Social Science & Medicine 91 (2013) 84–93

Contents lists available at SciVerse ScienceDirect

Social Science & Medicine

journal homepage: www.elsevier.com/locate/socscimed

A randomized controlled trial of combined exercise and psycho-education for low-SES women: Short- and long-term outcomes in the reduction of stress and depressive symptoms

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ARTICLE INFO

Article history:
Available online 28 May 2013

Keywords:
Exercise
Psycho-education
Depression
Stress
Low-SES women
Netherlands

ABSTRACT

Exercise may have both a preventive and a therapeutic impact on mental health problems. The Exercise without Worries intervention aims to reduce stress and depressive symptoms in low-SES women by means of a group-based program combining physical exercise and psycho-education. Between September 2005 and May 2008, 161 Dutch low-SES women with elevated stress or depressive symptom levels were randomly assigned to the combined exercise/psycho-education intervention (EP), exercise only (E) or a waiting list control condition (WLC). The E condition provided low to moderate intensity stretching, strength, flexibility, and body focused training as well as relaxation, while the EP program integrated the exercise with cognitive-behavioral techniques. Depressive symptoms (CES-D) and perceived stress (PSS) were measured before and immediately after the intervention and at 2, 6 and 12 month follow-up. Multilevel linear mixed-effects models revealed no differential patterns in reduction of CES-D or PSS scores between the EP, E and WLC groups on the short (post-test and 2 month follow-up) or long term (6 and 12 months follow-up). Depressive symptom outcomes were moderated by initial depressive symptom scores: women from the EP and E groups with fewer initial symptoms benefited from participation on the short term. Further, women in the EP and E groups with the lowest educational level reported more stress reduction at post-test than women with higher educational levels. In the overall target population of low-SES women, no indications were found that the Exercise without Worries course reduced depressive symptom and stress levels on the short or long term. The findings do suggest, however, that exercise alone or in combination with psycho-education may be a viable prevention option for certain groups of disadvantaged women. Especially those low-SES women with less severe initial problems or those with low educational attainment should be targeted for future depression prevention practice.

Introduction

Compared to women with higher socio-economic status (SES), low-SES women have a high risk (ORs between 2.7 and 5.4) for depressive symptoms, which in turn considerably increases their likelihood of developing major depression (Cuijpers & Smit, 2004; Kahn, Wise, Kennedy, & Kawachi, 2000). Chronic stress and daily hassles are considered strong predictors of depressive symptoms and episodes in this group (Falconnier & Elkin, 2008; McConagle & Kessler, 1990). One commonly used psychological intervention for the indicated prevention of depression is the Coping with Depression course (CWD) (Brown & Lewinsohn, 1984). Several studies have shown that the CWD course is effective in the prevention of new cases of major depressive disorders (Cuijpers, Munoz, Clarke, & Lewinsohn, 2009). Nevertheless, it appears that low-SES participants have more difficulties with the cognitive

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http://dx.doi.org/10.1016/j.socscimed.2013.05.015

orientation of the CWD course, due to the high level of required verbal skills and the execution of homework assignments. This results in low-SES participants dropping out of the intervention more often (Allart-van Dam & Hosman, 2002). Based on the observation that low-SES women do often not engage in depression prevention, innovative ways to offer them preventive activities need to be found.

Exercise may have both a preventive and a therapeutic impact on mental health problems and stress and has been found to be effective in reducing depressive symptoms (Alderman, Rogers, Johnson, & Landers, 2003; Stathopoulou, Powers, Berry, Smits, & Otto, 2006). Meta-analyses on the effect of exercise on depressive symptoms report effect sizes ranging between 0.35 and 0.59 (Conn, 2010). In addition to its application as a monotherapy, exercise is increasingly accepted as an adjunct intervention in the management of depressive symptoms and depression (Stathopoulou et al., 2006). The underlying assumption in offering these multidisciplinary interventions is that combining different types of effective interventions will increase and prolong their positive effects (Jané-Llopis, Hosman, Jenkins, & Anderson, 2003). However, research on the combination of exercise with empirically supported psychosocial approaches for depression has been limited (Stathopoulou et al., 2006) and the effects of an exercise regimen in combination with a psychosocial intervention component have not yet been tested within a low-SES population.

To address this evidence gap, the Exercise without Worries (EWW) course was developed and evaluated in the Netherlands combining an exercise regimen with a CBT-approach. The development of the intervention was guided by the Stress Process Model of mental health disparities first proposed by Pearlin and colleagues (Pearlin, 1989, 1999; Pearlin, Menaghan, Lieberman, & Mullan, 1981). In short, this model proposes that ongoing stress may diminish the availability of women's psychosocial protective resources to cope with stressful circumstances, thus creating both increased psychological distress and diminished resilience. EWW was developed as a multi-component intervention to counter the negative effects of stressful events and increase psychosocial resources. The intervention has been tailored to the specific needs of adult low-SES women by way of its focus on risk factors for stress and depression relevant for this group. The exercise component has been included because of its potential impact on depressive symptoms. Further, it offers a solution for the low perceived attractiveness of exclusively cognitive-oriented programs among low-SES women. Experience from community programs suggests that exercise-based interventions might also appeal to this study population (Craft, Freund, Culpepper, & Perna, 2007; Lowther, Mutrie, & Scott, 2002).

