The power of visualization: back to the future for pain management in fibromyalgia syndrome

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Abstract

Objective: Previous studies have demonstrated the effects of positive psychological factors on pain adjustment. Specifically, optimism has been linked to better physical functioning and less psychological distress. Until recently, these beneficial effects have mostly been examined in correlational studies or laboratory settings. The aim of this study is to test the efficacy of the Best Possible Self intervention using information and communication technologies with fibromyalgia patients.

Methods: Seventy-one patients were randomly allocated to the Best Possible Self intervention or a Daily Activities control condition. The Best Possible Self intervention used an interactive multimedia system with the support of an Internet platform to practice the guided imagery exercise online.

Results: Intent-to-treat analyses showed that, compared to the control condition, Best Possible Self patients showed significant improvements in depression, positive affect, and self-efficacy at post-intervention. Moreover, at 3-month follow-up, patients that received the intervention improved their optimism and negative affect significantly more than participants in the control condition.

Discussion: This study shows how a technology-supported intervention aimed at augmenting positive affect and promoting positive functioning works in the case of fibromyalgia, expanding the intervention's efficacy data in clinical populations and adding knowledge about the role that positive psychological factors play in pain experience. Moreover, it demonstrates the specific effects of the Best Possible Self intervention in order to incorporate this exercise in pain treatment protocols.

Keywords: fibromyalgia, treatment outcome, optimism, best possible self, self-efficacy

Introduction

Fibromyalgia syndrome (FMS) is a chronic widespread pain condition characterized by fatigue, functional disability, disturbed sleep, cognitive impairment, and mood disorders [1]. Due to the heterogeneity in the presentation and severity of symptoms among patients, to date, no specific psychological or pharmacological treatment has been found to be equally effective for all patients. FMS patients take more medication, make six more yearly medical visits, and show a higher average of work days missed than the reference population [2]. FMS affects up to 3% of the population, and these data suggest annual incremental costs of up to approximately €12 billion for a population of 80 million for every year these patients are not treated [3].

FMS patients experience significantly low levels of quality of life that remain stable over time, even compared to other chronic pain disorders [4]. Comorbid depression is very common among FMS patients, with a lifetime prevalence of 62-86% [5], often accompanied by cognitive dysfunctions and pain catastrophizing, which lead to avoidance and withdrawal from daily life activities [6]. Approximately 35% of patients report difficulties in performing common everyday activities [7].

In sum, pain experience in FMS is complex and multidimensional. Therefore, established guidelines recommend a multi-component approach [8]. Treatment options include pharmacotherapy (evidence-based treatment guidelines recommend four drug classes: anti-epileptic drugs, tricyclic anti-depressants, selective serotonin reuptake inhibitors, and serotonin-norepinephrine reuptake inhibitors [9]; as well as aerobic exercise, relaxation, acupuncture, massage therapy, and psychological treatments. Psychological approaches comprise behavioral interventions, such as activity pacing or graded exposure to movement, combined with cognitive components (e.g. cognitive restructuring, problem-solving, and coping skills) [10, 11, 12] and the use of mindfulness strategies and acceptance and commitment therapy skills [13]. Novelty

interventions that have demonstrated efficacy in reducing key symptoms of FMS include guided imagery and hypnosis, sometimes in combination with cognitive behavioural therapy [14]. These approaches have commonly focused on reducing negative emotions, cognitions, and maladaptive coping associated with pain [15].

Although psychological approaches have traditionally concentrated on reducing negative symptoms associated with pain, new developments in pain management emphasize the role of positive affect and positive adjustment factors in coping with pain (for a review, see [16]). In this regard, some empirically supported psychosocial treatments have included interventions to enhance positive factors, but they are presented to patients as an approach designed to minimize negative appraisals of pain or as part of a "treatment package" [17, 18, 19] that includes several exercises. Therefore, the specific role of positive psychology interventions is difficult to analyze.

There is considerable variation in the combinations of treatment strategies across trials, and most of them report small to moderate effect sizes in reducing pain-related disability, emotional distress, and maladaptive coping [20]. However, in order to improve their efficacy and accessibility, a change in the design and implementation of pain treatments is needed [21].

In terms of theoretically-driven treatment models, treatment protocols combine several components, but with little evidence about merits of one combination of components over another or the rationale for including specific components [12]. Most of these treatment components have shown their efficacy in broader fields of research, but they have not been individually tested in people with chronic pain [22]. In this study, we focus on testing a single component designed to enhance positive affect and positive adjustment.

In the implementation of pain treatments, an important aspect is to promote self-management [23]. To do so, face to face applications could benefit from the integration

of technologies to enhance self-management and extend the reach and feasibility of psychological interventions for chronic pain [24]. Recent meta-analyses and research studies provide evidence for the efficacy of Internet-based interventions [25, 26], virtual reality [27, 28, 29], and smartphone applications [30] in managing pain. These technologies reduce barriers to accessing health care, while decreasing costs, increasing treatment efficiency, and promoting self-management [31], a core aspect of chronic conditions. Technologies can also help to promote positive functioning, improve wellness, and foster strength and resilience in individuals. They are referred to as Positive Technologies [32, 33, 34].

Although current directions in pain management aim to incorporate ICTs in healthcare and promote protective factors against experiencing pain, to date, research combining these efforts in chronic pain patients is limited. In this sense, a study by Müller et al. [19] determined the efficacy, feasibility and acceptability of a computer-based tailored intervention based on positive psychology to enhance well-being in individuals with physical disabilities. Positive psychology exercises included kindness, gratitude, savoring, flow, goals, forgiveness, and optimism. They found that individuals in the intervention group reported significant improvements in pain intensity, pain control, pain catastrophizing, pain interference, life satisfaction, positive affect, and depression. Hausmann et al. [18] also evaluated the effectiveness of web-based positive activities (e.g. kindness, strengths, gratitude, savoring and life summary) in 417 individuals with mild or moderate body pain. Although it was not tested in chronic pain patients, results supported the reduction of bodily pain. In the only study that included FMS patients, a randomized controlled trial was carried out with three conditions: an internet-delivered positive psychology program, an internet delivered cognitive behavioural program, and a waitlist control. Both treatments effectively increased happiness and decreased depression, although they did not reduce pain [35]. The content

of the program included self-compassion exercises, savoring, gratitude, and optimism. However, none of these studies has tested a single positive intervention in a chronic pain population to analyze its isolated effect.

For these reasons, we adapted a positive future-thinking intervention using Information and Communication Technologies (ICTs) [36], the Best Possible Self (BPS), which combines positive imagery with goal setting in different self-domains. An ICT-based computerized system [37, 38] (*Emotional Activities Related to Health, EARTH*) supported by a web-based online platform [39] (*Emotional Therapy Online, TEO*) with a brief automated short message service (SMS) was developed to provide therapist support and encourage exercise practice in FMS patients. The aim of this study is to extend the findings of the pilot study and test the efficacy of the BPS intervention in FMS compared to an active control condition. To our knowledge, this is the first controlled study to test this intervention in FMS patients.

Taking into account previous results that demonstrated the efficacy of this intervention in general population [40, 41] and experimentally-induced pain [42, 43] samples, the first hypothesis is that FMS patients will present lower levels of negative expectations and negative affect and higher levels of positive affect and positive future expectations after a single session of the BPS intervention. The second and main hypothesis is that patients in the BPS condition will present significant improvements in depression, positive and negative mood, and future expectations after the one month intervention, compared to patients in the daily activities condition. Also, we expect that the BPS intervention would improve self-efficacy, quality of life and pain related outcomes. Finally, because there is a lack of empirical evidence about maintenance of changes after this intervention, we preliminary explored the effects of the BPS intervention at 1-month and 3-months follow-ups.

Materials and Method

Participants

Participants were referred by a rheumatologist from the Rheumatology Unit of the Hospital Arnau of Vilanova. Inclusion criteria established that patients had to be diagnosed with FMS by a rheumatologist according to the American College of Rheumatology criteria [44, 45]. Exclusion criteria were suffering from severe mental disorders such as schizophrenia, bipolar disorder, mental retardation, or substance abuse or dependence (evaluated by the Mini-International Neuropsychiatric Interview; MINI).

Sample size calculations were performed a priori using the statistical program G* Power (version 3.0.10 for Windows). Previous research found effect sizes ranging from medium to small [17, 36]. In the analysis, we found that for an expected small effect size (0.2), with a p <0.05, an expected power of 0.95%, and with a total of two groups and 4 measures, a sample size goal of 56 was large enough to provide reliable effect size estimates.

Measures

Demographic and pain-related information

A brief structured interview was conducted to assess demographic variables and pain duration. Self-reported psychological distress was assessed by the Spanish version of the Brief Symptom Inventory (BSI) [46, 47].

Depression and mood

Depression. The Beck Depression Inventory (BDI-II is a 21-item self-report measure of cognitive, affective, and somatic symptoms of depression. It presents good psychometric properties in the English and Spanish versions [48, 49].

*The Positive and Negative Affect Scale (PANA*S) includes two 10-item scales evaluating positive and negative affect. The rating scale ranges from: 1 ‘very slightly or not at all’

to 5 ‘very much’. It has demonstrated both reliability and validity across cultures and languages, including Spanish [50, 51].

