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Effects of Twelve Weeks of Virtual Square Stepping Exercises on Quality of Life, Satisfaction with the Life, Mental Health, and Cognitive Function in Women with Fibromyalgia: A Randomized Control Trial

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Abstract: Fibromyalgia is a condition that primarily affects women and compromises the quality of life (QoL), life satisfaction (SWL), mental health and cognitive function of sufferers. This study aimed to analyze the effects of a physical activity program based on Virtual Square Step Exercise on the above conditions in women with FM. A 12-week randomized controlled trial was designed with 61 women with FM assigned to a control group (CTL) and an experimental group (VSEE). The VSSE group performed VSSE sessions three times a week for 12 weeks, while the CTL continued with their usual treatment. The applicability and safety of the program was tested in this population. In addition, the participants' QoL, SWL, mental health status, and cognitive function were assessed before and after the intervention program using different questionnaires and tests. VSEE was found to be applicable (with adherence greater than 85%) and safe (with no accidents, injuries, or health-compromising incidents) in women with FM. The VSEE showed a significant reduction in self-perceived depressive symptoms compared to the control group ($p < 0.05$). In contrast, no significant changes in QoL, SWL, mental health and cognitive function were observed in the VSEE compared to the CTL ($p > 0.05$). Therefore, even though our VSEE-based intervention was found to be applicable and safe in women with FM, it did not produce significant changes in improving QoL, SWL, mental health, and cognitive function in our sample. The small sample size and post-pandemic context may have affected the findings. More research with a larger sample size is needed to confirm the effects and applicability of VSEE in women with FM.

Keywords: pain; depression; anxiety; memory; rehabilitation

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1. Introduction

1.1. Fibromyalgia and Its Impact on Health and Quality of Life

Fibromyalgia (FM) is a chronic disorder that causes generalized pain, sleep problems, fatigue, and cognitive difficulties [1–3]. Although anyone can suffer from FM, this pathology is more prevalent in women than in men with a ratio between 3:1 and 9:1 [4,5]. The risk of this condition increases with age, especially from middle age onwards [6]. In the general population, the prevalence of FM is 2–4% [1,7]; although, this prevalence may differ depending on the diagnostic criteria [5].

Due to the marked symptomatology of this disease, the life of those who suffer from it is directly affected with great repercussions on the quality of life (QoL) [8,9], autonomy [10], and self-esteem [11] of the people with this condition. Even the patient's personal relationships can be negatively affected with problems in the partner relationship or in the work and/or family scope [12]. In addition, people with FM tend to have negative self-perceived health (SPH) [13]. In fact, in some studies, more than 80% of participants with this condition perceived their health as bad or regular [14]. The nature of this pathology, with its complicated symptomatology, may be one of the reasons why people with FM are more likely to have a reduced satisfaction with life (SWL) [15,16]. In this line, it has been found that people with FM have greater incidence of mental health problems, with poorer mood states [17,18] and a greater incidence of anxiety [19] and depression [20,21]. Additionally, people with this pathology may experience several difficulties in cognitive function [22], with cognitive problems such as memory loss, language problems, limited attention capacity and problems in executive function [23,24], which may have major implications for patients' lives [23].

1.2. Physical Activity in Symptom Management

Although there is no cure for this condition, the symptoms of FM can be managed with a combination of selected pharmacological treatment, psychological therapy, and exercise and movement therapies [6,7,25]. Thus, several investigations have shown that physical activity and exercise interventions can have great benefits for people affected by this pathology [26]. Exercise in FM sufferers could affect nociceptive, neuroendocrine, and autonomic systems, reducing pain and morning stiffness, and stimulating the production of growth hormones [27]. Furthermore, in relation to the aforementioned aspects, the practice of physical activity (PA) has been shown to be associated with a better SPH in people with FM [28]. Similarly, SWL and PA were shown to be associated with greater SWL for those FM sufferers with increased PA participation [29]. As for mental health, there is much evidence showing associations of increased PA with a reduction in anxiety [30] and depression [18] in fibromyalgia patients. Finally, exercise has shown a positive effect on the cognitive function of those who suffer from FM [31,32].

1.3. Square-Stepping Exercise: Fundamentals and Overview of Benefits

Square-stepping exercise (SSE) is an exercise modality originated in Japan that aimed to reduce the risk of falls of its participants [33]. This type of exercise consists of the execution of step patterns, previously memorized, on a fine mat of 200 × 100 cm divided into 40 squares of 25 × 25 cm [34,35]. The practice of SSE requires participants to have concentration, memory, and good executive function, making it demanding for both physical and cognitive function [35].

Several interventions have found improvements in physical fitness after the practice of SSE, with increases in lower limb strength, balance, agility, aerobic endurance, and even augmented confidence in their own ability to perform daily activities [36–39]. Additionally, improvements in SPH [38] and SWL [40] have been found because of SSE interventions [41].

In addition, some investigations have found a beneficial effect of SSE on mental health, with this exercise modality causing a reduction in the depression scores [40] and preventing depressive symptoms [42]. SSE has been shown to have a positive effect on cognitive function, with improvements in overall cognitive state [35], attention [35], mental flexibility [35,43], abstract reasoning, and problem-solving skills [43]. Therefore, SSE could have positive effects on the health-related quality of life (HRQoL), SWL, SPH, mental health, and cognitive function in different population groups such as older adults or people with Parkinson's disease [41,44–46]. However, after reviewing the scientific literature, we did not find any studies evaluating the effects of SSE on these variables in Spanish women with FM.

1.4. Aims and Hypotheses

Our study was based on a hybrid version of the SSE, combining the participants' face-to-face presence with the virtual support of a coach (Virtual SSE), with the aim of evaluating the effects of a 12-week program based on the Virtual SSE on HRQoL, SWL, SPH, mental health, and cognitive function in Spanish women with fibromyalgia. In addition, to analyze whether Virtual SSE is applicable and safe in this population, a hybrid version was chosen to expand the coverage of our study without increasing costs, which allowed the intervention program to be carried out at sites located in different parts of the country. This modality would favor the accessibility of the program, as participants could conduct the sessions in their own localities and in familiar surroundings, which could also contribute to improved adherence. The hypotheses of the present research were that a 12-week Virtual SSE intervention in Spanish women with fibromyalgia is applicable (adherence $\geq$ 80%) and safe (lack of accidents, injuries or health compromising incidents), and improvements were greater than the real minimum differences, or statistically significant differences in health-related quality of life, life satisfaction, perceived health, mental health, and cognitive function.

2. Results

After performing the Shapiro–Wilk test, there was insufficient evidence to assume that the continuous variables followed a normal distribution.

2.1. Sample Characteristics

A total of 61 Spanish women with FM were included in the study. Characterization of the sample according to the continuous variables was presented in Table 1, including the comparative analysis between the experimental and control groups.

Table 1. Descriptive analysis for study participants: Continuous variables.