Barriers to participation in mental health interventions by low-SES women are often related to financial costs, transportation and time (Beeber et al., 2007; Weinreb, Perloff, Goldberg, Lessard, & Hosmer, 2006). Even though financial barriers form no, or at most a minor, impediment for disadvantaged populations to access mental health care in the Netherlands (Sareen et al., 2007), the EWW course is offered free of charge, and additional expenses related to child care and public transport are reimbursed. In addition, because the intervention is presented and executed as a course rather than as therapy, it is non-stigmatizing. This is of special importance in low-SES groups since this population is more likely to report stigma concerns for mental health issues, which generally inhibit their use of mental health services (Grote, Zuckoff, Swartz, Bledsoe, & Geibel, 2007).

The objective of the current study was to evaluate the effects of this multidisciplinary preventive intervention aimed at reducing stress and depressive symptoms among low-SES women. We directly looked at whether the combination of exercise and psychoeducation led to synergetic effects on participants' mental wellbeing in comparison to participants receiving exercise only and to a waiting list condition. Since previous research has shown differential intervention effects relating to socio-economic status (Cuijpers, Van Straten, Warmerdam, & Smits, 2008), baseline symptom levels (Allart-van Dam, Hosman, Hoogduin, & Schaap, 2003), current depression treatment and intervention adherence (Stuart, Perry, Le, & Ialongo, 2008), we further explored whether the intervention itself would lead to differential effects among the groups based on these moderators.

Methods

Study design and participants

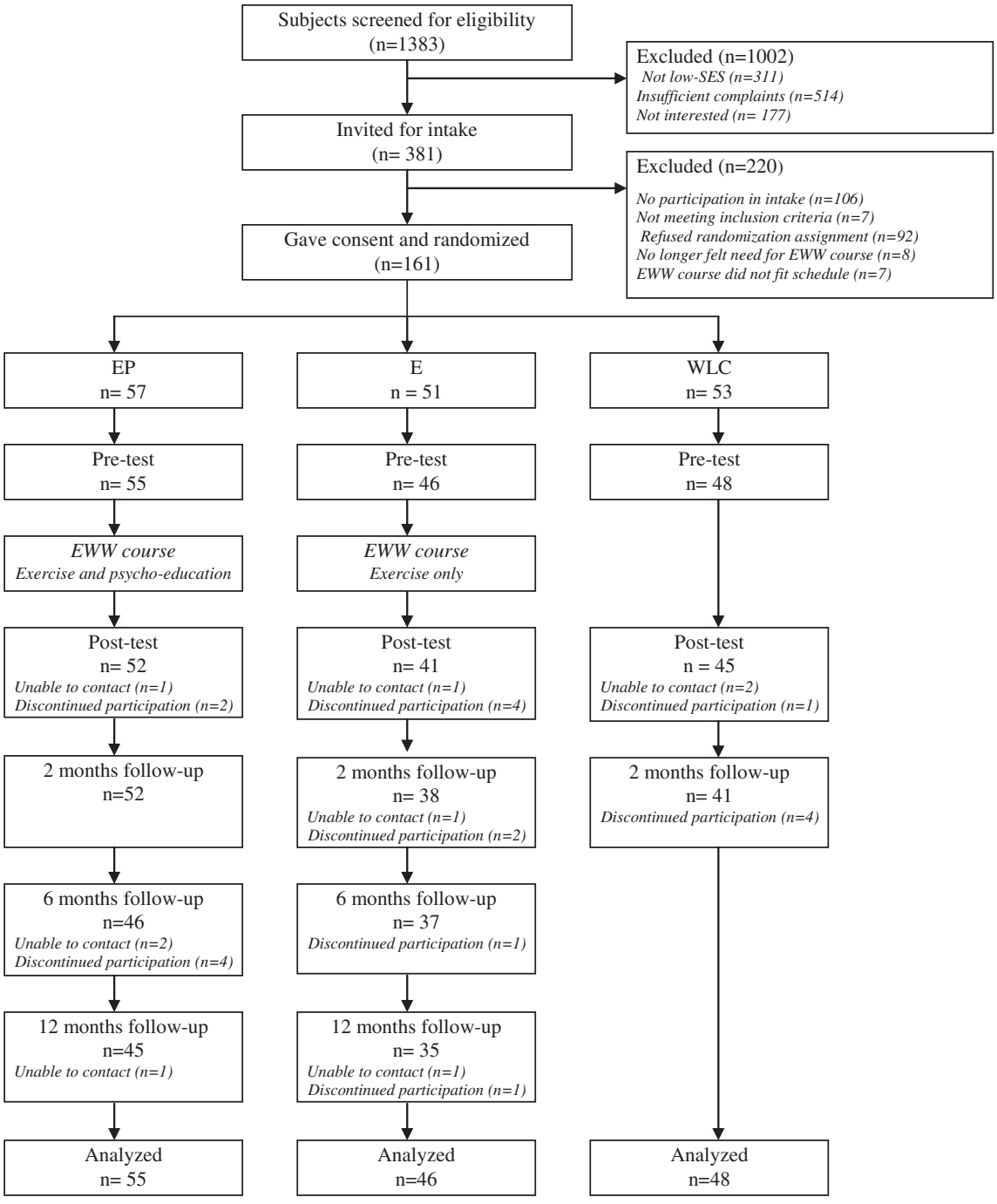
The efficacy of the EWW course was tested in a randomized control trial. The target population of the EWW intervention were Dutch low-SES women (20–55 years) with depressive symptoms or who suffered from stress-related complaints. Participants were recruited through referral by general practitioners active in or near socioeconomically deprived neighborhoods and intermediaries working in social work, debt reform, a community mental health centre and public health services. Women could also self-refer in response to local media-campaigns. Women who were referred to the EWW course completed a 10-min telephone interview conducted by trained lay interviewers to screen for the presence of stress and depressive complaints. Women who satisfied low-SES criteria, had stress *or* depression levels above the cut-off scores (see Measures), and were interested in participating in EWW were invited to an intake session during which course objectives were explained and study eligibility was further determined. Information on the women's psychological complaints and functional status were collected by an intervention staff member by means of a semi-structured interview.