Positive functioning measures

Optimism and Future expectancies. The *Life Orientation Test-revised* (LOT-R) includes 10 items (four are filler items) that assess dispositional optimism on a 5-point scale (1=disagree - 5=agree). For this study, the Spanish version was used [52, 53]. The *Subjective Probability Task* (SPT) was used as a measure of positive (10 items) and negative (20 items) future expectancies. The SPT consists of 30 items scored on a 7-point Likert scale ranging from 1 (‘not at all likely to occur’) to 7 (‘extremely likely to occur’). For this study, our group performed a Spanish adaptation of the scale [54, 55].

General Self-Efficacy Scale-12 (GSES-12). This is a 12-item scale that evaluates perceived overall self-efficacy and three of its main aspects: initiative, persistence, and effort. All items are responded to on a 5-point scale ranging from 1 (‘never happens to me’) to 5 (‘always happens to me’). For this study, we used the the Spanish version, which has shown good psychometric properties [56, 57].

Quality of life. The Spanish version of the *Quality of Life Index (QLI-Sp)* consists of 10 items evaluating different dimensions of psychological well-being: physical well-being, psychological/emotional well-being, self-care and independent functioning, occupational functioning, interpersonal functioning, social-emotional support, community and services support, personal fulfillment, and spiritual fulfillment. The Spanish version of the Quality of Life Index has demonstrated good construct validity and test-retest reliability (reliability coefficient of .89) [58, 59].

Pain related measures

Fibromyalgia Impact Questionnaire (FIQ-R). The FIQ-R is a 10-item self-report questionnaire that measures the health status of patients with FMS by assessing the interference FMS produces in their daily lives. It includes four sections that assess the

patient's ability to perform daily and physical activities, his/her functional status, and other symptoms (pain, fatigue, morning tiredness, stiffness, anxiety, and depression). This instrument is widely used and has demonstrated good psychometric properties across cultures and languages, including Spanish [60]. The Spanish version of the FIQ-R has good internal consistency and test-retest reliability [60, 61].

Pain Catastrophizing. On the Pain Catastrophizing Scale (PCS), the patient is asked to reflect on past painful experiences and indicate the degree to which s/he experiences each of 13 thoughts or feelings when experiencing pain, on 5-point scales ranging from (0) not at all to (4) all the time. The PCS yields a total score and three subscale scores assessing rumination, magnification, and helplessness. For the purpose of this study, we used the PCS total score [62, 63].

Design

A single-blind randomized controlled trial with repeated measures (pre-intervention, post-session, post-intervention, 1-month follow-up, and 3-month follow-up) and two conditions: Best Possible Self intervention (BPS) and the active control condition (Daily Activities, DA). The random assignment of the participants to the different experimental conditions was carried out by an independent researcher who had no knowledge about the study or the intervention received by the different groups. This investigator performed the randomized assignment according to a randomization list created by the Random Allocation Software, version 1.0. The study was registered in the United States National Institute of Health Registration System (http://www.clinicaltrials.gov) with Clinical Trials Registration Number: NCT02375061. https://clinicaltrials.gov/show/NCT02375061

Intervention

BPS: In the face to face session at the university, patients in the BPS condition were asked to think of and write down all the aspects that their future best possible self should include in the personal, social, professional, and health domains. Patients used an interactive system called the *Book of Life* [37, 38]. This application was used so that participants could write down and imagine their BPS and incorporate multimedia content as a personal diary to promote positive narrative and enrich visualization. Besides writing their future goals in the computer diary, patients could choose images, sounds and videos from the *Book of Life* database. Patients were given 20 minutes to complete the exercise, and the last 5 minutes were used to visualize what they had just written. The visualization consisted of viewing in the form of a video the narrative, images and sound selected by the patient to construct their future possible self. Instructions to perform the writing exercise and visualization were extracted from the study by Meevissen et al. [41].

In order for patients to practice the guided imagery at home, all the contents included by the participants in the "*Book of Life*" were exported to a web platform ("*Emotional Therapy Online*", TEO) [39]. TEO is an open web-based system where patients can access therapeutic material over the Internet using a personal password. Patients could access their personal diary with the narrative and multimedia they had selected at the lab session. After the lab session, patients were instructed to continue visualizing their BPS at home at least three times a week accessing TEO. Please see Molinari et al. [36] for a complete description of the rationale and development of the technology-supported BPS system.

Daily Activities (DA): Patients were asked to think about and write down everything they had done in the past 24 hours. Participants in this condition were provided with a PowerPoint document to write the content of the exercise for 20 minutes and then

visualize it as a power point presentation for the last 5 minutes. As in the BPS condition, instructions were adapted from the study by Meevissen et al. [41]

In both conditions, during the whole intervention, participants received two short message services (SMS) per week with reminders to practice their exercise and reinforcements. Messages like: *"Happiness is not a rational ideal, but rather one of imagination. Don't forget to continue to practice the imagination exercise! Thank you very much";* or *"Hello! You're doing great! We encourage you to continue to practice the imagination exercise. Thank you very much"*, were sent in a randomized way.

Procedure

The rheumatologist at the local public hospital gave general information about the study and referred FMS patients who were interested in participating. All participants attended voluntarily and received no incentives. Once the participants had given their written informed consent to participate, a brief structured interview was conducted to assess pain history, treatments, and other diagnoses. Patients were assessed at baseline with the BSI and they were interviewed using the MINI in order to screen diagnosis of mental disorders. They took the rest of the assessment protocol home, and it had to be completed for the following lab session. In the following session, patients completed the SPT and the PANAS before performing the exercise. Then, participants in both conditions received a manual and listened to the instructions through headphones in order to guarantee standardization and facilitate concentration [41]. Next, the researcher presented the *Book of life* system to the BPS patients and explained how to use it. After 25 minutes of writing about their BPS and selecting their images, music and videos, they performed the 5-min imagery exercise. Patients were told that they would receive an email giving them access to *TEO* to practice their exercise at home at least three times a week. Participants in the DA condition also

performed the exercise on a computer using a PowerPoint presentation, and then they visualized it for 5 minutes. They also were instructed to practice the daily activities exercise at home.

The post intervention session took place at the university in the fourth week. The measures of depression, positive and negative affect, future expectancies, optimism, pain catastrophizing, pain disability, anxiety, self-efficacy and quality of life were administered. An interview was conducted in order to assess the frequency with which the imagery exercise was applied, and the acceptance and perceived usefulness of the intervention. Finally, patients were asked to continue to practice their exercise, and they were informed that they were going to be contacted at 1-month and 3-month follow-ups.

At the follow-ups, patients were asked to come again to the University and completed the same questionnaires as at post-intervention. After finishing their participation, participants allocated in the control condition were offered the Best Possible Self intervention. Participation was voluntary and participants did not receive any compensation for their participation. All the sessions were administered by a psychologist who was not blind to the hypotheses of the study.

Data analyses

A *t* student and chi-square tests were performed to check for baseline differences between conditions. In order to improve the quality of the study, and following the CONSORT guidelines [64, 65, 66], Intent-To-Treat (ITT) analyses were carried out following Newman's guidelines [67] and using Maximum Likelihood (ML) estimation performed via Expectation Maximization imputation (EM). For the treatment of missing data, the procedure suggested by Hair and colleagues [68] was followed. First, the type of missing data was explored, concluding that construct-level data were missing and, thus, susceptible for imputation. Second, the quantity of missing values was analyzed,

determining that none of the measures exceeds the recommended limits [69]. Third, a diagnosis of the random pattern of missing data was carried out with the Little MCAR test (χ^2 (709) = 686.26, p >.05), concluding that missing data are completely random. Finally, Maximum Likelihood estimation (ML) was performed for the missing values, and sensitivity analysis compared the results of the completers to the estimated values. These sensitivity analyses showed that there was no chance of falling into biased estimations by using the ML estimation.

Three sets of analyses were carried out. First, to test our first hypothesis, we analyzed the single-session effects (pre-post session) through an analyses of covariance (ANCOVA) (with condition as the between-subject variable and pre-session scores as the covariate) to compare the effects of the intervention on affect and future expectations in the BPS and DA conditions. Second, to test our second and third hypothesis, we analyzed the efficacy of the self-applied intervention at post-intervention for each measure through analyses of covariance (ANCOVA), using condition as the between-subject factor and their respective pre-intervention scores as the covariate. Finally, effects of the BPS intervention were analyzed including the 1-month and 3-month follow-ups by carrying out a 2x4 mixed ANOVA for each measure (Pre, Post-intervention, 1-month follow-up, 3-month follow-up). All the assumptions for the ANOVAs performed were checked. In the case of mixed 2x4 ANOVAs, the degrees of freedom were corrected using Greenhouse–Geisser in those cases where the sphericity assumption was not fulfilled. Bonferroni correction was used for multiple comparisons. Effect sizes (Cohen's *d*) [70] and confidence intervals were calculated for within-group and between-group changes, based on the pooled standard deviation.