Variables	Total (n = 61)		Experimental (n = 33)		Control (n = 28)		p-Value
	Median	(IQR)	Median	(IQR)	Median	(IQR)	
Age (Years)	58	(11)	58	(7)	58	(11)	0.489
Height (m)	1.58	(0.07)	1.59	(0.08)	1.58	(0.06)	0.827
Weight (kg)	72.0	(19.4)	72.5	(23.9)	68.2	(14.6)	0.094
BMI (kg/m^2)	28.1	(8.1)	28.1	(12.1)	27.3	(6.7)	0.105
Waist (cm)	94.5	(15.8)	98.5	(13.0)	89.0	(16.0)	0.014
Hip (cm)	108.0	(15.0)	110.0	(20.5)	106.0	(9.5)	0.124
Waist:Hip ratio	0.86	(0.09)	0.88	(0.08)	0.84	(0.10)	0.091
Years since diagnosis	13	(14)	12	(13)	14	(12)	0.614
Years with symptoms	20	(20)	21	(20)	20	(18)	0.544
IFIS (Score 0–25)	13.5	(4.0)	13.5	(4.0)	13.5	(4.5)	0.626
FIQ (Score 0–100)	57.9	(21.5)	58.3	(24.5)	57.0	(16.1)	0.904

Table 1. *Cont.*

Variables	Total (n = 61)		Experimental (n = 33)		Control (n = 28)		p-Value
	Median	(IQR)	Median	(IQR)	Median	(IQR)	
VAS Pain (Score 0–10)	6.5	(2.2)	6.9	(2.5)	6.3	(1.5)	0.085
SF-12_Physical	9	(3)	9	(4)	10	(4)	0.963
SF-12 Mental	15	(5)	14	(4)	15	(6)	0.047
SF-12 Total	24	(7)	23	(6)	26	(6)	0.188
The_15-D	0.653	(0.229)	0.671	(0.212)	0.635	(0.165)	0.253
EQ5D-5L Index	0.525	(0.302)	0.473	(0.300)	0.657	(0.273)	0.045
EQ5D-5L VAS	50	(30)	50	(25)	53	(33)	0.476
Self-Perceived Health (Score 1–5)	2.0	(1.0)	2.0	(1.0)	2.0	(0.0)	0.540
Satisfaction with Life Scale (Score 5–25)	14.0	(7.0)	14.0	(5.3)	15.0	(9.0)	0.617
Self-Reported Depression (Score 0–10)	7.0	(3.0)	8.0	(2.0)	7.0	(3.0)	0.506
Self-Reported Anxiety (Score 0–10)	8.0	(4.5)	8.0	(5.0)	9.0	(4.0)	0.500
Beck's Depression Inventory II (Score 0–63)	18.0	(16.0)	18.0	(17.0)	16.5	(12.3)	0.959
Self-Reported Memory Problems (Score 0–10)	4.0	(5.0)	5.0	(3.5)	3.5	(6.8)	0.800
SDMT	33	(16)	33	(18)	33	(15)	0.468
CVLT	45	(15)	46	(15)	43	(14)	0.188
BVMT-R	6	(3)	6	(2)	6	(3)	0.078

n (participants); IQR (Interquartile range); p-value (From Mann–Whitney U Test with Bonferroni correction. Significant differences with $p < 0.001$); IFIS (International Fitness Scale. L5–9, ow perceived physical fitness; 10–19, Between moderately poor to moderately high perceived physical fitness; 20–25, High perceived physical fitness); FIQ (Fibromyalgia Impact Questionnaire. 0: Minimal Impact; 100: Maximum Impact); VAS (Visual Analogic Scale. 0: Minimal Pain; 10: Maximum Pain); SDMT (Symbol Digit Modalities Test); CVLT (California Verbal Learning Test); BVMT-R (Brief Visuospatial Memory Test-Revised); Beck's Depression Inventory (0–13, minimal depression; 14–19 mild; 20–28, moderate; 29–63, severe depression).

The median age of the participants was 58 years (Interquartile Range (IQR) = 11). Their median years since the diagnosis of FM and since the occurrence of their first symptoms were 13 (IQR = 14) and 20 (IQR = 20) years, respectively. Participants had an impact of FM according to the FM Impact Questionnaire (FIQ) of 59.0 (IQR = 31.7) and a pain score (Visual Analogic Scale Pain (VAS Pain)) of 6.5 (IQR = 2.2). In all these characterization variables, no significant differences were found between the control group and the experimental group. In the study, variables (HQRoL: SF-12 Total, SF-12 Physical, SF-12 Mental, The 15-D, EURO-QOL-5D-5L (EQ5D5L) and EQ5D5L Visual Analogic Scale (EQ5D VAS); SPH, SWL Score (SWLS), Mental Health: S-RD, (Self-related Depression Symptons), S-RA (Self-related Anxiety Symptons) and Beck Depression Inventory Second Edition (BDI-II); and Cognitive Function: Self-related Memory Problems (S-RMP), Symbol Digit Modalities Test (SDMT), California Verbal Learning Test (CVLT) and Brief Visual–spatial Memory Test Revised (BVMT-R)) no significant differences were found between groups either.

Table S1 shows the characterization of the sample according to the categorical variables (Civil Status, Employment Situation, Education Level, Smoking Status, Drinking Status, SPH, Depression Status and Depression Symptoms). A total of 89.8% of the sample reported being non-smokers and only 16.9% reported drinking alcohol frequently or very frequently. In addition, 88.1% had a negative SPH, while only 40.4% were satisfied or very satisfied with their life. Finally, only 34.7% had no symptoms of depression: 20.4% and 26.5% had mild or moderate symptoms, respectively, while 18.4% had severe symptoms. No dependency relationships were found between each of these variables and the group to which the participants were assigned are as follows: SPH ($p = 0.091$), Depression Status ($p = 0.970$) and Depression Symptoms ($p = 0.815$).

2.2. Pre- and Post-Intervention Analysis

2.2.1. Applicability and Security

Virtual SSE was found to be applicable and safe in this population. Participants assigned to the experimental group attended at least 85% of the sessions. During the duration of the training program, no accidents occurred during the sessions, nor did the participants suffer any injuries during the execution of the exercises.

2.2.2. Intra-Group Comparision

In the experimental group, significant pre- and post-intervention differences were found in the mental health dimension of the SF-12 ($p = 0.016$), SPH ($p = 0.036$), S-R Depression ($p < 0.001$), CVLT ($p < 0.001$) and BVMT-R ($p = 0.002$). In all these cases, the participants showed slightly better post-intervention results (Table S2). In the control group, significant differences were only found in the cognitive variables: SDMT ($p = 0.047$), CVLT ($p < 0.001$) and BMVT-R ($p < 0.001$).

2.3. Comparision Between Experimental and Control Group

2.3.1. Health Related Quality of Life

Virtual SSE was not found to be effective in improving participants' HRQoL according to SF-12 (SF-12 Physical Health, SF-12 Mental Health and SF-12 Total), The 15-D, EQ5D-5L and EQ5D VAS (Table S2).

Both groups showed a slight improvement in post-intervention SF-12 total scores. However, no significant intragroup (Exp: 24 vs. 26, $p = 0.071$; Con: 25 vs. 28, $p = 0.300$) or intergroup ($p = 0.305$) differences were found. Therefore, Virtual SSE was not found to be effective in improving HRQoL based on the SF-12 scores. In the analysis of the components of the HRQoL according to the SF-12, no differences were found between the medians of the intergroup differences (SF-12 Physical Health: $p = 0.635$; SF-12 Mental Health: $p = 0.056$). These results were despite finding pre–post intervention differences in the experimental group in the mental component ($p = 0.016$) that were slightly better post intervention. Figure 1 shows the pre–post intervention differences in both groups on the HRQoL and its components according to the SF-12.