Women were excluded from participation in the course if their Dutch was limited, if they had cognitive disturbances or emotional instability that might impede participation in a group intervention or physical problems that might hinder their participation in the exercise component of the course. Those women suitable and willing to participate in the RCT signed a written informed consent form for participation and were subsequently randomly assigned using a randomization list. Participants were assigned to one of three intervention conditions: the full EWW intervention with exercise and psycho-education (EP) component, the intervention with the exercise only (E) or a waiting-list control (WLC) condition with postponed intervention four months later. Baseline measurements for all conditions were completed after randomization and before the start of the first session. Until the start of the first session, all participants were blinded to the treatment group to which they were assigned to, including those in the control condition.

Further measurements in the EP and E conditions were a post-test directly after the 8-week intervention, and 2 months, 6 months and 12 months follow-up (FU). Participants in the control condition completed a post-test and a 2 month follow-up at the same time as the EP and E conditions. After this measurement, they were given the opportunity to participate in the intervention. Between September 2005 and May 2008, a total of 161 eligible women gave informed consent and were randomly allocated to the EP, E and control conditions (Fig. 1). Approval for conducting this study was granted by the Medical Review Ethics Committee of Maastricht University in the Netherlands.

Intervention and comparison group activities

Exercise without Worries (EWW) is a new preventive course that has been tailored to the specific needs of low-SES women. The



Notes: EP Exercise and psycho-education; E Exercise; WLC wait-list control

Fig. 1. Flow of the participants through the study.

main goal of the intervention is to reduce stress and depressive complaints and increase coping related competences. The emphasis lies on empowering women instead of focusing on their problems. A core element of the EWW course is its group-based format in which psycho-educative topics link up with body focused exercises. This is further elaborated through four themes (I Self-image, II Balance, III Strength, and IV Boundaries) which form the basis of eight two-hour sessions (van der Waerden, Jansen, Hoefnagels, & Hosman, 2011).

Psycho-education is based on the Coping with Depression course and addresses factors for depression such as constructive thinking, social skills, self-esteem, and pleasant activities (Cuijpers et al., 2009). These topics are extended with other evidence-based risk factors for stress and depression found among low-SES women, such as low perceived mastery over life, and the negative effects of stressful events (Sterk, Theall, & Elifson, 2006; Taylor & Seeman, 1999). The exercise component is performed at a low to moderate intensity for 60 min and employs stretching, strength exercises to

reinforce muscle resistance, flexibility, body focused exercise (bodywork techniques to improve posture and awareness of the mind-body connection) and relaxation. Since low-SES women do not commonly have intense exercise habits (Ball, Salmon, & Crawford, 2006; Droomers, Schrijvers, van de Mheen, & Mackenbach, 1998), the physical exercise was designed not to be much more strenuous than their habitual level of exercise to avoid negative feelings combined with exhaustion (Salmon, 2001). One of the most important elements within the EWW course is that each session coordinates the psycho-education and exercise components as far as possible with the aim of reciprocally reinforcing these intervention themes. This means that participants not only talk about a topic, but also experience it through the exercises. For example, during a session on strength they learn both to experience their physical strength and to discover their psychological strengths. Social interaction and social support from other participants were encouraged through the group based format, and also through the exercise component in which participants train together (Paluska & Schwenk, 2000). Each session was led by two trainers, a licensed psychologist or mental health provider and an exercise professional such as a physical therapist or licensed sports instructor. The trainers provide positive feedback to enhance participants' self-esteem and confidence. A more comprehensive description of the EWW course has been reported elsewhere (van der Waerden et al., 2011).

The exercise only (E) condition included the same exercises as the combined program, but without the psycho-educative component. During the exercise only sessions, the refreshment breaks were extended to correspond with the time provided for the staff–client contact in the EP course. Finally, the women in the waiting list control condition did not start the intervention until four months later and were instructed to continue life as normal and were free to engage in both physical activity and mental health counseling elsewhere.

Measures

Eligibility measures

To determine study eligibility, women completed the 10-item version of the Perceived Stress Scale (PSS; range 0–40, cut-off score 14) (Cohen, Kamarck, & Mermelstein, 1983) to assess the frequency of stress-inducing situations and feelings of stress over the last month. Also, they completed the 10-item version of the Center for Epidemiological Studies Depression (CESD-SF; range 0–30, cut-off score 5) (Andresen, Malmgren, Carter, & Patrick, 1994) to determine whether they had experienced depressive symptoms over the last week. The cut-off scores were not applied to establish the presence or absence of clinical levels of stress or depression, but rather were used to select women considered to be at high risk.

Baseline demographics

The following socio-demographic variables were determined at baseline: age, nationality, educational level, and previous depressive episodes. Employment status, net monthly family income, marital status, current depression treatment and current exercise behaviors were also established at baseline, and during each subsequent time point.