Additionally, in order to assess the clinical significance of the change resulted from the intervention, clinical significant change was calculated using Jacobson and Truax's Reliable Change Index (RCI) [71]. First, we established the cut-off point for the

post-intervention score in order to be considered in the range of a functional distribution. Then we calculated the RCI to analyze the second condition to test the clinical significant change, where an RCI equal to or greater than |1.96| ($p < .05$) indicates a reliable change. Finally, taking both criteria into account, participants were classified into four categories: (a) *Recovered*: when the change is significantly reliable ($RCI \geq |1.96|$; $p < 0.05$) and the post-intervention score is located within the range of the functional distribution (M ± 2 SD); (b) *Improved*. When the change is significantly reliable ($RCI \geq |1.96|$; $p < 0.05$), but the post-intervention score does not reach the functional level; (c) *Not changed*. When the change is not significantly reliable and the post-intervention score does not reach the functional level; (d) *Deteriorated*. When the change is significantly reliable ($RCI \geq |1.96|$; $p < 0.05$), but the post-intervention score is worse than the pre-intervention score.

All statistical analyses were conducted using IBM SPSS Statistics 22.

Results

Participants Flow

One hundred and fifteen participants were contacted, but 35 were not allocated to the conditions for several reasons (see flow diagram in Figure 1). The main reason for declining to participate was that the study involves coming to the University a few times to receive the intervention. Most of the patients depended on another family member to get around or presented mobility problems. After the screening interviews, 80 patients were accepted in the study and randomly allocated to the two experimental conditions: e-BPS, n=40; DA, n=40. Nine participants did not come back for a second session to return the assessment protocol and receive the allocated intervention. Thus, there were pre-intervention assessments for 38 participants in the e-BPS condition and for 33 participants in the DA condition. During the intervention program, there were 15

dropouts from the BPS group and 5 dropouts from the DA condition. At the 1-month follow-up, there were 5 dropouts from the BPS condition and 9 from the DA condition. Fifteen participants in the BPS group and 13 participants in the DA group completed the whole intervention (see Figure 1).

The final sample comprised 71 participants with a diagnosis of FMS. The mean age of the sample was 51.08 years old (*SD* = 10.54), ranging from 23 to 71 years, and the mean duration of suffering from pain was 13.1 years (*SD* = 10.07). All participants consented to the research protocol as approved by the Ethical committee at the University Jaume I.

INSERT FIGURE 1 HERE

Pre intervention comparisons

Chi-square tests showed no differences between the groups at pre-test in any of the demographic variables: sex (χ^2 (1) = 1.168; p = 0.28); education (χ^2 (3) = 2.627; p = 0.453); marital status (χ^2 (3) = 2.427; p = 0.489); and occupation. A student t test revealed no differences between the groups regarding age (t [69] = -1.0; p = 0.169) or years with pain (t [67] = -0.61; p = 0.543). Moreover, there were no statistically significant differences between the groups on any of the outcome variables, which indicated that the random assignment was successful.

Baseline characteristics

Patients were all women with a mean age of 51.08 years (range=23-71, *SD*= 10.54) and a mean disease duration of 13.10 years (*SD*=10.07). Most of the patients were married (71.8%) and had a basic level of education (37.5%). Eighty percent reported having received psychological treatment before. In terms of psychological distress and symptomatology, scores on the General Disability Index showed great psychological discomfort ($\overline{X}$=70.87; *SD*=32.36).

Intervention effects

Pre-post-session effects (Single-session effects)

There was no significant condition effect for the ANCOVA on post-session changes in scores for any of the measures. The post-hoc comparisons of the "moment of measurement" variable revealed statistically significant reductions in negative future expectancies between the pre-session and post-session in both conditions (p <.001). Increases in positive affect at post session were only significant in the BPS group (p <.001). A moderate effect size was found for the BPS condition on negative future expectancies (d=-.45; 95% CI [.21, .68]) and positive affect (d=.47; 95% CI [-.76, -.18]). For the control condition, a small effect size was found for positive affect (d=.29; 95% CI [-.53, -.05]) and negative future expectancies (d=-.33; 95% CI [.14, .52]). Figure 2 shows the graph of the changes in scores for both conditions

INSERT FIGURE 2 HERE

Pre-post intervention effects

Depression and mood

The ANCOVAs on the baseline corrected post-intervention scores revealed a main effect of condition for depression ($F_{(1, 68)} = 7.45$, p<.01, $\eta^2_{partial} = .10$) and positive affect, reflecting that the BPS group significantly reduced their depressive symptoms and increased their positive affect at post-intervention, a difference that was not found in the control group. No condition effects were found for negative affect ($F_{(1, 68)} = 1.95$, p=.16).

Positive functioning measures

Analysis yielded a significant condition effect for self-efficacy ($F_{(1, 68)} = 8.58$, p<.01, $\eta^2_{partial} = .11$), indicating larger increases in self-efficacy in the BPS condition, compared to the DA condition at post-intervention. No condition effects were found for

either optimism ($F_{(1, 68)} = 2.02$, $p=.16$), positive future expectancies ($F_{(1, 68)} = .60$, $p=.44$), negative future expectancies ($F_{(1, 68)} = 2.18$, $p=.14$) or quality of life ($F_{(1, 68)} = 1.59$, $p=.21$).

Pain related measures

Regarding health status associated with FMS, the effect of condition was not significant ($F_{(1, 68)} = .18$, $p=.67$), indicating that participants in the BPS group did not differ significantly from the DA group on pain functioning at post intervention. No condition effects were found on pain catastrophizing either ($F_{(1, 68)} = .89$, $p=.35$).

The descriptive statistics, effect sizes and confidence intervals are presented in Table 1.

INSERT TABLE 1 HERE

Follow-up effects of the self-applied intervention

Depression and mood

Analysis revealed no interaction effects on depression ($F_{(2.17, 150.12)} = 1.99$, $p=.12$). There was a significant time effect on depression scores ($F_{(2.17, 150.12)} = 20.5$ $p<.01$, $\eta^2_{partial} = .31$), post-hoc comparisons revealed statistically significant differences between the pre-intervention and 1-month and 3-month follow-ups ($p<.001$); and between the post-intervention and the 1-month and 3-month follow-ups ($p<.001$). Although the interaction effect is not statistically significant, post-hoc analysis of the interaction for depression show that the differences between pre and post-intervention ($p<.01$), pre and 1-month ($p<.001$) and 3-month follow-ups ($p<.001$), post-intervention and the 1-month and 3-month follow-ups, are significant for the intervention group ($p<.05$). For the control group, differences between pre and 1-month follow-up ($p<.05$), and between post-intervention and 1-month ($p<.001$) and 3-months follow-ups ($p<.01$) are significant.

Regarding negative affect, a significant interaction effect was found ($F_{(1, 69)}$ = 2.75, p<.05, $\eta^2_{partial}$ = .04), indicating larger decreases in negative affect in the BPS condition compared to the DA condition at the follow-ups. Post-hoc analysis of the interaction for negative affect show that the differences between pre and 1-month follow-up (p<.05), and between pre and 3-month follow-up (p<.001), are significant for the intervention group but not for the control group (p=1). The effects of time were not significant either ($F_{(1, 69)}$ = 1.98, p=.13).

No significant Group x Time interaction on positive affect was found ($F_{(1, 69)}$ = 2.09, p=.10). The effects of time were not significant either ($F_{(1, 69)}$ = 2.31, p=.07).

Positive functioning measures

A significant Group x Time interaction was found on optimism, indicating larger increases in optimism in the BPS condition compared to the DA condition at follow-ups ($F_{(1, 69)}$ = 2.62, p<.05, $\eta^2_{partial}$ = .04). Post-hoc analysis of the interaction show that the differences between pre and post-intervention in optimism (p<.05), and between pre and 3-month follow-up (p<.001; d=.91, 95% CI [-1.36, .46]), are significant for the intervention group but not for the control group (p=1). There was a significant main effect of time on optimism scores ($F_{(1, 69)}$ = 3.38, p<.05, $\eta^2_{partial}$ = .05). The post-hoc comparisons revealed statistically significant differences between pre-intervention and 3-month follow-up (p<.05).

No significant interaction effects of Group x Time were found on positive expectancies ($F_{(1, 69)}$ = 0.49, p=.69). There was a significant main effect of time ($F_{(1, 69)}$ = 6.61, p<.001, $\eta^2_{partial}$ = .09), indicating statistically significant differences in positive expectancies between pre-intervention and 1-month follow-up (p<.001); and between post-intervention and 1-month follow-up (p<.05).

No significant interaction effects of Group x Time were found on negative future expectancies ($F_{(1, 69)}$ = 1.23, p=.29). Although the interaction effect is not statistically

significant, post-hoc analysis show that the differences between pre and post-intervention ($p<.05$), pre and 1-month ($p<.01$) and 3-month follow-ups ($p<.001$) are significant for the intervention group. For the control group, only differences between pre and 3-month follow-up ($p<.01$) are significant. There was a significant main effect of time on negative expectancies ($F_{(1, 69)} = 9.33$, $p<.001$, $\eta^2_{partial} = .12$). Statistically significant differences were found between pre-intervention and the 1-month and 3-month follow-ups ($p<.001$); and between the first and last follow-ups ($p<.05$).

