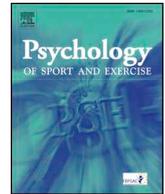




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The feasibility of Pilates to improve symptoms of anxiety, depression, and fatigue among people with Multiple Sclerosis: An eight-week randomized controlled pilot trial

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ABSTRACT

Objective: Evidence supports benefits of exercise for mental health among people with Multiple Sclerosis (PwMS). However, non-traditional exercise modes like Pilates remain understudied. This eight-week randomized pilot trial explored indicators of feasibility of supervised or home-based Pilates compared to wait-list control on mental health outcomes among PwMS.

Method: The pilot trial took place in Limerick (August to October 2017). We recruited through the MS Society of Ireland Midwest region. Seventeen females (49.8 ± 8.4 y) were randomized to two weekly 60-min supervised or home-based Pilates sessions guided by a DVD, or wait-list control. Feasibility relative to recruitment, retention, compliance, and presence/absence of adverse events was examined. Well-validated questionnaires assessed symptoms of anxiety, depression, and fatigue. Standardized mean differences and Hedges' d were calculated to explore magnitude of change in response to Pilates compared to wait-list.

Results: Nineteen participants registered interest. Following screening, 17 met inclusion criteria and accepted randomization. Attrition was 40% for supervised Pilates; no home-based or wait-list participant withdrew. Pilates compliance was > 80%. No adverse events were reported. Compared to wait-list, home-based Pilates scores were significantly lower for feelings of depressed mood at weeks 4, 6, and 8 ($d = 0.47$ – 1.25 ; all $p \leq 0.02$), physical symptoms of fatigue at weeks 4 and 8 ($d = 0.82$ – 0.84 ; all $p \leq 0.005$), and total fatigue at weeks 4 and 8 ($d = 0.57$ – 0.60 ; all $p \leq 0.02$).

Conclusions: Findings support the feasibility of home-based Pilates to improve mental health outcomes among women with MS with minimal-to-mild mobility disability. Results support development of future larger home-based randomized controlled trials to better understand Pilates' effects.

1. Introduction

Elevated symptoms of depression, anxiety, and fatigue are highly prevalent among people with Multiple Sclerosis (PwMS) (Jones et al., 2012; Zajicek et al., 2010). Despite poor engagement in physical activity by PwMS (Motl et al., 2017), increased physical activity and exercise training are viable alternative therapies for symptom management. Positive effects of traditional exercise modes, including aerobic and resistance exercise, on anxiety, depressive, and fatigue symptoms among PwMS (Herring, O'Connor, & Dishman, 2010; Herring, Puetz, O'Connor, & Dishman, 2012; Herring, Fleming, Hayes, Motl, & Coote, 2017; Pilutti, Greenlee, Motl, Nickrent, & Petruzzello, 2013) are established; however, less is known about the effects of non-traditional exercise modes like Pilates.

Recent meta-analytic evidence supported moderate-to-large improvements in anxiety and depressive symptoms, energy and fatigue, and quality of life in healthy and chronically-ill populations following Pilates (Fleming & Herring, 2018). Among PwMS, supervised Pilates demonstrated effectiveness in core stability (Fox, Haugh, Creanor, Gear, & Freeman, 2016), balance, mobility, and strength (Freeman et al., 2010; Guclu-Gunduz, Citaker, Irkec, Nazliel, & Batur-Caglayan, 2014), fatigue (Kucuk, Kara, Coskunar Poyraz, & Idiman, 2016; Tarakci, Yeldan, Huseyinsinoglu, Zenginler, & Eraksoy, 2013), walking (Kalron, Rosenblum, Frid, & Achiron, 2017), and functional ability (Duff et al., 2018). Home-based Pilates improved function and physical activity among older adults with MS (McAuley et al., 2015).

Current research supports feasibility trial provision to underpin prospective exercise research among PwMS (Learmonth & Motl, 2018)

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and development of larger RCTs (Thabane et al., 2010). Pilates feasibility research among PwMS supports improved physical function and self-perceived fatigue (Sanchez-Lastra, Martinez-Aldao, Molina, & Ayan, 2019), and sitting stability, posture and reduced pain among wheelchair users (van der Linden et al., 2014). To date, no randomized controlled trial (RCT) has examined the four domains of feasibility of supervised and home-based Pilates among PwMS as suggested by Arain, Campbell, Cooper, and Lancaster (2010) and Eldridge et al. (2016). Thus, the primary aim of this trial was to assess the feasibility metrics of process, resources, management and scientific (Learmonth & Motl, 2018) of an 8-week supervised or home-based Pilates intervention for symptoms of anxiety, depression, and fatigue among PwMS, to inform the effective design of a larger RCT. A secondary aim was to explore the magnitude of change in symptoms of anxiety, depression, and fatigue within and between groups. We hypothesized that, compared to wait-list control, supervised and home-based Pilates would result in moderate-to-large improvements in outcomes.

2. Methods

2.1. Trial Design

This study protocol was approved by the University Research Ethics Committee. Participants were equally randomized 1:1 to supervised, home-based, or waitlist groups.

2.2. Participants

Inclusion criteria were: adults (> 18 years old) with physician-diagnosed Multiple Sclerosis (Patient Determined Disease Steps (PDDS) score < 3) who were free from any other significant physical or psychiatric condition, had no previous Pilates experience, and had no medical contraindications to safe participation in physical activity established by the Physical Activity Readiness Questionnaire (PAR-Q) (Shephard, 1988). Recruitment was through the MS Society of Ireland Midwest region via distribution of posters and participation information leaflets on social media, and text alerts to members. Interested participants contacted the lead researcher (KF) via phone or email. All potential participants provided written informed consent, assessment of physical activity readiness, and PDDS (Hadjimichael, Kerns, Rizzo, Cutter, & Vollmer, 2007) prior to testing.

2.3. Interventions

Both Pilates groups involved two weekly sessions for eight weeks completed with at least 48-h between sessions. Pilates sessions required approximately one hour and were comprised of mat-based beginner's level exercise (see Table 1). Four repetitions of each movement were performed during sessions in the first two weeks, and intensity was self-regulated by the participant based on physical condition level (Bullo et al., 2015). Repetitions gradually progressed at biweekly intervals, resulting in ten repetitions being performed for weeks 7 and 8. Post-stretches were maintained for a minimum of thirty seconds. RPE was recorded following session completion.

2.3.1. Supervised Pilates (SP)

The SP group completed sessions at the University of Limerick. To ensure correct exercise technique, the instructor (KF), who is a certified Pilates Instructor, provided instruction on all movements, maintained visual contact, and provided individual participant feedback if required.

2.3.2. Home-based Pilates (HB)

The HB group performed two weekly sessions at home, supported by a DVD developed and previously implemented by the lead researcher. Compliance was documented via self-report exercise diaries containing

Table 1
Pilates exercise protocol.