Outcome measures

The primary outcomes in the comparison between intervention conditions were related to depressive symptoms and perceived stress. Depressive symptoms were assessed using the Center for Epidemiological Studies Depression (CES-D) questionnaire (Radloff, 1977). This 20-item questionnaire measures the number of depressive symptoms over the past week, including depressed mood, loss of interest or pleasure in activities, sleep and appetite disturbances and social difficulties. Scores range between 0 and 60. Scores ranging from 16 to 26 are considered indicative of mild depression and scores of 27 or more indicate a high risk of major depression (Thomas, Jones, Scarinci, Mehan, & Brantley, 2001). The reliability of the CES-D scale was acceptable to good with Cronbach's alphas ranging between 0.77 and 0.91 across the various time points. These alphas are consistent with ranges found in Dutch community samples (Bouma, Ranchor, Sanderman, & van Sonderen, 1995).

Participants' general perceived stress over the past month was assessed using the PSS (Cohen et al., 1983). The scale assesses the frequency of stress-inducing situations and feelings of stress over the last month, and was designed for use in the general community to determine how much stress people experience in their everyday lives. Scores range from 0 to 40 with higher scores indicating higher perceived stress levels. As the PSS is not a diagnostic instrument, clinical cut-offs for the general population have not been well established. However, the PSS has demonstrated adequate reliability and validity (Cohen & Janicki-Deverts, 2012), and Cronbach's alpha in the present study ranged from 0.77 to 0.90 across the consecutive measurements, indicating adequate-to-good internal consistency of this instrument.

At the 12 month follow-up, participants also completed the Dutch Recent Life Events Questionnaire (RLEQ) which counts the total number of major life events experienced over the past 12 months (Willige, Schreurs, Tellingen, & Zwart, 1985). The Cronbach's alpha in this sample was 0.89.

All but one questionnaire were administered at participants' homes by trained interviewers to assure maximum response from the target group (Picavet, 2001). The 2 month follow-up measure was administered by phone.

Data analysis

An a priori power analysis conducted to compare the three conditions on the primary outcome for depressive symptoms estimated a sample size of 49 participants in each condition to detect a moderate effect size ($d = 0.40$) with a power of 0.80 and a two-tailed test of 0.05 (Cohen, 1988). Accounting for an estimated drop-out of 10%, 54 participants were needed in each condition. The data analysis included descriptive statistics of the socio-demographic and other background variables and primary outcome measures. Women were included in the analyses if they had completed the baseline assessment. Drop-out analyses were conducted using logistic regression analyses to explore differences in socio-demographic characteristics and symptom scores for those participants who did not complete all measurements after the baseline assessment. To check for pre-existing differences among the three conditions on descriptive variables and outcome measures at study entry despite randomization, analysis of variance was carried out for continuous variables and Chi-square analyses were performed for categorical variables. Analyses were performed using PASW statistics version 17.0.

Since participants were nested within EWW course groups and participated in multiple measurements, multilevel linear regression analyses were used to account for dependency in the consecutive outcomes (Snijders & Bosker, 1999). A multilevel approach with random intercept for three levels (course group, participant and time) was completed to analyze the changes in outcome variables between intervention conditions and moderation effects using MLWin (version 2.02). Separate analyses were performed for each of the outcome measures. Multilevel analyses have also been shown to be useful in handing missing data, since analyses can be done on available cases instead of complete cases

only (Twisk, 2006). For respondents with no more than 20% of missing values on a given scale and time point, the missing values were substituted by the respondent's mean score on that particular scale (Moons, Donders, Stijnen, & Harrell, 2006).

To test the change in outcome on the CES-D and PSS between the intervention conditions, a fixed occasions model was fitted for each outcome variable, with a random group effect and an unspecified 5*5 covariance matrix for participant effects at all five time points. Included predictors were intervention condition variables coded into two dummies (using the control condition as a reference), time of measurement which was recoded into four dummies (with baseline as reference time point), and eight two-way interaction terms for each combination of intervention condition*time to test whether the intervention effect varied over time. Baseline socio-demographic variables, baseline PSS and CES-D scores, intervention adherence, current depression treatment and number of life events were included as between-subject covariates because these variables were assumed to be related to intervention outcomes. By including these covariates, power and precision of treatment-effect testing and estimation are improved due to reduced residual outcome variance.

The overall intervention effects, and those at post-test, short (2 months follow-up) and long term (at 6 and 12 months follow-up) were analyzed by following a top-down procedure, starting with the most elaborate model and successively leaving out the least significant components (using alpha = 0.10 to prevent type II errors). In the most reduced model, which contained time and group by time effects plus significant covariates, the intervention effects were statistically tested using the likelihood ratio test with a 0.05 significance cut-off point for regression coefficients. In all of the analyses, a correction was made for baseline CES-D and PSS scores, as well as for number of life events.

Differential effects of the intervention could be present in participant subgroups. We included moderators for SES indicators (educational level, employment status, and net monthly family income), current treatment, intervention adherence, and risk at baseline levels (based on the sample median of the pre-test scores for the CES-D and PSS respectively). Higher order interactions of these covariates with intervention condition*time were included into the model, as well as all lower order terms involving the same covariate. If a higher order interaction was found between a covariate and group by time, the treatment effect was evaluated within subgroups based on that covariate.