Regarding the interaction effects, the ANOVA revealed no significant effects on self-efficacy ($F_{(1, 69)} = 2.52$, $p=.07$). The effects of time were not significant either ($F_{(1, 69)} = 1.98$, $p=.13$).

No interaction effects were found on quality of life ($F_{(1, 69)} = 1.92$, $p=.13$). The analysis revealed a significant time effect ($F_{(1, 69)} = 8.80$, $p<.001$, $\eta^2_{partial} = .11$), indicating significant increases in quality of life between pre-intervention and 1-month follow-up ($p<.001$); pre-intervention and 3-month follow-up ($p<.05$), and post-intervention and 1-month follow-up ($p<.05$). Although the interaction effect is not statistically significant, post-hoc analysis of the interaction for quality of life show that the differences between pre and post-intervention ($p<.05$), pre and 1-month ($p<.001$) and 3-month follow-ups ($p<.01$) are only significant for the intervention group.

Pain related measures

Regarding the impact of FMS on health status, the effects of the Group x Time interaction were not significant ($F_{(1, 69)} = .37$, $p=.77$). However, the analysis revealed a significant time effect ($F_{(1, 69)} = 4.68$, $p<.05$, $\eta^2_{partial} = .06$), indicating that an improvement in pain functioning was achieved at follow-ups. The post-hoc analysis revealed statistically significant differences between pre-treatment and 3-month follow-up ($p<.05$) and between the 1-month and 3-month follow-ups ($p<.05$).

No interaction effects were found on pain catastrophizing ($F_{(1, 69)} = .65$, $p=.58$). The analysis revealed a significant time effect on pain catastrophizing ($F_{(1, 69)} = 24.99$, $p<.01$, $\eta^2_{partial} = .27$), indicating significant decreases in pain catastrophizing over time. The post-hoc comparisons revealed statistically significant differences in pain catastrophizing between pre-intervention and the 1-month and 3-month follow-ups ($p<.001$); between post-intervention and the 3-month follow-up ($p<.001$); and between the 1-month and 3-month follow-ups ($p<.001$).

The descriptive statistics, effect sizes and confidence intervals are presented in Table 2.

INSERT TABLE 2 HERE

Clinical relevance

Changes in depression scores, self-efficacy and positive affect achieved at post-intervention, were analyzed using the RCI [71].

Changes in Depression

First, cut-off scores at post-intervention showed statistically significant differences between the number of participants in both conditions that achieved a functional score in depressive symptoms (($\chi2$ (1) = 4.57; $p<.05$); 61.9% of patients from the intervention group achieved functional changes in their depression scores above the estimated cut-off point, whereas only 30.8% of patients from the control group achieved a functional change. Second, the RCI results also showed statistically significant differences in reliability of change in depression scores between groups ($\chi2$ (2) = 7.14, $p <.05$); 42.9% of patients from the intervention group achieved a reliable change compared to the 19.2% of the control group. Finally, to determine the clinical significant change, all patients were classified into four categories, taking into account the post-intervention score and the RCI score. In the intervention group, 42.9% of the patients were “recovered”, 19% were “improved”, 33.3% were “not changed”, and 4.8% were

"deteriorated". While in the control group, 19.2% of the patients were "recovered", 11.5% were "improved", 34.6% were "not changed", and 34.6% were "deteriorated" (See Figure 3). Differences between intervention and control conditions in response rates at post-intervention were marginally significant ($\chi 2$ (3) = 7.49; p = .05).

Changes in positive affect

There were no statistically significant differences between the number of participants in both conditions that achieved a functional score in positive affect ($\chi 2$ (1) = 2.58; p>.05); however, 58.3% of patients from the intervention group achieved functional changes in their positive affect scores above the estimated cut-off point, whereas only 41.7% of patients from the control group achieved a functional change. The RCI results did not showed statistically significant differences in reliability of change in positive affect scores between groups ($\chi 2$ (1) = 1.27, p>.05); 5% of patients from the intervention group achieved a reliable change compared to none of the control group. Finally, in the intervention group, 5% of the patients were "recovered", 65% were "improved", 30% were "not changed", and none were "deteriorated". While in the control group, none of the patients were "recovered", 45.5% were "improved", 54.5% were "not changed", and none were "deteriorated" (See Figure 4). Differences between intervention and control conditions in response rates at post-intervention were not significant ($\chi 2$ (2) = 3.30; p>.05).

Changes in self-efficacy

There were no statistically significant differences between the number of participants in both conditions that achieved a functional score in self-efficacy ($\chi 2$ (1) = 0.47; p>.05); however, 47.6% of patients from the intervention group achieved functional changes in their self-efficacy scores above the estimated cut-off point, compared to 37.5% of patients from the control group. The RCI results showed statistically significant differences in reliability of change in self-efficacy scores between groups ($\chi 2$ (2) = 8.60,

p<.05); 33.3% of patients from the intervention group achieved a reliable change compared to 16.7% of the control group. Finally, in the intervention group, 33.3% of the patients were "recovered", 14.3% were "improved", 42.9% were "not changed", and 9.5% were "deteriorated". While in the control group, 16.7% of the patients were "recovered", 20.8% were "improved", 12.5% were "not changed", and 50% were "deteriorated" (See Figure 5). Differences between intervention and control conditions in response rates at post-intervention were statistically significant ($\chi 2$ (3) = 11.31; *p*<.05).

INSERT FIGURES 3, 4 AND 5 HERE

Discussion

The aim of this study was to test the efficacy of a positive future thinking intervention in a randomized controlled trial with FMS patients. To our knowledge, this is the first study to test the specificity of the BPS manipulation in FMS patients using the benefits of technology to enhance intervention adherence and self-management.

Regarding the single-session effects, the BPS intervention and the daily activities exercise both produced significant decreases in negative expectations and increases in positive affect. However, increases in positive affect at post-session were only significant in the BPS condition. Positive effects of thinking and writing about daily activities could be explained by the fact that reflecting about the events that happened during the day could generate a higher level of awareness of activity goals. Thus, it could act as a simple behavioral activation exercise. This exercise was chosen as the control condition because it was selected in several similar studies [40, 41, 72]. Furthermore, it is possible that the significant time effects were due to the placebo effect or "expectation inductions" [73]. Informing patients about and emphasizing the positive intended and expected outcomes could have optimized the exercise's effectiveness. Moreover, the selected imagery intervention was brief, but cognitively challenging for

FMS patients. More practice time may be required to obtain substantial effects of the BPS, as suggested in a recent meta-analysis of the effects of imagery interventions on pain [74].

Given the possible benefit of more BPS practice, patients self-applied both exercises at home counting only with online support for one month. The results showed that compared to an active control condition, the daily imagery of the BPS exercise led to a significant decrease in depression and negative affect and an increase in positive affect. These results are in line with the findings of Pietrowsky and Mikutta [75], who showed that, after practicing the BPS, depressive patients decreased their BDI levels. Unlike previous BPS studies that did not find any interaction effect of induced optimism on negative affect, compared to a control condition [40, 41, 72, 76], we found a significant effect on negative affect. Moreover, these changes were maintained at the follow-ups. Changes in positive affect suggest that both exercises had beneficial effects in terms of augmenting positive mood, but it increased significantly more in the BPS intervention group. For FMS patients, this can be especially significant, considering that they report significantly lower positive affect than patients with other rheumatology diseases [77]. In FMS, affect balance styles have been shown to be predictive of psychiatric comorbidity, pain severity, and functional status [78], especially the Depressive affect balance style (high negative affect/low positive affect). A Healthy style (low negative affect/high positive affect) was associated with lower symptoms of depression, anxiety and pain-related outcomes.

Interestingly, even though the BPS intervention primarily targeted future expectancies, we found no interaction effects on the SPT-POS or the SPT-NEG. Expectancies for negative outcomes decreased after both the BPS and the control intervention, but this reduction was only significant in the BPS group. A significant increase in optimism levels was found at follow-ups in the BPS condition compared to

the control group. The BPS exercise is a brief and focal intervention. Due to the dimensional and trait nature of optimism [79], interventions aimed at increasing optimism should expect to gradually achieve more flexible and optimistic thinking. Moreover, it should be noted that previous studies that found changes in future expectancies were performed on healthy subjects and these differences could be explained by differences in populations [40, 41, 72]. Further studies in different clinical samples should clarify these discrepancies.

Analyses revealed a significant interaction effect on self-efficacy. In this case, post intervention effects showed the specificity of the BPS intervention. It seems that the visualization of positive future goals helped patients to increase their belief in their ability to perform specific behaviors [80]. It is difficult for FMS sufferers to set goals related to activities that are positive and meaningful for them. Fear of movement, fatigue, low mood, and pain get in the way of their willingness to perform the activities, causing avoidance activity patterns and low motivation and persistence [81]. In the current study, we extended previous findings by demonstrating that a BPS manipulation can have an effect on self-efficacy in chronic pain patients who have been experiencing pain for approximately 10 years. This is important because a recent meta-analysis indicated that self-efficacy has significant associations with impairment, affective distress, and pain severity in chronic pain samples, and it represents an important protective factor for subsequent adjustment [82]. Moreover, self-efficacy has been characterized as a protective psychological resource and a resilience factor associated with improved physical function in patients with chronic pain [83].