Warm Up	Basic Mat Exercises	Cool Down (1 Repetition of Stretch) 30-60 seconds
Head Nods	Ab Prep	Quadricep
Sliding Leg	C-Curve	Lower Back
Knee Drops	Single Leg Circle	Hamstrings
Knee Folds	Single Leg Stretch	Glutes
Hip Rolls	Double Leg Stretch	Adductors
Scapula Stabilisation	Hamstring Challenge	Calves
Arm Circles	Spine Stretch	Shoulders
	The Saw	Chest
	The Dart	Upper Back
	Prone Hip Extension	
	Cat Stretch	
	Shoulder Bridge	
	Side Lying Arm Opening	
	Adductor Raise	

session date, number of repetitions completed, and RPE, recorded by the participant immediately following session completion. Exercise diaries were supplemented by a weekly telephone call.

2.3.3. Wait-list (WL)

WL participants were asked to maintain pre-trial activity levels and completed on-line outcome assessments. Following the 8-week intervention, WL participants were offered their choice of SP or HB, but no data were collected.

2.4. Outcomes

The following indicators of feasibility were monitored and examined (Learmonth & Motl, 2018):

Process: The lead researcher monitored and recorded recruitment numbers, eligibility and details of those interested in participating both prior to and following screening. Because the trial involved supervised sessions, recruitment was limited to the local regional MS Society, avoiding unnecessary travel difficulties for potential participants. No Pilates research among PwMS has been conducted in the region previously; so, an estimated level of interest by those fulfilling inclusion criteria was unknown, and results would critically inform recruitment methods for a larger RCT.

Resources: Retention rates of allocated arms over trial duration were monitored and recorded by the lead researcher. Logged details included drop-out reasons, any adverse events during SP or events reported to the lead researcher from HB and WL. Attendance and compliance with exercise dosage were self-reported by participants immediately after SP, while completed activity records (session date, exercise repetitions, RPE) for the HB group were returned post-intervention.

Management: The lead researcher recorded any reported issues by participants during SP pertaining to venue accessibility, facilities or equipment usage, and verified data completeness of the online outcome assessments weekly, while noting participant completion through a password protected database.

Scientific: To determine appropriateness of data collection methods for each group, the lead researcher monitored and recorded any reported difficulties by participants with online questionnaire administration. If required, paper versions of the outcome assessments were provided with a self-addressed envelope.

2.5. Primary outcome measures

Well-validated outcome measures were electronically administered via www.surveymonkey.com at baseline, and weeks two, four, six and eight of the intervention. The lead researcher verified completion of the biweekly outcome assessments, and participants were contacted if measures had not been completed. To improve comparability of the

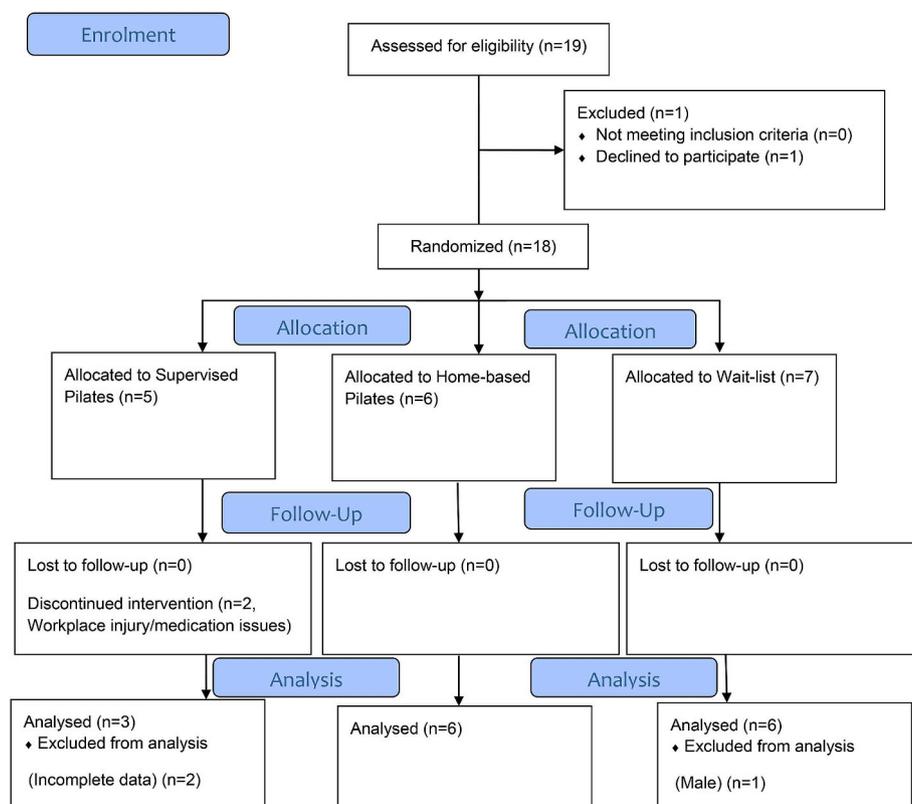


Fig. 1. Participant flow through 8-week randomized controlled pilot trial.

current findings with previous reports in PwMS, multiple assessments of anxiety, depressive, and fatigue symptoms were completed as detailed below.

The Modified Fatigue Impact Scale (MFIS): The 21-item MFIS is a recommended core outcome measure in exercise studies in PwMS (Paul et al., 2014), that measured physical, cognitive, and psychosocial components of fatigue. It has been proposed by the Multiple Sclerosis Council for Clinical Practice Guidelines as a reliable assessment tool of perceived fatigue (1998), with excellent test-retest reliability (Rietberg, Van Wegen, & Kwakkel, 2010).

Profile of Mood States – Brief Form (POMS-B): The 30-item POMS-B assessed the intensity of feelings of tension, depressed mood, energy and fatigue. The psychometric properties of the POMS-B are well established across diverse samples (McNair, Lorr, & Dropplemann, 1992).

The State Trait Anxiety Inventory (STAI-Y1): The 20-item State and Trait subscales of the widely used and well-validated STAI were completed to assess anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983). The STAI has well-documented psychometric properties in PwMS (Santangelo et al., 2016).

The Hospital Anxiety and Depression Scale (HADS): The seven-item anxiety and depression subscales of the 14-item HADS measured anxiety and depressive symptoms over the prior week (Zigmond & Snaith, 1983). Favourable psychometric properties support the HADS among PwMS (Marrie et al., 2018), demonstrating acceptable sensitivity (90% and 89% for depression) and specificity (87% and 81% for anxiety) (Honarmand & Feinstein, 2009).

Quick Inventory of Depressive Symptomatology (QIDS): The 16-item QIDS assessed depressive symptom severity across nine core criteria for depression based on the prior week (Rush et al., 2003). The psychometric properties of the QIDS have been supported among PwMS (Fischer et al., 2015).