The intervention effect sizes were determined by dividing the difference between two means by the pooled SDs for those means (Cohen, 1988). Effect sizes were calculated for the effect of the EP and E groups compared to the control group and between EP and E groups on both the CES-D and PSS. Effect sizes were interpreted as small when they were equal to or less than 0.32, medium when they were between 0.33 and 0.55, and large when they were equal to or greater than 0.56 (Lipsey & Wilson, 2001).

Results

381 Women were found to be eligible for participation in the course after screening. Of the 275 women who consented to an intake, 161 (58.5%) were enrolled in the study. A further 12 women dropped out before the baseline assessment took place and were excluded from any further analyses. The participants who dropped out after the baseline measurement did not differ from those who completed all assessments ($p > 0.05$). Table 1 presents the socio-demographic characteristics, as well as the presence of previous depressive episodes, current depression treatment and current exercise behavior at baseline for each of the three study conditions. No significant differences were found among the three conditions for any of these variables, with the exception of nationality. All participants in the control condition were Dutch, versus 91% in the EP condition and 84% in the E-condition (χ^2 (2) = 7.47, $p = 0.02$). Furthermore, the 12-month follow-up showed that women in the E condition had experienced significantly more life events during the study period than women in the other conditions, $F(2, 146) = 2.97$, $p < 0.05$. Women attended on average 5.06 (SD = 2.79) sessions, without any significant differences between the two intervention conditions. Current treatment for depressive symptoms consisted of antidepressant medication, psychotherapy or a combination of those. Those women who performed exercise activities at baseline were mostly engaged in transport related physical activity such as walking or cycling or participated in leisure time activities as swimming or fitness training.

Intervention effects

No significant differences were found in baseline outcome measures among the three research conditions. Table 2 shows the descriptive study measures from baseline to 12 month follow-up. Multilevel linear mixed-effects analyses revealed that women in the EP and E, but not the control, conditions showed significant ($p < 0.05$) improvements on their score for depressive symptoms at post-test. For the E condition, the change to the baseline scores was still significant at 6 and 12 month follow-up ($p < 0.01$). However, this change in depressive symptom scores was not significantly different ($p = 0.12$) between the EP, E and control conditions on any of the measurement time-points (Table 3).

Outcomes on perceived stress levels demonstrated a similar pattern. Compared to their baseline scores, women in both the EP and E conditions showed a significant decrease in their perceived stress levels at post-test and all follow-up time points ($p < 0.01$); there was no decrease, however, in the scores of the women in the control condition. Yet, overall intervention effects on decreases in stress levels among the three conditions were not significant at any of the measurement time-points ($p = 0.34$).

Intervention effects in subgroups

The moderation analyses showed intervention effects in some subgroups. For depressive symptoms, women in the EP and E conditions with a CES-D baseline score *below* the 16-point cut-off score reported significantly fewer depressive symptoms at 2 months follow-up ($\beta_{EP} = -7.77$, $p = 0.01$, $ES = 0.71$; $\beta_E = -7.28$, $p = 0.03$, $ES = 0.63$) than women in the control condition. Conversely, women in the E condition with a CES-D baseline score *above* the 16-point cut-off had significantly more depressive symptoms at 2 months follow-up than women in the control condition ($\beta_E = 8.05$, $p = 0.009$, $ES = -0.56$).

Subgroup analyses for the PSS showed that women from the EP and E conditions with the lowest educational level had lower perceived stress scores at post-test than women from the control condition ($\beta_{EP} = -4.12$, $p = 0.024$, $ES = 0.53$; $\beta_E = -4.13$, $p = 0.025$, $ES = 0.35$). None of the other condition × time × subgroup variable interactions was significant for either outcome measure.

Discussion

This randomized trial evaluated program effects on the reduction of depressive symptoms and perceived stress levels in a sample of low-SES women. It was the first study on the possible benefits of combined exercise and psycho-education for this population. This has also been the first trial to extend follow-up measures for possible intervention effects to one year after participation in these types of combined interventions. While women in the combined

Table 1
Baseline characteristics 149 participants, means (SD), frequencies (%).

