallel treatment arms [20]. After completion of all baseline assessments, participants were randomly allocated to the experimental, pseudo-experimental, or control group. In addition to treatment as usual (TAU), the experimental group participated in an ESM procedure (three days per week over a six-week period). This group received weekly standardized feedback on personalized patterns of positive affect. The pseudo-experimental group also participated in the ESM procedure (three days per week over a six-week period) in addition to TAU, but without feedback. The control group received no additional intervention during TAU.

Randomization (allocation ratio 1:1:1) was stratified by (i) duration of antidepressant pharmacotherapy (receiving the current antidepressant or mood stabilizing medication for shorter vs. longer than 8 weeks prior to study entry), and (ii) current psychotherapy (yes or no). Interviewers were not blind to the patients' treatment allocation. After randomization, the participants were considered part of the study regardless of whether they decided to leave the study prematurely.

Participants allocated to the experimental group engaged in a weekly three-day ESM procedure for six consecutive weeks and received standardized feedback based on the participant's ESM data in six feedback sessions, in addition to TAU. The pseudo-experimental group was identical in procedure to the experimental group except that no feedback was given. Instead, during these weekly sessions, participants engaged in a structured conversation with the researcher, i.e. an HDRS interview, to keep duration of contacts equivalent to the experimental group. During these six consecutive weeks, participants allocated to the control group received TAU only.

3.3. Procedure

The study protocol consisted of a telephone interview, a screening, a baseline assessment (week 0), a six-week intervention period (weeks 1 to 6), a post-assessment (week 7), and five follow-up assessments (at weeks 8, 12, 16, 20, 32). The recruitment process started with a short telephone interview conducted by a psychologist or psychiatrist to establish whether inclusion criteria were likely met. During a face-to-face screening, two weeks before randomization, the SCID-I and HDRS were administered to assess whether individuals met inclusion criteria. ESM-assessments took place as part of the baseline assessment, during the six-week intervention period, and at the post-assessment. Empowerment was assessed twice, at screening and at post-assessment, with nine weeks between the two assessments. Fig. 1 shows participant flow and procedure throughout the trial period from enrolment to post-assessment.