Seven-day Physical Activity Recall Scale (7d-PAR): This measures the approximate number of hours the participant slept and engaged in moderate, hard, and very hard activity. It is a valid measure

used extensively in MS research (Motl, McAuley, Snook, & Scott, 2006), with high test-retest reliability (Sallis et al., 1985).

Godin Leisure-Time Exercise Questionnaire (GLTEQ): This is a valid self-report measure of physical activity commonly applied in research among PwMS (Godin, 2011; Godin & Shephard, 1985) and is sensitive to change following interventions (Sikes et al., 2018).

2.6. Sample size

As this was a pilot study to inform the design of a larger definitive RCT, a sample size was not estimated based on *a priori* power analysis (Thabane et al., 2010). The trial involved attendance to SP, therefore it was estimated that numbers would be curtailed due to possible access barriers for potential participants (Stroud, Minahan, & Sabapathy, 2009).

2.7. Randomization

Following screening and initial baseline testing, eligible participants were randomized to SP, HB, or WL by an independent researcher who was not involved in outcome assessments, using www.randomizer.org. The lead researcher informed participants of group allocation, and distributed DVD's to the HB group.

2.8. Data analysis

Analysis of feasibility indicators from study records were reported descriptively (Lancaster, Dodd, & Williamson, 2004). IBM SPSS Statistics Version 25.0 (IBM Corp., Armonk, NY) was used to conduct exploratory analyses. One-way ANOVA examined baseline differences between groups. Paired t-tests were used to evaluate within-group differences between pre- and post-intervention. Three group (SP, HB, WL) X 4 time (weeks 2, 4, 6, 8) ANCOVA adjusted for baseline values examined between-group differences in outcomes. Significant interactions were decomposed with simple effects analysis.

Table 2
Baseline participant characteristics.

Variable	Supervised (n = 5)	Home-based (n = 6)	Wait-List (n = 7)	Overall Total (n = 18)
Age, years, mean (SD)	53.8 (7.95)	46.0 (9.4)	51.3 (6.8)	50.2 (8.2)
Sex (women: men)	5:0	6:0	6:1	17:1
STAI-Y1	30.0 ± 8.0	34.1 ± 8.8	40.3 ± 12.2	35.4 ± 10.5
STAI-Y2	31.8 ± 10.0	39.8 ± 9.3	46.4 ± 13.1	40.2 ± 12.1
MFIS Total	39.0 ± 12.3	33.7 ± 12.4	49.0 ± 15.7	41.1 ± 14.7
MFIS PHYS	22.4 ± 8.7	18.3 ± 7.2	23.6 ± 7.4	21.5 ± 7.6
MFIS COGN	12.6 ± 4.4	12.0 ± 4.8	20.1 ± 9.2	15.3 ± 7.6
MFIS PSYCH	4.0 ± 2.3	3.3 ± 2.7	5.3 ± 1.5	4.3 ± 2.2
HADS Total	20.8 ± 1.3	19.3 ± 2.2	19.6 ± 1.9	19.8 ± 1.9
HADS-A	13.4 ± 1.1	11.8 ± 1.8	11.1 ± 2.4	12.0 ± 2.1
HADS-D	7.4 ± 1.1	7.5 ± 1.4	8.4 ± 1.4	7.8 ± 1.3
QIDS	7.4 ± 2.9	5.3 ± 4.1	8.7 ± 4.8	7.2 ± 4.2
POMS TMD	12.8 ± 14.1	12.1 ± 14.9	21.4 ± 15.6	15.9 ± 14.8
TENSION	2.8 ± 3.6	2.7 ± 3.3	2.7 ± 2.6	2.7 ± 2.9
DEPRESSION	1.4 ± 2.6	2.7 ± 4.1	3.0 ± 2.8	2.4 ± 3.2
ANGER	0.8 ± 1.1	2.2 ± 2.6	2.0 ± 2.8	1.7 ± 2.3
FATIGUE	5.8 ± 4.8	6.5 ± 4.2	8.7 ± 4.5	7.2 ± 4.4
VIGOR	2.4 ± 4.8	5.0 ± 3.9	2.4 ± 3.3	3.3 ± 3.9
GLTEQ - Total	34.2 ± 21.8	43.2 ± 29.2	32.6 ± 22.0	36.6 ± 23.6
GLTEQ - HC	24.6 ± 14.9	29.2 ± 22.9	19.7 ± 15.2	24.2 ± 17.5
GLTEQ - ACT	1.2 ± 0.4	1.3 ± 0.5	1.4 ± 0.5	1.3 ± 0.5
7D-PAR, kcal/kg/wk	249.0 ± 35.6	249.0 ± 22.8	274.1 ± 36.4	258.8 ± 32.8
RPAL	1.4 ± 0.5	1.2 ± 0.4	1.0 ± 0.0	1.2 ± 0.4
PA-MOD	6.6 ± 9.0	4.8 ± 2.8	12.9 ± 11.1	8.5 ± 8.9
PA-HARD	1.2 ± 2.7	0.2 ± 0.4	1.1 ± 1.8	0.8 ± 1.8
PA-VHARD	0.0 ± 0.0	0.7 ± 1.0	1.2 ± 1.5	0.7 ± 1.2

Abbreviations: SD: Standard deviation; STAI-Y1: State Subscale of the State-Trait Anxiety Inventory; STAI-Y2: Trait Subscale of the State-Trait Anxiety Inventory; MFIS Total: Modified Fatigue Impact Scale total score; MFIS PHYS: Physical Subscale of the Modified Fatigue Impact Scale; MFIS COGN: Cognitive Subscale of the Modified Fatigue Impact Scale; MFIS PSYCH: Psychosocial Subscale of the Modified Fatigue Impact Scale; HADS Total: Hospital Anxiety and Depression Scale total score; HADS-A: Anxiety Subscale of the Hospital Anxiety and Depression Scale; HADS-D: Depression Subscale of the Hospital Anxiety and Depression Scale; QIDS: Quick Inventory of Depressive Symptomatology; POMS TMD: Total Mood Disturbance Subscale of the Profile of Mood States-Brief; Brief; TENSION: Tension Subscale of the Profile of Mood States-Brief; DEPRESSION: Depression Subscale of the Profile of Mood States-Brief; ANGER: Anger Subscale of the Profile of Mood States-Brief; FATIGUE: Fatigue Subscale of the Profile of Mood States-Brief; VIGOR: Vigor Subscale of the Profile of Mood States-Brief; GLTEQ - Total: Godin Leisure Time Exercise Questionnaire total leisure activity score; GLTEQ-HC: Godin Leisure Time Exercise Questionnaire Health Contribution Score; GLTEQ-ACT: Godin Leisure Time Exercise Questionnaire Activity Indicator; RPAL: Meeting recommended Physical Activity Levels; PA-MOD: Moderate Physical Activity category of the 7d-PAR; PA-HARD: Hard Activity category of the 7d-PAR; PA-VHARD: Very Hard Physical Activity category of the 7d-PAR.