	EP group ($n = 55$)	E group ($n = 46$)	WLC group ($n = 48$)	Total sample
Age (years)	44.68 ($SD = 8.43$)	43.06 ($SD = 8.88$)	43.87 ($SD = 7.67$)	43.90 ($SD = 8.31$)
Nationality (Dutch)*	50 (90.9)	39 (84.8)	48 (100.0)	137 (91.9)
Marital status				
Single, Divorced, Widowed	22 (40.0)	26 (56.5)	17 (35.4)	65 (43.6)
Married, cohabitating	33 (60.0)	20 (43.5)	31 (64.6)	84 (56.4)
Educational level[a]				
Low	27 (49.1)	28 (60.9)	24 (50.0)	79 (53.0)
Middle	21 (38.2)	14 (30.4)	22 (45.8	57 (38.3)
High	7 (12.7)	4 (8.7)	2 (4.2)	13 (8.7)
Employment status				
Employed	13 (23.6)	13 (28.3)	16 (33.3)	42 (28.2)
Housewife	14 (25.5)	8 (17.4)	10 (20.8)	32 (21.5)
Unemployed	12 (21.8)	8 (17.4)	4 (8.3)	24 (16.1)
Disabled	16 (29.1)	17 (37.0)	18 (37.5)	51 (34.2)
Net family income per month[b]				
€0–500	1 (1.8)	3 (6.5)	1 (2.1)	5 (3.4)
€500–835	11 (20.0)	14 (30.4)	11 (22.9)	36 (24.2)
€835–1100	18 (32.7)	8 (17.4)	9 (18.8)	35 (23.4)
€1100–1665	17 (30.9)	15 (32.6)	16 (33.3)	48 (32.2)
€1665–2500	5 (9.1)	3 (6.5)	6 (12.5)	14 (9.4)
≥€2500	3 (5.5)	3 (6.5)	5 (10.4)	11 (7.4)
Previous depressive symptoms				
No	7 (12.7)	12 (26.1)	12 (25.0)	31 (20.8)
Yes	48 (87.3)	34 (73.9)	36 (75.0)	118 (79.2)
Current treatment for symptoms				
No	34 (61.8)	31 (67.4)	36 (75.0)	101 (67.8)
Yes	21 (38.2)	15 (32.6)	12 (25.0)	48 (32.2)
Current exercise activities				
No	36 (65.5)	27 (58.7)	32 (66.7)	95 (63.8)
Yes	19 (34.5)	19 (41.3)	16 (33.3)	54 (36.2)
No. of life events*	11.35 ($SD = 9.59$)	16.70 ($SD = 16.51$)	12.35 ($SD = 6.53$)	13.32 ($SD = 11.63$)
Intervention adherence (No. of sessions attended)	5.47 ($SD = 2.63$)	4.57 ($SD = 2.94$)	–	5.06 ($SD = 2.79$)

Continuous data: mean (standard deviation); categorical data: frequency (percentage).
EP exercise and psycho-education; E exercise only; WLC waiting-list comparison.
*$p < 0.05$.
[a] Educational level: low ≤9 years; mid = 10–14 years; high ≥15 years.
[b] The average net family monthly income in the Netherlands in 2007 was €1743.

exercise and psycho-education and the exercise-only groups showed significant decreases in their depressive symptoms and perceived stress levels over time, this decrease was not significantly different from what was found in a wait list control group. Nor did the combined exercise and psycho-education group outperform the exercise only condition on either outcome. Our findings are largely consistent with the limited number of previous reports on the effectiveness of integrated exercise/psychosocial interventions for mental health. These studies did not show a significant additive effect for exercise combined with empirically supported psychosocial approaches compared to exercise alone (Fremont & Craighead, 1987; McGale, McArdle, & Gaffney, 2011). With the current study we have been able to generalize outcomes for these additive effects to a population of low-SES women.

The lack of clear overall intervention effects may be attributable to several factors. First, we assumed that the perceived stress and depressive symptom levels of women in the control group would not improve during the four month period before they started the EWW course. The perceived stress and depressive symptom scores of the control group as a whole did improve, although this was to a lesser extent than the intervention groups. In their meta-analysis of waiting list controls, Posternak and Miller (2001) suggested that the effect of seeking treatment and obtaining a thorough evaluation in the context of research in itself may very well cause an increased remission rate in depressive symptomatology. While this may be true for treatment studies, there is no evidence to show whether this effect of treatment seeking also applies for prevention. Participants in preventive interventions may have lower initial levels

Table 2
Observed, uncorrected means (SD) for CES-D and PSS scores per time point and group.

	Baseline*	Post-test	FU 2 months	FU 6 months	FU 12 months
CES-D					
EP	24.91 ($SD = 11.83$)	21.29 ($SD = 10.49$)	21.52 ($SD = 11.75$)	22.12 ($SD = 11.33$)	20.87 ($SD = 12.76$)
E	25.69 ($SD = 12.30$)	20.44 ($SD = 11.47$)	24.22 ($SD = 13.55$)	18.95 ($SD = 11.87$)	17.30 ($SD = 11.08$)
WLC	23.24 ($SD = 12.54$)	20.51 ($SD = 11.91$)	20.95 ($SD = 11.48$)	–	–
PSS					
EP	23.25 ($SD = 6.76$)	20.96 ($SD = 6.78$)	18.94 ($SD = 7.02$)	20.11 ($SD = 6.16$)	20.38 ($SD = 6.41$)
E	24.39 ($SD = 6.60$)	21.32 ($SD = 7.59$)	21.97 ($SD = 7.97$)	21.19 ($SD = 6.49$)	20.20 ($SD = 6.74$)
WLC	23.02 ($SD = 6.27$)	21.88 ($SD = 6.76$)	21.39 ($SD = 6.42$)	–	–

EP exercise and psycho-education; E exercise only; WLC waiting-list comparison; FU follow-up.
*Baseline group differences $p > 0.05$.

Table 3
Corrected intervention effects and effect size[a] of group comparisons on CES-D and PSS scores per time point.