Although pain was not a primary outcome measure in this study, pain disability, as measured by the Fibromyalgia Impact questionnaire, showed reductions at follow-ups in both conditions. Current directions in chronic pain treatments suggest that reductions in pain may not be requirements for decreasing distress and promoting better

functioning [84]. This could be especially important in interventions aimed at augmenting positive affect and promoting positive functioning, where the focus of the intervention is on teaching patients skills to help them live a meaningful life in spite of their pain. Both exercises were effective in reducing pain catastrophizing and increasing quality of life, although changes in quality of life from pre-intervention to follow-ups were only significant in the BPS group. These findings are in line with previous studies that experimentally induced pain and optimism and found a reduction in situational and dimensional pain catastrophizing in healthy participants [40, 41]. Although previous BPS studies have not included quality of life as an outcome measure, these results suggest that positive imagery is capable of improving the functional status in FMS, coinciding with guided imagery studies for rheumatic diseases that found improvements in psychological well-being [85, 86].

Even though the results from this study are promising, several limitations should be mentioned. First, the sample size was small, and this study needs to be replicated with larger samples. Moreover, all the participants were women. Although the prevalence of FMS in women is higher than in men (approximately 22 to 1 in Spain) [87], future studies should include men in order to assess if there are differences in the response to the BPS intervention according to gender. Second, it is important to note that the efficacy of the technologies was not compared to a condition without technologies, which means that we are unable to know the differential role of the technology in the implementation of the BPS exercise. In light of the results obtained in this study, an important point to highlight is the effect produced by the control condition, the Daily Activities exercise. Patients from both conditions received the same description of the study, which stated that performing the exercise could have a positive influence on their mood. This instruction could have influenced the results. It has been demonstrated that expectancies about treatment outcomes can enhance or reduce the

analgesic effects of active interventions [73]. However, the information was extracted from other studies in which expectations had no effect on the results [41, 72]. Furthermore, thinking and writing about daily activities could have acted as a behavioral activation intervention, and this could have positively influenced the participants' mood. Furthermore, the control condition focused on the last 24 hours, unlike the BPS exercise, which is oriented toward the future. These patients often express thoughts about fear of the future and hopelessness about what the future may bring [88], and so thinking about the future might be a very challenging activity for them. Considering interventions were completely self-applied, attrition rate at post-intervention in the present study was similar to internet-based positive psychology interventions (20% and 25% in recent studies) [19, 35]. Nonetheless, drop-out rates at follow-ups were considerable (50% for the two conditions). Although recent studies have found comparable rates [35], this limitation cannot be excluded. Future studies could include minimal therapist contact, such as weekly telephone calls to engage and motivate participants, as well as to resolve any problems with the performance of the intervention. Another limitation has to do with the assessment procedure. Due to time constraints, patients were asked to complete the self-report questionnaires at home. This procedure did not allow us to have control of the exact date of completion of the questionnaires. However, all participants came back to the clinic in a week period, so we know that the questionnaires were filled out in the week before the intervention started. Also, the post-intervention assessment was conducted by a psychologist who was not blind to the experimental condition.

Although the role of positive factors as a buffer for the disabling effects of chronic pain has been widely studied, the positive psychology components of treatment approaches for chronic pain had not previously been extracted and tested [16]. We believe our study makes an important contribution to pain research, helping to

understand how a positive psychology intervention supported by technologies works in FMS, expanding its efficacy data in clinical populations and adding knowledge about the role of positive psychological factors in the pain experience. Moreover, our findings show the specific effects of the Best Possible Self intervention, helping to draw conclusions about the usefulness of incorporating this exercise in treatment protocols.

Thus, a larger question remains about how interventions aimed at augmenting positive affect and promoting positive functioning work, and which mechanisms act as facilitators of change. Should we place a primary emphasis in treatment on positive factors as a pathway to improving chronic pain symptoms? Should we first alleviate distress symptoms in order to achieve changes in positive functioning measures? Mechanisms linking positive activity interventions to happiness have included positive emotions, thoughts and behaviors [22]. However, these mechanisms have not been evaluated in chronic pain populations. Future investigations should determine what specific mechanisms (e.g. increased positive affect or self-efficacy) in interventions promote positive factors, and whether effect sizes can be improved.

Psychological intervention therapies for chronic pain are often complex and address different therapeutic targets. Perhaps it is time to take a step back and design and test particular interventions to produce changes in specific variables, and then include them in treatment protocols.

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Table 1 presents the means, standard deviations, effect sizes, and coefficient intervals for changes from pre to post intervention according to condition (n=71)

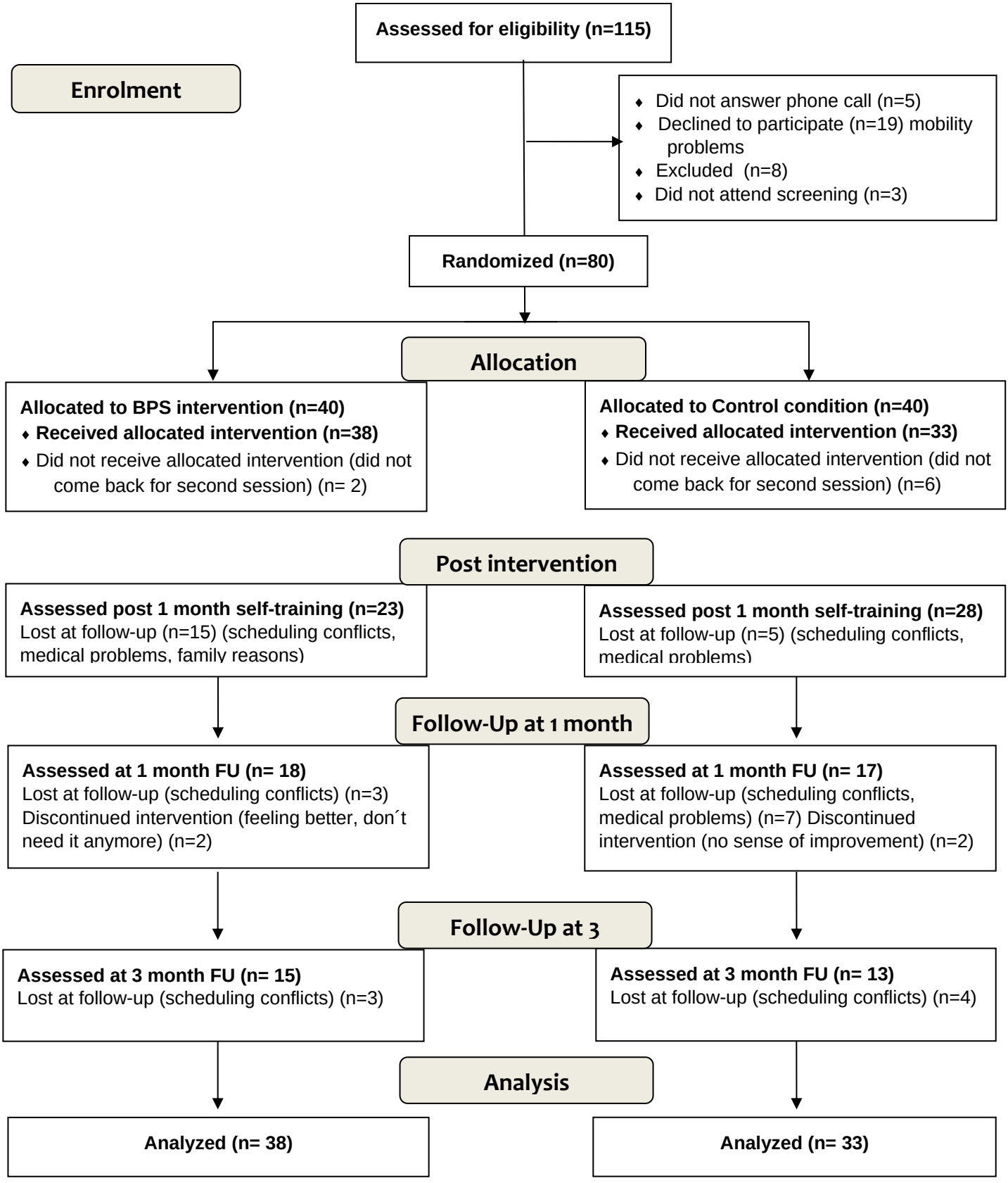
	Best Possible Self			Daily Activities			
	Pre M (SD)	**Post M (SD)**	**Within-group effect size, *d* [95% CI]**	**Pre M (SD)**	**Post M (SD)**	**Within-group effect size, *d* [95% CI]**	**Between-group effect size, *d* [95% CI]**
Depression and mood							
BDI-II	23.13 (11.18)	19.14 (11.75)	**-.35** ** **[.13, .57]**	23.24 (9.47)	24.25 (12.27)	.10 [-.34, .13]	-.42 [-.89, .05]
PA	2.23 (.81)	2.5 (.78)	**.33** ** **[-.56, -.10]**	2.2 (.68)	2.18 (.79)	-.03 [-.21, .27]	.40 [-.07, .87]
NA	2.4 (.84)	2.01 (1.06)	**-.45** ** **[.07, .84]**	2.13 (.81)	2.23 (1.0)	.12 [-.52, .28]	-.21 [-.68, .26]
Positive Functioning							
LOT	18.61 (3.95)	20.1 (4.86)	.37 [-.76, .02]	19.51 (4.11)	19.78 (4.89)	.06 [-.42, .29]	.06 [-.40, .53]
SPT-POS	4.54 (1.02)	4.44 (.99)	.10 [-.23, .43]	4.56 (1.14)	4.29 (1.2)	-.23 [-.04, .50]	.13 [-.33, .60]
SPT-NEG	3.36 (1)	2.73 (1.62)	**-.62** ** **[.22, 1.01]**	3.44 (1.08)	3.29 (1.6)	.14 [-.22, .49]	-.34 [-.81, .13]
GSES	41.08 (8.47)	43.01 (7.44)	.22 [-.45, 0]	42.57 (7.36)	40.27 (8.76)	**-.31** ** **[.03, .58]**	.33 [-.13, .81]
QLI	48.81 (15.81)	54.01 (15.06)	**.32** ** **[-.56, -.09]**	48.76 (13.71)	50.76 (16.07)	**.32** ** **[-.59, -.05]**	.21 [-.26, .67]
Pain							
FIQ-R	64.94 (15.72)	64.46 (17.04)	-.03 [-.26, .32]	66.25 (13.2)	66.82 (17.62)	.04 [-.35, .26]	-.13 [-.60, .33]
PCS	26 (14.24)	21.45 (13)	**-.31** ** **[.14, .49]**	28.75 (13.57)	25.26 (13.16)	**-.25** ** **[0, .5]**	-.29 [-.75, .18]