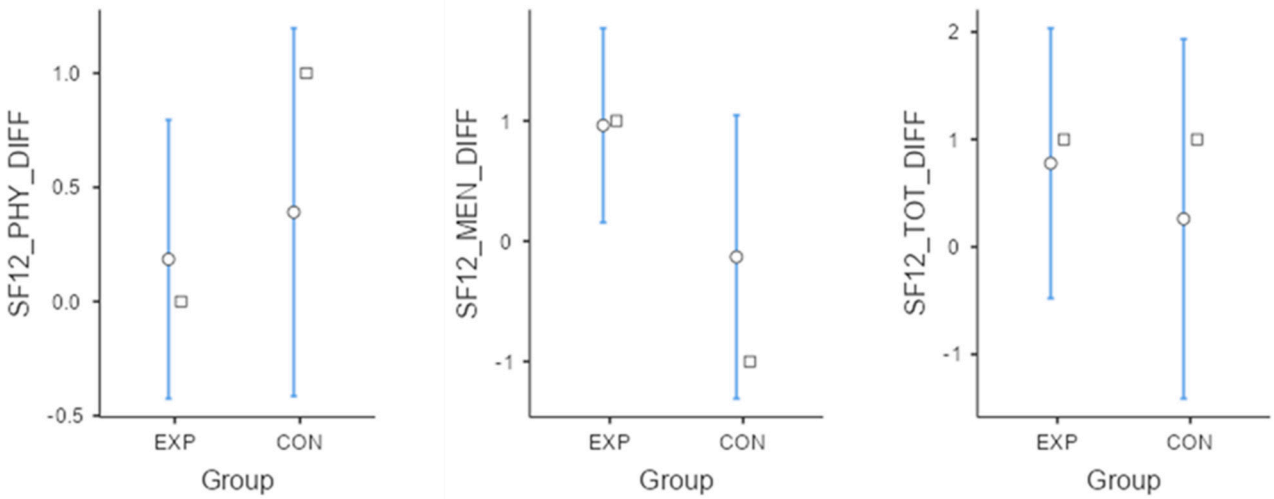

Figure 1. Differences in SF-12 scores and its dimensions (SF-12 Physical Health and SF-12 Mental Health) pre- and post-intervention in both groups. The circle shows the mean score, and the square shows the median.

No significant inter- and intra-group differences were found pre- and post-intervention in the rest of the variables related to the HRQoL (Table S2). Neither group showed sig-

nificant differences in the pre–post intervention analysis in the 15-D (Exp: $p = 0.450$; Con: $p = 0.121$), EQ5D-5L (Exp: $p = 0.121$; Con: $p = 0.190$), and EQ5 VAS (Exp: $p = 0.090$; Con: $p = 0.591$). For these variables, no intergroup differences were found between the medians of the intergroup differences (15-D: $p = 0.839$; EQ5D-5L: $p = 0.645$; EQ5 VAS: $p = 0.162$). Figure 2 shows the differences in EQ5-VAS scores for the experimental and control groups.

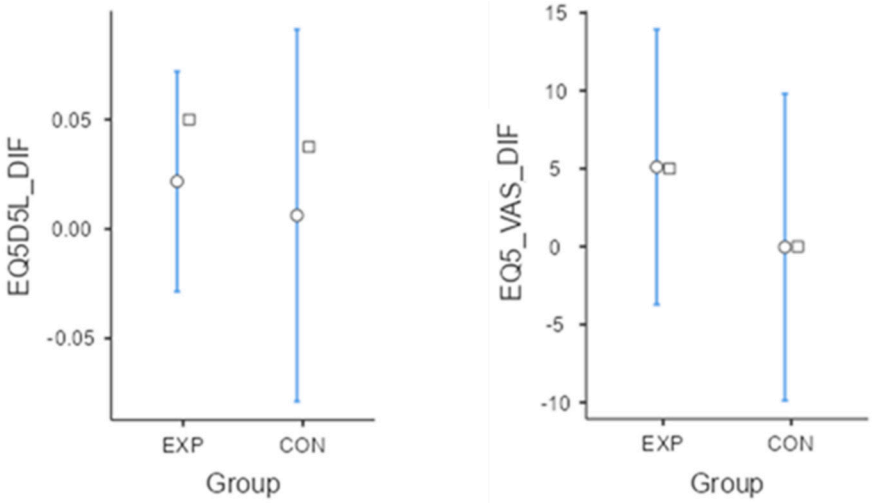

Figure 2. Differences in EQ5D5L Index and EQ5VAS pre- and post-intervention in both groups. The circle shows the mean score, and the square shows the median.

2.3.2. Self-Perceived Health, Satisfaction with Life, Mental Health and Cognitive Function

Among the variables, a significant intra-group difference found in the experimental group was SPH ($p = 0.036$), with a slight improvement observed in this group. These differences were not observed in the control group ($p = 0.242$). Despite these findings, no intergroup differences were found ($p = 0.270$), so we could not be sure that Virtual SSE was effective in improving SPH in this population (Table S2).

Regarding SWLS, no significant intergroup (EXP: $p = 0.856$; CON: $p = 0.244$) or intra-group post-intervention differences were found ($p = 0.118$). Virtual SSE was not effective in improving participants' SWLS (Table S2).

In the perceptual variables of mental health, S-RD was the only variable that showed significant pre–post intervention differences in the experimental group ($p < 0.001$); a slight improvement in symptoms that was not observed in the control group and intergroup differences were found (−2 vs. 0, $p = 0.029$, E.S. = 0.317). In contrast, no differences were found in the perception of anxiety symptoms, nor in the assessment of mental health through BDI-II (Table S2).

In the variables related to cognitive function, no significant differences were found in the S-MP intra- (EXP: $p = 0.645$; CON: $p = 0.671$) and intergroup ($p = 0.411$) post-intervention. Virtual SSE was not effective in improving participants' perception of memory. On the other hand, despite finding significant intra-group post-intervention improvements in the results obtained in the CVLT (46 vs. 49, $p < 0.001$) and BVMT (6 vs. 8, $p < 0.001$) in the experimental group, no significant differences were found with the control group ($p > 0.05$); therefore, it could not be assumed that these changes were due to the intervention program with Virtual SSE (Table S2).

Figure 3 shows the descriptive plot of the between-group comparative analysis of these variables.