CES-D	EP–E[†]		EP–WLC[†]		E–WLC[†]	
	B (SE)	ES (95%CI)	*B* (SE)	ES (95%CI)	*B* (SE)	ES (95%CI)
Post-test	2.24 (2.37)	−0.08 (−0.31–0.47)	−1.10 (2.31)	0.07 (−0.32–0.46)	−3.34 (2.45)	0.00 (−0.41–0.40)
FU 2 months	−2.50 (2.40)	0.21 (−0.61–0.18)	0.22 (2.36)	−0.05 (−0.34–0.44)	2.76 (2.53)	−0.26 (−0.15–0.66)
FU 6 months	2.25 (2.45)	−0.27 (−0.12–0.66)	–	–	–	–
FU 12 months	2.92 (2.47)	−0.30 (−0.09–0.68)	–	–	–	–
p-Value overall intervention effect 0.12						
PSS						
Post-test	0.77 (1.37)	0.05 (−0.44–0.34)	−1.20 (1.33)	0.13 (−0.52–0.25)	−1.97 (1.42)	0.07 (−0.48–0.33)
FU 2 months	−2.13 (1.39)	0.40 (−0.79 to −0.01)	−2.14 (1.37)	0.36 (−0.75–0.03)	−0.01 (1.47)	−0.08 (−0.32–0.48)
FU 6 months	−0.82 (1.43)	0.17 (−0.56–0.22)	–	–	–	–
FU 12 months	0.89 (1.43)	−0.02 (−0.36–0.41)	–	–	–	–
p-Value overall intervention effect 0.34						

EP exercise and psycho-education; E exercise only; WLC waiting-list comparison; FU follow-up.
B – Regression weight; SE – standard error; ES – Effect size.
The second group[†] is the reference category.
[a] Corrected for baseline differences on the outcome variable and covariates.

of mental distress than those persons seeking treatment (Cuijpers, Smit, & van Straten, 2007). Although it has been suggested that the level of spontaneous recovery is not greatly influenced by initial symptom severity (Posternak & Miller, 2001), it has also been observed that control groups in preventive interventions do not always show a decline in depressive symptomatology (e.g. Allart-van Dam et al., 2003; Clarke et al., 2001). Therefore it remains speculative as to whether a treatment seeking effect occurred. The reduction of depressive symptoms among control participants may well reflect regression to the mean as improvements can occur in a population that already has increased depressive symptoms and stress levels at enrollment in the study.

A second factor to take in consideration is the intervention format and content. Previous research has indicated that in the Netherlands low-SES groups drop out more frequently from psycho-educative interventions like the Coping With Depression course due to the cognitive orientation and written homework assignments included in these courses (Allart-van Dam & Hosman, 2002). The EWW course tried to meet these concerns by adapting its course contents to a low-SES target group. This included, among other measures, extending the CWD contents with topics related to risk factors for low-SES women (such as mastery and rumination) and removing barriers to facilitate adherence. In addition, the course contents were tailored to the skills of the target group and there were no homework assignments. Finally, the exercise component was added. However, given the lack of an overall effect, the eight-week intervention may have been too short to exert the full physiological or psychological benefits for this disadvantaged population. A previous meta-analysis has indicated that depression prevention interventions with 8 sessions or more were more effective than shorter interventions (Jané-Llopis et al., 2003). The CWD course included 12 to 15 sessions, which is similar to the duration of most other programs that are aimed at preventing depression and that have shown evidence of efficacy. See for instance Clarke et al. (2001), Cuijpers et al. (2008), and Munoz et al. (2007). Compared to these effective interventions, the EWW course covered more topics in fewer sessions. Participants' knowledge of intervention themes may have remained too limited to effectively counter the structural stressors and problems present in their daily lives, and a longer intervention may well have been needed for them to internalize this content. Adherence data for the EWW intervention show that women attended on average 5 out of 8 sessions. Although it is possible that this low participation may have further decreased the intervention's effect, our results did not show a moderating effect of adherence on intervention outcomes.

Generally, the proposed explanatory factors for exercise on depressive symptom reduction include physiological, psychological and social support mechanisms (Paluska & Schwenk, 2000; Stathopoulou et al., 2006). Findings from several studies exploring the dose–response relation of exercise and reduction in depressive symptoms are conflicting (Mead et al., 2009; Teychenne, Ball, & Salmon, 2008). It has been suggested that physical activity can contribute to beneficial effects on depressive symptomatology when it is executed in the amount of the recommended public health dose (Dunn, Trivedi, Kampert, Clark, & Chambliss, 2005). The exercise component in the EWW course did not meet the public health dose, which is at least 150 min of moderate physical activity throughout the week (WHO, 2010). While some studies (Anderson et al., 1999; Brown, Ford, Burton, Marshall, & Dobson, 2005) have reported favorable effects on depressive symptoms for activity below this norm, the EWW course did not result in improved outcomes. However, since we did not formally assess energy expenditure or exercise intensity it is impossible to determine whether the dose of the intervention was too low to have activated any physiological mechanisms associated with the reduction of depressive symptoms. In general, more knowledge is needed on the minimal dosage of exercise needed to produce preventive effects in depression symptomatology (Dunn et al., 2005). The same applies to the amount of education needed for each of the themes in the psycho-educative part, including the use of homework.

The lack of any additional effect for the EP intervention over the exercise only (E) condition could lie in the nature of the exercise only (E) condition. In the present trial, this condition was conducted in a group based format, as was the EP condition. Also, intervention time was extended to match the staff–client contact time in the EP course groups. This extended time could have provided more opportunities for social interaction and individual support in the E condition, which in turn might have resulted in improved mental health outcomes and thus contributed to the lack of differential effects between the E and EP conditions. Alternatively, the E and EP conditions both contained active components which overall masked a discrimination between the groups. The exercise component in the intervention could have activated psychological and social support mechanisms. For instance, it has been suggested that exercise may enhance a person's sense of mastery by creating a sense of independence and success through the command of a challenging pursuit (Craft & Perna, 2004; Paluska & Schwenk, 2000). Engaging in physical activity may also lead to distraction from negative emotions and unpleasant thoughts and may result in an improved affect following exercise sessions

(Brosse, Sheets, Lett, & Blumenthal, 2002; Hassmén, Koivula, & Uutela, 2000). With the hypothesis that exercise leads to mental health benefits by directly affecting psychosocial outcomes (Stathopoulou et al., 2006), the unique contribution of the psycho-education could have been too small to result in significant differences above those effected by the exercise.