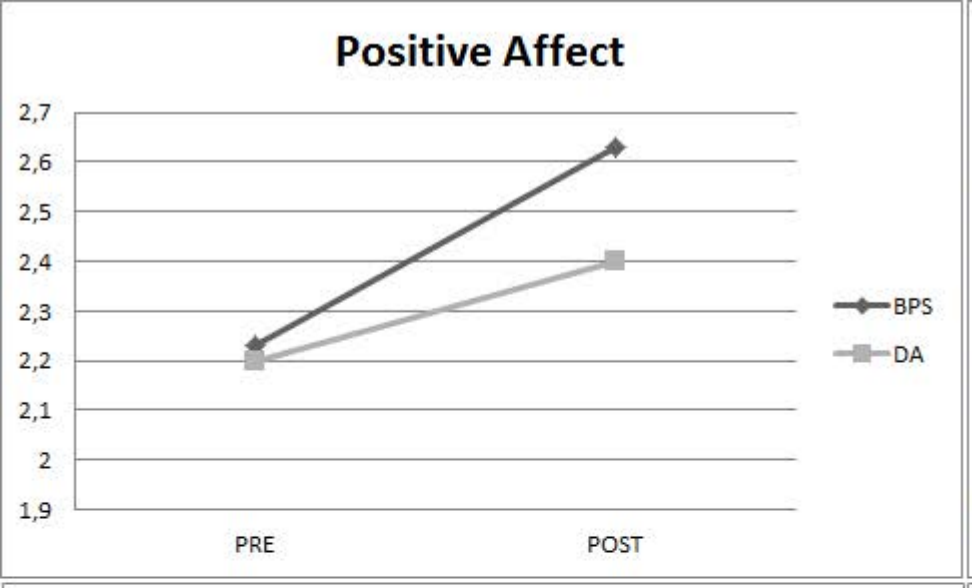
Note. BDI-II= Beck Depression Inventory; LOT-R= Life Orientation Test; SPT-POS and SPT-NEG= positive and negative future expectations; PA and NA, positive and negative affect scale; FIQ-R=Fibromyalgia Impact Questionnaire; PCS= Pain Catastrophizing Scale; GSES= General self-efficacy total scale, QLI= Quality of Life Inventory. Effect size (*d*) calculation from Cohen [68] *d*=0.2 are regarded as a ‘‘small’’ effect size, *d*=0.5 as ‘‘medium,’ and *d*=0.8 as ‘‘large”. ** *p<.01*

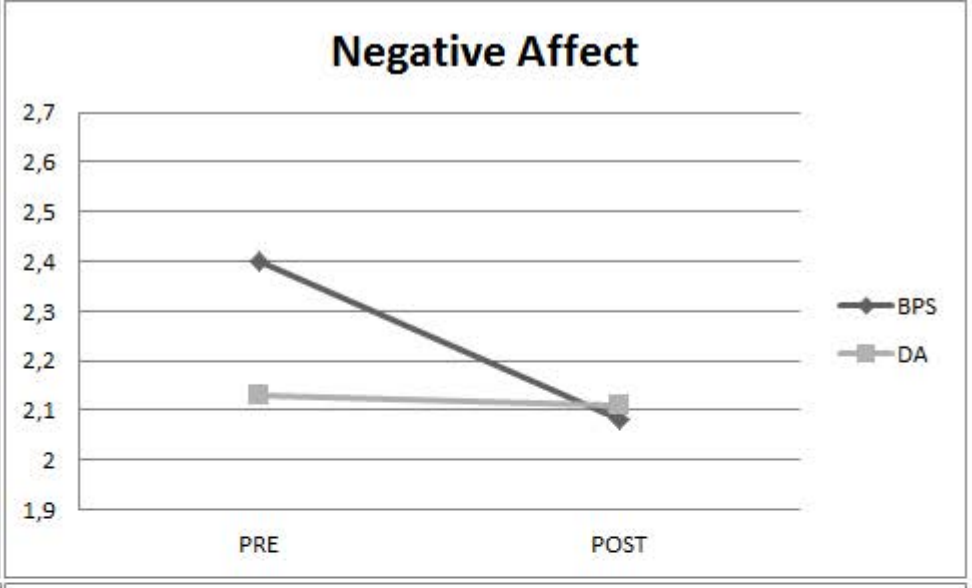
Table 2 presents the means, standard deviations, effect sizes, and coefficient intervals for changes at follow-ups according to condition (n=71)

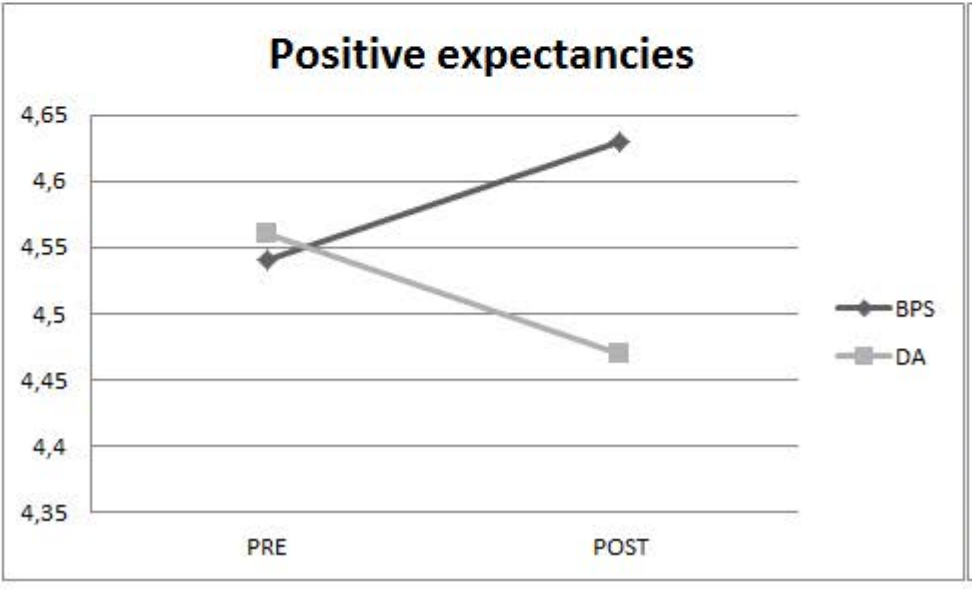
	Best Possible Self			Daily Activities			
	1 FU M (SD)	**3 FU M (SD)**	**From Pre to 3 FU Within-group effect size, *d* [95% CI]**	**1 FU M (SD)**	**3 FU M (SD)**	**From Pre to 3 FU Within-group effect size, *d* [95% CI]**	**From Pre to 3 FU Between-group effect size, *d* [95% CI]**
Depression and mood							
BDI-II	15.82 (11.06)	14.15 (9.57)	**-.79** [**] **[.35, 1.22]**	17.88 (12.08)	18.05 (12.06)	**-.54** [**] **[.19, .88]**	-.42 [-.89, .05]
PA	2.56 (.84)	2.48 (.92)	**.30** [**] **[-.57, -.03]**	2.22 (.76)	2.23 (.81)	.04 [-.24, .16]	.40 [-.07, .87]
NA	2.03 (.58)	1.92 (.61)	**-.56** [**] **[.26, .86]**	2.32 (.82)	2.09 (.60)	-.05 [-.30, .39]	-.21 [-.68, .26]
Positive Functioning							
LOT	20.5 (5.57)	22.29 (5.56)	**.91** [**] **[-1.36, .46]**	19.55 (5.65)	19.69 (5.07)	.04 [-.46, .37]	.06 [-.40, .53]
SPT-POS	4.18 (1.1)	4.33 (1.34)	.20 [-.09, .50]	3.94 (1.02)	4.13 (1.3)	**-.37** [**] **[.07, .66]**	.13 [-.33, .60]
SPT-NEG	2.88 (1.1)	2.61 (0.79)	**-.73** [**] **[.37, 1.10]**	3.1 (1.09)	2.8 (.93)	**-.58** [**] **[.16, 1]**	-.34 [-.81, .13]
GSES	42.32 (8.12)	43.10 (8.96)	.23 [-.59, .12]	41.37 (7.90)	40.92 (7.79)	-.22 [-.20, .64]	.33 [-.13, .81]
QLI	58.61 (15.29)	56.68 (14.64)	**.49** [**] **[-.78, -.19]**	53.41 (16.46)	50.19 (14.38)	.09 [-.39, .22]	.21 [-.26, .67]
Pain							
FIQ-R	65.96 (14.95)	60.44 (12.33)	-.28 [-.03, .60]	70.95 (18.22)	62.15 (15.10)	**-.30** [**] **[.02, .58]**	-.13 [-.60, .33]
PCS	19.42 (12.26)	17.17 (12.65)	**-.61** [**] **[.35, .86]**	24.59 (11.65)	21.86 (11.15)	**-.50** [**] **[.25, .74]**	-.29 [-.76, .18]