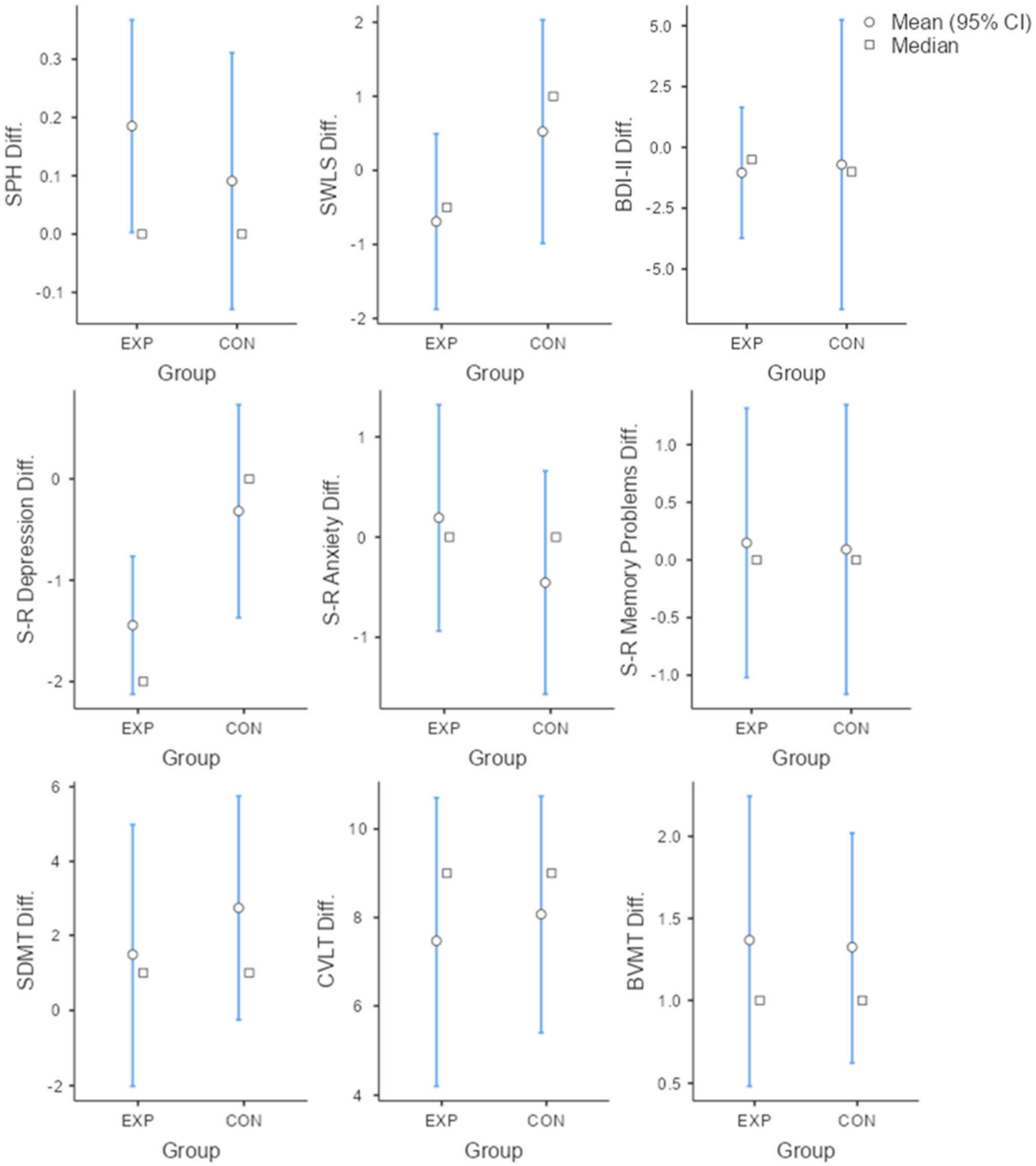

Figure 3. Descriptive plot of differences pre- and post-intervention in the study variables: SPH (Self-Perceived Health); Diff. (Differences); SWLS (Satisfaction With Life Score); BDI-II (Beck's Depression Inventary II); S-R (Self-Reported); SDMLT (Symbol Digit Modalities Test); CVLT (California Verbal Learning Test); BVMT-R (Brief Visuospatial Memory Test-Revised); EXP (Experimental); CON (Control).

Finally, according to the results of McNemar's test, no significant associations were found between the intervention program and the categorical variables related to SPH (EXP: $p = 0.564$; CON: $p = 0.083$), depression status (EXP: $p = 0.655$; CON: $p = 0.180$), and depression symptoms (EXP: $p = 0.306$; CON: $p = 0.277$) in both groups. Therefore, Virtual

SSE was also ineffective in improving these variables. Table 2 shows the distributions of these variables pre- and post-intervention in experimental and control groups.

Table 2. Percentage frequency distributions of Self-Perceived Health, Depression Status and Depression Symptoms by groups before and after interventions based to Virtual Step Square Exercise in Spanish women with Fibromyalgia.

Variables	Experimental		*p*-Value	Control		*p*-Value
	Pre	Post		Pre	Post	
Self-Perceived Health						
Positive	22.2%	25.9%	0.564	4.5%	0.0%	0.083
Negative	77.8%	74.1%		95.5%	100.0%	
Depression Status (BDI-II)						
No	41.7%	45.8%	0.655	35.3%	52.9%	0.180
Yes	58.3%	54.2%		64.7%	47.1%	
Depression Symptoms (BDI-II)						
None	41.7%	45.8%	0.306	35.3%	52.9%	0.277
Mild	16.7%	33.3%		17.6%	5.9%	
Moderates	25.0%	4.2%		23.5%	17.6%	
Severes	16.7%	16.7%		23.5%	23.5%	

n (participants); *p* (*p*-value from McNemar Test for tables 2 × 2 and McNemar Bowker for table 4 × 4); % (percentage).

3. Discussion

This was the first research to evaluate the effects of a 12-week training program based on the Virtual Square Stepping Exercise on QoL, SWL, SPH, mental health, and cognitive function in Spanish women with FM. Furthermore, this study was the first to evaluate the applicability and safety of the program in this population. The first finding was that the Virtual SSE could be applicable and safe in Spanish women with FM, given the follow-up is conducted by the participants and there is an absence of accidents and injuries during the program, confirming the first hypothesis of the study.

In addition, the other main finding of this study was that a 12-week intervention based on the Virtual SSE program in Spanish women with FM had no significant effect on QoL, SWL, SPH, mental health, and cognitive function in this population. Therefore, Virtual SSE, in the form in which it was applied, in the sample analyzed, was not effective in improving QoL, SWL, SPH, mental health, and cognitive function. Significant positive effects were only found in the subjective perception of depressive symptoms of the participants in the experimental group compared to those in the post-intervention control group.

3.1. Quality of Life

Previous research has found that SSE-based PA programs may have positive effects on QoL-related aspects of the populations in which they have been applied. Among these aspects, improvements in physical function, health perception, mental health or cognitive function have been found, as well as reduced risk of falls, a potential risk for loss of QoL in older people and other populations [35,39,42,47,48]. In this sense, a recent systematic review [41] examined the effects of SSE on physical function, body composition, mental health, and cognitive function in healthy older people. The authors expected that the implementation of an SSE-based PA program could not only improve balance, coordination, executive function, and reduce the risk of falls in this population but also improve QoL. However, despite these authors' comments on the potential of SES to improve QoL in older people, no research was found that specifically examined the effects of SES on QoL in this or other populations. One of the main objectives of our study was to evaluate the effects of a virtual version of the SSE on the QoL of Spanish women with FM,

hypothesizing that 12 weeks of Virtual SSE-based exercise would have a positive effect on participants' QoL. Despite analyzing QoL with different instruments, SF-12 (analyzing the total and component scores: SF-12 Physical Health and Mental Health), EQ5D-5L (including analysis of the EQ5-5L VAS) and the 15-D, Virtual SSE had no effect on any of them. The consistency of the results found in all instruments only reinforced the decision to reject the first hypothesis of our study and to confirm that a 12-week training program based on Virtual SSE does not improve the QoL of Spanish women with FM. However, these results may have been affected by a limited sample and the statistical power achieved for the comparative analysis between groups. Therefore, these results and interpretations should be taken with caution and further research is needed.

3.2. Self-Perceived Health

Although significant differences were found in participants' post-intervention SPH with respect to pre-intervention SPH in the experimental group, reporting a slight improvement post-intervention (0.2 points on average), this variation was not statistically significant with respect to that experienced by the control group. There were also no significant changes in the proportions of positive and negative SPH in both groups. This finding was not expected, and the hypothesis that Virtual SSE would improve the SPH of Spanish women with FM could not be confirmed. Our findings are contrary to those found in a previous study on Japanese older adults, which had found that SPH increased by 0.5 points; although, this was an intervention based on a 12-week SSE face-to-face program [38]. In that study, the age of the participants was higher than in our study (69 years vs. 58 years), and this difference, together with cultural differences, may have affected the disparate results. In addition, the authors made minor modifications during the program to increase lower limb strength. Participants were required to perform the movement patterns with their heels raised and the authors suggested that this may have increased leg strength. This modification may have affected the participants' SPH, as studies indicate that greater lower limb strength is related to better SPH [49,50]. The adaptations made by these authors, as well as their findings, lead us to consider that our program may not have provided sufficient stimulus for the participants and that it would be necessary to increase the intensity of the program and integrate strength exercises to produce significant changes in the participants. However, the interpretation of these results should be taken with caution, given that our sample was small and research involving a larger sample could provide further support for these findings.