Within-group and between-group magnitude of change was quantified using standardized mean differences (*d*) and Hedges' *d* (Hedges & Olkin, 1985), respectively. Effect sizes were calculated such that improved outcomes resulted in a positive effect size. Consistent with Cohen's suggestion, effect sizes of 0.2, 0.5, and 0.8 were judged as small, moderate, and large, respectively (Cohen, 1988). Session RPE was averaged across the sixteen Pilates sessions and compared between groups using independent samples *t*-tests.

3. Results

Fig. 1 illustrates participant flow through the trial. Table 2 presents baseline participant characteristics.

3.1. Feasibility outcomes

Process: Participants were recruited from March through June 2017. Nineteen PwMS indicated initial interest following recruitment strategies. One refused randomization and the one male was omitted from data analyses. To avoid unnecessary delays for those already registered, interventions commenced with small samples. Seventeen (89%) eligible females (49.8 ± 8.4 y), agreed to randomization to either SP (n = 5) or HB (n = 6) or WL (n = 6).

Resources: Attrition was high for SP (n = 2 of 5; 40%), one participant withdrew in week 3 (side effect from medication) and one in week 7 (injured at work). No HB or WL participant withdrew. Pilates compliance was high across groups (> 80%). In SP, two participants completed 14 (87.5%) and one completed 13 (81.25%) of the 16 sessions. Self-completed exercise diaries indicated all HB participants

(100%) complied fully with both exercise frequency and progression guidelines. HB and WL had 100% completion rates for outcome assessments. No adverse events were reported.

Management: The venue for SP classes was freely available as it was outside the academic year, and there were no reports of accessibility issues. There were no missing data from the groups.

Scientific: Two HB participants requested paper versions of outcome questionnaires due to lack of confidence in online skills, resulting in data collection facilitated by the lead researcher entering results following questionnaire return.

3.2. Primary outcomes

At baseline, there was a statistically significant difference in state anxiety ($F_{(2,12)} = 4.430$, $p = 0.04$) and trait anxiety ($F_{(2,12)} = 5.485$, $p = 0.02$) between SP and WL. There were no statistically significant differences between any other groups at baseline (all $p \geq 0.07$). Table 3 presents means (SD), standardized mean differences, and Hedges' *d* for each assessment point. Fig. 2 presents symptom-based scores across time. A statistically significant Group × Time interaction was found for feelings of depressed mood ($F_{(6,33)} = 2.799$, $p \leq 0.026$), physical symptoms of fatigue ($F_{(6,33)} = 4.92$, $p \leq 0.001$) and total fatigue ($F_{(6,33)} = 3.76$, $p \leq 0.006$). Compared to WL, scores for HB were significantly lower for feelings of depressed mood at weeks 4 ($d = 1.25$), 6 ($d = 0.47$), and 8 ($d = 0.90$; all $p \leq 0.02$), physical symptoms of fatigue at weeks 4 ($d = 0.84$) and 8 ($d = 0.82$; all $p \leq 0.005$), and total fatigue at weeks 4 ($d = 0.60$) and 8 ($d = 0.57$; all $p \leq 0.02$).

Statistically significant main effects for group were found for trait anxiety ($F_{(2,11)} = 5.38$, $p \leq 0.023$) and feelings of tension

Table 3
Primary Outcomes - Baseline, Week 2, Week 4, Week 6, Week 8 means (SD), standardized mean differences (d), and Hedges' d (95%CI).