In a few subgroups of low-SES women we did find an effect for the EWW intervention. In the short term, women from the EP and E conditions with moderate baseline depression levels significantly outperformed the WLC group. This finding is at odds with some previous exercise studies (e.g. Atlantis, Chow, Kirby, & Singh, 2004; Da Costa et al., 2009) which showed that worse symptoms predicted larger effects. Yet, our outcomes do concur with previous research on the prevention of depression. A trial studying the effects of the CWD course in a sample of adults at risk of developing major depression (Allart-van Dam et al., 2003) showed that the positive effects of the intervention were exclusively confined to participants with low to moderate pre-test depression levels. This repeated finding suggests that the current intervention might be adequate for low-SES women with moderately increased levels of depressive complaints, but might not be long or intensive enough for those with higher symptom levels.

In addition, both the EP and E conditions showed post-intervention effects in reducing perceived stress levels among women with the lowest educational level. This group is generally more affected by the negative impact of chronic stressors related to a low-SES status than women with a higher education (Stronks, van de Mheen, Looman, & Mackenbach, 1998). Even though women followed only 5 sessions on average, their participation still resulted in reduced feelings of stress. Lower educated women may be less familiar with the intervention topics (e.g. relaxation exercises), and may thus have profited more from participation. Previous studies have documented the beneficial effects of exercise on stress responsivity (Salmon, 2001). Since women in both the EP and E conditions showed reduced perceived stress levels, the exercise itself may also have been an important mechanism for improved mental health outcomes. While women maintained their reduced perceived stress and depressive symptom levels at 6 and 12-month follow-up, the levels of the combined group were equal to the exercise only group. Since we did not study long-term outcomes for the wait-listed controls, we cannot infer that this long-term reduction on both outcomes is attributable to the EWW intervention.

The strengths of the present study were the length of the follow-up period and its focus on a study population of low-SES women who are generally considered to be hard to reach for participation in prevention and research trials (Gadalla, 2008). Some limitations should be mentioned as well. Firstly, for ethical reasons, control participants were free after these first four months to enter the intervention and thus could not provide data to test long-term follow-up of intervention effects. Secondly, the study design did not include a psycho-education only (P) condition, since this component has already been shown to be evidence-based in the reduction of depressive symptoms (Cuijpers et al., 2009). However, we did make several changes to the psycho-educative content for the EWW course to adapt it to our low-SES target group. Therefore our intervention is not completely comparable to the CWD psycho-education, which possibly explains the differential effects for the EWW course. Yet, alternative versions of the CWD course have also been adapted by reducing the number of sessions and simplifying the texts used in the intervention. There is no indication that these versions are less effective (Haringsma, Engels, Cuijpers, & Spinhoven, 2005; Miranda et al., 2006). Thirdly, the effect sizes for study group comparisons across several time points were smaller than anticipated at the a priori power calculation. This, together with some attrition of participants before baseline measurement, may have resulted in a lack of power to detect significant differences with small effect sizes. Fourth, at the 12 month follow-up women in the E condition appeared to have experienced significantly more life events during the study period than women from the other conditions. We corrected for this post hoc selective randomization by including the number of life events as a covariate in the analyses (Rochon, 1999). However, it is possible that this difference in number of life events did account for some of our overall lack of results. Fifth, the results relied on self-report questionnaires that could have posed problems to a low-SES population. We tried to accommodate response by having a trained interviewer to administer the questionnaires. This, in turn, could have caused participants to give socially desirable responses (Bowling, 2005). Finally, perceived stress and depressive symptoms are generally considered as the last link in a chain of effects (Aneshensel, 2009; Sterk et al., 2006). It is conceivable that the EWW intervention led to significant changes in proximal variables, such as rumination and social support, since these were explicitly targeted during the course.

In this study, a 'hard to reach' population of low-SES women participated in an exercise intervention. A process evaluation showed that the participants highly appreciated the intervention organization and contents and reported a subjective reduction in their stress and depressive symptoms after 8 sessions (van der Waerden et al., 2011). Like previous reports, the current study has not been able to give unequivocal support for the integration of exercise with psychosocial approaches to benefit mental health, above and beyond the beneficial effects of exercise or psychotherapy alone. However, it would be premature to conclude that combining exercise and psycho-education has no merit. Further program improvements might be needed before definitive conclusions can be made on effectiveness. A new trial would be advised using the EWW program with a higher dosage and a longer duration for both intervention components, enhancing also the potential of sustainable social support. Although adherence was reasonable, it could be further improved by using motivational techniques (Grote et al., 2007). Finally, given the outcomes of our subgroup analyses, we recommended that this intervention be specifically targeted at low-SES women with moderate risk levels. This suggests that the EWW intervention could well be implemented as part of a stepped-care approach (Bower & Gilbody, 2005). Given these considerations, coupled with the notable burden of depression among low-SES women, the study of viable prevention options among this high-risk group should remain a priority.

Acknowledgments

This research was supported by the Netherlands Organisation for Health Research and Development (ZonMw), project number 4016.0004. The funding agency had no role in the design, conduct or data analysis of this study.

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