3.4. Empowerment

Empowerment was assessed with the Dutch Empowerment questionnaire [3]. This is a 40-item self-rating scale to assess patient empowerment developed by the Dutch Trimbos Institute and validated for use in severe mental illness (see [32] for an English translation). It incorporates the dimensions professional help, social support, own wisdom, sense of belonging, self-management, and community inclusion. Items are formulated in positive statements of strengths as perceived by the participant
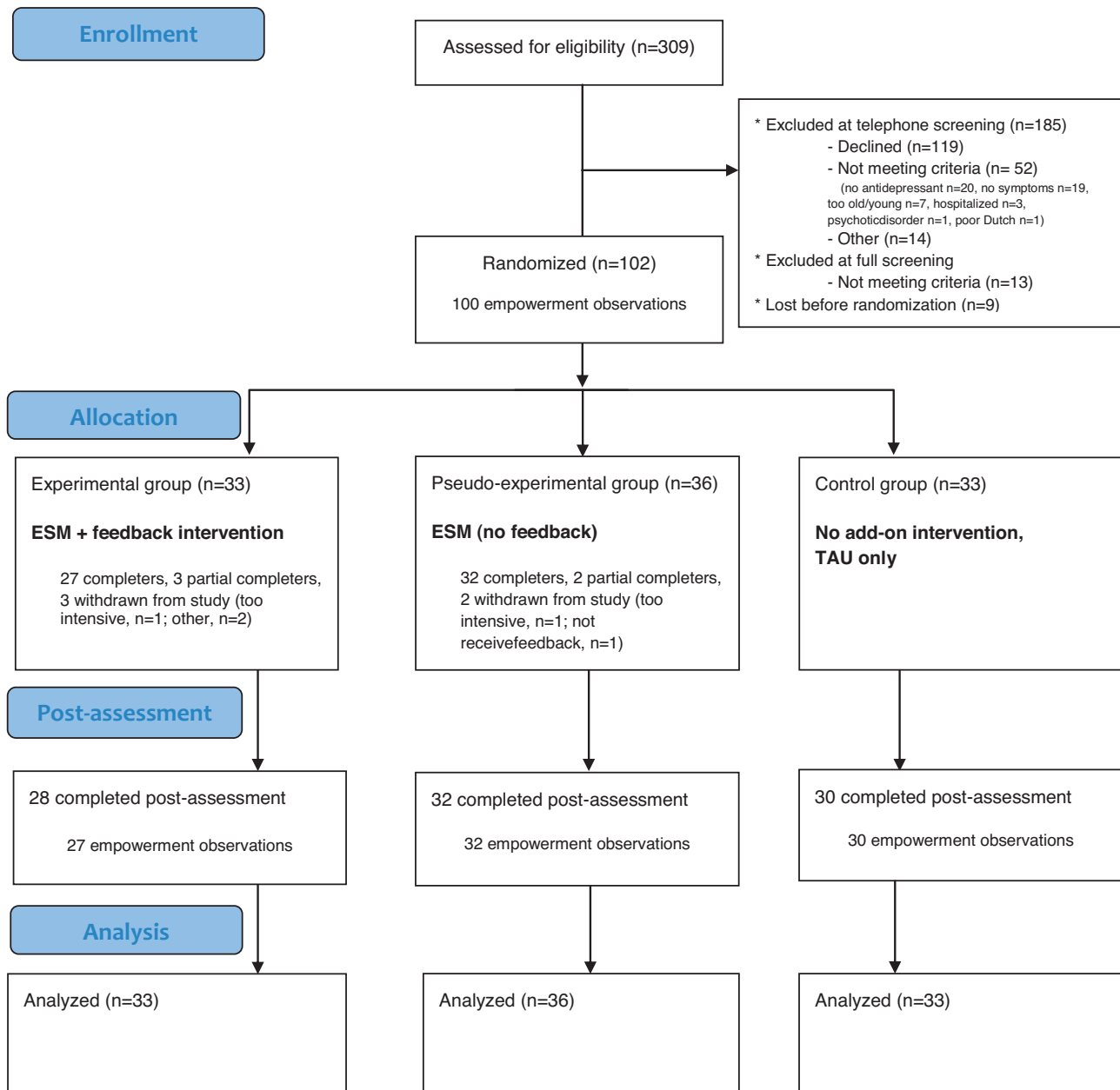
Fig. 1. Flow diagram of the study. ESM: experience sampling method; TAU: treatment as usual.

and are rated on five-point Likert scales ranging from 1 ('strongly disagree') to 5 ('strongly agree'), with four items regarding professional health care having the additional option 'not applicable'. A total score (range 40–200) was calculated, with higher scores indicating more empowerment. Cronbach's alpha for the 40 items was 0.92 at pre-assessment and 0.94 at post-assessment. Previous research has shown a similar Cronbach's alpha of 0.93 and has indicated satisfactory construct validity with correlations with related instruments ranging from small to large in the expected directions [3].

3.5. Experience sampling method

ESM, a validated, structured diary technique consisting of repeated in-the-moment micro-measurements of affect and context, was carried out in accordance with previous studies [6,8,21,38,24]. Participants received a dedicated electronic ESM device ('PsyMate' [23]) to digitally collect daily life momentary assessments of affect, activity and context. The PsyMate was programmed to emit a signal (beep) ten times per day at random intervals in each of ten 90-min time blocks between 07:30 am–10:30 pm, prompting participants to fill in self-assessments. At each beep, participants used the PsyMate to digitally complete a brief questionnaire including current affect (positive and negative affect) as well as current context and activities ("daily life activities", "people present", "physical activity", and "events"). Positive affect indicators included the adjectives "cheerful", "satisfied", "enthusiastic" and "relaxed". Negative affect was indexed by the adjectives "down", "suspicious", "guilty", "irritated", "lonely" and "anxious". The self-assessments were rated on 7-point Likert scales (ranging from 1 = "not at all" to 7 = "very"). Participants were instructed to complete the questionnaire as quickly as possible after the beep.