Outcome	Baseline			Wk 2			Wk 4			Wk 6			Wk 8		
	Mean	± SD	d	Mean	± SD	d	Hedges' d from baseline	Mean	± SD	d	Hedges' d from baseline	Mean	± SD	d	Hedges' d from baseline
STAI-Y1															
Supervised	24.7	± 3.5	-5.29	22.3	± 4.0	-0.66	0.16 (-1.22, 1.55)	25.0	± 7.8	0.09	0.56 (-0.86, 1.97)	23.7	± 6.3	-0.28	-0.15 (-1.53, 1.24)
Homebased	34.2	± 8.8	-1.02	38.2	± 18.1	0.45	-0.44 (-1.59, 0.70)	30.8	± 8.2	-0.38	0.89 (-0.30, 2.07)	30.0	± 5.2	-0.47	0.16 (-0.97, 1.29)
Waitlist	43.2	± 10.5	-2.71 ^b	42.5	± 7.3	-0.06	0.73 ^a (-0.69, 2.16)	49.2	± 11.2	0.57	-0.42 ^a (-1.82, 0.98)	40.7	± 15.7	-0.24	-0.37 ^a (-1.76, 1.03)
STAI-Y2															
Supervised	24.7	± 1.5	-16.00	30.0	± 4.4	3.48	-0.53 (-1.94, 0.88)	29.7	± 5.5	3.26	-0.46 (-1.87, 0.94)	26.7	± 5.5	1.31	-0.37 (-1.76, 1.03)
Homebased	39.8	± 9.3	-0.96	40.5	± 14.6	0.07	-0.15 (-1.28, 0.98)	39.0	± 12.6	-0.09	0.01 (-1.19, 1.15)	37.7	± 11.8	-0.23	-0.03 (-1.16, 1.10)
Waitlist	48.7	± 12.8	-10.07 ^b	47.5	± 11.8	-0.09	-0.52 ^a (-1.93, 0.88)	48.0	± 11.9	-0.05	-0.65 ^a (-2.07, 0.76)	46.2	± 16.9	-0.19	-0.47 ^a (-1.87, 0.94)
MFIS Total															
Supervised	32.3	± 7.4	2.35	26.7	± 5.0	-0.77	0.19 (-1.20, 1.58)	28.3	± 13.0	-0.54	0.29 (-1.11, 1.68)	28.0	± 10.6	-0.59	-0.20 (-1.59, 1.19)
Homebased	33.7	± 12.4	-1.29	34.7	± 14.9	0.08	-0.22 (-1.35, 0.92)	24.8	± 10.7	-0.71	0.60 (-0.56, 1.75)	26.3	± 10.0	-0.59	-0.02 (-1.15, 1.11)
Waitlist	49.7	± 17.1	-0.19 ^b	47.2	± 9.1	-0.15	0.53 ^a (-0.88, 1.93)	50.5	± 9.0	0.05	-0.38 ^a (-1.78, 1.01)	42.0	± 16.2	-0.45	-0.24 ^a (-1.63, 1.15)
MFIS PHYS															
Supervised	16.7	± 2.1	-2.90	13.3	± 3.0	-1.60	0.29 (-1.10, 1.68)	15.7	± 3.2	-0.48	0.31 (-1.08, 1.70)	16.0	± 1.0	-0.32	-0.26 (-1.65, 1.13)
Homebased	18.3	± 7.2	-0.62	17.3	± 7.8	-0.14	-0.02 (-1.15, 1.11)	12.8	± 4.2	-0.76	0.84 (-0.34, 2.02)	15.3	± 6.6	-0.41	0.04 (-1.09, 1.17)
Waitlist	22.8	± 7.8	-0.76 ^b	21.7	± 4.2	-0.15	0.33 ^a (-1.06, 1.72)	24.2	± 4.7	0.17	-0.64 ^a (-2.06, 0.77)	20.2	± 4.5	-0.34	-0.33 ^a (-1.73, 1.06)
MFIS COGN															
Supervised	12.7	± 6.0	-1.43	11.3	± 8.1	-0.22	0.07 (-1.32, 1.46)	9.7	± 9.6	-0.50	0.34 (-1.05, 1.74)	9.3	± 9.4	-0.55	0.00 (-1.39, 1.39)
Homebased	12.0	± 4.8	-1.94	14.5	± 5.4	0.52	-0.39 (-1.53, 0.75)	9.3	± 4.8	-0.55	0.37 (-0.77, 1.51)	8.5	± 4.9	-0.73	0.02 (-1.11, 1.15)
Waitlist	21.3	± 9.0	0.12 ^b	20.7	± 7.9	-0.07	0.66 ^a (-0.76, 2.08)	21.7	± 7.8	0.04	0.06 ^a (-1.33, 1.44)	18.00	± 11.68	-0.35	-0.03 ^a (-1.41, 1.36)
MFIS PSYCH															
Supervised	3.0	± 1.0	-2.50	2.0	± 0.0	-1.00	0.21 (-1.17, 1.60)	3.0	± 1.0	0.00	-0.53 (-1.94, 0.88)	2.7	± 0.6	-0.33	-0.86 (-2.30, 0.59)
Homebased	3.3	± 2.7	-0.81	2.8	± 2.7	-0.19	-0.07 (-1.20, 1.06)	2.7	± 2.5	-0.25	-0.07 (-1.20, 1.06)	2.5	± 2.2	-0.31	-0.36 (-1.50, 0.78)
Waitlist	5.5	± 1.5	-0.30 ^b	4.8	± 0.7	-0.44	0.19 ^a (-1.20, 1.58)	4.7	± 0.8	-0.55	-0.25 ^a (-1.64, 1.14)	3.8	± 1.7	-1.10	-0.119 ^a (-1.58, 1.20)
HADS Total															
Supervised	21.0	± 1.7	1.06	21.0	± 2.0	0.00	0.79 (-0.64, 2.23)	21.7	± 2.3	0.39	0.30 (-1.09, 1.70)	20.7	± 2.5	-0.19	1.11 (-0.36, 2.59)
Homebased	19.3	± 2.2	0.05	20.0	± 3.3	0.30	0.40 (-0.74, 1.54)	21.3	± 0.8	0.89	-0.34 (-1.48, 0.80)	22.3	± 1.7	1.33	-0.54 (-1.69, 0.61)
Waitlist	19.2	± 1.7	1.00 ^b	20.7	± 2.2	0.90	0.28 ^a (-1.11, 1.67)	20.4	± 1.8	0.73	0.56 ^a (-0.85, 1.97)	21.0	± 2.7	1.06	1.40 ^a (0.13, 2.93)
HADS-A															
Supervised	13.7	± 1.2	2.66	14.0	± 1.0	0.28	0.35 (-1.04, 1.75)	13.7	± 1.5	0.00	0.17 (-1.22, 1.56)	13.7	± 1.5	0.00	0.43 (-0.97, 1.83)
Homebased	11.8	± 1.8	0.72	11.8	± 3.0	0.00	0.50 (-0.65, 1.65)	12.3	± 1.5	0.27	-0.08 (-1.22, 1.05)	13.3	± 1.9	0.82	-0.33 (-1.17, 0.81)
Waitlist	10.5	± 1.9	1.58 ^b	11.5	± 1.5	0.53	-0.18 ^a (-1.56, 1.21)	10.8	± 1.7	0.18	0.27 ^a (-1.12, 1.66)	11.3	± 2.2	0.44	0.80 ^a (-0.63, 2.23)
HADS-D															
Supervised	7.3	± 1.5	-0.93	7.0	± 1.7	-0.22	0.31 (-1.09, 1.70)	8.0	± 1.7	0.44	-0.01 (-1.39, 1.38)	7.0	± 1.7	-0.22	0.73 (-0.70, 2.15)
Homebased	7.5	± 1.4	-0.86	8.2	± 0.7	0.49	-0.34 (-1.48, 0.80)	9.0	± 0.9	1.09	-0.56 (-1.72, 0.59)	9.0	± 1.4	1.09	-0.45 (-1.60, 0.69)
Waitlist	8.7	± 1.4	-0.13 ^b	8.8	± 1.7	0.12	0.62 ^a (-0.79, 2.04)	9.3	± 1.6	0.48	0.52 ^a (-0.89, 1.92)	9.5	± 1.6	0.61	1.14 ^a (-0.34, 2.62)
QIDS															
Supervised	5.7	± 2.1	-1.90	4.3	± 1.1	-0.64	0.45 (-0.95, 1.85)	7.3	± 4.9	0.80	-0.19 (-1.57, 1.20)	4.3	± 1.5	-0.64	0.67 (-0.75, 2.09)
Homebased	5.3	± 4.1	-1.07	5.0	± 2.6	-0.08	0.21 (-0.92, 1.35)	6.2	± 6.4	0.20	-0.00 (-1.13, 1.13)	5.3	± 4.4	0.00	0.35 (-0.79, 1.50)
Waitlist	9.7	± 4.5	0.19 ^b	10.3	± 4.7	0.15	0.25 ^a (-1.15, 1.64)	10.5	± 6.7	0.18	-0.20 ^a (-1.59, 1.19)	11.3	± 6.8	0.37	0.33 ^a (-1.07, 1.72)

(continued on next page)

Table 3 (continued)