3.3. Mental Health and Satisfaction with Life

The subjective perception of depressive symptoms was found to be significantly reduced in the experimental group post-intervention, while it remained the same in the control group. This finding is in line with that found in a previous study with 32 older adults in Brazil [42]. In that study, Pereira et al. reported that, after 16 weeks of face-to-face intervention with SSE, scores on the Geriatric Depression Scale-15 decreased by 8.6% in the experimental group, while increasing by 29.8% in the control group. However, although our study found a significant reduction in self-reported depressive symptoms, these were not supported by results on BDI-II scores, self-reported symptoms of anxiety or life satisfaction. Of all these variables, no post-intervention modifications were found in or between the two groups. Contact with the instructor and the group context in the face-to-face activities may have influenced mental health in the Pereira et al. study and conditioned our virtual intervention. However, another study with a hybrid intervention like the one used in our study (online monitor and participants in group settings) reported improvements in psychological function; although, they did not study depression or depressive symptoms [43].

The authors assessed psychological functioning with the Subjective Vitality Scale, reporting an increase in vitality in the experimental group. However, the conditions under which the intervention was carried out, in a post-pandemic period for COVID-19, with mandatory use of masks and maintaining distance between participants, could also have had a negative impact on our results. Therefore, the hypotheses related to the positive effects of Virtual SSE on the mental health and SWL of Spanish women with FM were rejected. However, the size of the sample, the statistical power achieved, and the presence of possible uncontrolled confounding factors—especially those derived from the context of uncertainty generated by the COVID-19 pandemic—force us to be cautious about affirming whether Virtual SSE is effective in this population. Therefore, we believe that further research is needed to clarify its real impact.

3.4. Cognitive Function

Participants in the experimental group showed a slightly lower median (−12.5%) in self-reported memory problems post-intervention, as opposed to women in the control group (+12.5%). However, these trends were not statistically confirmed, and no intra- and inter-group differences were found. The results found in the cognitive tests showed an increase in post-intervention scores in the experimental group in SDMT, CVLT, and BVMT. Significant differences were found in the CVLT and BVMT scores, but not in the SDMT. In the control group a reduction in SDMT was found, in contrast to the experimental group, but no significant differences were found between groups. In addition, the control group improved their scores on the CVLT and BVMT, with no differences between groups. Therefore, the results observed in cognitive tests should be interpreted with caution. This increase in the scores of both groups could be more conditioned by the participants' learning than by the effects of the intervention. Therefore, we cannot be sure that our VSSE-based PA program is effective in improving cognitive function in Spanish women with FM. Given that the cognitive tests were administered repeatedly, it is possible that participants may have improved their performance due to familiarization with the tasks, rather than an actual improvement in cognitive functions. This finding is particularly relevant in tests such as the CVLT and BVMT, where repetitions may have favored the memorization of prompts and facilitated higher performance without reflecting a real improvement in the participants' cognitive ability. Although these tests are commonly used to assess cognitive function and are valid and reliable, they are limited by participants' recall of the task as a factor that may positively influence repeated measures. However, as no differences between groups were found, our findings are contrary to what is expected and what other researchers have found in other populations. A study of 93 older adults (19 men and 74 women) in Singapore [43], after 12 weeks of hybrid intervention with SSE, found significant improvements in cognitive function in the experimental group as assessed by the Stroop test. Another study with 41 older adults from Brazil [35] found, after 16 weeks of face-to-face intervention with SSE, improvements in global cognitive status, focused attention and mental flexibility assessed with the Mini-Mental State Examination, the Digit Span test, the Toulouse–Pieron Attention Test and the Modified Card Sorting Test. Another study with 24 Japanese older adults [51] found that a 6-month program with SSE improved memory and language as assessed with Five Cog, but found no differences in attention, visuospatial function, and reasoning scores. In contrast, our findings are in line with a systematic review by Yin-Hsiang et al. [52] including 10 articles and 920 older adults that found no beneficial effects of SSE on cognitive function. These authors presented as a limitation that the number of investigations found on SSE and cognitive function were few and that further research would be necessary to strengthen their findings. However, the evidence found is limited [41]. In some cases, as in the study by Teixeira et al. [35,41], only the results of the experimental group were shown,

without showing the comparison with a control group. Our study found improvements in cognitive function in Spanish women with FM post-intervention; however, as we found no significant differences with the control group, we rejected the initial hypothesis related to the improvement of cognitive function. However, again, the sample size and the statistical power achieved may affect the results found and make us cautious as to whether VSSE can be effective in improving cognitive function in women with FM. Furthermore, we believe that it would be necessary to expand the battery of tests by assessing cognitive function. Therefore, the authors believe that further research is needed to further explore the effects of SSE and VSSE on cognitive function in women with FM. In addition, in the experimental group, three participants (8.3%) were lost during the intervention. These drop-outs occurred before the final assessments. Despite a low dropout rate, the inclusion of an intention-to-treat analysis could have increased the robustness of the interpretation of the results; although, this could not be performed due to lack of data. Finally, since no measures, such as the counterbalancing of tests or use of additional control groups, were applied, the interpretation of these results are limited, and we recommend that future studies consider these methodological strategies to address this potential bias.

3.5. Practical Applications

This study was the first to evaluate the applicability, safety, and effects of Virtual SSE on QoL, SPH, mental health, SWL, and cognitive function in Spanish women with FM. Since Virtual SSE was found to be applicable and safe in this population, it could be a useful tool for health promotion through physical activity in this population. On the other hand, we found an improvement in the subjective perception of depression in the participants. This finding, together with the findings related to an improvement in mental health reported by other researchers, could suggest that Virtual SSE could be a useful tool for improving mental health in women with FM. However, the authors believe that further research on its implementation and effects would be necessary before recommending its use for this purpose. Given that Virtual SSE is a program that can be adapted to the level, age, abilities, or cultural differences in the participants, as well as allowing for other adaptations in its execution, we believe that it may have potential in health promotion beyond our findings. In middle-aged women with FM, it would be convenient to increase the intensity of PA programs based on Virtual SSE, integrating strength exercises while performing the patterns or performing concurrent training in which Virtual SSE is combined with strength training. These could be lines of future research that could improve our intervention and obtain better results than those found after our program. Being a hybrid type of training that combines face-to-face and virtual components can reduce implementation costs; the trainer does not need to travel to the venues and can attend several venues at the same time, providing contact and supervision to the participants. In addition, participants can maintain social contact with other women with similar characteristics, encouraging adherence to the program.