The ESM procedure was explained to the participant in an initial briefing session, and a practice run was performed to ensure that the participants understood the questions and the device.

3.6. Intervention

For six consecutive weeks, participants in the experimental group received standardized feedback based on the participant's ESM data. The six feedback sessions immediately followed the weekly three-day ESM procedure. In these face-to-face sessions, protocolled feedback was provided by the researcher (a psychologist or psychiatrist, $n = 5$). Feedback on participants' momentary affective state in specific daily life contexts and the association with depressive symptoms was given verbally, graphically, and in writing. Feedback showed actual levels of positive affect in the context of daily life activities, events, and social situations, and changes in positive affect level over the course of the ESM-intervention (see [20] for examples). A written bullet-point summary report of the feedback based on a fixed template was given to both the participant and the mental health professional.

3.6.1. Feedback structure

Every feedback session consisted of two parts. In the first part, information with respect to experiences during the most recent week was presented. In the second part, this information was placed in the context of the previous ESM weeks.

3.6.2. Feedback content

The feedback intervention was divided in three modules. Each feedback session consisted of information regarding magnitude of and fluctuations in positive affect experienced during the past week was presented, as well as graphs displaying the course of experienced positive across the weeks. In addition to these fixed feedback elements, the first two weeks of the intervention (module 1), focused on positive affect experience during daily activities. The third and fourth week (module 2) focused on daily events differentiating between affect experienced during events appraised with an internal vs. external locus of control. The last two weeks (module 3) focused on positive affect experienced during social interactions in daily life.

3.7. Statistical analysis

Statistical analyses were conducted using STATA 13.1 [26], using all available data from participants included at randomization. The data had a hierarchical structure. This means that multiple assessments (pre- and post-assessment) of empowerment are clustered within participants. Multilevel regression analysis is suitable for this type of data because it takes the variability associated with each level of nesting into account. It is preferred to ANOVA, because it processes all available data and can handle missing values, thus retaining statistical power. The xtmixed command was used to perform a multilevel regression analysis with the two-way interaction between assessment (pre- vs. post-intervention) and group as fixed effects and participants as random effects. Model fit was restricted maximum likelihood. Estimated between- and within-group effects were calculated by linear combination of the appropriate terms in the model containing the assessment $\times$ group interaction term (Stata's Lincom Procedure). Between-group differences were also translated to standardized mean differences (Cohen's d) using the pooled standard deviation of the observed scores obtained at pre-assessment.

Additionally, groups were compared at the level of individual participant change. A reliable change index was calculated according to the widely used method of Jacobson and Truax [18]: (empowerment score at post-assessment – empowerment score at pre-assessment)/SE_{diff}. The standard error of the difference, SE_{diff}, was calculated using the formula $SE_{diff} = \sqrt{(2[S_1\sqrt{(1 - r)}]^2)}$, where S_1 is the standard deviation ($SD_{pre} = 18.4$) and r is the reliability, in this case the internal reliability (Cronbach's $\alpha_{pre} = 0.92$). Individual reliable change scores >1.96 were considered to reflect statistically reliable positive change; change scores < -1.96 reflected reliable negative change; and change scores in between these values reflected no reliable change [18]. X^2-tests were used to test for differences between groups in the proportions of participants showing statistically reliable change (increased, decreased, no change).

4. Results

Characteristics of the included participants sample are shown in Table 1. Of the 69 patients allocated to the experimental or pseudo-experimental group, 59 (85.5%) completed the six-week intervention period; number of attended intervention sessions did not differ between these groups ($F(1, 68) = 1.66$, $P = 0.20$). There was no significant difference in baseline HDRS depressive symptoms between patients who fully completed the intervention period and those who did not ($B = 0.76$, $P = 0.72$).