Outcome	Wk 2			Wk 4			Wk 6			Wk 8				
	Mean ± SD	d	Hedges' d from baseline	Mean ± SD	d	Hedges' d from baseline	Mean ± SD	d	Hedges' d from baseline	Mean ± SD	d	Hedges' d from baseline		
POMS TMD														
Supervised	4.7 ± 5.1	-3.53	-0.7 ± 5.5	-1.04	0.54 (-0.87, 1.94)	7.7 ± 15.5	0.58	0.24 (-1.15, 1.63)	0.0 ± 6.2	-0.91	0.14 (-1.24, 1.53)	1.3 ± 5.5	-0.65	0.41 (-0.99, 1.81)
Homebased	12.2 ± 14.9	-0.70	17.2 ± 27.5	0.36	-0.10 (-1.23, 1.03)	6.3 ± 6.6	-0.39	0.74 (-0.43, 1.91)	4.2 ± 3.9	-0.54	0.33 (-0.81, 1.47)	1.8 ± 5.6	-0.69	0.80 (-0.38, 1.97)
Waitlist	22.7 ± 16.7	-1.47 ^b	26.0 ± 25.8	0.20	0.71 ^a (-0.71, 2.14)	29.5 ± 19.5	0.41	-0.61 ^a (-2.02, 0.80)	20.3 ± 21.2	-0.14	-0.23 ^a (-1.62, 1.16)	26.0 ± 20.6	0.20	-0.48 ^a (-1.89, 0.92)
POMS Subscales														
TENSION														
Supervised	1.3 ± 1.5	-1.00	0.7 ± 0.6	-0.43	0.48 (-0.92, 1.89)	0.7 ± 1.1	-0.43	1.48 (-0.06, 3.03)	0.7 ± 0.6	-0.43	0.95 (-0.51, 2.40)	0.0 ± 0.0	-0.87	1.42 (-0.11, 2.96)
Homebased	2.7 ± 3.3	-0.03	4.3 ± 5.0	0.51	-0.29 (-1.43, 0.85)	1.2 ± 0.7	-0.46	1.52 (0.23, 2.80)	1.2 ± 1.2	-0.46	1.06 (-0.15, 2.27)	0.0 ± 0.0	-0.82	1.62 (0.32, 2.93)
Waitlist	2.8 ± 2.8	-0.93 ^b	3.5 ± 4.4	0.25	0.72 ^a (-0.71, 2.14)	6.3 ± 3.5	1.25	-0.26 ^a (-1.65, 1.13)	4.8 ± 4.7	0.72	-0.26 ^a (-1.65, 1.13)	5.5 ± 3.4	0.96	-0.41 ^a (-1.81, 0.99)
DEPRESSION														
Supervised	0.0 ± 0.0	0.00	0.0 ± 0.0	0.00	0.36 (-1.04, 1.75)	1.0 ± 1.7	0.00	0.72 (-0.71, 2.14)	0.0 ± 0.0	0.00	-0.12 (-1.51, 1.27)	0.0 ± 0.0	0.00	0.36 (-1.04, 1.75)
Homebased	2.7 ± 4.1	-0.15	3.3 ± 7.7	0.16	0.09 (-1.04, 1.22)	0.8 ± 1.3	-0.44	1.25 (0.01, 2.48)	0.5 ± 1.2	-0.53	0.47 (-0.67, 1.62)	0.2 ± 0.4	-0.61	0.90 (-0.29, 2.09)
Waitlist	3.3 ± 2.9	0.00 ^b	4.3 ± 4.8	0.34	0.17 ^a (-1.22, 1.56)	6.3 ± 4.3	1.02	-0.72 ^a (-2.15, 0.70)	3.0 ± 2.8	-0.11	-0.55 ^a (-1.96, 0.86)	4.3 ± 3.9	0.34	-0.64 ^a (-2.05, 0.78)
ANGER														
Supervised	0.0 ± 0.0	0.00	0.0 ± 0.0	0.00	0.41 (-0.99, 1.80)	0.7 ± 1.1	0.00	0.23 (-1.16, 1.62)	0.7 ± 1.1	0.00	-0.29 (-1.68, 1.10)	0.0 ± 0.0	0.00	-0.11 (-1.50, 1.27)
Homebased	2.2 ± 2.6	0.08	3.2 ± 5.0	0.39	0.06 (-1.08, 1.19)	0.8 ± 1.6	-0.52	0.88 (-0.31, 2.06)	0.3 ± 0.8	-0.72	0.55 (-0.60, 1.70)	0.3 ± 0.8	-0.72	0.50 (-0.65, 1.65)
Waitlist	2.0 ± 3.0	0.00 ^b	3.2 ± 5.0	0.39	0.41 ^a (-0.99, 1.81)	3.3 ± 3.8	0.44	-0.83 ^a (-2.26, 0.61)	1.8 ± 3.0	-0.06	-1.03 ^a (-2.50, 0.43)	1.7 ± 2.1	-0.11	-0.76 ^a (-2.19, 0.67)
FATIGUE														
Supervised	3.0 ± 1.0	-5.70	2.7 ± 1.1	-0.33	0.35 (-1.05, 1.74)	4.3 ± 4.5	1.00	-0.35 (-1.74, 1.04)	2.7 ± 1.1	-0.33	-0.11 (-1.49, 1.28)	3.0 ± 1.0	0.00	0.14 (-1.25, 1.53)
Homebased	6.5 ± 4.2	-0.52	6.7 ± 5.6	0.04	0.23 (-0.90, 1.37)	4.5 ± 2.0	-0.48	0.33 (-0.81, 1.47)	3.7 ± 2.8	-0.68	0.40 (-0.74, 1.54)	2.7 ± 1.6	-0.92	0.90 (-0.29, 2.09)
Waitlist	8.7 ± 5.0	-3.50 ^b	10.0 ± 5.8	0.27	0.12 ^a (-1.26, 1.51)	8.3 ± 5.6	-0.07	-0.83 ^a (-2.27, 0.61)	7.8 ± 5.6	-0.16	-0.62 ^a (-2.04, 0.79)	9.3 ± 6.6	0.13	-0.96 ^a (-2.41, 0.50)
VIGOR														
Supervised	3.7 ± 6.3	0.30	6.3 ± 4.0	0.42	0.48 (-0.92, 1.88)	3.3 ± 5.8	-0.05	-0.14 (-1.53, 1.25)	6.3 ± 5.5	0.42	0.27 (-1.12, 1.66)	4.3 ± 4.2	0.10	0.14 (-1.25, 1.52)
Homebased	5.0 ± 3.9	0.82	5.3 ± 3.2	0.08	-0.00 (-1.34, 1.13)	4.2 ± 3.7	-0.21	-0.31 (-1.44, 0.83)	4.3 ± 3.2	-0.17	-0.53 (-1.68, 0.63)	4.0 ± 4.2	-0.26	-0.26 (-1.40, 0.87)
Waitlist	1.8 ± 3.1	-0.21 ^b	2.2 ± 3.2	0.11	0.44 ^a (-0.96, 1.84)	2.2 ± 2.6	0.11	0.09 ^a (-1.29, 1.48)	3.2 ± 4.3	0.42	0.63 ^a (-0.79, 2.04)	1.8 ± 2.5	0.00	0.31 ^a (-1.08, 1.71)