3.6. Limitations

This study had some limitations that may have affected the results of our study. The context in which the recruitment and execution of the study took place, a post-pandemic period of COVID-19, made it very difficult to recruit a large sample and complicated the development of the sessions as planned. Fear of COVID infection, fear of social interaction, and legislative uncertainty were some of the reasons given by potential patients for not participating in the study. Although, with the sample size achieved, we can conclude that our 12-week intervention was not effective in improving quality of life in women with fibromyalgia, since no significant intra-group differences were found between pre- and post-

intervention measurements. However, given that we did not reach the required sample size for bilateral testing, we cannot rule out the possibility that intergroup differences could have been detected if a larger sample had been available. This sample size limitation could have influenced the results obtained. In addition, the sessions had to be conducted while wearing a mask and respecting a safe distance, avoiding contact between participants. In addition, given the special circumstances, it is possible that the mental and cognitive health of the women was conditioned by the environmental conditions and that the results of the tests were affected. On the other hand, there was no homogeneity in the tests performed with other studies to assess depressive symptoms and cognitive function, so it is not possible to make comparisons with the results obtained in other studies and this may be the reason for finding results contrary to other research. As this was the first study in women with FM, we also had no possibility to compare with the results of other studies in this population, so here is a first step with which to continue research. Another limitation of the study was related to the single-blind design. As the participants could not be blinded, the results could be conditioned by expectation bias. Although measures were taken to reduce this bias, such as giving neutral information to the participants, avoiding emphasizing possible benefits, or expectations of improvement, we believe that recording the participants' prior expectations to analyze their effects on the results would have enhanced our study and should be included in future research. Finally, although the control group did not subsequently receive the VSSE-based intervention program (workbooks and mats), these materials were made available in the collaborating associations, and control group participants had free access to them. However, having formally offered the intervention to the control group at a later stage might have further strengthened internal comparisons and mitigated the effects of expectations in our study, which is another limitation of our research.

4. Materials and Methods

4.1. Design

This study was a single-blind randomized controlled trial. The staff who performed the evaluation tests were blinded to the group to which the participants had been assigned. In contrast, a double-blind design was not possible due to the characteristics of the intervention to be performed. The researchers could not blind the participants to their assignment to the control or experimental group and, therefore, the participants were informed of the group to which they belonged from the moment of their designation. Participants were assigned to the control group (usual care) or experimental group (Virtual SSE) using Research Randomizer computer software (v.4.0, Geoffrey C. Urbaniak and Scott Plous, Middletown, CT, USA; http://www.randomizer.org) before baseline testing. To this end, a simple randomization sequence was created prior to participant enrollment by randomly assigning participants 1:1 to each group. Participants were assigned an identifying code. The assignment was performed by a member of the research team with no clinical involvement in the trial and concealed from the evaluators.

This study had ethical approval by the Bioethics and Biosafety Committee of the University of Extremadura (approval number: 79/2018), as well as being registered with the Australian and New Zealand Clinical Trials Registry (application number: 378330; https://www.anzctr.org.au. Accessed on 29/11/2019). The Consolidated Statement of Consolidated Standards for Reporting Trials (CONSORT) for randomized controlled trials [53] was followed for the submission of the study.

4.2. Participants

To participate in this randomized clinical trial, participants had to meet the following inclusion criteria: (1) Be a female over 18 years of age and resident in Spain. (2) Have been

diagnosed with FM by a rheumatologist meeting the criteria of the American College of Rheumatology. (3) Have been diagnosed with FM by a rheumatologist meeting the criteria of the American College of Rheumatology [54]: pain in at least 4 of 5 regions, prolonged symptoms with a similar level for 3 months, a generalized pain index (WPI) greater than or equal to 7 and scores on the symptom severity scale (SSS) greater than or equal to 5 or WPI between 4 and 6 and SSS Score $\geq$ 9. (4) Not suffering from other pathologies that contraindicated physical activity or required special attention during physical activity (moderate or severe cardiac, renal, bone, or pulmonary pathologies). For this purpose, the physical activity readiness questionnaire (PAR-Q) was administered [55]. (5) Not presenting any pathology requiring the taking of psychotropic drugs or other drugs that could affect the vestibular system and influence the balance of the participants. (6) Not suffering from any neurodegenerative disease (Parkinson's, Multiple Sclerosis, or similar). (7) Not having performed PA according to the World Health Organization (WHO) in the 3 months prior to the intervention [56]. (8) Have the ability to walk and communicate autonomously. (9) Have access to a device that would allow videoconferencing. (10) Try to remain in the same FM association for the duration of the intervention. The exclusion criteria were as follows: (1) Not accepting informed consent to participate in the study. (2) Not completing the initial assessments. (3) Not completing the post-intervention assessments.

An a priori sample size calculation was performed to estimate the minimum number of participants needed for the study. The sample calculation was performed with the G*Power 3.1.9.2 software and was based on the parameters of the main dependent variable of the project (quality of life assessed through the EQ5D5L). The minimum number of participants needed to detect intragroup differences was calculated for a t-student test for paired samples. The parameters used for the calculation based on this test and this variable were SD of 0.26, minimum real change of 0.15, and an alpha and beta risk of 0.05 and 0.2, respectively, were assumed. This estimated a minimum necessary sample of 26 participants per group to be able to detect a change of 0.15 units between pre- and post-intervention measurements. On the other hand, based on the parameters of the main dependent variable of the project, accepting an alpha and beta risk of 0.05 and 0.2, respectively, and using the t-student test for independent samples, a minimum sample of 98 women was estimated to be necessary to detect intergroup differences (experimental versus control).

The sample was recruited from December 2021 to April 2022 through local and national FM associations. After prior contact with FM associations, participants were recruited from four Spanish provinces: Cáceres, Elche, Madrid, and Palencia. An initial sample of 89 women with FM was obtained and screened for selection. After applying the selection criteria, 10 women did not meet the criteria and were excluded. Despite meeting the study requirements, 8 women declined to participate in the study. For the group allocation process, 71 women with FM were included in the study. Thirty-six women were assigned to the experimental group and 35 to the control group. The intervention program started with 36 participants in the experimental group and 31 participants in the control group. During the intervention, 3 participants in the experimental group and 3 participants in the control group decided not to continue in the study for personal reasons. A total of 4 participants from the control group did not attend the post-intervention tests and were excluded. The final sample analyzed was 61 participants: 33 (experimental group) and 28 (control group). Figure 4 shows the organization chart of the participants. Figure 4 shows the flow chart of the participants.