Pre-intervention empowerment scores were available for respectively 32 of 33 (control), 35 of 36 (pseudo-experimental), and 33 of 33 (experimental) participants. Post-intervention empowerment scores were available for 30 (control), 32 (pseudo-experimental), and 27 (experimental) participants. Two participants had incomplete assessments of empowerment (front page only, i.e. 15 items), their total scores (mean item score $\times$ 40) were retained in the analyses. Analyses were thus conducted in 102 participants of whom 87 had pre- and post-assessment empowerment scores (i.e., 189 observations).

Table 1
Characteristics of study participants at screening.

Variable	Total (n = 102)	Experimental (n = 33)	Pseudo-experimental (n = 36)	Control (n = 33)	Between-group comparison	
					Test parameter	P
Age	48.0 (SD = 10.2)	48.7 (SD = 10.2)	46.7 (SD = 9.6)	48.9 (SD = 10.9)	$\chi^2_{df=2} = 2.06$	0.36[a]
Sex M/F	46/56	17/16	14/22	15/18	$\chi^2_{df=2} = 1.11$	0.57
Ethnicity: Dutch	91	27	35	29	$\chi^2_{df=2} = 4.34$	0.11[b]
Educational level						
No/primary low secondary	25	6	9	10		
High school/low vocational	38	12	14	12	$\chi^2_{df=4} = 1.73$	0.79
Higher vocational/university	39	15	13	11		
Full- or part-time work	35	13	10	12	$\chi^2_{df=2} = 1.12$	0.57
Illness/unemployment benefits	62	18	20	24	$\chi^2_{df=2} = 1.06$	0.59
Living with partner/own family	53	18	17	18	$\chi^2_{df=2} = 0.50$	0.78
Bipolar disorder	9	5	2	2	$\chi^2_{df=2} = 2.43$	0.39
DSM axis-I comorbidity	40	12	16	12	$\chi^2_{df=2} = 0.64$	0.73
Empowerment scores	126.9 (SD = 18.4)	126.9 (SD = 17.5)	124.6 (SD = 19.6)	129.5 (SD = 18.2)	$F_{(99,2)} = 0.56$	0.56

[a] Kruskal-Wallis test adjusted for tied ranks.
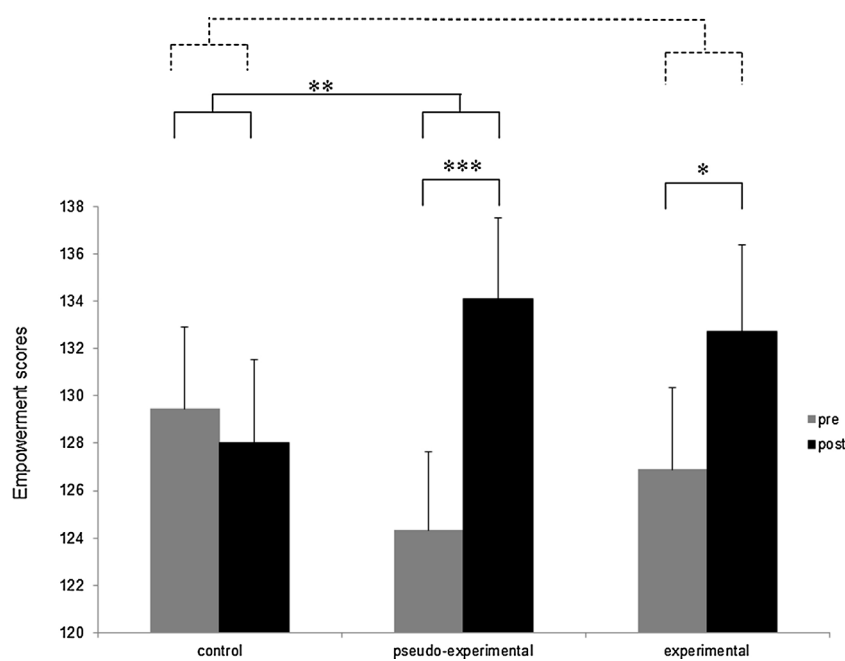[b] Fisher exact P-value.

Fig. 2. Estimated marginal means with standard errors for pre- and post-intervention empowerment sum scores, stratified for condition [$n = 102$, 189 obs]. $^*P < 0.05$, $^{**}P < 0.01$, $^{***}P < 0.001$, dashed line $P < 0.10$.