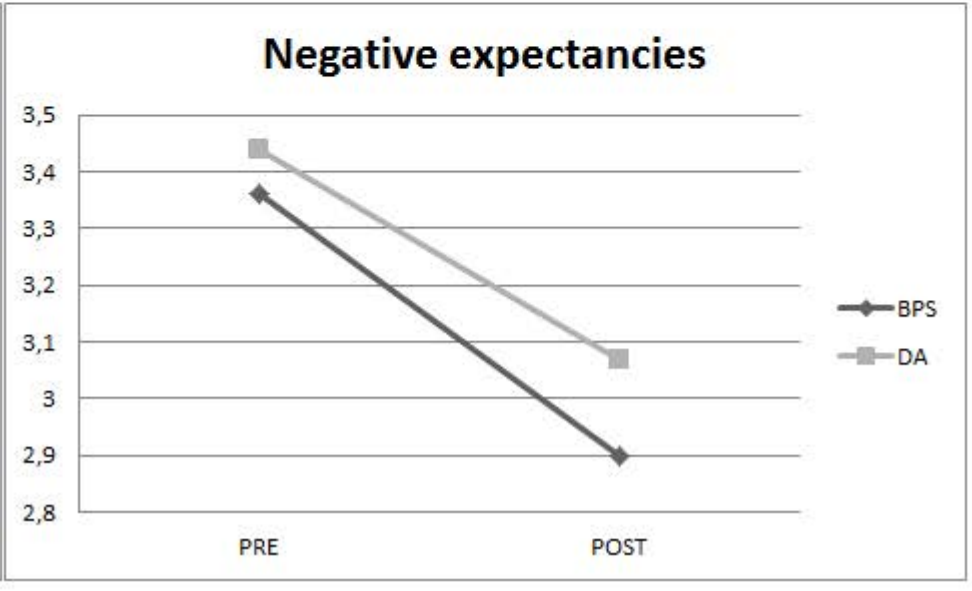
Note. 1 FU= 1 month follow-up; 3 FU= 3 month follow-up; BDI-II= Beck Depression Inventory; LOT-R= Life Orientation Test; SPT-POS and SPT-NEG= positive and negative future expectations; PA and NA, positive and negative affect scale; FIQ-R=Fibromyalgia Impact Questionnaire; PCS= Pain Catastrophizing Scale; GSES= General self-efficacy total scale, QLI= Quality of Life Inventory. Effect size (*d*) calculation from Cohen [68] *d*=0.2 are regarded as a ‘‘small’’ effect size, *d*=0.5 as ‘‘medium,’ and *d*=0.8 as ‘‘large”. [**] *p<.01*

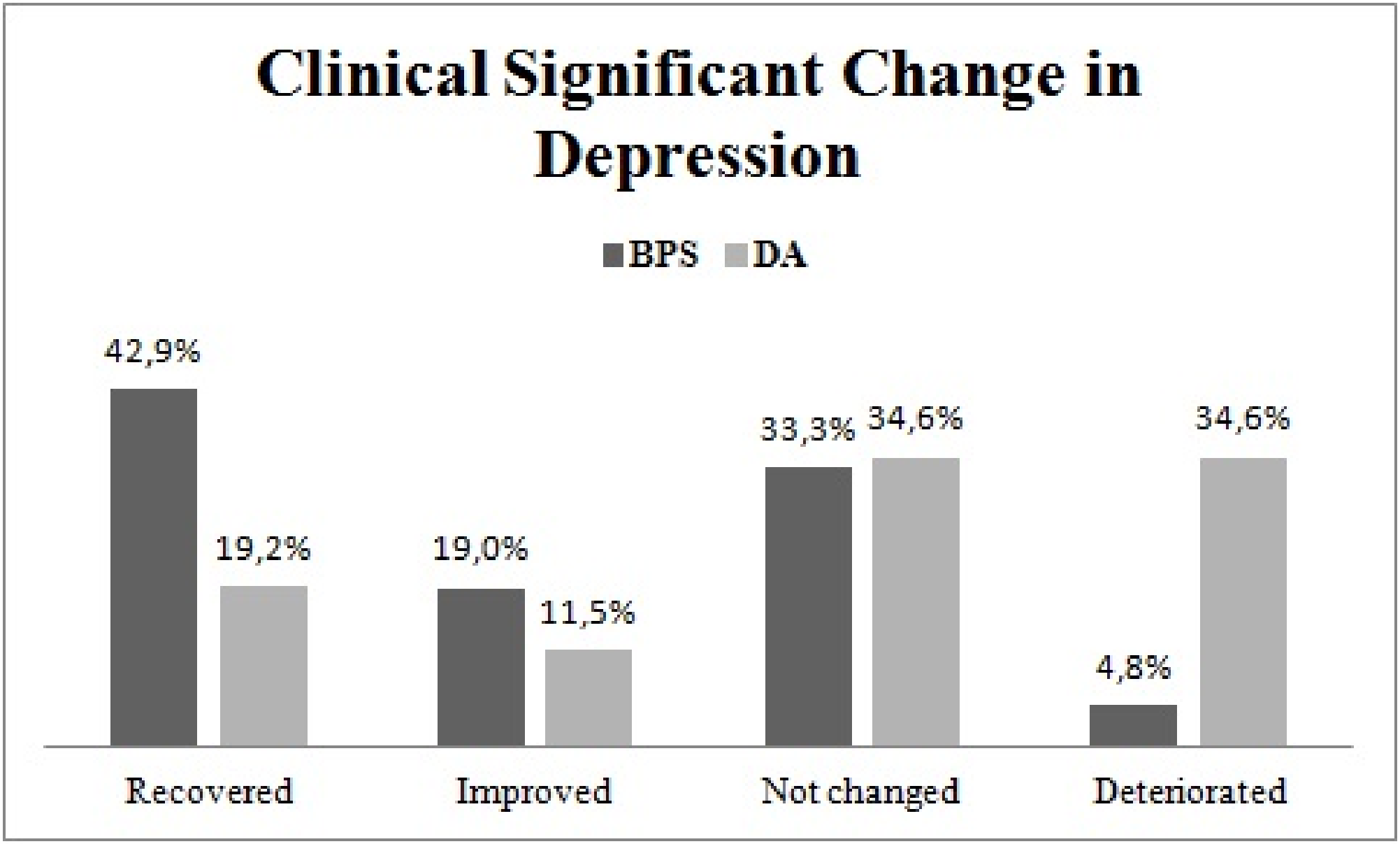

Assessed for eligibility (n=115)
Enrolment
♦ Did not answer phone call (n=5)
♦ Declined to participate (n=19) mobility problems
♦ Excluded (n=8)
♦ Did not attend screening (n=3)
Randomized (n=80)
Allocation
Allocated to BPS intervention (n=40)
♦ Received allocated intervention (n=38)
♦ Did not receive allocated intervention (did not come back for second session) (n= 2)
Allocated to Control condition (n=40)
♦ Received allocated intervention (n=33)
♦ Did not receive allocated intervention (did not come back for second session) (n=6)
Post intervention
Assessed post 1 month self-training (n=23)
Lost at follow-up (n=15) (scheduling conflicts, medical problems, family reasons)
Assessed post 1 month self-training (n=28)
Lost at follow-up (n=5) (scheduling conflicts, medical problems)
Follow-Up at 1 month
Assessed at 1 month FU (n= 18)
Lost at follow-up (scheduling conflicts) (n=3)
Discontinued intervention (feeling better, don´t need it anymore) (n=2)
Assessed at 1 month FU (n= 17)
Lost at follow-up (scheduling conflicts, medical problems) (n=7) Discontinued intervention (no sense of improvement) (n=2)
Follow-Up at 3
Assessed at 3 month FU (n= 15)
Lost at follow-up (scheduling conflicts) (n=3)
Assessed at 3 month FU (n= 13)
Lost at follow-up (scheduling conflicts) (n=4)
Analysis
Analyzed (n= 38)
Analyzed (n= 33)