*p value < 0.05

Abbreviations: STAI-Y1: State Subscale of the State-Trait Anxiety Inventory; STAI-Y2: Trait Subscale of the State-Trait Anxiety Inventory; MFIS Total: Modified Fatigue Impact Scale total score; MFIS PHYS: Physical Subscale of the Modified Fatigue Impact Scale; MFIS COGN: Cognitive Subscale of the Modified Fatigue Impact Scale; MFIS PSYCH: Psychosocial Subscale of the Modified Fatigue Impact Scale; HADS Total: Hospital Anxiety and Depression Scale total score; HADS-A: Anxiety Subscale of the Hospital Anxiety and Depression Scale; HADS-D: Depression Subscale of the Hospital Anxiety and Depression Scale; QIDS: Quick Inventory of Depressive Symptomatology; POMS TMD: Total Mood Disturbance Subscale of the Profile of Mood States-Brief; POMS: Profile of Mood States-Brief; TENSION: Tension Subscale of the Profile of Mood States-Brief; DEPRESSION: Depression Subscale of the Profile of Mood States-Brief; ANGER: Anger Subscale of the Profile of Mood States-Brief; FATIGUE: Fatigue Subscale of the Profile of Mood States-Brief; VIGOR: Vigor Subscale of the Profile of Mood States-Brief; SD: Standard deviation; SMD: Standardized mean difference.

^a Effect size for the difference between Supervised and Homebased

^b SMD for the difference between Supervised and Homebased at baseline

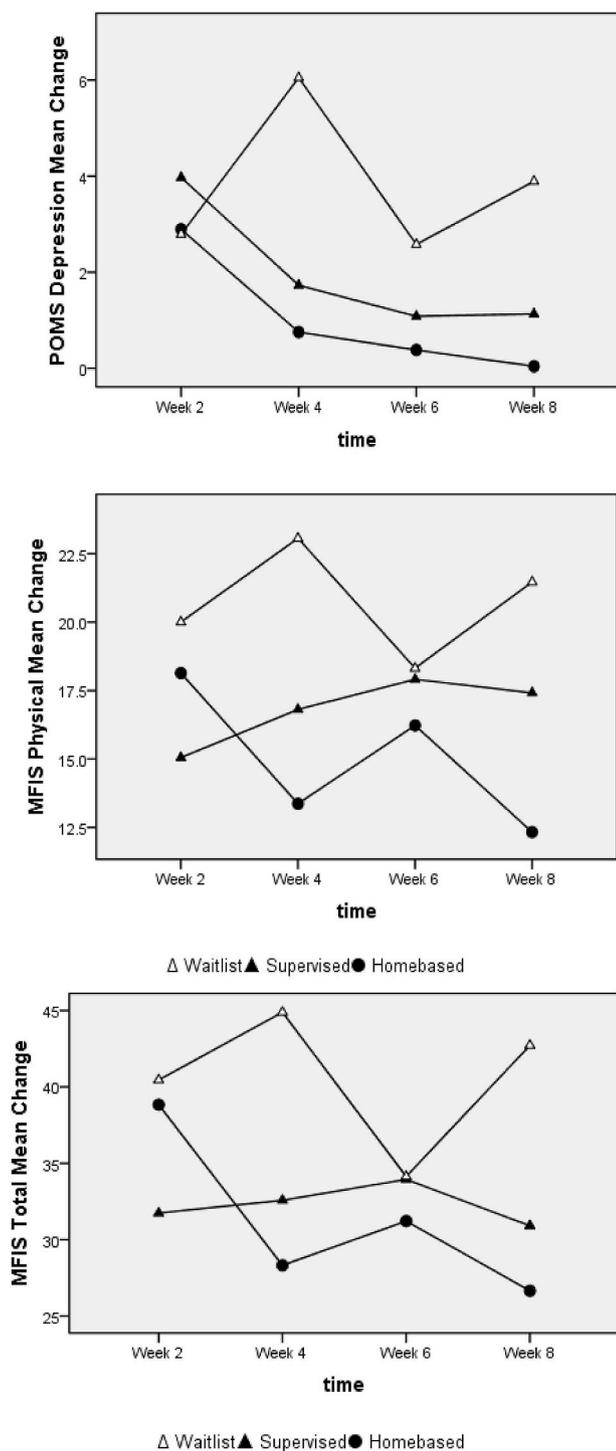


Fig. 2. Outcomes changes over time for feelings of depressed mood, physical symptoms of fatigue, and total fatigue.

($F_{(2,11)} = 6.79, p \leq 0.023$), and a statistically significant main effect for time was found for feelings of energy ($F_{(3,33)} = 3.44, p \leq 0.028$). Anxiety symptoms were significantly higher among SP compared to HB (mean difference = 6.93, $p \leq 0.023$), and non-significantly higher among SP compared to WL (mean difference = 7.03, $p \geq 0.053$). Bonferroni-corrected *post-hoc* comparisons showed significantly lower feelings of tension for SP (mean difference = -4.00, $p \leq 0.039$) and HB (mean difference = -3.46, $p \leq 0.025$) compared to WL.

As shown in Table 3, compared to WL, SP resulted in moderate-to-large non-significant improvements in STAI-Y1 at week 8 ($d = 0.64$), HADS-D at week 6 ($d = 0.73$), QIDS at week 6 ($d = 0.67$), feelings of

tension at weeks 2 ($d = 0.48$), 4 ($d = 1.48$), 6 ($d = 0.95$), and 8 ($d = 1.43$). Compared to WL, HB resulted in moderate-to-large, significant improvements in feelings of depressed mood at week 4 ($d = 1.25$, 95%CI: [0.01, 2.48]) and feelings of tension at weeks 4 ($d = 1.52$, [0.23, 2.80]), and 8 ($d = 1.62$, [0.32, 2.93]). Moderate-to-large non-significant improvements were found for MFIS total at weeks 4 ($d = 0.60$) and 8 ($d = 0.57$), MFIS Physical at weeks 4 ($d = 0.84$), and 8 ($d = 0.82$), HADS-A at weeks 2 ($d = 0.50$), TMD at weeks 4 ($d = 0.74$) and 8 ($d = 0.80$), feelings of tension at week 6 ($d = 1.06$), feelings of depressed mood at week 8 ($d = 0.90$), and feelings of fatigue at week 8 ($d = 0.90$).

Compared to SP, HB resulted in moderate-to-large, non-significant improvements in STAI-Y2 at weeks 4 ($d = 0.65$) and 8 ($d = 0.88$), MFIS Physical at weeks 4 ($d = 0.64$) and 8 ($d = 0.86$), TMD at week 4 ($d = 0.61$), feelings of depressed mood at weeks 4 ($d = 0.72$), 6 ($d = 0.55$), and 8 ($d = 0.64$), and feelings of fatigue at weeks 4 ($d = 0.83$), 6 ($d = 0.62$), and 8 ($d = 0.96$).