The results from the multilevel regression analysis are displayed in Fig. 2. The experimental group as well as the pseudo-experimental group showed a significant increase in empowerment scores from pre- to post-assessment (B = 5.85, 95% CI 0.40–11.29 $P = 0.035$, and B = 9.78, 95% CI 4.68–14.87, $P < 0.001$, respectively). The experimental group, compared to the control group, showed a larger, but statistically imprecise, increase in empowerment sum scores from pre- to post-assessment (B = 7.26, 95% CI −0.32–14.84, $P = 0.061$, $d = 0.44$). The pseudo-experimental group also showed a significantly larger increase in empowerment sum scores from pre- to post-assessment compared to the control group (B = 11.19, 95% CI 3.86–18.52, $P = 0.003$, $d = 0.76$). The experimental group did not differ significantly in pre-to-post change in empowerment scores compared to the pseudo-experimental group (B = −3.93, 95% CI −11.38–3.52, $P = 0.30$, $d = −0.37$).

At post-assessment, however, there were no significant between-group differences in empowerment scores (experimental vs. control group: B = 4.70, 95% CI −5.18–14.59, $P = 0.35$, $d = 0.36$; pseudo-experimental vs. control group: B = 6.07, 95% CI −3.50–15.64, $P = 0.21$, $d = 0.23$; experimental vs. pseudo-experimental group: B = −1.37, 95% CI −11.07–8.34, $P = 0.78$, $d = −0.04$).

Fig. 3 shows the changes in empowerment scores (post-assessment minus pre-assessment) and the cut-off levels of the 95% confidence interval of the Jacobson-Truax reliability change index [18]. In the pseudo-experimental group, 29% of the participants showed a reliable increase and 0% a reliable decrease, in the experimental group 19% showed a reliable increase and 4% a reliable decrease, compared to 17% reliable increase and 21% reliable decrease in the control group. The pseudo-experimental group differed significantly from the control group in terms of individual change scores ($\chi^2 = 7.48$, Fisher exact $P = 0.02$), whereas the experimental group did not differ significantly from the control group ($\chi^2 = 3.74$, Fisher exact $P = 0.18$).

5. Discussion

Experience sampling methodology allows for the collaborative monitoring of symptoms and context to aid person-tailored treatment. Instead of being a passive receiver of care, the patient

assumes an active role, possibly enhancing empowerment and mobilizing individual resources. The results of the current study are inconclusive. Allocation to the six-week ESM-intervention with personalized feedback was associated with an increase in empowerment scores, whereas no pre-to-post change in empowerment scores was observed in the control group. This tentatively suggests that the use of ESM to complement standard antidepressant treatment may indeed increase empowerment in patients suffering from mild to severe depressive symptoms. However, these results need to be carefully interpreted given that no between-group effects were observed at post-assessment and the larger increase in the experimental compared to the control group was statistically imprecise. Furthermore, there were no significant differences between the experimental and pseudo-experimental group, and only the pseudo-experimental group showed a significantly higher percentage of participants with reliable increase in empowerment compared to the control group. These
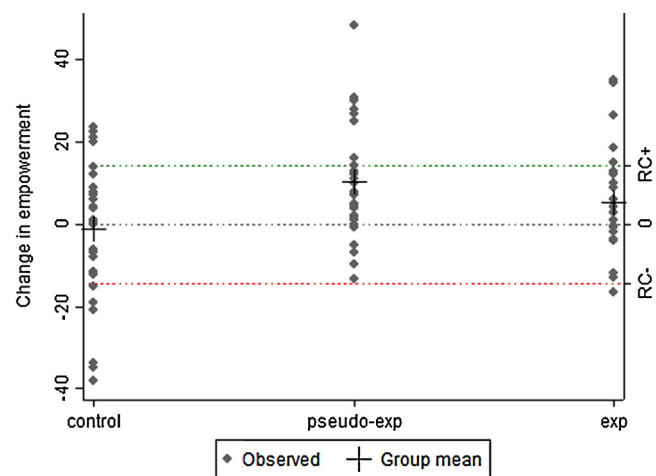