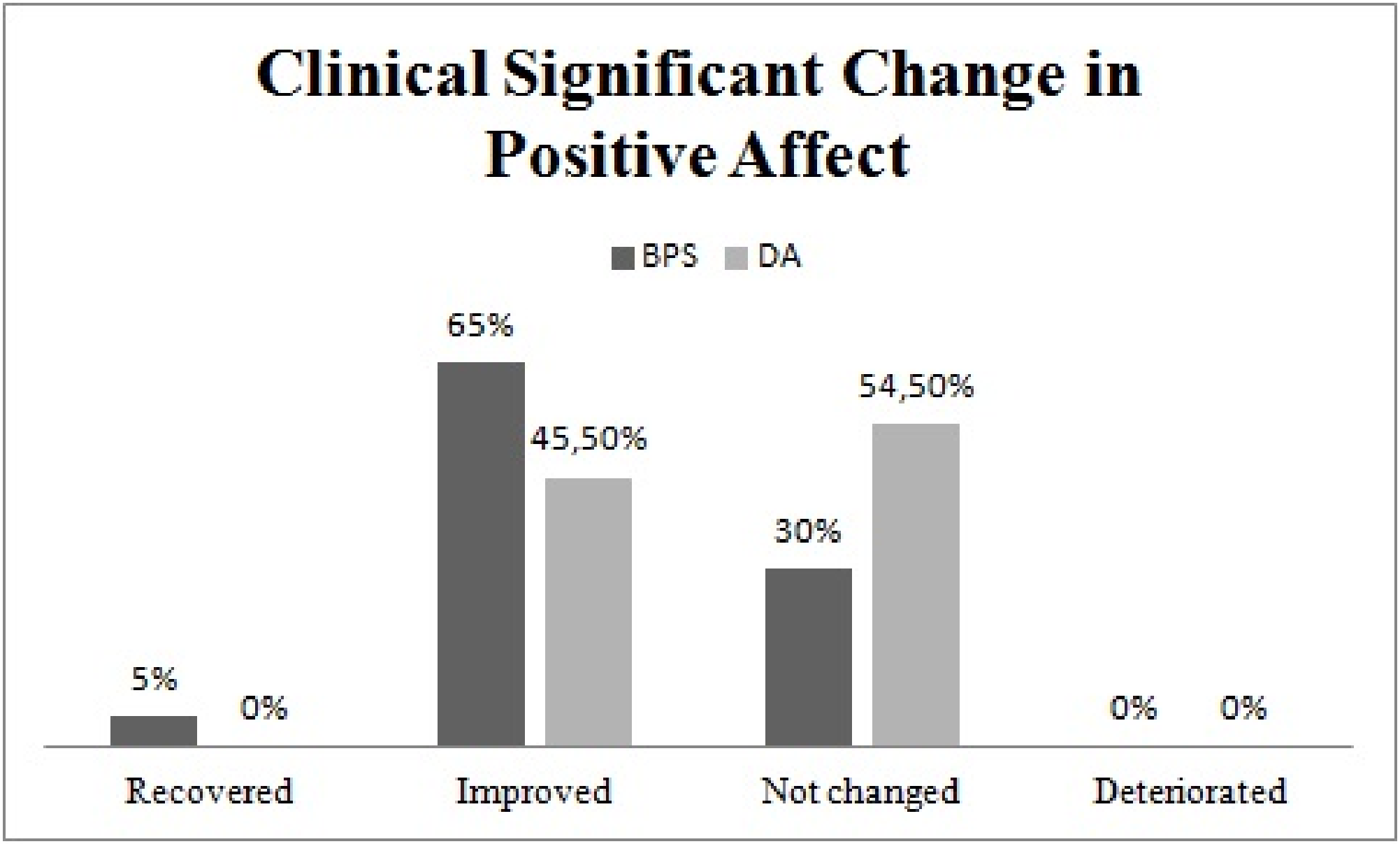

Positive Affect
2,7
2,6
2,5
2,4
2,3
2,2
2,1
2
1,9
PRE
POST
BPS
DA

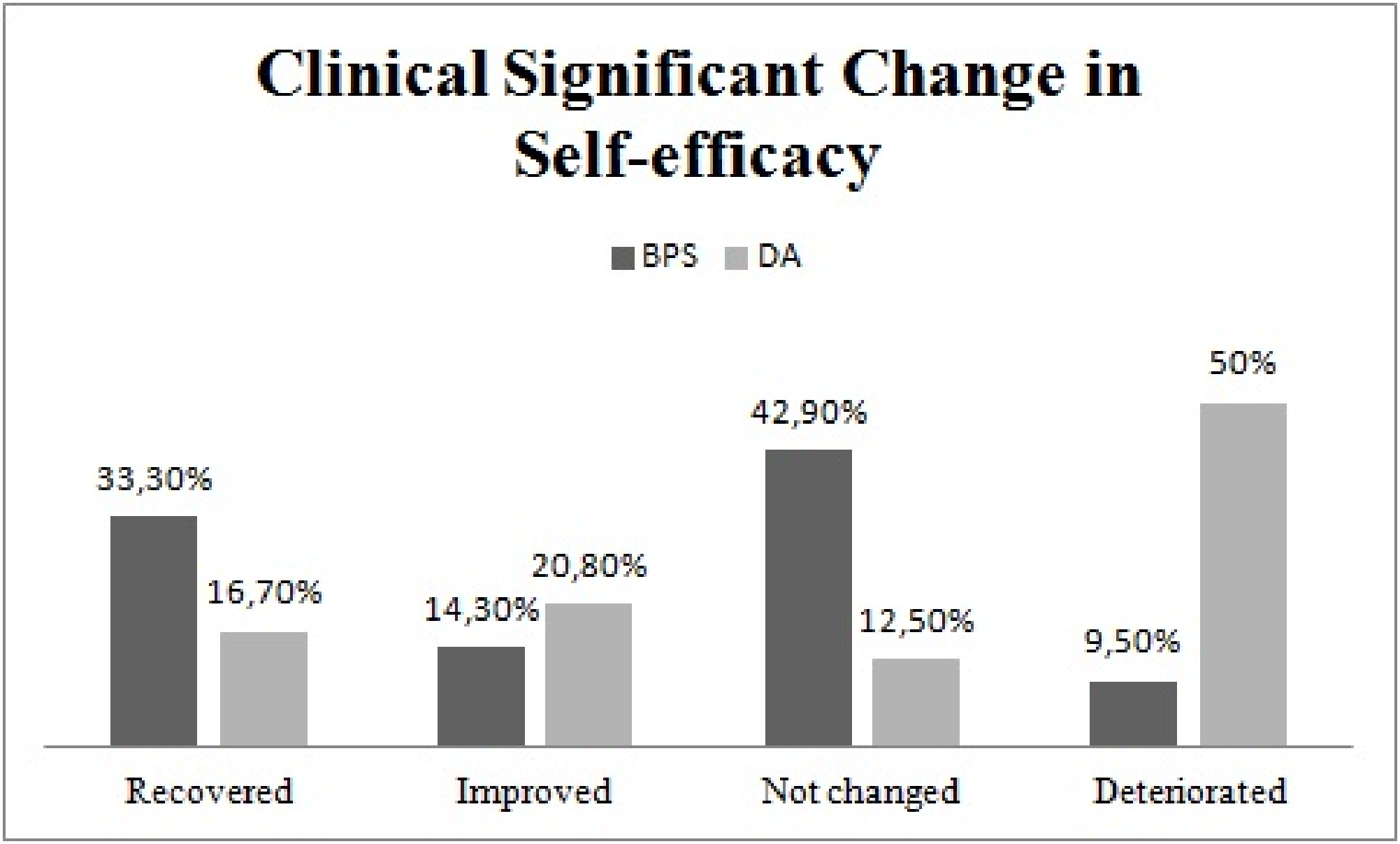

Negative Affect
2,7
2,6
2,5
2,4
2,3
2,2
2,1
2
1,9
PRE
POST
BPS
DA


Positive expectancies
4,65
4,6
4,55
4,5
4,45
4,4
4,35
PRE
POST
BPS
DA


Negative expectancies
3,5
3,4
3,3
3,2
3,1
3
2,9
2,8
PRE
POST
BPS
DA


Clinical Significant Change in Depression
BPS
DA
42,9%
19,2%
19,0%
11,5%
33,3%
34,6%
4,8%
34,6%
Recovered
Improved
Not changed
Deteriorated


Clinical Significant Change in Positive Affect
BPS
DA
65%
45,50%
54,50%
30%
5%
0%
0%
0%
Recovered
Improved
Not changed
Deteriorated


Clinical Significant Change in Self-efficacy
BPS
DA
33,30%
16,70%
14,30%
20,80%
42,90%
12,50%
9,50%
50%
Recovered
Improved
Not changed
Deteriorated