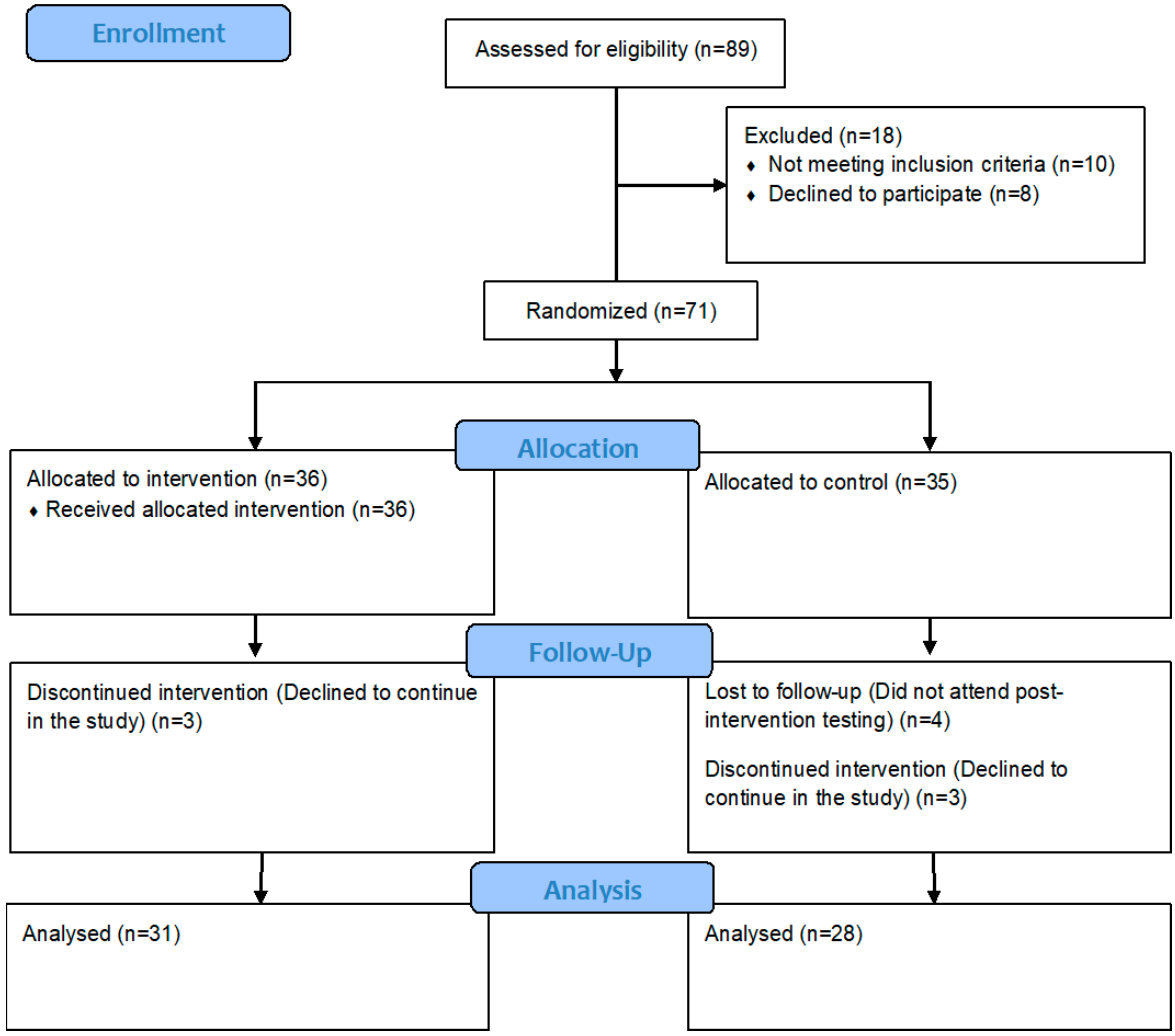

Figure 4. Flow Diagram.

Given that in our study, the group of participants who carried out the intervention was composed of 33 women, we can say that the statistical power achieved in the within-group analysis was 89.5%. In addition, given that our study sample consisted of 33 participants in the experimental group and 28 in the control group, the post hoc analysis determined that a statistical power of 59.8% was achieved for the intergroup analysis.

4.3. Intervention Program

Experimental group (Virtual SSE): The experimental group received training based on the Virtual SSE for 12 weeks, three sessions per week. Before starting the intervention, participants received a thin carpet designed for SSE. The training mats had dimensions of 250 × 100 cm and were divided into 40 squares of 25 × 25 cm. In addition, they were given a booklet with 200 different movement patterns classified into three levels of difficulty: Beginner (with two sub-levels), Intermediate, and Advanced (with three sub-levels, respectively) [34,39,57]. With the delivery of the mats and exercise booklets, they were given training guidelines. The intervention included progression through the 200 movement patterns, starting with the simplest level (simple walking pattern) and progressing to levels with more complex patterns (steps and movements in multiple directions), up to the maximum level. Participants carried out the sessions in groups of 2 to 6 participants in a common room provided by the participating associations. In these

rooms, the participants had training mats, pattern booklets, an internet connection, and a screen to connect to an SSE expert, who monitored the sessions by videoconference.

SSE expert connected with the groups to conduct the sessions, indicating the patterns to be performed during the session. Participants had to review the first pattern and try to memorize it, for which they could do several repetitions on the mats. Once memorized, the participants had to perform the pattern without the help of the booklet. After successfully performing the pattern, the participants continued with the next pattern autonomously. At the end of the session, the expert reconnected with the group to resolve any doubts, note down any incidents and record the last pattern performed. In successive sessions, the SSE expert recalled the final pattern of the previous session and maintained the connection until the participants were able to perform the pattern without the help of the booklet, usually after 4–5 repetitions [51]. After indicating the patterns to be performed in the session, the participants continued autonomously. The sessions lasted approximately 50 min, and the participants had to memorize and perform 6–8 patterns per session.

Control group: The control group continued with their usual treatment within the public health system. No physical activity-based intervention was included in their usual treatment.

4.4. Measures and Procedures

Baseline assessments were conducted in the week prior to the start of the intervention, while final assessments were conducted one week after the intervention. Before completing the questionnaires and taking the baseline tests, participants had to review the informed consent document and agree to participate in the study. During the assessments, participants had to complete a series of questionnaires and pass a series of tests conducted by a Graduate in Sport Sciences.

4.4.1. Descriptive Variables

These questionnaires and measures were carried out in the week prior to the intervention.

Socio-demographic variables: Participants completed a generic questionnaire to indicate their age, civil status, employment situation, education level, smoking status, drinking status, years with fibromyalgia symptoms and years since fibromyalgia diagnosis.

Body composition: Participants' height (Stadiometer Seca 22, Hamburg, Germany) and weight (TANITA MC 780 MA) were taken, and their body mass index (BMI) was calculated using the formula: kg/m^2. In addition, waist and hip circumference measurements were taken and the waist/hip ratio was calculated.

International Fitness Scale (IFIS): A questionnaire used to assess subjective fitness as perceived by participants. It is a scale composed of five questions related to perceived physical fitness. Each question corresponds to a component of physical fitness: overall fitness, cardiorespiratory fitness, muscular fitness, speed–agility, and flexibility. Participants must rate each item on a Likert scale ranging from 0 (very poor) to 5 (very good). Higher scores indicate better perceived physical fitness. The IFIS has shown moderate reliability in Spanish women with FM (Kappa = 0.45) [58].

Fibromyalgia Impact Questionnaire (FIQ): A questionnaire that assesses the disability caused by FM in the lives of patients. Through 20 items, a total score is constructed that can take values between 0 and 100, where 0 indicates the absence of disability due to FM and 100 indicates the maximum disability due to FM [59].

Pain: A Visual Analog Pain Scale (VAS Pain) was used to assess the pain perceived by the participants [60,61].

4.4.2. Outcome Variables

These questionnaires and tests were conducted in the week before and the week after the intervention.

Safety and Applicability

Safety: A record was kept of possible accidents, injuries, or incidents that occurred during the sessions that could compromise the safety or integrity of the participants. For the VSSE to be considered safe, there had to be no accidents, injuries or incidents that compromised the health of the participants.

Applicability: This was assessed by analyzing the percentage of sessions completed by participants who completed the intervention program. The number of participants who abandoned the program and the reason for this was recorded. For the VSSE to be considered applicable, adherence of more than 80% and a drop-out rate of less than 20% had to be found.

Quality of Life (QoL)

SF-12: This tool is a shortened version of the SF-36 questionnaire. It assesses health status based on 12 items with response options that form Likert-type scales with scores ranging from 3 to 6. With the responses of the 12 items, a scale is constructed with scores ranging from 12 to 47, where 12 is the worst health status and 47 is the best, this scale is then normalized to a scale of 0 to 100, where 0 is the worst health status and 100 is the best, representing 100% health. In addition, this tool assesses two components of health status, physical health, and mental health. Physical health can take scores ranging from 6 to 20, where 6 is the worst physical health status and 20 is the best. Mental health can take scores ranging from 6 to 27, where 6 is the worst mental health status and 27 is the best. In both cases, these scores are also normalized to a scale of 0 to 100, where 0 is the worst state and 100 is the best, representing 100% physical and mental health. This tool has been found to be reliable in the Spanish population (Cronbach's alpha > 0.79) [62].