Fig. 3. Scatterplot of post-minus pre-assessment empowerment scores, stratified for condition [$n = 87$]. RC–is lower threshold (reliable decrease) for reliable change, RC+ is upper threshold for reliable change (reliable increase); control: control group; pseudo-exp: pseudo-experimental group; exp: experimental group.

results may suggest that ESM self-monitoring (independent of feedback) may be beneficial with regard to feelings of empowerment, as ESM self-monitoring may allow patients to become more mindful of affective states, increasing awareness of variability of their emotions, including moments of high affective states [29]. However, it cannot be excluded that the increase in empowerment scores is attributable to the weekly in-the-office appointments in the intervention period.

In contrast to the hypothesis, the experimental group did not show larger effects on empowerment compared to the pseudo-experimental group that received ESM self-monitoring without feedback. It may be hypothesized that providing the patient with systematic feedback about self-collected ESM-data, and, more specifically, feedback focused on daily positive affective experience, is an important factor in empowering patients, by giving patients insight into their own strengths and moments of daily life successes, setting the path for potential self-reinforcing changes in daily life dynamic patterns. That is, the feedback focused on daily life patterns of positive affect may motivate an individual to explore activities evoking positive affect in daily life, engagement in these activities leads to increased positive affect, which may broaden attention towards reward-oriented behaviors, increasing the likelihood of future experiences of positive affect [12]. ESM feedback intervention could thus be a tool for creating affective changes through behavioral activation, which has been shown to be an effective strategy in reducing depressive symptoms [9,7]. The present study, however, could not support a (additional) beneficial role of providing feedback in terms of increasing patient's self-reported empowerment at immediate post-assessment. It may be argued that effects of self-monitoring interventions may not be observable directly after the intervention, because patients need some time to apply their newly developed insight about their dynamic emotional patterns into their daily lives and to experience changes in their daily lives as a result thereof, and only then may feel more empowered. In line with this, effectiveness of the feedback intervention in terms of reduction of depressive symptoms was not evident directly after the intervention [20]. Initially, both the experimental group receiving ESM with feedback and the pseudo-experimental group receiving ESM without feedback showed a decrease in depressive symptoms. However, depressive symptoms in the experimental group continued to decline over the six-month follow-up period, whereas the depressive symptoms in the pseudo-experimental group again worsened during the follow-up period. It may be speculated that empowerment scores also continued to increase in the experimental group during the follow-up period, whereas the pattern of empowerment scores over time may have been different in the other two groups.

The inconclusive findings may also relate to difficulties with the concept of empowerment and its operationalization. Empowerment is a complex construct and relying only on a single self-report questionnaire at post-assessment is likely insufficient to capture the mechanisms explaining the impact of ESM-intervention. However, empowerment is a key component in recovery that is only weakly and inconsistently related to symptoms, and it is important to assess subjective evaluations of constructs of the self, like empowerment, in addition to assessing symptoms [2]. More research is therefore necessary to investigate long-term effects of self-monitoring in combination with feedback on patient empowerment.

5.1. Limitations

Owing to the nature of the intervention, it was not possible to blind participants, which may have biased the outcomes of the trial. However, if knowledge of allocation resulted in biased empowerment ratings by the patient one would, in contrast to the current results, expect that the experimental group (relative to the control group) demonstrated the largest increase. Instead, the pseudo-experimental group showed the largest increase in empowerment scores. Interviewers were also not blind to treatment allocation, but effects of interviewer bias may be considered minimal given that the assessment of empowerment relied on a self-report questionnaire.

The trial was limited to three arms. It was designed to address the question of interest whether ESM self-monitoring in combination with feedback would be efficacious in reducing depressive symptoms, not to address the question whether ESM self-monitoring *per se* would be efficacious. The lack of an arm that consisted of self-monitoring only without weekly visits to the researcher or, alternatively, an arm with weekly visits to the researcher without self-monitoring, precludes separating effects of self-monitoring from effects attributable to the weekly contacts.

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