4. Discussion

To the authors' knowledge, this trial is the first to evaluate feasibility metrics of an 8-week SP or HB intervention for symptoms of anxiety, depression, and fatigue among PwMS. Feasibility findings suggest Pilates, particularly home-based, is a safe, acceptable exercise mode, with excellent retention (83%) and compliance (> 80%) rates. Preliminary data, which should be heeded with caution due to small sample size (Thabane et al., 2010), supported moderate-to-large magnitude improvements in symptoms of anxiety, depression and fatigue among this small sample of women with MS with minimal-to-mild mobility disability.

Recruitment was lower than previous feasibility trials for PwMS in similar settings (Carter et al., 2013; Sosnoff, Finlayson, McAuley, Morrison, & Motl, 2014; Uszynski, Purtill, Donnelly, & Coote, 2016), and one participant refused randomization. Trial administration during the summer (June–August), along with potential travel and accessibility issues may have hindered recruitment and adherence. Offering home-based alternatives facilitates expansive geographical recruitment, while reducing logistical and accessibility barriers to exercise participation for PwMS (Plow & Finlayson, 2011; Prosperini et al., 2013; Stroud et al., 2009). Full home-based retention rates are comparable with other home-based exercise interventions (> 90%) among PwMS (DeBolt and McCubbin, 2004; Prosperini et al., 2013), and favourable group compliance is consistent with systematic review evidence (> 80%) examining exercise safety among PwMS (Pilutti, Platta, Motl, & Latimer-Cheung, 2014). Although full compliance by home-based was positive, self-reported exercise diaries are subject to under/overreporting biases, device-based measures and monitoring of physical activity and exercise intensity are needed (Prince et al., 2010). Comprehensive outcome measure completion suggest participants were not excessively burdened by assessment procedures, which is consistent with other feasibility trials (Dean et al., 2018).

Pilates' low-to-moderate intensity, allows participants to exercise at their own level, and previous research has supported that the interplay between preferred and prescribed intensity influence both compliance and the magnitude of improvements in mental health outcomes following acute and chronic exercise (Callaghan, Khalil, Morres, & Carter, 2011; Herring, Hallgren, & Campbell, 2017; Meyer et al., 2016). Self-reported RPE among both supervised (11 ± 2) and home-based (11 ± 1) groups is consistent with previously reported acute yoga ratings (10) that elicited mood state improvements among PwMS (Ensari, Sandroff, & Motl, 2016). Previous research examining anxiolytic effects of exercise primarily comprise aerobic and/or resistance modalities of low-to-moderate intensity (Strickland & Smith, 2014). Outcome improvements in this trial following the low intensity stimulus suggests Pilates may provide an alternative exercise mode to improve debilitating comorbidities among PwMS for whom traditional

exercise may be hampered due to mobility dysfunction (Motl & Sandroff, 2015) and body temperature considerations (Guthrie & Nelson, 1995). However, given the small sample and high attrition among supervised participants, larger trials, including comparisons of multiple exercise modes in the same population sample, are warranted.

Of note, the timing of questionnaire administration, based on the standard recall timeframe for the majority of questionnaires, illustrated moderate-to-large effects across outcomes at bi-weekly intervals. These results may have several implications. It is important for health care providers to identify the minimum exercise stimulus to initiate change in mental health outcomes among PwMS. Although participants were beginners to the core principles of the Pilates method, the provision of a novel, alternative and appropriate exercise modality may have resulted in a larger effect that tapered off as the intervention developed. This is important considering the poor activity levels by PwMS (Motl et al., 2017), and warrants further investigation.

The magnitude of improvement among home-based in feelings of depressed mood compared to wait-list ($d = 0.90$) and supervised ($d = 0.64$), is comparable to previously reported effects ($d = 1.27$) of predominantly supervised interventions on depressive symptoms among healthy and chronically-ill adults (Fleming & Herring, 2018), but considerably larger following exercise on depressive symptoms among PwMS ($d = 0.27$ – 0.38) (Adamson, Ensari, & Motl, 2015; Dalgas, Stenager, Sloth, & Stenager, 2015; Ensari, Motl, & Pilutti, 2014), demonstrating the practicality of this home-based exercise modality towards reduced depressive symptoms among PwMS and supporting the need for future research.

Previous MS research suggest exercise trials targeting concurrent improvement in both depressive symptoms and feelings of fatigue as a symptom cluster may prove beneficial (Herring, Fleming et al., 2017a). In this trial, the moderate magnitude of improvement in home-based total fatigue compared to wait-list ($d = 0.57$) and supervised ($d = 0.38$) is consistent with previously reported responses to exercise ($d = 0.45$ – 0.57) on feelings of fatigue in PwMS (Asano, Berg, Johnson, Turpin, & Finlayson, 2015; Heine, van de Port, Reitberg, van Wegen, & Kwakkel, 2015; Pilutti et al., 2013), but smaller than the recently reported mean effect ($\Delta = 0.93$) from eight Pilates trials among healthy and chronically-ill adults (Fleming & Herring, 2018). This is important as fatigue is a highly prevalent symptom among PwMS (Nagaraj, Taly, Gupta, Prasad, & Christopher, 2013) and the home-based approach may be a suitable means for PwMS who may be unable to fully commit to regular exercise programs.

Large magnitude of improvements in home-based participants plausibly was influenced by self-reported full compliance to the prescribed program. Home-based accessibility, convenience and suitability (Wójcicki et al., 2014), including the opportunity to perform Pilates earlier in the day when less fatigued (de Sa et al., 2011), may augment compliance. Although this exploratory finding is positive, caution is warranted in its interpretation due to the small sample size involved and may not represent true population effects (Szucs & Ioannidis, 2017).

5. Strengths and limitations

A key strength of this research is PwMS were provided with an accessible exercise modality facilitating full compliance. Utilisation of a large range of measures, sensitive to symptom change through program duration, did not discourage participation and promoted data comparison with previous research among PwMS. Detailed trial specifics of session structure, frequency and repetition can enable replication in future research. The trial is not without limitations. Participants were not recruited based on fatigue, anxiety, or depression status. Although the MFIS has been recommended for MS research and outcome measurement was assessed two-weekly intervals, despite its 4-week timeframe, the authors are cognizant of the risk of interpreting intervention effect sizes based on the MFIS alone in future trials. Caution is warranted in the interpretation of current findings as the small samples across respective groups limits definitive conclusions on effect.

6. Conclusion

This is the first randomized controlled trial to examine the four domains of feasibility of supervised and home-based Pilates among PwMS. Preliminary findings support home-based Pilates as a feasible, acceptable, and safe exercise modality that may improve symptoms of anxiety, depression, and fatigue among women with MS who have minimal-to-mild mobility disability. Although based on a small sample, the encouraging outcome results following home-based Pilates training among PwMS lay the foundation for the development and design of larger definitive home-based randomized control trials, to better understand Pilates's clinical effectiveness, while expanding previous MS research of the impact of Pilates on symptom management.

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Conflicts of interest

The authors report no conflicts of interest.

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