15-D: A tool that assesses health-related quality of life (HRQoL) through a 15-item questionnaire. Each item corresponds to a dimension, with five response levels. With the answers given to each item a final score between 0 and 1 is constructed, where 0 is the worst possible HRQoL, while 1 corresponds to the best HRQoL. This questionnaire has been found to be reliable, with Cronbach's alpha = 0.79 [63,64].

EURO-QOL-5D-5L (EQ-5D-5L): This tool assesses HRQoL of individuals through a questionnaire with five items, representing five dimensions (mobility, self-care, daily activities, pain/discomfort, and anxiety/depression) with five possible answers on health status in the form of a scale from 1 to 5, where 1 is the best health status and 5 is the worst. In addition, this questionnaire includes a visual analog scale (EQ-5D-5L-VAS) that assesses health status on a scale from 0 to 100, where 0 is the worst health status and 100 is the best health status. This tool has been found to be reliable in the Spanish population with FM (ICC: 0.69–0.94). With the answers to the five items, a total of 3125 health states can be obtained, from 11111 (full health) to 55555 (worst health) [65,66].

Self-Perceived Health

Participants were asked about their self-perceived health status, with five response options that could take a value between 1 and 5, where 1 was 'Very bad', 2 was 'bad', 3 was 'fair', 4 was 'good' and 5 was 'Very good'. For this study, a dichotomous variable was created that grouped responses into Negative SPH (responses between 1 and 3) and Positive SPH (responses between 4 and 5).

Satisfaction with Life

Satisfaction With the Life Scale (SWLS): Participants' perceived life satisfaction was assessed using the SWLS. This scale was found to be reliable with Cronbach's Alpha = 0.78 [67]. It is a 5-item measure with a 5-point Likert scale ranging from 'Strongly Disagree' to 'Strongly Agree'. The total score can take values between 5 and 25, where 5 indicates the best SWL and 25 the best SWL [16].

Mental Health

Beck Depression Inventory second edition (BDI-II): This is an instrument that assesses depressive symptoms through 21 items with four response options ordered from least to most severe, with participants choosing the option that most closely matches their emotional state in the previous two weeks. Each item is scored from 0 to 3 points, and the total score can range from 0 to 63 points, where 0 is the best mental health and 63 is the worst. This instrument has been found to be valid and reliable in several populations. According to the BDI-II scores, four levels of depressive symptoms can be established, and a categorical variable was created to analyze them: 0–13, minimal depression (None); 14–19, mild depression (Mild); 20–28, moderate depression (Moderates); and 29–63, severe depression (Severes). In addition, a dichotomous variable was created that grouped participants according to depression status based on BDI-II scores: Yes (14 or more) or No (0–13) [68,69].

Self-Reported Depression (S-R Depression): Self-perceived depressive symptoms were assessed on a visual scale from 0 to 10, where 0 was the absence of depressive symptoms and 10 was the highest intensity of depressive symptoms [70].

Self-Reported Anxiety (S-R Anxiety): Self-perceived anxiety symptoms were assessed on a visual scale from 0 to 10, where 0 was the absence of anxiety symptoms and 10 was the highest intensity of anxiety symptoms [70].

Cognitive Function

Self-Reported Memory Problems (S-R Memory Problems): Self-perceived anxiety symptoms were assessed on a visual scale from 0 to 10, where 0 was the absence of anxiety symptoms and 10 was the highest intensity of anxiety symptoms [70].

Symbol Digit Modalities Test (SDMT): This instrument was used to assess cognitive processing speed, attention, working memory, and executive function. The test consisted of presenting the participant with a reference key in which 9 symbols are associated with a number from 1 to 9. Subsequently, the participant received a list of 105 symbols and the participant had to write down the number corresponding to each symbol. The number of correct answers achieved in 90 s was counted [71–73].

California Verbal Learning Test (CVLT): This test assessed verbal learning and memory. The test consisted of presenting the participant with a list of 16 words grouped into four semantic categories. The words were read by the evaluator and had to be repeated immediately by the participant regardless of the order. This procedure was repeated five times, noting the number of hits for each repetition, with 80 being the maximum number of hits possible [74,75].

Brief Visual–spatial Memory Test (BVMT): This test assessed visual–spatial learning and memory. The test consisted of showing the participant six abstract images for 10 s and, subsequently, the participant had to represent on a sheet of paper the images that he/she could remember. The representations could be scored from 0 to 2 points: 0 for not remembering the image, 1 for remembering the correct image or location, and 2 for remembering the correct image and location [76].

4.5. Statistical Analysis

First, the normality of the data was assessed using the Shapiro–Wilk test. Subsequently, a descriptive analysis was performed to characterize the overall sample and the control and experimental groups. Continuous variables were displayed in terms of median and interquartile range (IQR). For these variables, a comparative analysis between both groups was performed using the Mann–Whitney U-test with Bonferroni adjustment. Categorical variables were presented in terms of absolute and relative frequencies. To identify possible intergroup differences, the dependence between the results of these variables and the group was analyzed using the Chi-square test.

To analyze the possible effects of the intervention, a descriptive analysis was performed showing the pre- and post-intervention results in the experimental and control groups for the variables of interest. Continuous variables were presented as median and IQR. To test for possible intra-group differences in these variables pre- and post-intervention, the Wilcoxon test was used. To assess possible intergroup differences, the Mann–Whitney U-test with Bonferroni adjustment was used; previously, the medians of the differences in the variables of interest in both groups were calculated. Effect size was assessed using biserial rank correlation. The McNemar Test for tables 2×2 and McNemar Bowker tests were used to assess effects on categorical variables. All analyses were performed with the statistical software Jamovi (version 2.5, Sydney, Australia). The value of $p < 0.05$ was used to assume significant differences.

5. Conclusions

SSE is an exercise program that has shown positive effects on physical function, cognitive function, mental health or life satisfaction especially in older populations. In this population, the scientific literature suggests that SSE may have positive effects on QoL. Although our study found that VSSE was applicable (adherence ≥ 85) and safe (with no accidents, injuries, or health-compromising incidents) during our intervention, this study found that a hybrid (face-to-face and virtual) 12-week SSE-based physical activity program was not effective in improving QoL, SWL, mental health, and cognitive function in Spanish women with FM.

Virtual SSE slightly improved the subjective self-perception of depressive symptoms post-intervention compared to the control group. However, these improvements were not supported by other objective measures obtained through the BDI-II. Although cognitive function improved in the experimental group, these were not statistically greater than those found in the control group. Therefore, in this study, Virtual SSE did not produce significantly change in these variables in Spanish women with FM.

Considering the limitations discussed in our study, future research exploring the efficacy of VSSE in women with fibromyalgia is needed. In them, it would be interesting to assess whether modifications in exercise intensity, frequency, or supervision can improve the efficacy of Virtual SSE in women with fibromyalgia. Increasing the intensity of Virtual SSE-based physical activity programs, integrating strength exercises into movement patterns or combining it with concurrent training, could enhance its effects.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/women5020017/s1, Table S1: Characterization of the sample according to the categorical variables (Civil Status, Employment Situation, Education Level, Smoking Status, Drinking Status, SPH, Depression Status and Depression Symptoms); Table S2: Effects of a 12-week intervention based on the 'Virtual Step Square Exercise'.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data presented in this study are available on request from the corresponding author. Data are not publicly available due to privacy and ethical restrictions.

Conflicts of Interest: The authors declare no conflicts of interest.

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